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

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

GENERAL ACCOUNTING OFFICE

4 CFR Part 28

Personnel Appeals Board; Procedural Rules

AGENCY: General Accounting Office Personnel Appeals Board.

ACTION: Final rule.

SUMMARY: The General Accounting Office Personnel Appeals Board hereby amends its regulations to permit charging parties to bring their cases directly to the Board after the passage of 180 days from the filing of the charge, if the Board's General Counsel has not yet completed the investigation of the charge, if the Board's General Counsel has not yet completed the investigation of the charge and issued a Right to Appeal Letter. This amendment offers employees an option for expedited processing and conforms Board procedures with those of other agencies that hear employment-related appeals.

DATES: This final rule is effective December 21, 2000.

ADDRESSES: General Accounting Office Personnel Appeals Board, Suite 560, Union Center Plaza II, 441 G Street, NW., Washington, DC 20548.

FOR FURTHER INFORMATION CONTACT: Beth Don, Executive Director, 202-512-6137.

SUPPLEMENTARY INFORMATION: The General Accounting Office Personnel Appeals Board performs for GAO employees the functions performed in the executive branch by the Merit Systems Protection Board, the Equal Employment Opportunity Commission, and the Federal Labor Relations Authority. In order to bring a case before the Board, except in cases involving a Reduction in Force, an employee must first file a charge with the Board's General Counsel. The General Counsel investigates the charge and determines whether there are reasonable grounds to believe that the employee's rights have

been violated. At the end of the investigation, the General Counsel issues to the employee a "report and recommendation" that explains the results of the investigation. If the General Counsel finds that there are reasonable grounds to believe that the employee's rights have been violated, then the General Counsel offers to represent the employee in a proceeding before the Board. If the General Counsel does not find "reasonable grounds," the General Counsel will not represent the employee. The employee, however, may still bring the case to the Board by representing him- or herself, or by obtaining private representation. Accompanying the report and recommendation, whether favorable or unfavorable, is a "Right to Appeal" Letter which permits the employee to file a petition for review with the Board.

Under the Board's current regulations, an employee may not bring his or her complaint to the Board until the General Counsel's investigation is completed and the employee has received a "Right to Appeal" Letter. In other agencies that hear employment-related appeals, employees are able to "opt-out" of the investigative phase and proceed directly to the hearing stage after they have waited a certain period of time.

The Board believes that the approach taken by these agencies is a reasonable and fair one. It therefore is adopting a similar approach for cases within its jurisdiction. The Board published this rule as a proposed rule on August 30, 2000 (65 FR 52674), and invited comments by October 30, 2000. One comment from a current litigant before the Board, supporting the proposed rule, was received within the comment period. The proposed rule is adopted as a final rule without change.

Under the final rule set forth below, GAO employees have the option of bringing their cases directly to the Board if 180 days have passed and the Board's General Counsel has not yet completed the investigation and issued a "Right to Appeal" Letter concerning their case. Thus, no employee will have to wait more than 180 days to have the opportunity to present his or her case to an administrative judge. The amendments do not require an employee to file with the Board as soon as the 180-day period has expired; he or she may file at any time after 180 days have passed, so long as no "Right to

Appeal" letter has been issued. An employee still retains the right to wait for the General Counsel to complete the investigation, before going forward.

Under the final regulations, certain consequences flow from an employee's decision to file a petition for review with the Board before the completion of the General Counsel's investigation. First, the investigation by the Board's General Counsel would be terminated as soon as the employee files a petition for review with the Board. The General Counsel would not gather any further evidence after that point, and the employee would not receive a report from the General Counsel analyzing the facts or law relevant to the employee's case. Second, the Board's rules only permit the General Counsel to represent employees before the Board if the General Counsel completes the investigation and finds "reasonable grounds" to believe that the charge is true. Under the final regulations, therefore, an employee who "opts out" of the investigation after 180 days, and files directly with the Board, would forego the opportunity to have the General Counsel present his or her case to the Board. Such an employee could either represent him- or herself, or obtain private representation.

The Board believes that these consequences are necessary features of its final regulation. While the Board wishes to extend a choice to employees, it does not believe that it would be justifiable to permit employees to go forward before both the General Counsel's Office and the Board simultaneously. Nor would it be appropriate to permit an employee to be represented at public expense in the absence of a finding of reasonable cause by the General Counsel.

The Personnel Appeals Board certifies under 5 U.S.C. 605(b), enacted by the Regulatory Flexibility Act (Pub. L. 96-354), that this rule will not have a significant economic impact on a substantial number of small entities, because it applies exclusively to employees and applicants for employment at the General Accounting Office. For this reason, a regulatory flexibility analysis is not required.

List of Subjects in 4 CFR Part 28

Administrative practice and procedure, Claims, Equal employment opportunity, Government employees, Labor-management relations.

For the reasons stated in the foregoing preamble, the General Accounting Office Personnel Appeals Board amends 4 CFR Chapter I, Subchapter B, Part 28 as follows:

PART 28—GENERAL ACCOUNTING OFFICE PERSONNEL APPEALS BOARD; PROCEDURES APPLICABLE TO CLAIMS CONCERNING EMPLOYMENT PRACTICES AT THE GENERAL ACCOUNTING OFFICE

1. The authority citation for Part 28 continues to read as follows:

Authority: 31 U.S.C. 753.

2. Amend § 28.12 by adding a new paragraph (g) to read as follows:

§ 28.12 General Counsel procedures.

* * * * *

(g) If 180 days have elapsed since the filing of the charge, and the General Counsel has not completed the investigation and issued a Right to Appeal Letter, the charging party may bring his or her case directly to the Board by filing a petition for review in accordance with § 28.18. If a charging party exercises this option to file a petition for review with the Board without waiting for the completion of the investigation, the General Counsel shall not represent the charging party in proceedings before the Board. The charging party may represent him- or herself or obtain other representation. The General Counsel shall close the investigation of the charge upon being notified by the Clerk of the Board that the charging party has filed a petition for review with the Board under this paragraph (g).

3. Amend § 28.18 by revising paragraphs (a) and (b) to read as follows:

§ 28.18 Filing a petition for review with the Board.

(a) *Who may file.* Any person who is claiming to be affected adversely by GAO action or inaction that is within the Board's jurisdiction under subchapter IV of chapter 7 of title 31, United States Code, or who is alleging that GAO or a labor organization engaged or is engaging in an unfair labor practice, may file a petition for review if one of the following is met:

(1) The person has received a Right to Appeal Letter from the Board's General Counsel; or

(2) At least 180 days have elapsed from the filing of the charge with the Board's General Counsel and the General Counsel has not issued a Right to Appeal Letter; or

(3) The person was separated due to a Reduction in Force and chooses to file an appeal directly with the Board,

without first filing with the Board's General Counsel, as provided in § 28.13.

(b) *When to file.* (1) Petitions for review filed pursuant to paragraph (a)(1) of this section must be filed within 30 days after service upon the charging party of the Right to Appeal Letter from the Board's General Counsel.

(2) Petitions for review filed pursuant to paragraph (a)(2) of this section may be filed at any time after 180 days have elapsed from the filing of the charge with the Board's General Counsel, provided that the General Counsel has not issued a Right to Appeal Letter concerning the charge.

(3) Petitions for review filed pursuant to paragraph (a)(3) of this section must be filed within 30 days after the effective date of the separation due to a Reduction in Force.

* * * * *

Michael Wolf,

Chair, Personnel Appeals Board, U.S. General Accounting Office.

[FR Doc. 00-32503 Filed 12-20-00; 8:45 am]

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DEPARTMENT OF AGRICULTURE

Food and Nutrition Service

7 CFR Part 246

RIN 0584-AC51

Special Supplemental Nutrition Program for Women, Infants and Children (WIC): Clarification of WIC Mandates of Public Law 104-193, the Personal Responsibility and Work Opportunity Reconciliation Act of 1996

AGENCY: Food and Nutrition Service, USDA.

ACTION: Final rule.

SUMMARY: This final rule amends the regulations governing the Special Supplemental Nutrition Program for Women, Infants and Children (WIC) to clarify one of the provisions required by the Personal Responsibility and Work Opportunity Reconciliation Act of 1996, enacted on August 22, 1996. The nondiscretionary provisions of that act were incorporated in the WIC Program regulations in an interim rule published September 5, 2000.

EFFECTIVE DATE: This rulemaking becomes effective January 22, 2001.

FOR FURTHER INFORMATION CONTACT: Debra R. Whitford at (703) 305-2746.

SUPPLEMENTARY INFORMATION:

Background

On September 5, 2000, we published an interim rule (65 FR 53523) that

amended the WIC Program regulations to incorporate certain nondiscretionary requirements of the Personal Responsibility and Work Opportunity Reconciliation Act of 1996 (Pub. L. 104-103). We received ten comments on the interim rule.

Nine of the comments concerned the provision in § 246.7(c)(2) providing WIC State agencies the option to limit WIC participation to U.S. citizens, nationals, and qualified aliens contained in section 742 of Pub. L. 104-193 (8 U.S.C. 1615). In particular, the commenters suggested that we incorporate into the regulations our statement in the preamble concerning the effect of a provision to implement this option on the State agency's WIC-eligible population. In the preamble (65 FR 53524-25) we said:

Because a State agency's decision to implement this option will effectively reduce the State agency's eligible WIC population, FNS, by regulatory authority, will make a downward adjustment of that State agency's estimated WIC-eligible population to reflect the number of aliens the State agency declares no longer eligible. If a State agency's participation decreases and food funds are not expended, for whatever reason, including the exclusion of certain categories of aliens, FNS may execute its regulatory authority to recover funds during the year from the State agency in question.

We use the estimated WIC-eligible population for each State agency to determine the State agency's fair share allocation of food funds. We believe that adjusting the State agency's WIC-eligible population to reflect the more limited population eligible for that State agency's WIC Program is a logical result under the current regulations. As such, we have adopted the commenters' suggestion. Accordingly, this final rule amends § 246.16(c)(3)(i)(A) to provide that if a State agency chooses to exercise the option in § 246.7(c)(2), FNS will reduce the State agency's population of income eligible persons to reflect the number of aliens the State agency declares no longer eligible.

Another commenter raised two concerns. First, the commenter objected to the change in § 246.7(b)(3) that makes food assistance referrals optional. We had no discretion on this point as the change was required by Pub. L. 104-193. Second, the commenter encouraged FNS to provide State and local agencies with two years' advance notice when making changes to the data required for the participant characteristic reports. Traditionally, we have worked closely with our State, tribal, and local government partners on any changes to the reporting on participant characteristics. We recognize that

system changes are often needed in order to collect different data and typically provide at least two years notice of any changes. We plan to continue this approach.

Executive Order 12866

This final rule has been determined to be not significant and, therefore, was not reviewed by the Office of Management and Budget (OMB) under Executive Order 12866.

Regulatory Flexibility Act

This final rule has been reviewed with regard to the requirements of the Regulatory Flexibility Act (5 U. S. C. 601–612). Shirley R. Watkins, Under Secretary for Food, Nutrition and Consumer Services, has certified that this rule will not have a significant impact on a substantial number of small entities. This rule relates to a provision providing WIC State agencies with increased flexibility in determining which individuals to serve. Although some WIC local agencies are small entities, the effect of this flexibility on local agencies will not be significant.

Paperwork Reduction Act

This final rule imposes no new reporting or recordkeeping requirements that are subject to OMB review in accordance with the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–20).

Executive Order 12372

The Special Supplemental Nutrition Program for Women, Infants and Children (WIC) is listed in the Catalog of Federal Domestic Assistance Programs under 10.557. For reasons set forth in the final rule in 7 CFR part 3015, subpart V, and related notice (48 FR 29115, June 24, 1983), this program is included in the scope of Executive Order 12372 which requires intergovernmental consultation with State and local officials.

Executive Order 12988

This final rule has been reviewed under Executive Order 12998, Civil Justice Reform. This rule is intended to have preemptive effect with respect to any State or local laws, regulations or policies which conflict with its provisions or which would otherwise impede its full implementation. This rule is not intended to have retroactive effect unless so specified in the **EFFECTIVE DATE** paragraph of this final rule. Prior to any judicial challenge to the application of provisions of this rule, all applicable administrative procedures must be exhausted.

Executive Order 13132

FNS has analyzed this final rule in accordance with the principles set forth in Executive Order 13132. As such, FNS has determined that the rule does not contain policies that have federalism implications as defined in the order and, consequently, a federalism summary impact statement is not required.

Public Law 104–4

Title II of the Unfunded Mandates Reform Act of 1995 (UMRA), Public Law 104–4, establishes requirements for Federal agencies to assess the effects of their regulatory actions on State, local, and tribal governments and the private sector. Under section 202 of the UMRA, the FNS generally must prepare a written statement, including a cost-benefit analysis, for proposed and final rules with “Federal mandates” that may result in expenditures to State, local, or tribal governments, in the aggregate, or the private sector, of \$100 million or more in any one year. When such a statement is needed for a rule, section 205 of the UMRA generally requires FNS to identify and consider a reasonable number of regulatory alternatives and adopt the least costly, more cost-effective or least burdensome alternative that achieves the objectives of the rule.

This rule contains no Federal mandates (under the regulatory provisions of Title II of the UMRA) for State, local, and tribal governments or the private sector of \$100 million or more in any one year. Thus, this rule is not subject to the requirements of sections 202 and 205 of the UMRA.

List of Subjects in 7 CFR Part 246

Administrative practice and procedure, Civil rights, Food assistance programs, Food and Nutrition Service, Food donations, Grant programs-health, Grant programs-social programs, Indians, Infants and children, Maternal and child health, Nutrition, Nutrition education, Penalties, Reporting and recordkeeping requirements, WIC, Women.

Accordingly, the interim rule amending 7 CFR part 246, which was published at 65 FR 53523 on September 5, 2000, is adopted as final with the following change:

PART 246—SPECIAL SUPPLEMENTAL NUTRITION PROGRAM FOR WOMEN, INFANTS, AND CHILDREN

1. The authority citation for Part 246 continues to read as follows:

Authority: 42 U.S.C. 1786.

2. Amend § 246.16(c)(3)(i)(A) by adding a new sentence at the end of the paragraph to read as follows:

§ 246.16 Distribution of funds.

* * * * *

(c) * * *

(3) * * *

(i) * * *

(A) * * * If the State agency chooses to exercise the option in § 246.7(c)(2) to limit program participation to U.S. citizens, nationals, and qualified aliens, FNS will reduce the State agency's population of income eligible persons to reflect the number of aliens the State agency declares no longer eligible.

* * * * *

George A. Braley,

Acting Administrator, Food and Nutrition Service.

[FR Doc. 00–32613 Filed 12–20–00; 8:45 am]

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DEPARTMENT OF JUSTICE

Immigration and Naturalization Service

8 CFR Parts 212, 236, and 241

[INS No. 2029–00; AG Order No. 2349–2000]

RIN 1115–AF82

Detention of Aliens Ordered Removed

AGENCY: Immigration and Naturalization Service, Justice.

ACTION: Final rule.

SUMMARY: This rule amends the Immigration and Naturalization Service (Service) regulations by providing a uniform review process governing the detention of criminal, inadmissible, and other aliens, excluding Mariel Cubans, who have received a final administrative order of removal, deportation, or exclusion but whose departure has not been effected within the 90-day removal period. Such a process is necessary to ensure periodic custody reviews for aliens detained beyond the removal period and to provide for consistency in decision-making. Because the Service is developing a specialized, ongoing administrative review process for these custody determinations, this rule eliminates the appellate role of the Board of Immigration Appeals (Board) in post-final order custody determinations. This rule also amends the Service's regulations to reflect the authority of the Commissioner, and through her, other designated Service officials, to release certain aliens from Service custody, issue orders of supervision, and grant stays of removal.

DATES: This rule is effective December 21, 2000.

FOR FURTHER INFORMATION CONTACT: Joan S. Lieberman, Office of the General Counsel, Immigration and Naturalization Service, 425 I Street NW, Room 6100, Washington, DC 20536, telephone (202) 514-2895 (not a toll-free call).

SUPPLEMENTARY INFORMATION:

Why Is the Service Issuing This Final Rule?

Congress has progressively acted to restrict the release into the community of aliens convicted of certain crimes, beginning with amendments affecting aggravated felons in the Anti-Drug Abuse Act of 1988 (ADAA), Public Law 100-690, and the Immigration Act of 1990 (Immact), Public Law 101-649. Congress extended these restrictions to other categories of crimes in the Antiterrorism and Effective Death Penalty Act of 1996 (AEDPA), Public Law 104-132, and the Illegal Immigration Reform and Immigrant Responsibility Act of 1996 (IIRIRA), Public Law 104-208. Pursuant to these amendments, the Service's continued detention of aliens convicted of aggravated felonies has not been subject to the statutory time limits that apply in the case of certain noncriminal aliens. Under section 241(a)(6) of the Immigration and Nationality Act (Act), 8 U.S.C. 1231(a)(6), certain classes of aliens may be detained in the discretion of the Attorney General beyond the 90-day statutory removal period set forth in section 241(a)(1) of the Act, 8 U.S.C. 1231(a)(1), including aliens determined by the Attorney General to constitute a risk to the community or to be unlikely to comply with the order of removal. As a result of this change in the law and other factors, there has been a considerable increase in the number of aliens in immigration custody who have a final order of removal but who the Service is unable to remove during the 90-day removal period.

The Department of Justice (Department) has determined that a separate custody review process is appropriate for aliens who are detained beyond the 90-day removal period. This rule permits a comprehensive and fair review of such post-order detention by establishing an automatic, centralized, and multi-layered process to determine whether detainees may be released from custody and sets forth the procedures governing such release or continued detention. As was the case with the implementation of the Mariel Cuban Review Plan, this review process is intended to balance the need to protect

the American public from potentially dangerous aliens who remain in the United States contrary to law with the humanitarian concerns arising from another country's unjustified delay or refusal to accept the return of its nationals. This provision also applies to criminal aliens granted withholding or deferral of removal for whom removal to a third country is impractical.

Currently, 8 CFR 241.4 provides the general procedures governing the detention of criminal, inadmissible, and other aliens who have received a final administrative removal order but whose departure has not been effected within the 90-day removal period specified in section 241(a)(1) of the Act, 8 U.S.C. 1231(a)(1). In 1999, pending promulgation of more specific procedures by regulation, and to institute a more uniform process nationwide, the Service issued a series of memoranda to provide specific guidance to field offices concerning implementation of interim procedures governing post-order custody cases. *Detention Procedures for Aliens Whose Immediate Repatriation is Not Possible or Practicable*, February 3, 1999; *Supplemental Detention Procedures*, April 30, 1999; *Interim Changes and Instructions for Conduct of Post-Order Custody Reviews*, August 6, 1999 (collectively "the Pearson memoranda").

This rule establishes permanent procedures for post-order custody reviews. The rule assists the decision-maker in determining whether an alien is an appropriate candidate for release from custody after the expiration of the removal period. On December 21, 2000, these procedures will supersede the Pearson memoranda. The new procedures are modeled after those governing the Mariel Cubans at 8 CFR 212.12 and consist of a records review, the opportunity for a panel interview and recommendation, and a final decision by a separate Service Headquarters unit, the Headquarters Post-Order Detention Unit (HQPDU). Although Mariel Cuban procedures will continue to be conducted pursuant to 8 CFR 212.12, the review process is similar for both groups of aliens.

On June 30, 2000, the Department published in the **Federal Register** at 65 FR 40540 a proposed rule with request for comments to implement a permanent, periodic custody review process for aliens whose removal has not been effected at the expiration of the 90-day removal period pursuant to section 241(a)(6) of the Act, 8 U.S.C. 1231(a)(6). The initial comment period was for 30 days and expired on July 31, 2000. However, in response to several

commenters' requests for an extension, the comment period was extended for 10 days until August 11, 2000.

The Department received numerous public comments recommending substantive modifications to the proposed rule. Many of the comments overlap or endorse the submissions of other commenters. For this reason, the Service will address the comments by issue rather than by reference to the individual comments.

After careful consideration of all comments, the Department will retain the basic structure of the proposed rule, with some modifications. This rule implements an important program in furtherance of congressional and executive policy to ensure the removal of aliens who commit serious crimes in this country and to protect the safety of our citizens and lawful residents against dangerous individuals or those posing a flight risk.

Constitutionality and Statutory Authority

Numerous commenters expressed the view that the proposed rule is not authorized by statute or violates the Constitution of the United States. Post-order detention cases are the subject of on-going litigation. Two courts of appeals have upheld the Attorney General's authority to continue detention after the removal period. *See Duy Duc Ho v. Joseph Greene*, 204 F.3d 1045 (10th Cir. 2000); *Zadvysdas v. Underdown*, 185 F.3d 279 (5th Cir. 1999), *cert. granted*, 121 S.Ct. 297 (2000).

The Ninth Circuit held, however, in *Ma v. Reno*, 208 F.3d 815, 822 (9th Cir. 2000), *cert. granted*, 121 S.Ct. 297 (2000), that detention may not be extended more than a "reasonable time" beyond the statutory removal period. The United States Supreme Court recently granted certiorari in the *Zadvysdas* and *Ma* cases to resolve the disagreements in the courts of appeals.

In *Ho*, the Tenth Circuit upheld the detention of inadmissible and deportable criminal aliens under 8 U.S.C. 1231(a)(6) on statutory and constitutional grounds. 204 F.3d at 1055-1060. The court held, among other things, that section 241(a)(6) of the Act, 8 U.S.C. 1231(a)(6), expressly allows the Attorney General, in her discretion, to continue detaining certain aliens, including aliens who she has determined would pose a risk of danger or flight if released, beyond the 90-day removal period while efforts are being made to remove them from the United States. *Id.* at 1057. The court declined to impose a time limit on detention, stating that it will not "substitute its

judgment for that of Congress by reading into the statute a time limit that is not included in the plain language of the statute." *Id.* at 1057.

Like the Tenth Circuit, the Fifth Circuit, in *Zadvydas*, also rejected a constitutional challenge to continued detention under section 241(a)(6) of the Act, 8 U.S.C. 1231(a)(6). 185 F.3d at 294–97. The Fifth Circuit did not question the statutory authority of the Attorney General to detain a criminal alien beyond the 90-day period where the country to which the alien had been ordered removed declined to accept his return in the near future, and it held that the continued detention of a dangerous criminal alien in these circumstances does not violate substantive or procedural due process. The court analyzed the constitutional question on the premise that the detained alien is able to obtain periodic review of his detention under Service regulations, *see* 185 F.3d at 287–88 & n.9, and that the availability of such periodic review precluded characterization of the alien's detention as indefinite or permanent. *Id.* at 291 (citations omitted). While acknowledging that a deportable resident alien is entitled to greater procedural due process rights during the removal proceedings themselves than those accorded an excludable alien, the court in *Zadvydas* concluded that once a removal order has become final and the only act remaining to be carried out is the actual expulsion of the alien, no distinction exists between the constitutional rights of former resident aliens and those of excludable aliens. *Id.* at 294–97. Therefore, the continued detention of a deportable criminal alien who cannot be immediately removed under section 241(a)(6) of the Act, 8 U.S.C. 1231(a)(6), does not violate substantive due process where the government has an interest in protecting society from further criminal activity by the alien and in ensuring that he or she does not flee and thereby frustrate his or her eventual removal. *Id.* at 296–97.

The Ninth Circuit has interpreted the detention statute in a manner that presents a direct conflict with the decisions of the Tenth and Fifth Circuits. In *Ma*, the court stated that it could avoid deciding the constitutional issues by construing the statute to prohibit detention, in many cases, beyond the 90-day removal period. While recognizing that section 241(a)(6) of the Act, 8 U.S.C. 1231(a)(6), unambiguously authorizes the Attorney General to continue criminal aliens in custody "beyond the removal period," the court nevertheless found that the statute does not specify a particular

length of time for detention and therefore can be construed to permit detention "only for a reasonable time beyond the statutory removal period." 208 F.3d at 821–22, 827. In *Ma* itself, because it concluded that there was not a reasonable likelihood that the alien would be returned to Cambodia in the reasonably foreseeable future, the court held that the Service was required to release him immediately upon the expiration of the statutory removal period. In reaching that result, the court relied on several Ninth Circuit decisions from the 1920's and 1930's interpreting a provision in the Immigration Act of 1917 and on international law. *Id.* at 822, 827–30. Because it concluded that detention beyond 90 days is not statutorily authorized in *Ma*'s case, the court did not address the substantive and procedural constitutional issues that were addressed in *Ho* and *Zadvydas*.

In formulating the proposed custody review procedure, the Department did not follow the Ninth Circuit's statutory ruling because it is not supported by the statute's text or history. The Attorney General construes section 241(a)(6) to authorize her to continue to detain, beyond the 90-day removal period, criminal aliens and other aliens whose release would present a risk of harm to the community or of flight by the alien. That interpretation is supported by the text of section 241(a)(6), which unambiguously authorizes the Attorney General to detain the specified aliens "beyond the removal period" and imposes no time limit; by the related detention provisions in sections 235(c) and 241(a)(2), which make clear that granting the Attorney General even the discretion to release criminal aliens after a notice to appear has been filed is an exception to a general statutory rule of *mandatory* detention of such aliens; by section 241(a)(7), which makes clear that when Congress wanted to create a special exception for aliens whose countries will not immediately accept their return it did so explicitly (*see also* IIRIRA §§ 303(b)(3)(B)(ii) and 307(a)) (referring to situations in which countries will not accept return of their nationals); and by the statutory history of the amendments to the Act leading up to the enactment of section 241(a)(6) in 1996, as well as the legislative history of that enactment itself.

The Attorney General's authority has been sustained by the Third, Fifth, and Tenth Circuits, which have upheld the constitutionality of post-order detention under section 241(a)(6) of the Act, 8 U.S.C. 1231(a)(6), and the Pearson procedures. According to these courts, detention under section 241(a)(6) of the

Act, 8 U.S.C. 1231(a)(6), is not unconstitutional where the alien's removal cannot be effected immediately, the alien is determined to be a danger or a flight risk if released, and he or she is afforded a periodic and meaningful opportunity to seek release from custody. *See, e.g., Ho*, 204 F.3d at 1057–60; *Ngo v. INS*, 192 F.3d 390, 397 (3rd Cir. 1999); *Zadvydas*, 185 F.3d at 287–88. The final rule is structured to afford this type of review. It provides a custody review procedure that is comparable to the Pearson review scheme that two circuit courts have endorsed, *see Ngo*, 192 F.3d at 395–98; *Zadvydas*, 185 F.3d at 297, and the Mariel Cuban Plan that the Ninth Circuit approved in *Barrera-Echavarria v. Rison*, 44 F.3d 1441, 1448 (9th Cir. 1995) (*en banc*). It has the procedural mechanisms that those courts have sustained against procedural due process challenges.

Another commenter felt that the final rule should express commitment to protecting and restoring the alien's liberty. Notwithstanding their physical presence in the United States, aliens under final orders of removal have no greater constitutional rights with respect to their application to be released from custody than excludable aliens seeking admission to the United States for the first time. *Ho*, 204 F.3d at 1058–59; *Zadvydas*, 185 F.3d at 294–95. The government has a compelling interest in expelling aliens under final removal orders, just as it does excludable aliens. *Ho*, 204 F.3d at 1059; *Zadvydas*, 185 F.3d at 296. Furthermore, the failure of another government to agree to the return of its nationals does not divest the United States of its sovereign authority to enforce its immigration laws, nor does it confer on the alien a right to be released back into the United States. *See Jean v. Nelson*, 727 F.2d 957, 975 (11th Cir. 1984) (*en banc*), *aff'd*, 472 U.S. 846 (1985). To conclude otherwise would mean that an alien who has been ordered removed from the United States nonetheless enjoys a constitutional right to release from custody that is greater than what the alien had when he or she was still in proceedings. *Zadvydas*, 185 F.3d at 296.

Finally, a commenter opined that § 241.4(k)(1)(ii) is illegal and should be deleted in its entirety, as well as any other reference in the rule to the additional three-month period that the district director may retain detention authority after the expiration of the removal period. Section 241(a)(6) of the Act, 8 U.S.C. 1231(a)(6), plainly authorizes the Attorney General to exercise her discretion in determining whether to retain custody of criminal

aliens beyond the 90-day removal period. *See* H.R. Rep. No. 104-469, pt.1, at 234 (1996). The Department, while carefully considering the views of the commenters, has determined that the government's statutory interpretation is consistent with the statutory text and history and will retain the basic structure of the proposed rule.

Scope

One commenter suggested changes to proposed §§ 241.4(a) and (a)(4) that would circumscribe the Attorney General's authority contrary to the express language of section 241(a)(6) of the Act, 8 U.S.C. 1231(a)(6). The commenter suggested inserting language that detention be permissible only if necessary to effectuate removal. The Department declines to limit the Attorney General's authority to exercise her discretion in the manner suggested by the commenter.

Some commenters objected to proposed § 241.4(a)(4) because the scope of the rule includes an alien who has been granted withholding or deferral of removal under 8 CFR 208. The nature of the comments suggest that there may be some confusion over the reference to withholding and deferral of removal in proposed § 241.4(a)(4). This section has been revised and paragraphs 241.4(a) and (b)(3) have been added to the final rule to clarify the applicability of these custody procedures.

Many commenters suggested that the rule should create a presumption of immediate release in the case of an alien granted withholding of removal under either section 241(b)(3) of the Act or under the Convention Against Torture. The Department declines to adopt this suggestion, as the decision to detain an individual granted withholding or deferral of removal requires a fact-specific analysis consistent with the provisions of section 241 of the Act. A grant of withholding or deferral of removal is limited to the specific country or countries designated in the order and does not protect an individual from removal to a third country. Moreover, a grant of withholding or deferral of removal does not constitute a grant of admission to the United States; decisions regarding detention and release are subject to section 241 of the Act. With respect to deferral of removal, 8 CFR 208.17(c) specifically provides that persons granted deferral who are otherwise subject to detention continue to be governed by section 241 of the Act. The grant of withholding or deferral is relevant, however, and the decision-maker may consider the grant of protection in reaching a custody determination.

Board Review and Procedural Safeguards

Many commenters expressed concerns over the adequacy of procedural safeguards in the proposed rule and objected to the elimination of Board review of the Service's custody determinations. One commenter opined that the Board ensures consistency of decision making through publication of decisions and suggested that if Board review is eliminated by the final rule, then the Service should publish precedent decisions made available to the public to inform and bind decision-makers in subsequent cases. Further, the commenter noted the regulations should specify that the decisions are binding on the district directors and the Headquarter Post-order Detention Unit (HQPDU). First, the law does not require independent review by the Board. *See Marcello v. Bonds*, 349 U.S. 302, 310 (1955). Second, the rule contemplates individualized determinations where each case must be reviewed on its particular facts and circumstances, and affords aliens periodic reconsideration in a non-adversarial process. Appropriate guidance to the public and the Service officers involved is provided by the rules themselves. Appropriate exercise of discretionary authority and consistency in decision making are further achieved by transferring the detention authority from the various district directors nationwide to the centralized HQPDU and provision for specially trained Service officers who will administer the program and make the periodic custody determinations. The Service concurs with the commenter who expressed concern over training issues and recommended that the Service staff should be trained by non-law enforcement personnel. One of the basic requirements for quality decision making is specific training of officers who will be making custody recommendations or determinations. The Service already has an on-going training program for Service officers who participate in Cuban Review Panels and that training program includes non-law enforcement trainers. Training is being provided to Service officers who will administer the program, and will be maintained and routinely monitored with the implementation of the final rule. The commenter also advocated that the final rule provide an enforcement mechanism if the established procedures are not followed, such as a complaint procedure to the Executive Associate Commissioner for Operations, or Director of the HQPDU. Nothing in the rule prevents the detainee from notifying the HQPDU

Director of delays in the processing of the detainee's custody review. The Service must maintain some flexibility in scheduling reviews, but any unusual delays or other problems should be brought to the Director's attention.

Several commenters expressed concern that the proposed rule does not give the alien a full opportunity to demonstrate why he or she should be released. The rule provides the alien the opportunity to submit advance documentation pertinent to consideration for release, and the alien has a full opportunity to supplement those materials during the panel interview. The panel will not proceed with or will interrupt an interview if it becomes apparent that the alien does not understand the proceedings. Further, the alien may advise the district director or HQPDU in advance of the scheduled review that he or she requests a translator, and, if appropriate, a competent interpreter will be provided.

Representation at no expense to the government is in accord with statutory requirements at section 292 of the Act, 8 U.S.C. 1362. Far from discouraging the alien from obtaining assistance for a custody review, the rule makes reasonable provision for the alien to secure legal services or assistance of his or her choosing at no expense to the government. The Service will provide detainees with a list of available pro bono or low cost legal representatives who may assist the alien in the custody review process.

Independent Adjudicator

The Service also received numerous comments that the district director and HQPDU custody reviews should be conducted by an independent adjudicator. Custody review procedures do not require an independent adjudicator. In *Marcello*, which dealt with deportation proceedings, the court noted that the fact that the special inquiry officer was subject to the supervision and control of Service officials charged with investigative and prosecuting functions did not so strip the hearing of fairness and impartiality as to make the procedure violative of due process. The court stated that: "The contention is without substance when considered against the long-standing practice in deportation proceedings, judicially approved in numerous decisions in the federal courts, and against the special considerations applicable to deportation which the Congress may take into account in exercising its particularly broad discretion in immigration matters." 349 U.S. at 311.

As indicated, this rule is modeled after the Cuban Review Plan, at 8 CFR 212.12, an analogous statutory and regulatory framework providing for the continued custody of excludable criminal aliens when, subject to periodic reconsideration, the Attorney General determines that release of such aliens would pose a danger to the community. The experience of the Cuban Review Plan concretely demonstrates that these procedures provide sound decision making for both the Government and the alien. Because the Cuban Review Plan's inception in April 1988, parole has been granted in over 7,000 cases (some of these may be the same individuals who are repared).

Under the current post-order custody review procedures set forth in 8 CFR 241.4 and the Pearson memorandum, approximately 6,200 aliens have been provided custody reviews by district directors during the period from February 1999 through mid-November 2000, to determine whether detention of the alien beyond the 90-day removal period is warranted. Of those aliens, approximately 3,380 were released.

The Department has carefully considered the views of the commenters, and will retain the proposed procedures in the final rule.

Showing by the Alien

The Service received numerous comments on the showing required of the alien under § 241.4(d)(1). These commenters believed that the Government should bear the burden of demonstrating why the alien should not be released. In other words, there should be a presumption of release. Some commenters objected to the standard of "to the satisfaction of the Attorney General" as confusing and also objected to the language that the alien's release not present a danger to the "safety of other persons or to property." One commenter expressed the belief that this was a lesser standard than "clear and convincing evidence" and was therefore unacceptable.

One commenter proposed language for § 241.4(d)(1) based on a presumption in favor of release and no detention unless conditions identified in 18 U.S.C. 3142(c) cannot reasonably ensure the alien's appearance for removal and protect against dangers to the community, other persons, or property.

A presumption in favor of release along the lines suggested by the commenters would be contrary to recent legislation. Through a series of enactments over the past 13 years, Congress has manifested a serious and growing concern regarding aliens

subject to removal who abscond or commit additional crimes while released from custody. Numerous provisions of the Act, as recently amended, address this concern. See generally 63 FR 27441 (May 18, 1998) (reviewing enactments and legislative history). Moreover, removal proceedings are civil in nature, and the Supreme Court has held consistently and in a variety of contexts that criminal procedures and legal standards are not applicable to such proceedings.

The language of section 241(a)(6) of the Act, 8 U.S.C. 1231(a)(6), the current provision governing post-order detention, does not create any such presumption of release, nor does an alien enjoy a right to liberty on account of the unwillingness of his or her own or another government to accept him or her. See *Gisbert v. Attorney General*, 988 F.2d 1437, 1443, 1447 (5th Cir.), amended, 997 F.2d 1122 (5th Cir. 1993); *Garcia-Mir v. Smith*, 766 F.2d 1478, 1484 (11th Cir. 1985).

The fact that an alien has been released on parole from a criminal sentence, and has not committed any additional offenses while on parole, may be considered by the Service in determining whether an individual alien may be released, but these facts are not dispositive. For example, an alien's release from criminal custody may be based on the expiration of his or her sentence or other factors such as overcrowding in the penal facility and not related to the alien's dangerousness to the community.

After full consideration of all pertinent comments, the Department will retain the required showing by the alien as provided in the proposed rule.

The Alien's Representative and His Role

Several commenters felt that the alien's representative should have a more active role in the custody review process, including questioning the alien and making closing statements. It was also suggested that the panel interview should be modeled after asylum interviews pursuant to 8 CFR 208.9(d). Nothing in the final rule prohibits the representative from speaking and assisting the alien or making a closing statement; however, the procedures are not formal or adversarial in nature, nor is this a criminal proceeding. The representative may be of assistance in bringing factors in support of the alien's request for release to the attention of the decision-maker that the alien may have neglected to mention and which may assist in explaining any documentation that requires clarification. However, the representative is an advocate and does

not replace the need for the initial decision-maker to evaluate the demeanor and credibility of the alien. The decision-maker will evaluate the alien's suitability for release based on observation as well as other relevant circumstances. If the representative could fulfill this function, there would be no need for an interview of the alien. Certainly it is within the decision-maker's discretion to order the alien released after hearing from counsel and receiving any written documentation in support of release just as the decision-maker can order release after a records review. It is not required that the alien participate in an interview, the rule requires that the opportunity be afforded to the alien, however, the decision-maker may draw negative inferences from the alien's failure to participate. The Department finds that it is not necessary to formalize the interview process as has been done with the asylum regulations and will retain the supplemental rule language as written.

A number of commenters objected to the language of §§ 241.4(h)(2) and (i)(3)(ii) referencing the discretion of the panel or the institution to exclude an alien's representative. The Department will modify the language of this section with language similar to that suggested by one of the commenters. To address any security concerns the panel or institution may have in regard to a particular representative, the final rule will reflect that the alien may obtain assistance from a person of his or her choice subject to the panel's and institution's reasonable security concerns.

One commenter also stated that assistance of counsel should be at no expense to the Service rather than at no expense to the Government. The Department has no authority to override the language of section 292 of the Act, 8 U.S.C. 1362, or to authorize expenditures by other government components, and will make no modification to this section of the rule.

Interpreters and Record of Interviews

Many commenters expressed the view that, at the alien's request, the Department should utilize professional interpreters only. One commenter added that interpreters should be utilized whenever one was used in the underlying criminal court case. The Department wishes to stress that wherever communication becomes problematic, the interview will be interrupted or postponed if necessary to secure competent translation. The panel members take notes during the interview process and are instructed

during their training to ensure that the alien understands the nature of the proceedings and has every opportunity to address the panel members and ask questions. Advance notification that the alien desires a translator will enable the decision-maker to investigate the necessity of securing the services of a qualified interpreter and will facilitate conducting the interview as scheduled.

The Department declines to require a taped recording of the interview as some commenters urged. The district director (under § 241.4(c)(1)) and the HQPDU Director (under § 241.4(c)(3)) maintain appropriate files respecting each detained alien who is reviewed for possible release. The HQPDU panel members conducting an interview make contemporaneous notes of the interview, which are made part of the alien's A file. Similarly, when an alien is interviewed as part of the district director's custody review, any notes made of such interview are made part of the alien's A file. In addition, decision-makers may rely on a variety of materials, including those from public records, the Executive Office for Immigration Review's administrative record, and from the alien and his family members and friends. As explained herein, access to the alien's A file is currently provided and that policy remains in effect. Also, as noted below, much of the information in an alien's A file is already in the detainee's possession or is a public record (such as a conviction), and a Freedom of Information Act (FOIA) request can be made for additional items. Any documentation the alien submits will become part of the A file, as does the written recommendation and decision.

Procedural Standards

Some commenters observed that the proposed rule did not impose criminal standards on the custody procedures and suggested that the rule should mandate adherence to principles of criminal law. However, immigration proceedings are civil, not criminal, in nature and rules that are applicable to criminal cases are not so here. *See INS v. Lopez-Mendoza*, 468 U.S. 1032, 1038–39 (1984); *Guti v. INS*, 908 F.2d 495, 496 (9th Cir. 1992) (*per curiam*) (holding Bail Reform Act inapplicable to immigration proceedings).

Specifically, one commenter said that requiring responses from the alien during the panel interview, *see* § 241.4(i)(4), denies the right against self-incrimination. It is up to the alien to demonstrate that he or she does not constitute a danger to the public safety or a flight risk. While responses are not required, if the alien chooses not to

answer questions put to him or her, negative inferences may be drawn from the alien's silence. *See Bilokumsky v. Tod*, 263 U.S. 149, 153–54 (1923).

The Decision Making Process

Many commenters felt that § 241.4(d) did not require sufficiently comprehensive decisions detailing how and why a decision to continue custody was made. Several commenters offered replacement language for this section. The Department will retain the language of the proposed rule that mirrors that of 8 CFR 212.12. A decision to continue custody under this rule must specify the reasons for the continued detention. A particular format is not required.

Several commenters noted that the HQPDU Director should not be able to overrule a panel recommendation of release. One commenter expressed the view that the HQPDU be eliminated altogether. The Department will make no changes to the rule in this respect. The purpose of the HQPDU is to act as a reviewing authority. The HQPDU must have discretion to review the panel recommendation. This discretionary authority does not nullify the interview process as one commenter opined. Rather, the process gives the central reviewer crucial information about the alien that will provide a major focal point for the custody review. To ensure consistency, the HQPDU should be authorized to reverse a favorable as well as an unfavorable panel recommendation in the exercise of the Attorney General's discretion. The procedure of centralized review has been successfully used in the Cuban Review Plan. Experience with that program has demonstrated that the Headquarters decision sometimes overrules the recommendation below, whether that recommendation is in favor of release or continued detention.

One commenter stated that the transfer of detention authority to the centralized unit would cause delays in the process. The final rule provides for periodic reviews at scheduled intervals. The Service will adhere to these timetables as provided in the final rule. Other commenters contend that the process has inherent bias as the composition of the panels is selected from Service professionals who are law enforcement personnel rather than social workers, probation officers, or mental health professionals. Decision making authority regarding custody has traditionally been entrusted to officers of the Service. The Supreme Court has long recognized the ability of Service officers to make immigration determinations, including custody determinations, and Service officers

have long carried out this responsibility. The present rule is intended to draw upon significant, specialized expertise and experience within the Service, particularly from the Mariel Cuban program, to assist the Department in reaching sound, well-considered custody decisions. The Department believes that this rule will improve the quality and consistency of post-order custody decisions, and will retain the pertinent provisions as currently drafted.

District Director Responsibilities

Several commenters stated that the district directors should be encouraged to interview the alien; that it is insufficient to rely on a records review that may not be complete. Under the final rule, the district director has the discretion to conduct a personal or telephonic interview.

Further, under the final rule the alien has the opportunity to submit any documentation that he or she feels supports his or her request for release. In that way, any recent and probative material including rehabilitative efforts may be considered in conducting the custody review. Also, the recent conclusion of immigration proceedings should mean that the A file maintained by the Service on the alien contains the most recent information available. The Department will not mandate a personal or telephonic interview by the district director for the 90-day custody review. It is impracticable to require a district director to personally interview every alien detained within his or her district. The district director must delegate many duties to the officers working for him or her in order to ensure that tasks for which he or she is responsible are carried out properly and as expeditiously as possible. The final rule provides for an interview after the HQPDU has conducted a records review and has not made an initial determination to order the alien's release.

Travel Documents

Some commenters expressed the view that whether or not the Service could obtain a travel document was either irrelevant or of minimal relevance to the issue of whether the alien was eligible for release. In addition, several commenters suggested that travel documents would have to be in the Service's actual possession in order to trigger an inquiry into further detention. The Department will not change the final rule based on these comments. The comments are contrary to the congressional goal, enacted into law, to ensure that aliens ordered removed from

the United States are available for prompt removal when travel documents are obtained. As indicated in the government's response to comments on the constitutionality of this rule and statutory interpretation, section 241(a)(6) of the Act grants the Attorney General specific authority to continue to detain an alien following the expiration of the removal period. An order of removal does not convert to a grant of admission or de facto admission because a foreign government delays or refuses to accept the return of one of its nationals. Similarly, an alien found deportable and ordered removed does not gain permission to remain in the United States simply because of the refusal of another country to admit the alien. Congress enacted the removal period at section 241(a) of the Act to facilitate the removal of criminal aliens, an objective of paramount importance. Detention has proven to be an effective enforcement tool in the removal of criminal aliens as nondetained aliens often fail to appear for pending immigration proceedings or removal after issuance of a final order. It is within the discretion of the Service to determine the likelihood of receipt of a travel document in the foreseeable future. A policy of automatic release pending the issuance of travel documents would thwart the intention of Congress that the Attorney General be vested with the discretion to detain certain aliens including those who pose a danger to the community or a risk of flight pending their removal. Such a policy could serve to encourage foreign governments to further delay or refuse to accept the return of their nationals if they expect the U.S. Government will release the alien. *See Mezei*, 345 U.S. at 216; *Barrera*, 44 F.3d at 1448.

Two commenters felt that the proposed rule improperly penalizes aliens who fail to cooperate with the Service in seeking a travel document. Although the purposes of immigration detention are not punitive, we wish to emphasize that cooperation in obtaining a travel document is required by law, and that failure of an alien subject to a final removal order to cooperate with the Service in obtaining a travel document is a felony punishable by imprisonment of four to ten years. *See* section 243(a)(1)(D) of the Act, 8 U.S.C. 1253(a)(1)(D) (Supp. IV 1998). An alien who fails or refuses to cooperate in obtaining a travel document not only engages in criminal conduct, but also helps to bring about the very condition he or she complains of—*i.e.*, prolonged detention—by that criminal conduct. Moreover, the Act specifically provides

for detention in the event that an alien subject to a final removal order fails or refuses to cooperate in obtaining a travel document. *See* section 241(a)(1)(C) of the Act, 8 U.S.C. 1231(a)(1)(C) (Supp. IV 1998). These provisions manifest a clear congressional policy with regard to cooperation in obtaining travel documents. The Department believes the rule as presently drafted is both consistent with this congressional policy and reasonable in allowing for consideration of the alien's cooperation and compliance with the law. The pertinent provisions will be retained without modification.

Criteria for Release

The Department received several comments objecting to the criteria specified in § 241.4(e) because they differ from the statutory criteria. Other commenters found it confusing to require two separate findings regarding risk to the community and opined that the focus of inquiry should be on prospective behavior in the community. Some commenters found this section gave too much discretion to the decision-maker whereas another felt there was too little discretion. The criteria in this section are consistent with the Mariel Cuban parole regulation at 8 CFR 212.12 and will assist the decision-maker in identifying and evaluating factors relevant to the exercise of discretion regarding continuation of custody. The criteria set out in § 241.4(e) provide essential guidance to the decision-maker in assessing future risk to the community. In making this determination, both past and present behavior are relevant. Restricting the custody review inquiry to behavior subsequent to the alien's release from incarceration or from the time of detention in Service custody would place unacceptable limitations on the decision-maker's ability to fully review the circumstances of an alien's case in making a custody decision.

One commenter suggested additional language for the end of § 241.4(e)(1) (suggested change in *italics*): “* * * immediate removal, while proper, is otherwise not practicable or not in the public interest, or *potentially detrimental to the health or well being of the alien.*” The humanitarian concerns expressed by the commenter are encompassed within the rule's current language of “not practicable or not in the public interest” and additional language is not necessary. The Service has the discretion to release a detainee or even to delay removal for humanitarian reasons.

One commenter suggested that the criteria of § 241.4(e)(3) that “the

detainee is likely to remain nonviolent” be replaced with *the detainee has expressed an intent to remain nonviolent*. The Department believes that the proposed rule correctly captures the relevant inquiry. An expression of intent to refrain from violence, though potentially relevant to a release determination, is not in itself necessarily determinative or even persuasive. Indeed, one of the aims of the process is to assess the detainee's credibility regarding rehabilitation. The language of the proposed rule will be retained, therefore, without modification.

Factors for Consideration

Several comments expressed the view that the commission of disciplinary infractions should not preclude a finding that the alien is not a risk to the community. Other commenters felt that their commission should be afforded minimal weight in the risk assessment because of disparity in detention standards and requirements, constant transfers, and language barriers. There is nothing in the rule that prohibits release in a case where the alien has been involved in the commission of disciplinary infractions. Disciplinary infractions represent one of several factors that are to be considered and afforded appropriate weight in making a recommendation or decision. Some infractions are more serious than others and will be weighed as warranted by the circumstances in each case. As a general matter, however, disciplinary infractions are relevant to danger to the community, because they reflect the alien's present ability to follow rules, respect the rights of others, and act appropriately on his or her own if released into a less structured environment.

The Department received some comments stating that consideration of the detainee's criminal conduct and other criminal history was too broad an inquiry because it allows consideration of unverified charges not resulting in a criminal conviction. However, under the immigration law, grounds of removability may include criminal conduct that does not result from a criminal conviction. Because such conduct is sufficient to support a finding of removability from the United States, it may also be considered for detention purposes. Consideration of criminal history is probative of the threat to the community posed by the alien's potential release. It is relevant to consider the alien's entire criminal history although the weight given to each factor will vary according to the individual facts and circumstances of a

particular case. The rule adequately provides, without additional specificity, for consideration of the nature and severity of the convictions, factors in mitigation of a criminal sentence, the sentence imposed, state parole findings, probation, and other criminal history. Moreover, to the extent that non conviction criminal history information may exist, the decision-maker can make clarifying inquiries with the alien or the alien's representative, as appropriate, and can give criminal history information whatever weight is appropriate in light of the information available.

Commenters suggested that the body of the rule as well as the supplemental information section should state that no negative inference will be made from non-participation in rehabilitation programs if such programs are not available in the facility where the alien is housed. Some commenters wanted the body of the rule to add that (1) barriers to participation include long waiting lists, waiting periods for new detainees, and the unavailability of some programs to detainees, and (2) that program availability at state and local institutions prior to Service detention may be considered.

The Department understands the concerns reflected in these comments, but does not believe that a change in the regulatory text is necessary or appropriate to address them. The relevance of nonparticipation in rehabilitative programs is a proper subject of internal training. It is not necessary, therefore, to reinforce this message through an alteration of regulatory text. Moreover, detainees seeking release are free to submit materials indicating the impossibility or difficulty of enrolling in rehabilitative programs if they wish.

Two commenters felt that the rule should specify the nature of participation in rehabilitation programs, freedom from disciplinary infractions, and other indicia of commitment to good conduct required to secure the alien's release, particularly after commission of violent crimes. In other words, these commenters invite the Department to specify criteria the satisfaction of which would require release from custody.

In general, the custody review determination involves highly individualized case reviews for which mandatory release pursuant to pre-established formulas would not be appropriate. Rather, the Department prefers an approach based on the consideration of factors included in the rule instead of mandatory criteria. The regulation cannot cover every

conceivable circumstance and provide enough flexibility to accommodate multiple issues considered in the exercise of discretion under section 241(a)(6) of the Act, 8 U.S.C. 1231(a)(6). To avoid what the commenter terms "rubber stamp denials," the listed factors and other pertinent information will be evaluated in relation to the alien's character, and ability to adjust in the community. The Department declines to change the rule based on this comment.

Similarly, the Department received numerous comments stating that the only factors that should be considered are the enumerated ones and that no single factor should be weighed so as to exclude all others. The Department declines to make any changes to the final rule based on these comments. Maintaining flexibility is essential to the exercise of discretion. The decision-maker may weigh the same factors differently depending on the circumstances of the individual case. Further, the list of factors for consideration provides a guideline (not an exclusive list) for the decision-maker to utilize in reaching a custody determination. If other relevant circumstances are present in a particular case, the decision-maker must be free to consider them. Several commenters suggested that favorable factors should be set out with more specificity in the rule, including prospects for employment, community care placement opportunities, ties to clergy or community organizations, and sponsorship. Such specificity is not needed in the final rule because the rule already addresses sponsorship and provides for consideration of community ties and other factors whether favorable or unfavorable.

Several commenters suggested that the body of the final rule state that there is no presumption of dangerousness due to the existence of a criminal record. The decision-maker's responsibility is to weigh the severity and circumstances of the criminal conduct along with other material considerations, whether favorable or unfavorable, in making a custody determination. The Department will not mandate a result either for release or detention based on the presence or lack of a particular factor for consideration. As discussed above, it is up to the alien ordered removed to demonstrate a lack of danger to the community and flight risk upon release.

Other commenters suggested that only immigration violations relevant to flight risk should be considered and only willful failures to appear. Failure to appear for probation appointments, court hearings, and other mandated

proceedings is highly probative of flight risk. As with any other factor, the specific circumstances surrounding the failure to appear will determine how much weight the decision-maker gives it. It is unnecessary to amend the final rule and address this with more specificity.

Two commenters wanted to add as a factor for consideration the length of time the detainee has been in immigration custody. The final rule does not exclude this factor, if relevant, from the decision-maker's consideration, but an explicit mention of this has not been included in the rule.

One commenter suggested that favorable factors such as ties to the United States and availability of work or other programs should not be considered because removable aliens may be deported from this country without regard to such considerations. The Department will not change the final rule based on this comment. The crux of this program is to make a custody determination based on an analysis and weighing of factors that may permit the alien's release into the community until such time as his or her removal can be effected. Ties to the community, work opportunities, and rehabilitative programs are relevant to making a custody determination.

Several commenters suggested the addition of a factor to be weighed heavily in favor of the alien: that the alien cannot be returned to his or her country of origin. Although nothing in the rule prevents a decision-maker from considering such a circumstance in rendering a custody decision, the overriding concerns of the rule are public safety and flight risk, and the likelihood of the alien's successful reintegration into the community pending removal. The Department feels that the list of discretionary factors properly focuses on these issues, but leaves decision-makers with broad discretion to consider other circumstances as may be appropriate in each case. Therefore, the text of the rule will not be modified.

Sponsorship

Several commenters believed that the sponsorship provision should be deleted or modified. The suggested language authorizes the district director or Executive Associate Commissioner, in the exercise of discretion, to condition release on the detainee's having a sponsor or participating in an approved halfway house or mental health or community project, whether residential or not. The language of the rule is sufficiently broad to allow the decision-maker to consider a wide range

of sponsorship possibilities. Given that sponsorship is a permissive rather than a mandatory condition of release, the Department will not expand the language of § 241.4(j)(2).

One commenter suggested that the rule should encourage employment authorization and mandate a grant or denial decision within 30 days of application. Such specificity is not required in the final rule. As with other provisions of the final rule, each case will receive individual consideration. The Service will make decisions on work authorization as expeditiously as possible. It was also suggested that the rule should authorize the presence of the sponsor at the panel interview. The Department has no objection to the sponsor's being selected as the alien's representative, subject to the security concerns of the panel or institution. If the alien desires the presence of his or her sponsor in addition to the presence of counsel or other representative, the alien must make advance arrangements with the panel and the facility.

Release or Order of Supervision

One commenter asked whether the release of an inadmissible alien constitutes a release on parole pursuant to section 212(d)(5) of the Act, 8 U.S.C. 1182(d)(5), and 8 CFR 212.5(d)(2)(i) or under an order of supervision pursuant to section 241(a)(3) of the Act, 8 U.S.C. 1231(a)(3), and 8 CFR 241.5. Reference to the parole statute and regulations is correct and will not be revised. An alien who has been denied admission to the United States continues to be an applicant for admission and pending removal is subject to release in accordance with the Attorney General's parole authority both before and after a final order of exclusion or removal on grounds of inadmissibility. *See, e.g., Leng May Ma v. Barber*, 357 U.S. 185, 188 (1958); *Palma v. Verdeyen*, 676 F.2d 100, 103 (4th Cir. 1982); *see also* sections 101(a)(13) and 212(d)(5) of the Act, 8 U.S.C. 1101 (a)(13), 8 U.S.C. 1182(d)(5)(A); 8 CFR 212.12. As in the Mariel Cuban program at 8 CFR 212.12, the Attorney General may impose a reporting requirement or other conditions of release in the case of an inadmissible alien who is detained pursuant to section 241(a)(6) of the Act and approved for parole.

Frequency and Timing of Reviews

Numerous commenters objected to the change from review of custody status every six months under the Pearson memoranda to annual reviews. The Department has fully considered this issue and will retain the annual review structure. The final rule is modeled after

the Cuban Review Plan, which also operates on an annual review schedule. The Pearson reviews were structured on an interim basis until more permanent procedures could be put in place. The final rule will allow sufficient time between reviews for interview scheduling and compiling of the materials for review. Further, interim reviews are not foreclosed by the annually scheduled custody review. Under § 241.4(k)(2)(iii), the HQPDU will respond to the alien's written request for release based on a showing of a material change in circumstances since the last annual review. One commenter asked why there were no sanctions in the rule if a review is late. The remedy if a review is late is a full review as soon as possible. The Department must preserve flexibility for redeployment of Service staff for national immigration emergencies or other mandates requiring immediate attention. Extreme weather conditions, or other transportation problems may delay a panel's visit to a particular facility. A panel member's illness or other personal emergency, a prison lock-down situation, or the alien's transfer to another facility are some other reasons that interviews might be delayed.

Several commenters objected to § 241.4(k)(3) of the rule allowing for suspension of reviews for removal or good cause. Other commenters urged that this section provide for notice and a right of appeal. The Department will retain this section in the rule as written. This section is essential for administration of the program and in furtherance of removal where practicable. Release under section 241(a)(6) of the Act is a privilege and can be revoked. As provided in the rule, if further review is appropriate after suspension, it will be rescheduled. Any administrative appeal and hearing would only delay the review further and would be inappropriate in cases where prompt removal is practicable.

Several commenters suggested that transfer of detention authority from the district director to the HQPDU should occur upon expiration of the removal period. The Department will retain the rule provisions regarding transfer as written. The rule provides for an orderly transfer of authority and fully sets out the procedures for automatic, periodic review.

One commenter noted that the rule is a tremendous improvement in providing for meaningful and periodic reviews. The balance of comments pertaining to § 241.4(k) concern requiring mandatory deadlines for conducting custody reviews, writing decisions, and serving them on the alien. The Department will

not make any changes to the final rule as a result of these comments. As indicated in previous responses, the Service must maintain flexibility for allocation of resources and for working cooperatively with other federal agencies as well as state and local authorities. The Service is obligated to make every reasonable effort to ensure that reviews are held timely and professionally.

Interim Reviews

Two commenters suggested revision of § 241.4(k)(2)(iii) to allow for quarterly interim reviews at the alien's request without restriction. The Department understands the commenters' concerns; however, implementing such a program would severely strain Service resources, which do not permit more frequent reviews without cause. The Service would scarcely have completed a review before it would be time to begin another. Frequent re-review of the same facts without any change in circumstances in support of release would merely serve to misdirect Service resources that otherwise could be more usefully employed and would result in delay of reviews in other cases. The Department disagrees with the comment that circumstances cannot change because the alien is detained. For example, an appropriate sponsor might be located, the alien might receive an employment offer, remain incident free, or become eligible for or successfully complete rehabilitative programs that might influence the decision-maker to approve release.

Notice and File Access

Some commenters requested that the notification of custody review be extended to 45 or 60 days prior to the review. The Department declines to extend this notification period. If the alien requires additional time to prepare for a custody review, it may be granted in accordance with the provisions of the final rule. The Department agrees with the commenter who suggests that the alien be given the address of the HQPDU. That information will be supplied to the alien with written notification of the Headquarters custody review.

Some commenters felt that § 241.4(h)(4) should specifically advise the alien if the district director is retaining jurisdiction over the case for the additional three-month period, rather than referring the case to the HQPDU at the expiration of the 90-day removal period. The structure of the final rule permits the district director flexibility in determining what options are available to him or her during the

initial period when the Service has assumed physical custody over the alien. During this additional three-month period, the district director may be able to execute the removal order, may order the alien's release pending removal, or may refer the case to the HQPDU for further review. The rule's notice requirements advise the alien of the results of the 90-day review while maintaining the district director's flexibility to determine what further action the case requires.

Numerous commenters requested full disclosure to the detainee and the representative of the alien's A file and the file of the detention facility. Others requested copies of all documents relied on by the Service at the custody review. Access to the alien A file will be provided to the detainee and the representative in accordance with current Service policy and practice as developed under the Cuban Review Plan, and subject to limited exceptions such as the identities of confidential informants, law enforcement personnel, and documents that cannot be released because the information therein would adversely effect an ongoing investigation.

Because access to the A file is provided, the Service will not provide copies as a matter of course. In any event, much of the information in the A file is already in the detainee's possession as it was originally obtained from the detainee or is a public record (such as conviction documents). A FOIA request can be made for additional items. The detainee or representative must make arrangements for access to files of the detention facility from the custodian of those records in advance of when the party wishes to review them. The Service is not the custodian of files maintained by a non-Service detention facility and has no authority to grant or deny access to such files.

One commenter proposed language changes to the provisions concerning service of notices and decisions to the alien and the representative of record. The Department will not change the wording of §§ 241.4(d)(2) or (d)(3). Section 241.4(d)(3) adequately ensures that the representative of record will receive a copy of any notice or decision.

One commenter requested that the notice required by § 241.4(h)(2) for the district director's 90-day review advise the alien of the criteria of § 241.4(e) and the factors in § 241.4(f). The Department will adopt this recommendation. The notice of a district director or HQPDU custody review will advise the alien of the criteria of § 241.4(e) (conclusions that must be drawn by the decision-maker before approving a release) and

factors in § 241.4(f) to assist the alien in preparing for the review. A notice of custody review, whether by the district director or the HQPDU, will briefly advise the alien of the review procedures and display the correct address for submission of any documents. For a more detailed explanation of review procedures, the detainee may consult the final rule.

The Department will not accept the recommendation of a commenter to amend the language of § 241.4(h)(2) so that the alien's request for additional time to submit documentation to the district director extends the time for conducting the custody review only until the additional information has been received. The custody review will be conducted as promptly as scheduling permits.

Withdrawal of Release Approval/Revocation

One commenter objected to § 241.4(l)(2) (Determination by the Service). Other commenters recommended limiting § 241.4(j)(4) (Withdrawal of release approval) to cases where removal is practicable or there is a material change in the detainee's conduct, indicating he poses a risk to the community. Commenters also requested written notice of withdrawal of release approval and provisions for a hearing process. Upon revocation, commenters suggested that the next review be conducted within 3 months. Depending on the circumstances of a particular case, revocation or withdrawal of release authorization under section 241(a)(6) of the Act, 8 U.S.C. 1231(a)(6), may be appropriate for any of the reasons listed in section 241.4(l)(2) of the rule, including the alien's violation of a condition of release. Cf. section 243 of the Act, 8 U.S.C. 1253(b) (authorizing criminal sanctions for violation of release conditions). Section 241.4(l)(1) of the rule provides that, upon revocation, the alien will be provided notice of the reasons for the revocation. In addition, the rule is being modified to provide that the alien will be afforded an initial informal interview promptly after his return to Service custody to provide the alien an opportunity to respond to the reasons for the revocation. The rule currently provides at § 241.4(l)(3) for a full custody review, including an interview, to be conducted within three months of the revocation of release. The rule is being modified to clarify that the custody review will include a final evaluation of any contested facts relevant to the revocation and a determination whether

the facts as determined warrant revocation and further denial of release.

Recordkeeping, Reporting, and Ombudsman

Several commenters stated that the district director should forward all documents submitted by the alien to the HQPDU. The Department agrees with this recommendation. The alien's submissions will be included in the HQPDU custody review file.

Several commenters endorsed a recommendation that the Service compile statistics on nationality, length and place of detention, and dates of review, and that these statistics be made available for independent review. The Service will maintain statistics on the detained post-order population. Such statistics may be available through authorized pre-existing procedures. The Department declines to appoint a separate ombudsman to oversee the implementation of the program and keep statistics. The Service has a Headquarters managerial position in the Detention and Removals Branch that fulfills the functions of an ombudsman.

Courts

Some commenters wanted the rule to permit federal court stays. *See* 8 CFR 241.6 (Administrative stay of removal). This rule concerns the delegation and exercise of powers by the Attorney General, not the courts. Thus, the rule will not be modified to account for judicial stays.

Executive Orders

One commenter predicted that the rule will prolong litigation with a corresponding increase in costs if promulgated. The commenter also noted the Government's litigation and detention costs. These comments concern policy determinations made by Congress, which sets immigration policy and passes legislation allocating expenditures within the federal budget. This is not an executive or judicial function.

This commenter also stated that the rule affects the relationship between the states and the federal government by nullifying prior determinations (to release) by state court judges, probation officers, prison authorities, and parole administrators. The commenter stated that the rule requires a federalism summary impact statement. The Department disagrees with the need for an impact statement. States have no authority to regulate immigration. This function is solely within the province of the federal government. This rule concerns civil immigration, not criminal law. The statutes and policies being

implemented by state courts, probation and parole departments, and penal authorities' release determinations are based on different goals and responsibilities than those that govern a release or detention decision affecting an alien under a final order of removal. For example, release from a term of imprisonment is mandated when an individual has been sentenced for commission of a criminal offense and that sentence has been served. There is no authority to detain the individual longer under that criminal sentence. Also, a particular sentence may be mandated by statute irrespective of the risk that the criminal poses to the community upon release. This is exemplified in "truth-in-sentencing" jurisdictions. There have also been various instances where a court order mandates the release of criminals because of prison overcrowding. Thus, the Department believes that no impact study is required.

Venue for Panel Reviews

Two commenters stated that panel reviews should be conducted at district processing centers to allow attorney representatives and family to attend. The Department cannot implement this suggestion. The rule already permits the attendance of the attorney representative. Panel interviews will be conducted at the facility where the alien is detained. Moving detainees for interviews would involve significant additional expenditures and security concerns that would detract from the expeditious and efficient operation of the program.

Transition Provisions

The Department will retain the transition provisions as written. Two commenters requested that transitional cases receive an interview irrespective of whether the last review was a records review or included an interview and that the reviews should be held more frequently than specified in the rule. The transition provisions of the rule more closely mirror the permanent procedures than do the commenters' suggestions, which in timing resemble the interim Pearson provisions. The provisions allow the Service to give full consideration to cases that have not yet received any review and advance equal treatment of all cases more expeditiously than the commenters' proposal.

Vera Institute of Justice Study

A commenter noted that the proposed rule did not mention the Vera Institute of Justice study recommending alternatives to detention for aliens

ordered removed. The Service recently received the final report of the Vera Institute Appearance Assistance Program, and is currently reviewing it. The Service agrees that there is potential for use of the processes and information from the study in the area of detention of aliens with final removal orders. The Service intends to establish additional pilot projects in several districts in the next year. The projects may include contract or governmental personnel and will test various levels of supervision. Supervised release of post-order detainees will be examined in some of the test sites. These projects may involve halfway houses or other support and rehabilitation programs to prepare detainees for release or for future consideration.

Several commenters suggested deletion of the language in the supplementary information addressing foreign and domestic affairs, availability of resources, public policy, and humanitarian concerns. The Attorney General must be able to take these factors into account and assess their impact on individual and institutional decision making. *INS v. Aguirre-Aguirre*, 526 U.S. 415, 424–25 (1999).

Who Is Covered Under This Final Rule?

This rule establishes a permanent review procedure applying to aliens who are detained following expiration of the 90-day removal period. It also applies to aliens released under the provisions of the final rule upon a finding that they do not constitute a risk to the community or a flight risk. The Attorney General is authorized to detain these aliens beyond the removal period consistent with section 241(a)(6) of the Act, 8 U.S.C. 1231(a)(6). This permanent review procedure governs all post-order custody reviews inclusive of aliens who are the subjects of a final order of removal, deportation, or exclusion, with the exception of inadmissible Mariel Cubans whose parole under section 212(d)(5) of the Act, 8 U.S.C. 1182(d)(5), is governed by the provisions of 8 CFR 212.12. Mariel Cuban custody reviews will continue to be conducted pursuant to those provisions.

What Are the Proposed Procedures for Post-Order Custody Reviews?

Under the final rule, the district director maintains the responsibility for the initial custody review when the alien's immediate removal is proper but not practicable at the expiration of the removal period. For the initial post-order custody review at the expiration of the removal period (the 90-day custody review), the district director will conduct a records review. In most

cases, it will be unnecessary for the district director to undertake a personal interview because the alien's immigration proceedings have recently concluded, and his or her records are therefore up-to-date. The district director has the discretion to conduct a personal or telephonic interview if he or she finds that it will assist him or her in making a custody determination. Further, the alien will be provided with the opportunity to present any relevant written information the alien desires in support of his or her release into the community.

After the 90-day custody review, the district director will notify the alien in writing that he or she is to be released from custody, or that the alien will be continued in detention pending removal or further review of his or her custody status.

Where the district director has notified the alien that he or she will continue to be detained pending removal, the district director's authority to reconsider an alien's custody status may be extended for an additional period of up to three months after expiration of the removal period. The additional three-month period will allow the district director to continue efforts to obtain the necessary travel documents to effect the alien's removal before the detention authority is transferred to Service Headquarters.

During the additional three-month period, the alien may submit a written request to the district director for further review of his or her custody status. The district director shall consider information that the alien submits in support of his or her release from detention demonstrating a material change in circumstances. The district director will provide a written response as appropriate to the alien's submission of such new information and may, in the exercise of discretion, conduct any further review of the alien's custody status that he or she deems appropriate. The district director retains the authority to release the alien during this period as well.

If the alien has not been removed or released from detention, detention authority transfers to the newly designated Service component, the HQPDU, under the authority of the Executive Associate Commissioner, Field Operations (Executive Associate Commissioner), either at the end of the 90-day removal period or at the expiration of the three-month extension period. Under either circumstance, the HQPDU will ordinarily commence a custody review within 30 days of the transfer of detention authority or as soon as possible thereafter should

unforeseen or emergent circumstances arise. The alien will receive written notice of the custody review approximately 30 days prior to the scheduled review. The HQPDU will conduct all further custody determinations as long as the alien remains in custody pending removal. Subsequent custody reviews will be conducted at annual intervals (or more frequently in the sole discretion of the HQPDU).

When the detention authority transfers to the HQPDU, that unit will conduct a records review for each alien previously ordered detained by the district director. If the records review does not result in a release decision, the alien will be given the opportunity for a panel interview. The two-member panel will be chosen from professional staff of the Service. The interview will be conducted in person and a translator will be provided if the Service official determines that a translator's assistance is appropriate. As under the Mariel Cuban Review Plan, the interviewing panel will make a custody recommendation to the HQPDU. Upon receipt of the panel's recommendation, the HQPDU shall determine whether to detain the alien or grant release consistent with the delegation of discretionary authority. The decision of the HQPDU will be final and will not be subject to further administrative review.

The HQPDU is not bound by the panel's recommendation. The HQPDU retains full statutory authority for custody determinations under sections 241(a)(6), 8 U.S.C. 1231(a)(6), and (for inadmissible aliens) 212(d)(5) of the Act, 8 U.S.C. 1182(d)(5). The panel's recommendation is designed to serve as an important guide to the exercise of discretion for the HQPDU, but the decision-maker must be free to assess all of the circumstances in arriving at a final custody determination. The decision-maker must also take into consideration changes in foreign and domestic affairs, the availability of fiscal resources, public policy and humanitarian concerns, and other factors that could weigh for or against the decision in an individual case.

The subsequent HQPDU periodic review, to be conducted within one year of a decision declining to grant release under these procedures or as soon as practicable thereafter in case of unforeseen circumstances or an emergent situation, will address whether the alien can be released into the community if the alien has not been removed since the last review. The HQPDU may conduct a custody review at more frequent intervals at its sole discretion and consider written

submissions demonstrating any material change in circumstances that supports the alien's release during the interval between reviews. Material change does not include mere disagreement with the decision denying release. The HQPDU will give a written response to the alien's submission of new information as appropriate under the rule. Written submissions, whether to the district director or the HQPDU, must be in English or they may not be given consideration.

The alien may be assisted by a person of his or her choice in preparing or submitting information in response to the notice of custody review. The Service has followed the guidelines set forth in 8 CFR 212.12(d)(4)(ii) (regarding representation of an alien before a Mariel Cuban parole panel) rather than the more formal rules regarding attorney representatives at 8 CFR 292.1. Both 8 CFR 212.12 and this final rule allow the alien to be accompanied by a person of his or her choice at the panel interview (subject to the discretion of the institution and panel). It may be difficult for the detained alien to secure the services of a licensed attorney for each annual review, or counsel may change between reviews. Further, giving the alien discretion in selecting who will assist him or her in preparation of materials for submission to the district director and who will accompany him or her to the panel proceeding promotes two important Service objectives. These objectives are to make this process as flexible and nonadversarial as possible and to promote the alien's level of comfort with the proceedings. The alien's representative will be required to complete a Form G-28, Notice of Entry of Appearance as Attorney or Representative, at the time of the interview or prior to reviewing the detainee's records. Attached to any notice of a records review or interview, the Service will provide a list of free or low cost attorneys and representatives who are located near the alien's place of confinement.

Although the Service will forward a copy of all notices and decisions relating to the custody review to counsel or other representative of record through regular mail, the alien bears primary responsibility for ensuring that the individual providing assistance to him or her is aware of any notices, decisions, or other documentation relating to the custody review. Experience with the Cuban Review Plan has demonstrated that an alien may have several representatives successively, or may be assisted by an attorney, other person, or organization whose representation is not known to the Service.

Any person assisting the alien should not answer for the alien but should assist the alien in the latter's presentation of information supporting a release decision. Whether the alien's case is before the district director for review or the panel for an interview, the purpose of the review process is to collect information. Because the decision-maker must evaluate the suitability of the alien for release, it is important for the alien to address the district director or panel directly and be able to speak freely. The district director and panel need to hear from the alien rather than his or her representative.

Both the Executive Associate Commissioner through the HQPDU and the district director have the authority to withdraw approval for release and to revoke release or parole in the exercise of discretion. Reasons for withdrawal of approval for release or revocation include the Service's ability to obtain a travel document and remove the alien, the alien's adverse conduct while awaiting release, the decision-maker's belief that the alien's actions while in the community pose a threat to public safety, or any other circumstance that indicates that release would no longer be appropriate. If the decision-maker withdraws release approval or revokes the alien's release or parole, the alien will receive written notification specifying the reasons for the withdrawal of approval for release or revocation of post-order release or parole. The alien will be afforded an initial informal interview promptly after his or her return to Service custody to afford the alien an opportunity to respond to the reasons stated in the notice. A full custody review, including an interview, will be conducted within three months of the revocation of release and will include a final evaluation of any contested facts relevant to the revocation, and a determination whether the facts as determined warrant revocation and further denial of release.

This rule addresses Service procedures for conducting post-order custody reviews. It does not circumscribe the exercise of the Commissioner's authority to direct otherwise, as appropriate. Section 2.1 delegates the authority vested with the Attorney General to the Commissioner. Section 241(a)(3) of the Act vests authority with the Attorney General to promulgate regulations governing supervision of aliens beyond the removal period and section 241(c)(2) of the Act vests authority with the Attorney General to grant stays of removal. Therefore, the Commissioner already has the authority to release certain aliens from Service custody,

issue orders of supervision, and grant stays of removal. As directed by the Commissioner or Deputy Commissioner, Service officials have authority to release certain aliens from Service custody, issue orders of supervision, and grant stays of removal. Therefore, this rule also amends 8 CFR 241.4, 241.5, and 241.6 to reflect the concurrent authority of the Commissioner and other designated Service officials.

What Other Changes Does This Rule Make?

This rule terminates the existing procedure of appeal to the Board of Immigration Appeals (Board) under 8 CFR 236.1 for an alien who receives an unfavorable custody decision from the district director. *See Matter of Saelee*, Interim Decision 3427 (BIA 2000). Because these aliens have final orders of removal, all legal issues involving removability (and any relief from removal, if available) have been resolved through the Executive Office for Immigration Review or through alternate procedures. Custody determinations at this stage of the process involve separate and distinct issues, and the Service has the knowledge and expertise required to make these custody decisions.

This rule for permanent procedures provides for an automatic multi-tiered annual review process subsequent to the district director's 90-day review as long as the alien remains in custody. The detainee is assured a periodic and thorough review that does not depend on the alien's request for a custody review or the filing of an appeal, but is required at regular intervals by regulation. This review process will ensure timely, scheduled reviews of each alien's custody status.

Accordingly, in order to implement a single comprehensive review process for post-order custody cases, this rule removes all references to post-order detention from 8 CFR 236.1. As revised, 8 CFR 236.1 would govern detention issues only for aliens who have not yet received a final removal order.

Any case pending before the Board on December 21, 2000 will be completed by the Board. Should the alien decide to withdraw his or her appeal, the Service shall continue to conduct custody reviews under the provisions of this rule.

This rule also removes 8 CFR 212.13 and any references to that section in 8 CFR 212.5 and 8 CFR 212.12. Section 212.13 established a single Departmental parole review for all excludable Mariel Cubans who on December 21, 2000 were detained by

virtue of the Attorney General's authority under the Act and whose parole had been denied after the exhaustion of the review procedures of 8 CFR 212.12. The Departmental Review Panels have completed the review of the cases of detainees eligible for such review. Thus, there is no longer a need for 8 CFR 212.13. This action will not otherwise affect the Cuban Review Plan set forth in 8 CFR 212.12.

What Must the Alien Demonstrate To Show His or Her Suitability for Release?

The alien must be able to show to the satisfaction of the decision-maker that he or she does not constitute a danger to public safety or a flight risk pursuant to the criteria set forth in this rule.

If a Travel Document Can Be Obtained, How Is The Custody Review Process Affected?

Detention or release of aliens with a final order of removal is tied to the Service's mission to enforce the immigration laws and protect the interests of the United States, pending the aliens' eventual removal from the United States. Accordingly, district directors will continue to make efforts to obtain travel documents even after review authority has transferred to the HQPDU. Headquarters Detention and Removals, Office of Field Operations will also assist in the effort to secure travel documents.

The ability to secure a travel document by itself supports a decision to continue detention pending the removal of the alien and obviates the need for further custody review because it means the alien can be deported promptly. *See* 8 CFR 212.12(g)(1). Custody reviews may be pretermitted in the case of an alien for whom travel documents are available. Pending litigation, an administrative or judicial stay, or other barrier to removal does not entitle a removable alien to be released within the United States pending resolution of the underlying action or event. Aliens whose removal is withheld under 8 CFR 208.16 or deferred under 8 CFR 208.17 may be considered for release.

Will There Be Special Release Conditions Under This Rule and Will Work Authorization Be Granted?

Release conditions and work authorization for aliens subject to a final order of removal will continue to be governed by 8 CFR 241.5. The district director or HQPDU may wish to impose conditions, in addition to those enumerated by regulation, such as that the alien obey all laws, not associate

with any persons involved in criminal activity, not associate with anyone convicted of a felony without permission, not carry firearms or other dangerous weapons, and such other conditions as the decision-maker deems appropriate. Under 8 CFR 241.5(c), a grant of work authorization is discretionary but requires the decision-maker to make an initial finding that the alien cannot be immediately removed because no country will accept the alien or that the alien's removal is impracticable or contrary to the public interest.

Sponsorship and evidence of financial support may be required as a precursor to release under the rule. The Service has determined that appropriate sponsorship is in the best interest of the alien and community when an alien is approved for release pending removal. *See, e.g., Fernandez-Roque v. Smith*, 734 F.2d 576, 583 (11th Cir. 1984). Although the Service reserves the authority to impose conditions of release, including appropriate sponsorship, this rule does not compel the Government to tailor existing programs to the needs of individual aliens or to create or fund additional programs if suitable sponsorship is not located or available for an alien.

If an alien is detained in a facility that does not provide any rehabilitative programs, no negative inference respecting release will be drawn against the alien in making a custody determination based on the fact that the alien did not participate in such programs. However, if the facility has such programs available to the alien but the alien refuses to participate, that fact may be considered by the decision-maker.

Effective Date of this Final Rule

The Department's implementation of this final rule effective upon publication in the **Federal Register** is based upon the "good cause" exception found at 5 U.S.C. 553(d)(3). The Pearson reviews were intended for interim use only; through this rule, the agency has now adopted permanent and more comprehensive procedures for post-order detainees. Implementation upon publication affords both the Government and detainees the benefits of the new procedures as soon as possible. Delaying the effective date of this rule would be contrary to the public interest.

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 this rule will not have a significant economic impact on a substantial number of small entities. This rule would provide a more uniform review process governing the detention of certain aliens who have received a final administrative removal order but whose departure has not been effected within the 90-day removal period. This rule does not affect small entities as that term is defined in 5 U.S.C. 601(6).

Unfunded Mandates Reform Act of 1995

This rule will not result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of \$100 million or more in any one year, and it will not significantly or uniquely affect small governments. Therefore, no actions were deemed necessary under the provisions of the Unfunded Mandates Reform Act of 1995.

Small Business Regulatory Enforcement Fairness Act of 1996

This rule is not a major rule as defined by section 251 of the Small Business Regulatory Enforcement Act of 1996, 5 U.S.C. 804. This rule will not result in an annual effect on the economy of \$100 million or more; a major increase in costs or prices; or significant adverse effects on competition, employment, investment, productivity, innovation, or on the ability of United States-based companies to compete with foreign-based companies in domestic and export markets.

Executive Order 12866

This rule is considered by the Department, to be a "significant regulatory action" under Executive Order 12866, section 3(f), Regulatory Planning and Review. Accordingly, this rule has been submitted to the Office of Management and Budget for review.

Executive Order 13132

This 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 section 6 of Executive Order 13132, it is determined that this rule does not have sufficient federalism implications to warrant the preparation of a federalism summary impact statement.

Executive Order 12988

This rule meets the applicable standards set forth in sections 3(a) and

3(b)(2) of Executive Order 12988, Civil Justice Reform.

List of Subjects

8 CFR Part 212

Administrative practice and procedure, Aliens, Immigration, Passports and visas, Reporting and recordkeeping requirements.

8 CFR Part 236

Administrative practice and procedure, Aliens, Immigration.

8 CFR Part 241

Administrative practice and procedure, Aliens, Immigration.

Accordingly, chapter I of title 8 of the Code of Federal Regulations is amended as follows:

PART 212—DOCUMENTARY REQUIREMENTS: NONIMMIGRANTS; WAIVERS; ADMISSION OF CERTAIN INADMISSIBLE ALIENS; PAROLE

1. The authority citation for part 212 continues to read as follows:

Authority: 8 U.S.C. 1101, 1102, 1103, 1182, 1184, 1187, 1225, 1226, 1227, 1228, 1252; 8 CFR part 2.

§ 212.5 [Amended]

2. Section 212.5(f) is amended by revising the phrase "§ 212.12 and 212.13" to read "§ 212.12".

§ 212.12 [Amended]

3. Section 212.12 is amended by:

- Revising the phrase "Except as provided in § 212.13, the authority" to read "The authority" in paragraph (b) introductory text; and by
- Removing the word "either" and removing the phrase "or § 212.13, whichever is later" in paragraph (g)(2).

§ 212.13 [Removed]

4. Remove section 212.13.

PART 236—APPREHENSION AND DETENTION OF INADMISSIBLE AND DEPORTABLE ALIENS; REMOVAL OF ALIENS ORDERED REMOVED

5. The authority citation for part 236 continues to read as follows:

Authority: 8 U.S.C. 1103, 1182, 1224, 1225, 1226, 1227, 1362; sec. 303(b) of Div. C of Pub. L. No. 104–208; 8 CFR part 2.

6. Section 236.1 is amended by:

- Removing the last sentence in paragraph (d)(1);
- Revising paragraph (d)(2); and by
- Removing paragraph (d)(3)(iii), to read as follows:

§ 236.1 Apprehension, custody, and detention.

* * * * *

(d) * * *

(2) *Application to the district director.* After expiration of the 7-day period in paragraph (d)(1) of this section, the respondent may request review by the district director of the conditions of his or her release.

* * * * *

PART 241—APPREHENSION AND DETENTION OF ALIENS ORDERED REMOVED

7. The authority citation for part 241 is revised to read as follows:

Authority: 8 U.S.C. 1103, 1223, 1227, 1231, 1251, 1253, 1255, and 1330; 8 CFR part 2.

8. Section 241.4 is revised to read as follows:

§ 241.4 Continued detention of inadmissible, criminal, and other aliens beyond the removal period.

(a) *Scope.* The authority to continue an alien in custody or grant release or parole under sections 241(a)(6) and 212(d)(5)(A) of the Act shall be exercised by the Commissioner or Deputy Commissioner, as follows: Except as otherwise directed by the Commissioner or his or her designee, the Executive Associate Commissioner Field Operations (Executive Associate Commissioner) or the district director may continue an alien in custody beyond the removal period described in section 241(a)(1) of the Act pursuant to the procedures described in this section. Except as provided in paragraph (b)(2) of this section, the provisions of this section apply to custody determinations for the following groups of aliens:

(1) An alien ordered removed who is inadmissible under section 212 of the Act, including an excludable alien convicted of one or more aggravated felony offenses and subject to the provisions of section 501(b) of the Immigration Act of 1990, Public Law 101–649, 104 Stat. 4978, 5048 (codified at 8 U.S.C. 1226(e)(1) through (e)(3)(1994));

(2) An alien ordered removed who is removable under section 237(a)(1)(C) of the Act;

(3) An alien ordered removed who is removable under sections 237(a)(2) or 237(a)(4) of the Act, including deportable criminal aliens whose cases are governed by former section 242 of the Act prior to amendment by the Illegal Immigration Reform and Immigrant Responsibility Act of 1996, Div. C of Public Law 104–208, 110 Stat. 3009–546; and

(4) An alien ordered removed who the decision-maker determines is unlikely to comply with the removal order or is a risk to the community.

(b) *Applicability to particular aliens.*—(1) *Motions to reopen.* An alien who has filed a motion to reopen immigration proceedings for consideration of relief from removal, including withholding or deferral of removal pursuant to 8 CFR 208.16 or 208.17, shall remain subject to the provisions of this section unless the motion to reopen is granted. Section 236 of the Act and 8 CFR 236.1 govern custody determinations for aliens who are in pending immigration proceedings before the Executive Office for Immigration Review.

(2) *Parole for certain Cuban nationals.* The review procedures in this section do not apply to any inadmissible Mariel Cuban who is being detained by the Service pending an exclusion or removal proceeding, or following entry of a final exclusion or pending his or her return to Cuba or removal to another country. Instead, the determination whether to release on parole, or to revoke such parole, or to detain, shall in the case of a Mariel Cuban be governed by the procedures in 8 CFR 212.12.

(3) *Individuals granted withholding or deferral of removal.* Aliens granted withholding of removal under section 241(b)(3) of the Act or withholding or deferral of removal under the Convention Against Torture who are otherwise subject to detention are subject to the provisions of this part 241. Individuals subject to a termination of deferral hearing under 8 CFR 208.17(d) remain subject to the provisions of this part 241 throughout the termination process.

(c) *Delegation of authority.* The Attorney General's statutory authority to make custody determinations under sections 241(a)(6) and 212(d)(5)(A) of the Act when there is a final order of removal is delegated as follows:

(1) *District directors.* The initial custody determination described in paragraph (h) of this section and any further custody determination concluded in the three-month period immediately following expiration of the 90-day removal period, subject to the provisions of paragraph (c)(2) of this section, will be made by the district director having jurisdiction over the alien. The district director shall maintain appropriate files respecting each detained alien reviewed for possible release, and shall have authority to determine the order in which the cases shall be reviewed, and to coordinate activities associated with these reviews in his or her respective district.

(2) *Headquarters Post-Order Detention Unit (HQPDU).* For any alien the district director refers for further

review after the 90-day removal period, or any alien who has not been released or removed by the expiration of the three-month period after the 90-day review, all further custody determinations will be made by the Executive Associate Commissioner, acting through the HQPDU.

(3) *The HQPDU review plan.* The Executive Associate Commissioner shall appoint a Director of the HQPDU. The Director of the HQPDU shall have authority to establish and maintain appropriate files respecting each detained alien to be reviewed for possible release, to determine the order in which the cases shall be reviewed, and to coordinate activities associated with these reviews.

(4) *Additional delegation of authority.* All references to the Executive Associate Commissioner and district director in this section shall be deemed to include any person or persons (including a committee) designated in writing by the district director or Executive Associate Commissioner to exercise powers under this section.

(d) *Custody determinations.* A copy of any decision by the district director or Executive Associate Commissioner to release or to detain an alien shall be provided to the detained alien. A decision to retain custody shall briefly set forth the reasons for the continued detention. A decision to release may contain such special conditions as are considered appropriate in the opinion of the Service. Notwithstanding any other provisions of this section, there is no appeal from the district director's or the Executive Associate Commissioner's decision.

(1) *Showing by the alien.* The district director or the Executive Associate Commissioner may release an alien if the alien demonstrates to the satisfaction of the Attorney General or her designee that his or her release will not pose a danger to the community or to the safety of other persons or to property or a significant risk of flight pending such alien's removal from the United States. The district director or the Executive Associate Commissioner may also, in accordance with the procedures and consideration of the factors set forth in this section, continue in custody any alien described in paragraphs (a) and (b)(1) of this section.

(2) *Service of decision and other documents.* All notices, decisions, or other documents in connection with the custody reviews conducted under this section by the district director or Executive Associate Commissioner shall be served on the alien, in accordance with 8 CFR 103.5a, by the Service district office having jurisdiction over

the alien. Release documentation (including employment authorization if appropriate) shall be issued by the district office having jurisdiction over the alien in accordance with the custody determination made by the district director or by the Executive Associate Commissioner. Copies of all such documents will be retained in the alien's record and forwarded to the HQPDU.

(3) *Alien's representative.* The alien's representative is required to complete Form G-28, Notice of Entry of Appearance as Attorney or Representative, at the time of the interview or prior to reviewing the detainee's records. The Service will forward by regular mail a copy of any notice or decision that is being served on the alien only to the attorney or representative of record. The alien remains responsible for notification to any other individual providing assistance to him or her.

(e) *Criteria for release.* Before making any recommendation or decision to release a detainee, a majority of the Review Panel members, or the Director of the HQPDU in the case of a record review, must conclude that:

(1) Travel documents for the alien are not available or, in the opinion of the Service, immediate removal, while proper, is otherwise not practicable or not in the public interest;

(2) The detainee is presently a non-violent person;

(3) The detainee is likely to remain nonviolent if released;

(4) The detainee is not likely to pose a threat to the community following release;

(5) The detainee is not likely to violate the conditions of release; and

(6) The detainee does not pose a significant flight risk if released.

(f) *Factors for consideration.* The following factors should be weighed in considering whether to recommend further detention or release of a detainee:

(1) The nature and number of disciplinary infractions or incident reports received when incarcerated or while in Service custody;

(2) The detainee's criminal conduct and criminal convictions, including consideration of the nature and severity of the alien's convictions, sentences imposed and time actually served, probation and criminal parole history, evidence of recidivism, and other criminal history;

(3) Any available psychiatric and psychological reports pertaining to the detainee's mental health;

(4) Evidence of rehabilitation including institutional progress relating

to participation in work, educational, and vocational programs, where available;

(5) Favorable factors, including ties to the United States such as the number of close relatives residing here lawfully;

(6) Prior immigration violations and history;

(7) The likelihood that the alien is a significant flight risk or may abscond to avoid removal, including history of escapes, failures to appear for immigration or other proceedings, absence without leave from any halfway house or sponsorship program, and other defaults; and

(8) Any other information that is probative of whether the alien is likely to—

(i) Adjust to life in a community,

(ii) Engage in future acts of violence,

(iii) Engage in future criminal activity,

(iv) Pose a danger to the safety of himself or herself or to other persons or to property, or

(v) Violate the conditions of his or her release from immigration custody pending removal from the United States.

(g) *Travel documents and docket control for aliens continued in detention beyond the removal period*—(1) *In general.* The district director shall continue to undertake appropriate steps to secure travel documents for the alien both before and after the expiration of the removal period. If the district director is unable to secure travel documents within the removal period, he or she shall apply for assistance from Headquarters Detention and Deportation, Office of Field Operations. The district director shall promptly advise the HQPDU Director when travel documents are obtained for an alien whose custody is subject to review by the HQPDU. The Service's determination that receipt of a travel document is likely may by itself warrant continuation of detention pending the removal of the alien from the United States.

(2) *Availability of travel document.* In making a custody determination, the district director and the Director of the HQPDU shall consider the ability to obtain a travel document for the alien. If it is established at any stage of a custody review that, in the judgment of the Service, travel documents can be obtained, or such document is forthcoming, the alien will not be released unless immediate removal is not practicable or in the public interest.

(3) *Removal.* The Service will not conduct a custody review under these procedures when the Service notifies the alien that it is ready to execute an order of removal.

(4) *Alien's cooperation.* Release will be denied if the alien fails or refuses to cooperate in the process of obtaining a travel document. *See, e.g.,* section 241(a)(1)(C) of the Act.

(h) *District director's custody review procedures.* The district director's custody determination will be developed in accordance with the following procedures:

(1) *Records review.* The district director will conduct the initial custody review. For aliens described in paragraphs (a) and (b)(1) of this section, the district director will conduct a records review prior to the expiration of the 90-day removal period. This initial post-order custody review will consist of a review of the alien's records and any written information submitted in English to the district director by or on behalf of the alien. However, the district director may in his or her discretion schedule a personal or telephonic interview with the alien as part of this custody determination. The district director may also consider any other relevant information relating to the alien or his or her circumstances and custody status.

(2) *Notice to alien.* The district director will provide written notice to the detainee approximately 30 days in advance of the pending records review so that the alien may submit information in writing in support of his or her release. The alien may be assisted by a person of his or her choice, subject to reasonable security concerns at the institution and panel's discretion, in preparing or submitting information in response to the district director's notice. Such assistance shall be at no expense to the Government. If the alien or his or her representative requests additional time to prepare materials beyond the time when the district director expects to conduct the records review, such a request will constitute a waiver of the requirement that the review occur prior to the expiration of the removal period.

(3) *Factors for consideration.* The district director's review will include but is not limited to consideration of the factors described in paragraph (f) of this section. Before making any decision to release a detainee, the district director must be able to reach the conclusions set forth in paragraph (e) of this section.

(4) *District director's decision.* The district director will notify the alien in writing that he or she is to be released from custody, or that he or she will be continued in detention pending removal or further review of his or her custody status.

(5) *District office staff.* The district director may delegate the authority to conduct the custody review, develop

recommendations, or render the custody or release decision to those persons directly responsible for detention within his or her district. This includes the deputy district director, the assistant director for detention and deportation, the officer-in-charge of a detention center, persons acting in such capacities, or such other persons as the district director may designate from the professional staff of the Service.

(i) *Determinations by the Executive Associate Commissioner.*

Determinations by the Executive Associate Commissioner to release or retain custody of aliens shall be developed in accordance with the following procedures.

(1) *Review panels.* The HQPDU Director shall designate a panel or panels to make recommendations to the Executive Associate Commissioner. A Review Panel shall, except as otherwise provided, consist of two persons. Members of a Review Panel shall be selected from the professional staff of the Service. All recommendations by the two-member Review Panel shall be unanimous. If the vote of the two-member Review Panel is split, it shall adjourn its deliberations concerning that particular detainee until a third Review Panel member is added. The third member of any Review Panel shall be the Director of the HQPDU or his or her designee. A recommendation by a three-member Review Panel shall be by majority vote.

(2) *Records review.* Initially, and at the beginning of each subsequent review, the HQPDU Director or a Review Panel shall review the alien's records. Upon completion of this records review, the HQPDU Director or the Review Panel may issue a written recommendation that the alien be released and reasons therefore.

(3) *Personal interview.* (i) If the HQPDU Director does not accept a panel's recommendation to grant release after a records review, or if the alien is not recommended for release, a Review Panel shall personally interview the detainee. The scheduling of such interviews shall be at the discretion of the HQPDU Director. The HQPDU Director will provide a translator if he or she determines that such assistance is appropriate.

(ii) The alien may be accompanied during the interview by a person of his or her choice, subject to reasonable security concerns at the institution's and panel's discretion, who is able to attend at the time of the scheduled interview. Such assistance shall be at no expense to the Government. The alien may submit to the Review Panel any information, in English, that he or she

believes presents a basis for his or her release.

(4) *Alien's participation.* Every alien shall respond to questions or provide other information when requested to do so by Service officials for the purpose of carrying out the provisions of this section.

(5) *Panel recommendation.* Following completion of the interview and its deliberations, the Review Panel shall issue a written recommendation that the alien be released or remain in custody pending removal or further review. This written recommendation shall include a brief statement of the factors that the Review Panel deems material to its recommendation.

(6) *Determination.* The Executive Associate Commissioner shall consider the recommendation and appropriate custody review materials and issue a custody determination, in the exercise of discretion under the standards of this section. The Executive Associate Commissioner's review will include but is not limited to consideration of the factors described in paragraph (f) of this section. Before making any decision to release a detainee, the Executive Associate Commissioner must be able to reach the conclusions set forth in paragraph (e) of this section. The Executive Associate Commissioner is not bound by the panel's recommendation.

(j) *Conditions of release.*—(1) *In general.* The district director or Executive Associate Commissioner shall impose such conditions or special conditions on release as the Service considers appropriate in an individual case or cases, including but not limited to the conditions of release noted in 8 CFR 212.5(c) and § 241.5. An alien released under this section must abide by the release conditions specified by the Service in relation to his or her release or sponsorship.

(2) *Sponsorship.* The district director or Executive Associate Commissioner may, in the exercise of discretion, condition release on placement with a close relative who agrees to act as a sponsor, such as a parent, spouse, child, or sibling who is a lawful permanent resident or a citizen of the United States, or may condition release on the alien's placement or participation in an approved halfway house, mental health project, or community project when, in the opinion of the Service, such condition is warranted. No detainee may be released until sponsorship, housing, or other placement has been found for the detainee, if ordered, including but not limited to, evidence of financial support.

(3) *Employment authorization.* The district director and Executive Associate Commissioner may, in the exercise of discretion, grant employment authorization under the same conditions set forth in § 241.5(c) for aliens released under an order of supervision.

(4) *Withdrawal of release approval.*

The district director or Executive Associate Commissioner may, in the exercise of discretion, withdraw approval for release of any detained alien prior to release when, in the decision-maker's opinion, the conduct of the detainee, or any other circumstance, indicates that release would no longer be appropriate.

(k) *Timing of reviews.* The timing of reviews shall be in accordance with the following guidelines:

(1) *District director.* (i) Prior to the expiration of the 90-day removal period, the district director shall conduct a custody review for an alien described in paragraphs (a) and (b)(1) of this section where the alien's removal, while proper, cannot be accomplished during the 90-day period because no country currently will accept the alien, or removal of the alien prior to expiration of the removal period is impracticable or contrary to the public interest. As provided in paragraph (h)(4) of this section, the district director will notify the alien in writing that he or she is to be released from custody, or that he or she will be continued in detention pending removal or further review of his or her custody status.

(ii) When release is denied pending the alien's removal, the district director in his or her discretion may retain responsibility for custody determinations for up to three months after expiration of the 90-day removal period, during which time the district director may conduct such additional review of the case as he or she deems appropriate. The district director may release the alien if he or she is not removed within the three-month period following the expiration of the 90-day removal period, in accordance with paragraphs (e), (f), and (j) of this section, or the district director may refer the alien to the HQPDU for further custody review.

(2) *HQPDU reviews.* (i) *District director referral for further review.* When the district director refers a case to the HQPDU for further review, as provided in paragraph (c)(2) of this section, authority over the custody determination transfers to the Executive Associate Commissioner, according to procedures established by the HQPDU. The Service will provide the alien with approximately 30 days notice of this further review, which will ordinarily be

conducted by the expiration of the removal period or as soon thereafter as practicable.

(ii) *District director retains jurisdiction.* When the district director has advised the alien at the 90-day review as provided in paragraph (h)(4) of this section that he or she will remain in custody pending removal or further custody review, and the alien is not removed within three months of the district director's decision, authority over the custody determination transfers from the district director to the Executive Associate Commissioner. The initial HQPDU review will ordinarily be conducted at the expiration of the three-month period after the 90-day review or as soon thereafter as practicable. The Service will provide the alien with approximately 30 days notice of that review.

(iii) *Continued detention cases.* A subsequent review shall ordinarily be commenced for any detainee within approximately one year of a decision by the Executive Associate Commissioner declining to grant release. Not more than once every three months in the interim between annual reviews, the alien may submit a written request to the HQPDU for release consideration based on a proper showing of a material change in circumstances since the last annual review. The HQPDU shall respond to the alien's request in writing within approximately 90 days.

(iv) *Review scheduling.* Reviews will be conducted within the time periods specified in paragraphs (k)(1)(i), (k)(2)(i), (k)(2)(ii), and (k)(2)(iii) of this section or as soon as possible thereafter, allowing for any unforeseen circumstances or emergent situation.

(v) *Discretionary reviews.* The HQPDU Director, in his or her discretion, may schedule a review of a detainee at shorter intervals when he or she deems such review to be warranted.

(3) *Postponement of review.* In the case of an alien who is in the custody of the Service, the district director or the HQPDU Director may, in his or her discretion, suspend or postpone the custody review process if such detainee's prompt removal is practicable and proper, or for other good cause. The decision and reasons for the delay shall be documented in the alien's custody review file or A file, as appropriate. Reasonable care will be exercised to ensure that the alien's case is reviewed once the reason for delay is remedied or if the alien is not removed from the United States as anticipated at the time review was suspended or postponed.

(4) *Transition provisions.* (i) The provisions of this section apply to cases that have already received the 90-day

review. If the alien's last review under the procedures set out in the Executive Associate Commissioner memoranda entitled *Detention Procedures for Aliens Whose Immediate Repatriation is Not Possible or Practicable*, February 3, 1999; *Supplemental Detention Procedures*, April 30, 1999; *Interim Changes and Instructions for Conduct of Post-order Custody Reviews*, August 6, 1999; *Review of Long-term Detainees*, October 22, 1999, was a records review and the alien remains in custody, the HQPDU will conduct a custody review within six months of that review (Memoranda available at <http://www.ins.usdoj.gov>). If the alien's last review included an interview, the HQPDU review will be scheduled one year from the last review. These reviews will be conducted pursuant to the procedures in paragraph (i) of this section, within the time periods specified in this paragraph or as soon as possible thereafter, allowing for resource limitations, unforeseen circumstances, or an emergent situation.

(ii) Any case pending before the Board on December 21, 2000 will be completed by the Board. If the Board affirms the district director's decision to continue the alien in detention, the next scheduled custody review will be conducted one year after the Board's decision in accordance with the procedures in paragraph (i) of this section.

(l) *Revocation of release—(1) Violation of conditions of release.* Any alien described in paragraph (a) or (b)(1) of this section who has been released under an order of supervision or other conditions of release who violates the conditions of release may be returned to custody. Any such alien who violates the conditions of an order of supervision is subject to the penalties described in section 243(b) of the Act. Upon revocation, the alien will be notified of the reasons for revocation of his or her release or parole. The alien will be afforded an initial informal interview promptly after his or her return to Service custody to afford the alien an opportunity to respond to the reasons for revocation stated in the notification.

(2) *Determination by the Service.* The Executive Associate Commissioner shall have authority, in the exercise of discretion, to revoke release and return to Service custody an alien previously approved for release under the procedures in this section. A district director may also revoke release of an alien when, in the district director's opinion, revocation is in the public interest and circumstances do not reasonably permit referral of the case to

the Executive Associate Commissioner. Release may be revoked in the exercise of discretion when, in the opinion of the revoking official:

- (i) The purposes of release have been served;
- (ii) The alien violates any condition of release;
- (iii) It is appropriate to enforce a removal order or to commence removal proceedings against an alien; or
- (iv) The conduct of the alien, or any other circumstance, indicates that release would no longer be appropriate.

(3) *Timing of review when release is revoked.* If the alien is not released from custody following the informal interview provided for in paragraph (l)(1) of this section, the HQPDU Director shall schedule the review process in the case of an alien whose previous release or parole from immigration custody pursuant to a decision of either the district director or the Executive Associate Commissioner under the procedures in this section has been or is subject to being revoked. The normal review process will commence with notification to the alien of a records review and scheduling of an interview, which will ordinarily be expected to occur within approximately three months after release is revoked. That custody review will include a final evaluation of any contested facts relevant to the revocation and a determination whether the facts as determined warrant revocation and further denial of release. Thereafter, custody reviews will be conducted annually under the provisions of paragraphs (i), (j), and (k) of this section.

9. Section 241.5 is amended by revising paragraph (a) introductory text to read as follows:

§ 241.5 Conditions of release after removal period.

(a) *Order of supervision.* An alien released pursuant to § 241.4 shall be released pursuant to an order of supervision. The Commissioner, Deputy Commissioner, Executive Associate Commissioner Field Operations, regional director, district director, acting district director, deputy district director, assistant district director for investigations, assistant district director for detention and deportation, or officer-in-charge may issue Form I-220B, Order of Supervision. The order shall specify conditions of supervision including, but not limited to, the following:

* * * * *

10. Section 241.6 is revised to read as follows:

§ 241.6 Administrative stay of removal.

(a) Any request of an alien under a final order of deportation or removal for a stay of deportation or removal shall be filed on Form I-246, Stay of Removal, with the district director having jurisdiction over the place where the alien is at the time of filing. The Commissioner, Deputy Commissioner, Executive Associate Commissioner Field Operations, regional director, or district director, in his or her discretion and in consideration of factors listed in 8 CFR 212.5 and section 241(c) of the Act, may grant a stay of removal or deportation for such time and under such conditions as he or she may deem appropriate. Neither the request nor the failure to receive notice of disposition of the request shall delay removal or relieve the alien from strict compliance with any outstanding notice to surrender for deportation or removal.

(b) Denial by the Commissioner, Deputy Commissioner, Executive Associate Commissioner Field Operations, regional director, or district director of a request for a stay is not appealable, but such denial shall not preclude an immigration judge or the Board from granting a stay in connection with a previously filed motion to reopen or a motion to reconsider as provided in 8 CFR part 3.

(c) The Service shall take all reasonable steps to comply with a stay granted by an immigration judge or the Board. However, such a stay shall cease to have effect if granted (or communicated) after the alien has been placed aboard an aircraft or other conveyance for removal and the normal boarding has been completed.

Dated: December 15, 2000.

Janet Reno,

Attorney General.

[FR Doc. 00-32432 Filed 12-18-00; 2:38 pm]

BILLING CODE 4410-10-P

NATIONAL CREDIT UNION ADMINISTRATION

12 CFR Part 705

Community Development Revolving Loan Program for Credit Unions

AGENCY: National Credit Union Administration (NCUA).

ACTION: Interim final rule with request for comments.

SUMMARY: The NCUA is revising its regulations pertaining to the Community Development Revolving Loan Program for Credit Unions (CDRLP) to make more flexible the manner in which NCUA may deliver

technical assistance to participating credit unions. This revision reflects the broad authority granted to NCUA by the Federal Credit Union Act (Act) in this context.

DATES: Effective December 21, 2000. NCUA welcomes comments on this interim final rule. Comments must be received on or before February 20, 2001.

ADDRESSES: Comments should be directed to Becky Baker, Secretary of the Board. Mail or hand-deliver comments to: National Credit Union Administration, 1775 Duke Street, Alexandria, VA 22314-3428. You may also fax comments to (703) 518-6319 or e-mail comments to boardmail@ncua.gov. *Please send comments by one method only.*

FOR FURTHER INFORMATION CONTACT: Frank S. Kressman, Staff Attorney, at the above address, or telephone: (703) 518-6540.

SUPPLEMENTARY INFORMATION: The CDRLP is intended to support the community development activities of participating credit unions. It does this by making low interest loans and providing technical assistance to those credit unions. This increases economic and employment opportunities for the credit unions' low-income members.

The Act authorizes the NCUA Board to use interest earned by the CDRLP to provide technical assistance to participating credit unions. 12 U.S.C. 1772c-1. The regulation implementing this authority provides: "Based on available earnings, NCUA may contract with outside providers to render technical assistance to participating credit unions." 12 CFR 705.10. When this rule was initially adopted, the rule's preamble noted, "NCUA plans to contract with a provider that can render necessary technical assistance to credit unions selected for participation in the [Community Development Revolving Loan] Program." 52 FR 34891, September 16, 1987. The NCUA Board later amended the regulation to allow the agency to contract with more than one technical assistance provider. 58 FR 21648, April 23, 1993. The technical assistance provision in the regulation is more restrictive than the statutory authority granted to the NCUA Board by the Act.

Congress has recently appropriated an additional \$1 million to the CDRLP, \$350,000 of which is specifically earmarked for technical assistance. NCUA has determined that, in conjunction with this additional funding, it is an appropriate time to amend § 705.10. The NCUA Board has determined that § 705.10 is unnecessarily restrictive and may

interfere with the CDRLP's ability to provide technical assistance to participating credit unions efficiently. Specifically, the CDRLP should have the flexibility to provide technical assistance to participating credit unions directly or through outside providers selected by the credit unions or NCUA. Applications for CDRLP technical assistance are available from NCUA and will be processed in accordance with established NCUA procedures and guidelines.

Interim Final Rule

The NCUA Board is issuing this rule as an interim final rule because there is a strong public interest in having in place rules that make CDRLP technical assistance as readily accessible and easily deliverable to participating credit unions as possible. This interim rule provides additional benefit to participating credit unions with no additional burden. Accordingly, for good cause, the Board finds that, pursuant to 5 U.S.C. 553(b)(3)(B), notice and public procedures are impracticable, unnecessary, and contrary to the public interest; and, pursuant to 5 U.S.C. 553(d)(3), the rule shall be effective immediately and without 30 days advance notice of publication. Although the rule is being issued as an interim final rule and is effective immediately, the NCUA Board encourages interested parties to submit comments.

Regulatory Procedures

Regulatory Flexibility Act

The Regulatory Flexibility Act requires NCUA to prepare an analysis to describe any significant economic impact any regulation may have on a substantial number of small entities. For purposes of this analysis, credit unions under \$1 million in assets will be considered small entities.

The NCUA Board has determined and certifies that this rule will not have a significant economic impact on a substantial number of small entities. The reason for this determination is that the revision provides the CDRLP with more options and flexibility in providing technical assistance to participating credit unions without any additional regulatory burden or expense to credit unions. Accordingly, the NCUA has determined that a Regulatory Flexibility Analysis is not required.

Paperwork Reduction Act

NCUA has determined that the revision does not increase paperwork requirements under the Paperwork Reduction Act of 1995 and regulations

of the Office of Management and Budget.

Executive Order 13132

Executive Order 13132 encourages independent regulatory agencies to consider the impact of their regulatory actions on state and local interests. In adherence to fundamental federalism principles, NCUA, an independent regulatory agency as defined in 44 U.S.C. 3502(5), voluntarily complies with the executive order. This rule will apply to some state-chartered credit unions, but it will not have substantial direct effect on the states, on the relationship between the national government and the states, or on the distribution of power and responsibilities among the various levels of government. NCUA has determined that this rule does not constitute a policy that has federalism implications for purposes of the executive order.

Agency Regulatory Goal

NCUA's goal is to promulgate clear and understandable regulations that impose minimal regulatory burden. We request your comments on whether this rule is understandable and minimally intrusive.

List of Subjects in 12 CFR Part 705

Community development, Credit unions, Loan programs-housing and community development, Reporting and recordkeeping requirements, Technical assistance.

By the National Credit Union Administration Board, on December 14, 2000.

Becky Baker,
Secretary of the Board.

For the reasons stated above, NCUA amends 12 CFR part 705 as follows:

PART 705—COMMUNITY DEVELOPMENT REVOLVING LOAN PROGRAM FOR CREDIT UNIONS

1. The authority citation for part 705 continues to read as follows:

Authority: 12 U.S.C. 1772c-1; 42 U.S.C. 9822 and 9822 note.

2. Remove the first sentence of § 705.10 and add 3 sentences in its place to read as follows:

§ 705.10 Technical assistance.

NCUA may provide technical assistance to participating credit unions directly or through outside providers selected by the credit unions or NCUA. NCUA will base technical assistance on funds availability, the needs of the participating credit union, and a demonstrated capability of the

participating credit union to provide financial and related services to its members. NCUA will consider applications for technical assistance and determine whether to grant them in accordance with established procedures and standards that are publicly available. * * *

[FR Doc. 00-32476 Filed 12-20-00; 8:45 am]

BILLING CODE 7535-01-P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. 2000-NM-154-AD; Amendment 39-12045; AD 2000-25-10]

RIN 2120-AA64

Airworthiness Directives; Airbus Model A300 B2 and B4 Series Airplanes, and Model A300 B4-600, A300 B4-600R, and A300 F4-600R (A300-600) Series Airplanes

AGENCY: Federal Aviation Administration, DOT.

ACTION: Final rule.

SUMMARY: This amendment adopts a new airworthiness directive (AD), applicable to all Airbus Model A300 B2 and B4 series airplanes, and Model A300-600 series airplanes, that requires verifying the correct location of the labels of the hydraulic pipes supplying the strut unlocking actuator of the left-hand main landing gear (MLG), and of the pipes of the left- and right-hand cross brace; reidentifying the pipes; and replacing any incorrectly located label with a new label. The actions specified by this AD are intended to prevent cross connection of the hydraulic hoses or pipes that supply the main strut unlocking actuator, and collapse of the MLG under lateral taxiing loads. This action is intended to address the identified unsafe condition.

DATES: Effective January 25, 2001.

The incorporation by reference of certain publications listed in the regulations is approved by the Director of the Federal Register as of January 25, 2001.

ADDRESSES: The service information referenced in this AD may be obtained from Airbus Industrie, 1 Rond Point Maurice Bellonte, 31707 Blagnac Cedex, France. This information may be examined at the Federal Aviation Administration (FAA), Transport Airplane Directorate, Rules Docket, 1601 Lind Avenue, SW., Renton, Washington; or at the Office of the

Federal Register, 800 North Capitol Street, NW., suite 700, Washington, DC.

FOR FURTHER INFORMATION CONTACT: Norman B. Martenson, Manager, International Branch, ANM-116, FAA, Transport Airplane Directorate, 1601 Lind Avenue, SW., Renton, Washington 98055-4056; telephone (425) 227-2110; fax (425) 227-1149.

SUPPLEMENTARY INFORMATION: A proposal to amend part 39 of the Federal Aviation Regulations (14 CFR part 39) to include an airworthiness directive (AD) that is applicable to all Airbus Model A300 and A300-600 series airplanes was published in the **Federal Register** on September 8, 2000 (65 FR 54445). That action proposed to require verifying the correct location of the labels of the hydraulic pipes supplying the strut unlocking actuator of the left-hand main landing gear (MLG), and of the pipes of the left- and right-hand cross brace; reidentifying the pipes; and replacing any incorrectly located label with a new label.

Clarification of Model Designation

Since the issuance of the proposed AD, the FAA has changed the manner in which it identifies the airplane models referred to as "Airbus Model A300 and A300-600 series airplanes" to reflect the model designation specified on the type certificate data sheet. This final rule has been revised to show the appropriate model designations for those airplanes.

Comments

Interested persons have been afforded an opportunity to participate in the making of this amendment. No comments were submitted in response to the proposal or the FAA's determination of the cost to the public.

Conclusion

After careful review of the available data, the FAA has determined that air safety and the public interest require the adoption of the rule with the change described previously. The FAA has determined that this change will neither increase the economic burden on any operator nor increase the scope of the AD.

Cost Impact

The FAA estimates that 87 Model A300 and A300-600 series airplanes of U.S. registry will be affected by this AD, that it will take approximately 1 work hour per airplane to accomplish the required actions, and that the average labor rate is \$60 per work hour. Required parts will be provided by the vendor at no cost to operators. Based on these figures, the cost impact of the AD

on U.S. operators is estimated to be \$5,220, or \$60 per airplane.

The cost impact figure discussed above is based on assumptions that no operator has yet accomplished any of the requirements of this AD action, and that no operator would accomplish those actions in the future if this AD were not adopted. The cost impact figures discussed in AD rulemaking actions represent only the time necessary to perform the specific actions actually required by the AD. These figures typically do not include incidental costs, such as the time required to gain access and close up, planning time, or time necessitated by other administrative actions.

Regulatory Impact

The regulations adopted herein will not have a substantial direct effect on the States, on the relationship between the national Government and the States, or on the distribution of power and responsibilities among the various levels of government. Therefore, it is determined that this final rule does not have federalism implications under Executive Order 13132.

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 final evaluation has been prepared for this action and it is contained in the Rules Docket. A copy of it 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. 106(g), 40113, 44701.

§ 39.13 [Amended]

2. Section 39.13 is amended by adding the following new airworthiness directive:

2000-25-10 Airbus Industrie: Amendment 39-12045. Docket 2000-NM-154-AD.

Applicability: All Model A300 B2 and B4 series airplanes, and Model A300 B4-600, A300 B4-600R, and A300 F4-600R (A300-600) series airplanes; certificated in any category.

Note 1: This AD applies to each airplane identified in the preceding applicability provision, regardless of whether it has been modified, altered, or repaired in the area subject to the requirements of this AD. For airplanes that have been modified, altered, or repaired so that the performance of the requirements of this AD is affected, the owner/operator must request approval for an alternative method of compliance in accordance with paragraph (b) of this AD. The request should include an assessment of the effect of the modification, alteration, or repair on the unsafe condition addressed by this AD; and, if the unsafe condition has not been eliminated, the request should include specific proposed actions to address it.

Compliance: Required as indicated, unless accomplished previously.

To prevent cross connection of the hydraulic hoses or pipes that supply the main strut unlocking actuator, which could lead to consequent collapse of the main landing gear (MLG) under lateral taxiing loads, accomplish the following:

Corrective Actions

(a) Within 1,000 flight hours or 3 months after the effective date of this AD, whichever occurs first: Verify the correct location of the labels of the hydraulic pipes supplying the strut unlocking actuator of the left-hand MLG, and of the pipes of the left- and right-hand cross brace, and reidentify the pipes, in accordance with Airbus Service Bulletin A300-32A0437 (for Model A300 series airplanes) or A300-32A6080 (for Model A300-600 series airplanes), both dated April 5, 2000, as applicable. If any label is located incorrectly, prior to further flight, replace the label with a new label in accordance with the applicable service bulletin.

Note 2: The service bulletins reference Airbus Service Bulletins A300-57A0234 and A300-57A6087, as well as Messier-Dowty International Service Bulletin No. 470-32-792, as additional sources of service information for accomplishment of the specified actions.

Alternative Methods of Compliance

(b) 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, International Branch, ANM-116, FAA, Transport Airplane Directorate. Operators shall submit their requests through an appropriate FAA Principal Maintenance Inspector, who may add comments and then send it to the Manager, International Branch, ANM-116.

Note 3: Information concerning the existence of approved alternative methods of compliance with this AD, if any, may be obtained from the International Branch, ANM-116.

Special Flight Permits

(c) Special flight permits may be issued in accordance with sections 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.

Incorporation by Reference

(d) The actions shall be done in accordance with Airbus Service Bulletin A300-32A0437, dated April 5, 2000; or Airbus Service Bulletin A300-32A6080, dated April 5, 2000; as applicable. 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 Airbus Industrie, 1 Rond Point Maurice Bellonte, 31707 Blagnac Cedex, France. Copies may be inspected at the FAA, Transport Airplane Directorate, 1601 Lind Avenue, SW., Renton, Washington; or at the Office of the Federal Register, 800 North Capitol Street, NW., suite 700, Washington, DC.

Note 4: The subject of this AD is addressed in French airworthiness directive 2000-204-309(B), dated May 17, 2000.

Effective Date

(e) This amendment becomes effective on January 25, 2001.

Issued in Renton, Washington, on December 11, 2000.

Donald L. Riggan,

Acting Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 00-31989 Filed 12-20-00; 8:45 am]

BILLING CODE 4910-13-P

DEPARTMENT OF TRANSPORTATION**Federal Aviation Administration****14 CFR Part 39**

[Docket No. 2000-NM-329-AD; Amendment 39-11988; AD 2000-23-16]

RIN 2120-AA64

Airworthiness Directives; Boeing Model 747 Series Airplanes Powered by Pratt & Whitney JT9D-3 and -7 Series Engines

AGENCY: Federal Aviation Administration, DOT.

ACTION: Final rule; correction.

SUMMARY: This document corrects a minor error that appeared in airworthiness directive (AD) 2000-23-16, that was published in the **Federal Register** on November 21, 2000 (65 FR 69862). The error resulted in a reference to a part number that does not exist.

That AD is applicable to certain Boeing Model 747 series airplanes, and requires repetitive inspections and torque checks of the hanger fittings and strut forward bulkhead of the forward engine mount and adjacent support structure, and corrective actions, if necessary. That AD also provides for optional terminating action for the repetitive inspections and checks.

EFFECTIVE DATE: Effective December 6, 2000.

FOR FURTHER INFORMATION CONTACT:

Tamara Anderson, Aerospace Engineer, Airframe Branch, ANM-120S, FAA, Seattle Aircraft Certification Office, 1601 Lind Avenue, SW., Renton, Washington 98055-4056; telephone (425) 227-2771; fax (425) 227-1181.

SUPPLEMENTARY INFORMATION:

Airworthiness Directive (AD) 2000-23-16, amendment 39-11988, applicable to certain Boeing Model 747 series airplanes, was published in the **Federal Register** on November 21, 2000 (65 FR 69862). That AD requires repetitive inspections and torque checks of the hanger fittings and strut forward bulkhead of the forward engine mount and adjacent support structure, and corrective actions, if necessary. That AD also provides for optional terminating action for the repetitive inspections and checks.

As published, the amendment contained a minor error in Note 4 which identifies installation of two "BACW10BP* auxiliary power unit" washers. However, this part number does not exist, the correct part number is "BACW10BP*APU." The letters "APU" were inadvertently defined as an acronym meaning "auxiliary power unit." In all other respects, the original document is correct.

Since no other part of the regulatory information has been changed, the final rule is not being republished.

The effective date of this AD remains December 6, 2000.

§ 39.13 [Corrected]

On page 69864, in the third column, Note 4 of AD 2000-23-16 is corrected to read as follows:

2000-23-16 Boeing: Amendment 39-11988, Docket 2000-NM-329-AD.

* * * * *

Note 4: Installation of two BACW10BP*APU washers on Group A fasteners accomplished prior to the effective date of this AD in accordance with Boeing Service Bulletin 747-54A2159, dated November 3, 1994, Revision 1, dated June 1, 1995, or Revision 2, dated March 14, 1996; and pin or bolt protrusion as specified in the 747 Structural Repair Manual, Chapter 51-30-02 (both referenced in Boeing Alert

Service Bulletin 747-54A2203, dated August 31, 2000); is considered acceptable for compliance with the terminating action specified in paragraph (b) of this AD.

* * * * *

Issued in Renton, Washington, on December 13, 2000.

Dorenda D. Baker,

Acting Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 00-32315 Filed 12-20-00; 8:45 am]

BILLING CODE 4910-13-U

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 71

[Airspace Docket No. 00-ACE-31]

Amendment to Class E Airspace; Dexter, MO; Correction

AGENCY: Federal Aviation Administration, DOT.

ACTION: Direct final rule; confirmation of effective date and correction.

SUMMARY: This document confirms the effective date of a direct final rule which revises the Class E airspace at Dexter, MO, and corrects an error in the Class E airspace description as published in the **Federal Register** on September 29, 2000 (65 FR 58343), Airspace Docket No. 00-ACE-31.

EFFECTIVE DATE: 0901 UTC, January 25, 2001.

FOR FURTHER INFORMATION CONTACT: Brenda Mumper, Air Traffic Division, Operations and Airspace Branch, ACE-520A, DOT Regional Headquarters Building, Federal Aviation Administration, 901 Locust, Kansas City, MO 64106; telephone: (816) 329-2524.

SUPPLEMENTARY INFORMATION:

History

Federal Register Document 00-24933, Airspace Docket No. 00-ACE-31, published on September 29, 2000 (65 FR 58343) revised the description of the Dexter, MO, Class E airspace. An error was inadvertently made in describing the length of the airspace extension. This action corrects the error and confirms the effective date of the direct final rule. After careful review of all available information related to the subject presented above, the FAA has determined that air safety and the public interest require adoption of the rule. The FAA uses the direct final rulemaking procedure for a non-controversial rule where the FAA believes that there will be no adverse

public comment. This direct final rule advised the public that no adverse comments were anticipated, and that unless a written adverse comment, or a written notice of intent to submit such an adverse comment, were received within the comment period, the regulation would become effective on January 25, 2001. No adverse comments were received, and thus this notice confirms that this direct final rule will become effective on that date.

Correction to the Direct Final Rule

Accordingly, pursuant to the authority delegated to me, the Dexter, MO, Class E airspace description as published in the **Federal Register** on September 29, 2000 (65 FR 58343), (**Federal Register** Document 00-24933; page 58344), column 3, is corrected as follows.

§ 71.1 [Corrected]

* * * * *

ACE MO E5 Dexter, MO [Corrected]

By removing "7.4 miles south of the NDB" and substituting "8 miles south of the NDB."

* * * * *

Issued in Kansas City, MO on December 8, 2000.

Herman J. Lyons, Jr.,

Manager, Air Traffic Division, Central Region.

[FR Doc. 00-32514 Filed 12-20-00; 8:45 am]

BILLING CODE 4910-13-M

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 71

[Airspace Docket No. 00-ACE-30]

Amendment to Class E Airspace; Moberly, MO

AGENCY: Federal Aviation Administration, DOT.

ACTION: Direct final rule; confirmation of effective date.

SUMMARY: This document confirms the effective date of a direct final rule which revises Class E airspace at Moberly, MO.

EFFECTIVE DATE: 0901 UTC, January 25, 2001.

FOR FURTHER INFORMATION CONTACT: Brenda Mumper, Air Traffic Division, Airspace Branch, ACE-520A, DOT Regional Headquarters Building, Federal Aviation Administration, 901 Locust, Kansas City, MO 64106; telephone: (816) 329-2524.

SUPPLEMENTARY INFORMATION: The FAA published this direct final rule with a

request for comments in the **Federal Register** on September 29, 2000 (65 FR 58344). The FAA uses the direct final rulemaking procedure for a non-controversial rule where the FAA believes that there will be no adverse public comment. This direct final rule advised the public that no adverse comments were anticipated, and that unless a written adverse comment, or a written notice of intent to submit such an adverse comment, were received within the comment period, the regulation would become effective on January 25, 2001. No adverse comments were received, and thus this notice confirms that this direct final rule will become effective on that date.

Issued in Kansas City, MO on December 8, 2000.

Herman J. Lyons, Jr.,

Manager, Air Traffic Division, Central Region.

[FR Doc. 00-32513 Filed 12-20-00; 8:45 am]

BILLING CODE 4910-13-M

NATIONAL AERONAUTICS AND SPACE ADMINISTRATION

14 CFR Part 1214

RIN 2700-AC40

Code of Conduct for the International Space Station Crew

AGENCY: National Aeronautics and Space Administration (NASA).

ACTION: Interim final rule.

SUMMARY: NASA is issuing new regulations entitled "International Space Station Crew," to implement certain provisions of the International Space Station (ISS) Intergovernmental Agreement (IGA) regarding ISS crewmembers' observance of an ISS Code of Conduct.

DATES: *Effective Date:* October 1, 2000.

FOR FURTHER INFORMATION CONTACT: John F. Hall, Jr., Senior Counsel (Commercial and International), 202-358-2432.

SUPPLEMENTARY INFORMATION: On January 29, 1998, the United States formally joined with fourteen nations in an unprecedented international partnership for cooperative space exploration and development, known as the ISS. The Agreement Among the Government of Canada, Governments of Member States of the European Space Agency, the Government of Japan, the Government of the Russian Federation, and the Government of the United States of America Concerning Cooperation on the Civil International Space Station, which forms the foundation of the ISS partnership, provides in Article 11, that each partner,

in exercising its right to provide ISS crew, shall ensure that its crewmembers observe a Code of Conduct to be developed and approved by the partners for the maintenance of order and conduct of crew activities in or on the Space Station.

At the present time, the Governments of the United States, Japan, and Canada have deposited instruments indicating their adherence to the IGA, and upon deposition of a similar instrument by the Government of the Russian Federation, the IGA will become operative. The signatory governments to the IGA (with the exception of three governments of the European Partner governments) have also signed a Provisional Arrangement committing themselves to abide by the terms and conditions of the IGA pending its formal entry into force.

In accordance with the underlying ISS Memoranda of Understanding (MOU) and other agreements concluded between NASA and each of the ISS partners and other participating states, the ISS Code of Conduct is intended to: establish a clear chain of command on-orbit; establish a clear relationship between ground and on-orbit management; establish a management hierarchy; set forth standards for work and activities in space, and, as appropriate, on the ground; establish responsibilities with respect to elements and equipment; set forth disciplinary regulations; establish physical and information security guidelines; and define the ISS Commander's authority and responsibility, on behalf of all the Partners, to enforce safety procedures, physical and information security procedures, and crew rescue procedures for the ISS.

Consistent with the provisions of the IGA and MOU's, and in order to ensure that NASA-provided ISS crewmembers are apprised of and observe the ISS Crew Code of Conduct, this interim final rule establishes a requirement that each such crewmember observe the Code of Conduct for the ISS Crew. Certain NASA-provided ISS crewmembers are further required to enter into an agreement with NASA in which they agree to accept and be governed by the standards specified in the ISS Crew Code of Conduct. This requirement is in addition to other responsibilities to which certain ISS crewmembers may be subject, including obligations regarding Space Shuttle standards of conduct agreements. Nothing in the ISS Code of Conduct or this rule limits or modifies the rights and obligations of NASA-provided ISS crewmembers under the Constitution or laws of the United States.

Additionally, this rule amends the title of 14 CFR part 1214, from "Space Shuttle" to "Space Flight," in order to more accurately reflect the scope of the provisions contained therein, including subpart 1214.4, as added by this rule.

Since this action is administrative in nature and involves Agency policy management procedures, no public comment period is required.

This rule is not subject to the requirements of the Regulatory Flexibility Act, since it will not exert a significant economic impact on a substantial number of small entities.

This rule is not a major rule as defined in Executive Order 12866.

List of Subjects in 14 CFR Part 1214

Code of conduct, Crewmembers, Exploration, Government employees, Government procurement, Security measures, Space transportation and exploration.

For the reasons set out in the preamble, 14 CFR Chapter V is amended as follows:

1. The title of Part 1214 is revised to read as follows:

PART 1214—SPACE FLIGHT

2. Subpart 1214.4 is added to read as follows:

Subpart 1214.4—International Space Station Crew

Sec.

1214.400 Scope.

1214.401 Applicability.

1214.402 International Space Station crewmember responsibilities.

1214.403 Code of Conduct for the International Space Station Crew.

1214.404 Violations.

Authority: 42 U.S.C. sections 2455, 2473, and 2475; 18 U.S.C. 799.

§ 1214.400 Scope.

(a) This subpart sets forth policy and procedures with respect to International Space Station crewmembers provided by NASA for flight to the International Space Station.

(b) In order to provide for the safe operation, maintenance of order, and proper conduct of crew aboard the International Space Station, the January 29, 1998, Agreement Among the Government of Canada, Governments of Member States of the European Space Agency, the Government of Japan, the Government of the Russian Federation, and the Government of the United States of America Concerning Cooperation on the Civil International Space Station (hereinafter Agreement), which establishes and governs the International Space Station, requires the

development and approval of a Code of Conduct for International Space Station crew. Pursuant to Article 11 of the Agreement, each International Space Station partner is obliged to ensure that crewmembers which it provides observe the Code of Conduct.

§ 1214.401 Applicability.

This subpart applies to all persons provided by NASA for flight to the International Space Station, including U.S. Government employees, uniformed members of the Armed Services, U.S. citizens who are not employees of the U.S. Government, and foreign nationals.

§ 1214.402 International Space Station crewmember responsibilities.

(a) All NASA-provided International Space Station crewmembers are subject to specified standards of conduct, including those prescribed in the Code of Conduct for the International Space Station Crew, set forth as § 1214.403. NASA-provided International Space Station crew members may be subject to additional standards and requirements, as determined by NASA, which will be made available to those NASA-provided crewmembers, as appropriate.

(1) NASA-provided International Space Station crewmembers who are not citizens of the United States will be required to enter into an agreement with NASA in which they agree to comply with specified standards of conduct, including those prescribed in the Code of Conduct for the International Space Station Crew (§ 1214.403). Any such agreement will be signed on behalf of NASA by the NASA General Counsel or designee.

(2) NASA-provided International Space Station crewmembers who are citizens of the United States but are not employees of the U.S. Government will be required to enter into an agreement with NASA in which they agree to comply with specified standards of conduct, including those prescribed in the Code of Conduct for the International Space Station Crew (§ 1214.403). Any such agreement will be signed on behalf of NASA by the NASA General Counsel or designee.

(3) NASA-provided International Space Station crewmembers who are employed by a branch, department, or agency of the U.S. Government may, as determined by the NASA General Counsel, be required to enter into an agreement with NASA to comply with specified standards of conduct, including those prescribed in the Code of Conduct for the International Space Station Crew (§ 1214.403). Any such agreement will be signed on behalf of

NASA by the NASA General Counsel or designee.

(b) All NASA-provided personnel on board the International Space Station are additionally subject to the authority of the International Space Station Commander and shall comply with Commander's orders and directions.

§ 1214.403 Code of Conduct for the International Space Station Crew.

The Code of Conduct for the International Space Station Crew, which sets forth minimum standards for NASA-provided International Space Station crewmembers, is as follows:

Code of Conduct for the International Space Station Crew

I. Introduction

A. Authority

This Code of Conduct for the International Space Station (ISS) crew, hereinafter referred to as Crew Code of Conduct (CCOC), is established pursuant to:

(1) Article 11 (Crew) of the intergovernmental Agreement Among the Government of Canada, Governments of Member States of the European Space Agency, the Government of Japan, the Government of the Russian Federation, and the Government of the United States of America Concerning Cooperation on the Civil International Space Station (the IGA) signed by the Partner States on January 29, 1998; and

(2) Article 11 (Space Station Crew) of the Memoranda of Understanding between, respectively, the National Aeronautics and Space Administration of the United States of America (NASA) and the Canadian Space Agency (CSA), NASA and the European Space Agency (ESA), NASA and the Government of Japan (GOJ), and NASA and the Russian Space Agency (RSA) Concerning Cooperation on the Civil International Space Station (the MOU's), which require, inter alia, that the crew Code of Conduct be developed by the partners.

B. Scope and Content

The partners have developed and approved this CCOC to: establish a clear chain of command on-orbit; establish a clear relationship between ground and on-orbit management; and establish a management hierarchy; set forth standards for work and activities in space, and, as appropriate, on the ground; establish responsibilities with respect to elements and equipment; set forth disciplinary regulations; establish physical and information security guidelines; and define the ISS Commander's authority and responsibility, on behalf of all the partners, to enforce safety procedures, physical and information security procedures and crew rescue procedures for the ISS. This CCOC and the disciplinary policy referred to in Section IV shall not limit the application of Article 22 of the IGA. This CCOC succeeds the NASA-RSA Interim Code of Conduct, which was developed pursuant to Article 11.2 of the MOU between NASA and RSA to cover early assembly prior to other partners' flight opportunities.

This CCOC sets forth the standards of conduct applicable to all ISS crewmembers during preflight, on-orbit, and post-flight activities, (including launch and return phases). ISS crewmembers are subject to additional requirements, such as the ISS Flight Rules, the disciplinary policy, and requirements imposed by their Cooperating Agency or those relating to the Earth-to-Orbit Vehicle (ETOV) transporting an ISS crewmember. Each ISS crewmember has a right to know about such additional requirements. ISS crewmembers will also abide by the rules of the institution hosting the training, and by standards and requirements defined by the Multilateral Crew Operations Panel (MCOP), the Multilateral Space Medicine Board (MSMB) and the Multilateral Medical Operations Panel (MMOP). Each ISS crewmember will be informed by the Cooperating Agency providing him or her of the responsibilities of ISS crewmembers under the IGA, the MOU's and this CCOC. Further, each ISS crewmember will be educated by the Cooperating Agency providing him or her through the crew training curriculum and normal program operations as to ISS program rules, operational directives and management policies. Completion of postflight activities shall not affect an ISS crewmember's continuing obligations under Section V of this CCOC.

C. Definitions

For the purposes of the CCOC:

(1) "Cooperating Agency" means NASA, CSA, ESA, Rosaviakosmos (formerly RSA) and, in the case of Japan, the Science and Technology Agency of Japan (STA) and, as appropriate, the National Space Development Agency of Japan (NASDA), assisting agency to STA.

(2) "Crew Surgeon" means a Flight Surgeon assigned by the MMOP to any given expedition. He or she is the lead medical officer and carries primary responsibility for the health and well-being of the entire ISS crew.

(3) "Disciplinary policy" means the policy developed by the MCOP to address violations of the CCOC and impose disciplinary measures.

(4) "ETOV" means Earth-to-Orbit Vehicle travelling between Earth and the ISS.

(5) "Flight Director" means the Flight Director in control of the ISS.

(6) "Flight Rules" means the set of rules used by the Cooperating Agencies to govern flight operations.

(7) "ISS crewmembers" means any person approved for flight to the ISS, including both ISS expedition crew and visiting crew, beginning upon assignment to the crew for a specific and ending upon completion of the postflight activities related to the mission.

II. General Standards

A. Responsibilities of ISS Crewmembers

ISS Crewmembers shall comply with the CCOC. Accordingly, during preflight, on-orbit, and postflight activities, they shall comply with the ISS Commander's orders, all Flight and ISS program Rules, operational directives, and management policies, as applicable. These include those related to

safety, health, well-being, security, and other operational or management matters governing all aspects of ISS elements, equipment, payloads and facilities, and non-ISS facilities, to which they have access. All applicable rules, regulations, directives, and policies shall be made accessible to ISS crewmembers through appropriate means, coordinated by the MCOP.

B. General Rules of Conduct

ISS Crewmembers' conduct shall be such as to maintain a harmonious and cohesive relationship among the ISS crewmembers and an appropriate level of mutual confidence and respect through an interactive, participative, and relationship-oriented approach which duly takes into account the international and multicultural nature of the crew and mission.

No ISS crewmember shall, by his or her conduct, act in a manner which results in or creates the appearance of: (1) Giving undue preferential treatment to any person or entity in the performance of ISS activities; and/or (2) adversely affecting the confidence of the public in the integrity of, or reflecting unfavorably in a public forum on, any ISS partner, partner state or Cooperating Agency.

ISS crewmembers shall protect and conserve all property to which they have access for ISS activities. No such property shall be altered or removed for any purpose other than those necessary for the performance of ISS duties. Before altering or removing any such property, ISS crewmembers shall first obtain authorization from the Flight Director, except as necessary to ensure the immediate safety of ISS crewmembers or ISS elements, equipment, or payloads.

C. Use of Position

ISS crewmembers shall refrain from any use of the position of ISS crewmember that is motivated, or has the appearance of being motivated, by private gain, including financial gain, for himself or herself or other persons or entities. Performance of ISS duties shall not be considered to be motivated by private gain. Furthermore, no ISS crewmember shall use the position of ISS crewmember in any way to coerce, or give the appearance of coercing, another person to provide any financial benefit to himself or herself or other persons or entities.

D. Mementos and Personal Effects

Each ISS crewmember may carry and store mementos, including flags, patches, insignia, and similar small items of minor value, onboard the ISS, for his or her private use, subject to the following:

(1) mementos are permitted as a courtesy, not an entitlement; as such they shall be considered as ballast as opposed to a payload or mission requirement and are subject to manifest limitations, on-orbit stowage allocations, and safety considerations;

(2) mementos may not be sold, transferred for sale, used or transferred for personal gain, or used or transferred for any commercial or fundraising purpose. Mementos which, by their nature, lend themselves to exploitation by the recipients, or which, in the opinion of the Cooperating Agency providing the ISS

crewmember, engender questions as to good taste, will not be permitted.

An ISS crewmember's personal effects, such as a wristwatch, will not be considered mementos. Personal effects of any nature may be permitted, subject to constraints of mass/volume allowances for crew personal effects, approval of the ISS crewmember's Cooperating Agency, and approval of the transporting Cooperating Agency and considerations of safety and good taste.

If a Cooperating Agency carries and stores items onboard the ISS in connection with separate arrangements, these items will not be considered mementos of the ISS crewmembers.

III. Authority and Responsibilities of the ISS Commander, Chain of Command and Succession Onorbit; Relationship Between Ground and On-Orbit Management

A. Authority and Responsibilities of the ISS Commander

The ISS Commander, as an ISS crewmember, is subject to the standards detailed elsewhere in this CCOC, in addition to the command-specific provisions set forth below:

The ISS Commander will seek to maintain a harmonious and cohesive relationship among the ISS crewmembers and an appropriate level of mutual confidence and respect through an interactive, participative, and relationship-oriented approach which duly takes into account the international and multicultural nature of the crew and mission.

For avoidance of doubt, nothing in this Section shall affect the ability of the MCOP to designate the national of any Partner State as an ISS Commander.

(1) During Preflight and Postflight Activities

The ISS Commander is the leader of the crew and is responsible for forming the individual ISS crewmembers into a single, integrated team. During preflight activities, the ISS Commander, to the extent of his or her authority, leads the ISS crewmembers through the training curriculum and mission-preparation activities and seeks to ensure that the ISS crewmembers are adequately prepared for the mission, acting as the crew's representative to the ISS program's training, medical, operations, and utilization authorities. During postflight activities, the ISS Commander coordinates as necessary with these authorities to ensure that the ISS crewmembers complete the required postflight activities.

(2) During On-Orbit Operations

(a) General

The ISS Commander is responsible for and will, to the extent of his or her authority and the ISS on-orbit capabilities, accomplish the mission program implementation and ensure the safety of the ISS crewmembers and the protection of the ISS elements, equipment, or payloads.

(b) Main Responsibilities

The ISS Commander's main responsibilities are to: (1) Conduct operations in or on the ISS as directed by the Flight Director and in accordance with the Flight Rules, plans and procedures; (2) direct the

activities of the ISS crewmembers as a single, integrated team to ensure the successful completion of the mission; (3) fully and accurately inform the Flight Director, in a timely manner, of the ISS vehicle configuration, status, commanding, and other operational activities on-board (including off-nominal or emergency situations); (4) enforce procedures for the physical and information security of operations and utilization data; (5) maintain order; (6) ensure crew safety, health and well-being including crew rescue and return; and (7) take all reasonable action necessary for the protection of the ISS elements, equipment, or payloads.

(c) Scope of Authority

During all phases of on-orbit activity, the ISS Commander, consistent with the authority of the Flight Director, shall have the authority to use any reasonable and necessary means to fulfill his or her responsibilities. This authority, which shall be exercised consistent with the provisions of Sections II and IV, extends to: (1) the ISS elements, equipment, and payloads; (2) the ISS crewmembers; (3) activities of any kind occurring in or on the ISS; and (4) data and personal effects in or on the ISS where necessary to protect the safety and well-being of the ISS crewmembers and the ISS elements, equipment, and payloads. Any matter outside the ISS Commander's authority shall be within the purview of the Flight Director.

Issues regarding the Commander's use of such authority shall be referred to the Flight Director as soon as practicable, who will refer the matter to appropriate authorities for further handling. Although other ISS crewmembers may have authority over and responsibility for certain ISS elements, equipment, payloads, or tasks, the ISS Commander remains ultimately responsible, and solely accountable, to the Flight Director for the successful completion of the activities and the mission.

B. Chain of Command and Succession On-orbit

(1) The ISS Commander is the highest authority among the ISS crewmembers on-orbit. The MCOP will determine the order of succession among the ISS crewmembers in advance of flight, and the Flight Rules set forth the implementation of a change of command.

(2) Relationship of the ISS Commander to ETOV and Other Commanders

The Flight Rules define the authority of the ETOV Commander, the Rescue Vehicle Commander, and any other commanders, and set forth the relationship between their respective authorities and the authority of the ISS Commander.

C. Relationship Between the ISS Commander (On-Orbit Management) and the Flight Director (Ground Management)

The Flight Director is responsible for directing the mission. A Flight Director will be in charge of directing real-time ISS operations at all time. The ISS Commander, working under the direction of the Flight Director and in accordance with the Flight Rules, is responsible for conducting on-orbit operations in the manner best suited to the

effective implementation of the mission. The ISS Commander, acting on his or her own authority, is entitled to change the daily routine of the ISS crewmembers where necessary to address contingencies, perform urgent work associated with crew safety and the protection of the ISS elements, equipment or payloads, or conduct critical flight operations. Otherwise, the ISS Commander should implement the mission as directed by the Flight Director. Specific roles and responsibilities of the ISS Commander and the Flight Director are described in the Flight Rules. The Flight Rules outline decisions planned in advance of the mission and are designed to minimize the amount of real-time discussion required during mission operations.

IV. Disciplinary Regulations

ISS crewmembers will be subject to the disciplinary policy developed and revised as necessary by the MCOP and approved by the Multilateral Coordination Board (MCB). The MCOP has developed an initial disciplinary policy which has been approved by the MCB. The disciplinary policy is designed to maintain order among the ISS crewmembers during preflight, on-orbit and postflight activities. The disciplinary policy is administrative in nature and is intended to address violations of the CCOC. Such violations may, inter alia, affect flight assignments as an ISS crewmember. The disciplinary policy does not limit a Cooperating Agency's right to apply relevant laws, regulations, policies, and procedures to the ISS crewmembers it provides, consistent with the IGA and the MOU's.

V. Physical and Information Security Guidelines

The use of all equipment and goods to which ISS crewmembers have access shall be limited to the performance of ISS duties. Marked or otherwise identified as export controlled data and marked proprietary data obtained by an ISS crewmember in the course of ISS activities shall only be used in the performance of his or her ISS duties. With respect to data first generated on-board the ISS, the ISS crewmembers will be advised by the appropriate Cooperating Agency or by the data owner or provider through that Cooperating Agency as to the proprietary or export-controlled nature of the data and will be directed to mark and protect such data and to continue such protection for as long as the requirements for such protection remain in place. Additionally, ISS crewmembers shall act in a manner consistent with the provisions of the IGA and the MOU's regarding protection of operations data, utilization data, and the intellectual property of ISS users. They shall also comply with applicable ISS program rules, operational directives, and management policies designed to further such protections.

Personal information about ISS crewmembers, including all medical information, private family conference, or other private information, whether from verbal, written, or electronic sources, shall not be used or disclosed by other ISS crewmembers for any purpose, without the consent of the affected ISS crewmember,

except as required for the immediate safety of ISS crewmembers or the protection of ISS elements, equipment, or payloads. In particular, all personal medical information, whether derived from medical monitoring, investigations, or medical contingency events, shall be treated as private medical information and shall be transmitted in a private and secure fashion in accordance with procedures to be set forth by the MMOP. Medical data which must be handled in this fashion includes, for example, biomedical telemetry, private medical communications, and medical investigation data. Nothing in this paragraph shall be interpreted to limit an ISS crewmember's access to all medical resources aboard the ISS, to ground-based medical support services, or to his or her own medical data during preflight, on-orbit, and postflight activities.

VI. Protection of Human Research Subjects

No research on human subjects shall be conducted which could, with reasonable foresight, be expected to jeopardize the life, health, physical integrity, or safety of the subject.

No research procedures shall be undertaken with any ISS crewmember as a human subject without: (1) written approval by the Human Research Multilateral Review Board (HRMRB) and (2) the full written and informed consent of the human subject. Each such approval and consent shall be obtained prior to the initiation of such research, and shall fully comply with the requirements of the HRMRB. The HRMRB is responsible for procedures for initiation of new experiments on-orbit when all consent requirements have been met, but the signature of the human subject cannot be obtained; explicit consent of the human subject will nonetheless be required in all such cases. Subjects volunteering for human research protocols may at their own discretion, and without providing a rationale, withdraw their consent for participation at any time, without prejudice, and without incurring disciplinary action. In addition, approval or consent for any research may be revoked at any time, including after the commencement of the research, by: the HRMRB, the Crew Surgeon, the Flight Director, or the ISS Commander, as appropriate, if the research would endanger the ISS Crew Member or otherwise threaten the mission success. A decision to revoke consent by the human subject or approval by the other entities listed above will be final.

§ 1214.404 Violations.

This subpart is a regulation within the meaning of 18 U.S.C. 799, and whoever willfully violates, attempts to violate, or conspires to violate any provision of this subpart or any order or direction issued under this subpart may be cited for violating title 18 of the U.S. Code and could be fined or imprisoned not more than 1 year, or both.

Daniel S. Goldin,
Administrator.

[FR Doc. 00-32381 Filed 12-20-00; 8:45 am]

BILLING CODE 7510-01-P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

18 CFR Part 260

[Docket No. RM01-1-000; Order No.621]

Natural Gas Service Interruption Reporting Procedures

Issued December 14, 2000.

AGENCY: Federal Energy Regulatory Commission.

ACTION: Final rule.

SUMMARY: The Federal Energy Regulatory Commission (Commission) is amending its rules regarding reports by natural gas pipeline companies on service interruptions to reflect changes in the Commission's internal structure. This revision changes only the official to whom such reports are made.

EFFECTIVE DATE: This final rule is effective January 22, 2001.

FOR FURTHER INFORMATION CONTACT: Wilbur Miller, Office of the General Counsel, 888 First Street, NE., Washington, DC 20426, (202) 208-0953.

SUPPLEMENTARY INFORMATION:

Natural Gas Service Interruption Reporting Procedures

Before Commissioners: James J. Hoecker, Chairman; William L. Massey, Linda Breathitt, and Curt Hebert, Jr.

I. Introduction

The Federal Energy Regulatory Commission (Commission) is amending 18 CFR Part 260 to change the official to whom natural gas pipeline companies must submit reports on service interruptions. This change is necessitated by changes in the Commission's internal organization and will avoid confusion on the part of companies filing such reports.

II. Background

Currently, 18 CFR 260.9(b) and (c) require natural gas pipeline companies to submit reports on service interruptions to the Director, Division of Environmental and Engineering Review, Office of Pipeline Regulation. As a result of internal reorganization, however, the Office of Pipeline Regulation no longer exists. The relevant responsibilities now are handled by the Director, Division of Pipeline Certificates, Office of Energy Projects.

III. Discussion

This revision changes the title of the official to whom reports are made.

The Commission is issuing this rulemaking as a final rule, without a

period for public comment. Under 5 U.S.C. 553(b), notice and comment procedures are unnecessary for rulemakings that concern only matters of agency practice and procedure. This rulemaking fits that description.

IV. Regulatory Flexibility Act Certification

The Regulatory Flexibility Act (RFA) requires agencies to prepare certain statements, descriptions and analyses of rules that will have a significant impact on a substantial number of small entities.¹ The Commission is not required to make such analyses if a rule would not have such an effect. The Commission certifies that this rule will not have such an impact on small entities.

V. Environmental Statement

Commission regulations require that an environmental assessment or an environmental impact statement be prepared for any Commission action that may have a significant adverse effect on the human environment.² The Commission has categorically excluded certain actions from this requirement as not having a significant effect on the human environment. Among these are rules that are clarifying, corrective, or procedural, or that do not substantively change the effect of the regulations being amended.³ This rule is procedural in nature and therefore falls under this exception; consequently, no environmental consideration is necessary.

VI. Information Collection Statement

The Office of Management and Budget's (OMB) regulations require OMB to approve certain information collection requirements imposed by agency rule.⁴ Respondents subject to the filing requirements of this Rule will not be penalized for failing to respond to these collections of information unless the collections of information display a valid OMB control number. This final rule does not contain any information collection subject to the Paperwork Reduction Act of 1995.⁵

VII. Document Availability

In addition to publishing the full text of this document in the **Federal Register**, the Commission provides all interested persons an opportunity to

¹ 5 U.S.C. 601-612.

² Order No. 486, Regulations Implementing National Environmental Policy Act, 52 FR 47897 (Dec. 17, 1987), FERC Stats. & Regs., Regulations Preambles 1986-1990 30,783 (1987).

³ 18 CFR 380.4(a)(2)(ii).

⁴ 5 CFR 1320.12.

⁵ U.S.C. 3501 *et seq.*

view and/or print the contents of this document via the Internet through FERC's Home Page (<http://www.ferc.fed.us>) and in FERC's Public Reference Room during normal business hours (8:30 a.m. to 5:00 p.m. Eastern time) at 888 First Street, N.E., Room 2A, Washington, DC 20426. From FERC's Home Page on the Internet, this information is available in both the Commission Issuance Posting System (CIPS) and the Records and Information Management System (RIMS).

- CIPS provides access to the texts of formal documents issued by the Commission since November 14, 1994.

- CIPS can be accessed using the CIPS link or the Energy Information Online icon. The full text of this document is available on CIPS in ASCII and WordPerfect 8.0 format for viewing, printing, and/or downloading.

- RIMS contains images of documents submitted to and issued by the Commission after November 16, 1981. Documents from November 1995 to the present can be viewed and printed from FERC's Home Page using the RIMS link or the Energy Information Online icon. Descriptions of documents back to November 16, 1981, are also available from RIMS-on-the-Web; requests for copies of these and other older documents should be submitted to the Public Reference Room.

User assistance is available for RIMS, CIPS, and the Website during normal business hours from our Help line at (202) 208-2222 (E-Mail to WebMaster@ferc.fed.us) or the Public Reference at (202) 208-1371 (E-Mail to public.referenceroom@ferc.fed.us). During normal business hours, documents can also be viewed and/or printed in FERC's Public Reference Room, where RIMS, CIPS, and the FERC Website are available. User assistance is also available.

VIII. Effective Date and Congressional Notification

This regulation becomes effective January 22, 2001. The Commission has concluded that this rule is not a "major rule" as defined in section 251 of the Small Business Regulatory Enforcement Fairness Act of 1996. The provisions of 5 U.S.C. 801, regarding Congressional review of rulemakings, do not apply to this rulemaking because it concerns agency procedure and practice and will not substantially affect the rights and obligations of non-agency parties. 5 U.S.C. 804(3)(C).

List of Subjects in 18 CFR Part 260

Administrative practice and procedure, Electric power, Penalties,

Pipelines, Reporting and recordkeeping requirements.

By the Commission.

David P. Boergers,
Secretary.

In consideration of the foregoing, the Commission amends Part 260, Chapter I, Title 18, Code of Federal Regulations, as follows:

PART 260—APPROVED FORMS, NATURAL GAS ACT

1. The authority citation for Part 260 continues to read as follows:

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

2. Sections 260.9(b) and (c) are revised to read as follows:

§ 260.9 Report by natural gas pipeline companies on service interruptions occurring on the pipeline system.

* * * * *

(b) Natural gas pipeline companies must report such interruptions to service by any electronic means, including facsimile transmission or telegraph, to the Director, Division of Pipeline Certificates, Office of Energy Projects, Federal Energy Regulatory Commission, Washington, DC 20426 (FAX: (202) 208-2853), at the earliest feasible time following such interruption to service, and must state briefly:

- (1) The location of the interruption,
- (2) The time of the interruption,
- (3) The customers affected by the interruption, and

- (4) Emergency actions taken to maintain service.

(c) If so directed by the Commission or the Director, Division of Pipeline Certificates, the company must provide any supplemental information so as to provide a full report of the circumstances surrounding the occurrence.

* * * * *

[FR Doc. 00-32383 Filed 12-20-00; 8:45 am]

BILLING CODE 6717-01-P

SOCIAL SECURITY ADMINISTRATION

20 CFR Parts 404 and 416

[Regulations Nos. 4 and 16]

RIN 0960-AF40

Supplemental Security Income; Determining Disability for a Child Under Age 18; Correction

AGENCY: Social Security Administration.

ACTION: Final rule and correction to final rule.

SUMMARY: This document contains corrections to the final rules published Monday, September 11, 2000 (65 FR 54747). These rules implement the childhood disability provisions of sections 211 and 212 of Public Law 104-193, the Personal Responsibility and Work Opportunity Reconciliation Act of 1996. These rules also conform to amendments to Public Law 104-193 made by the Balanced Budget Act of 1997, Public Law 105-33. In addition, we are correcting two invalid references shown elsewhere in the Code of Federal Regulations.

DATES: This correction is effective January 2, 2001.

FOR FURTHER INFORMATION CONTACT:

Georgia Myers, Regulations Officer, Social Security Administration, 6401 Security Boulevard, Baltimore, MD 21235-6401, regulations@ssa.gov, (410) 965-3632 or TTY (410) 966-5609 for information about these rules. For information on eligibility or filing for benefits, call our national toll-free number, 1-800-772-1213 or TTY 1-800-325-0778, or visit our Internet web site, *SSA Online*, at: <http://www.ssa.gov/>

SUPPLEMENTARY INFORMATION:

Background

On February 11, 1997, we published interim final rules with a request for comments to implement the Supplemental Security Income (SSI) childhood disability provisions of sections 211 and 212 of Public Law (Pub. L.) 104-193, the Personal Responsibility and Work Opportunity Reconciliation Act of 1996. On September 11, 2000, we published revised final rules in response to public comments. We also conformed our rules to amendments to Pub. L. 104-193 made by the Balanced Budget Act of 1997, Pub. L. 105-33.

Need for Correction

In our preamble, we found that we had inadvertently published an incorrect Internet address for a report on the effects of the new childhood disability legislation. We are correcting that address as shown below.

Additionally, we are correcting the regulatory language in two places. We found the need to make both an editorial change and a change needed to clarify our original intent. We are also correcting two invalid references shown elsewhere in the Code of Federal Regulations.

Correction of Rule Published September 11, 2000

The publication on September 11, 2000, of the subject final rules, is corrected as follows:

1. On page 54749, column three, the last sentence of the third paragraph under "Actions Since We Published the Interim Final Rules," is corrected to read as follows:

The report is also available at our public Internet site: <http://www.ssa.gov/policy/SSICChildDI/child001.htm>.

PART 416—[CORRECTED]

2. On page 54777, column 2, the definition of "The listings" is corrected to read as follows:

§ 416.902 General definitions and terms for this subpart.

* * * * *

The listings means the Listing of Impairments in appendix 1 of subpart P of part 404 of this chapter. When we refer to an impairment(s) that "meets, medically equals, or functionally equals the listings," we mean that the impairment(s) meets or medically equals the severity of any listing in appendix 1 of subpart P of part 404 of this chapter, as explained in §§ 416.925 and 416.926, or that it functionally equals the severity of the listings, as explained in § 416.926a.

* * * * *

3. On page 54783, column 3, the first sentence of § 416.926a(e)(3)(iv) is corrected to read as follows:

§ 416.926a Functional equivalence for children.

* * * * *

(e) * * *

(iv) For the sixth domain of functioning, "Health and physical well-being," we may also consider you to have an "extreme" limitation if you are frequently ill because of your impairment(s) or have frequent exacerbations of your impairment(s) that result in significant, documented symptoms or signs substantially in excess of the requirements for showing a "marked" limitation in paragraph (e)(2)(iv) of this section. * * *

* * * * *

Correcting Amendments to the Code of Federal Regulations**List of Subjects****20 CFR Part 404**

Administrative practice and procedure, Aged, Alimony, Blind, Disability benefits, Government employees, Income taxes, Insurance, Investigations, Old-age, Survivors and

Disability Insurance, Penalties, Railroad retirement, Reporting and recordkeeping requirements, Social security, Travel and transportation expenses, Treaties, Veterans, Vocational rehabilitation.

20 CFR Part 416

Administrative practice and procedure, Alcoholism, Drug abuse, Investigations, Medicaid, Penalties, Reporting and recordkeeping requirements, Supplemental Security Income (SSI), Travel and transportation expenses, Vocational rehabilitation.

Chapter III of title 20 of the Code of Federal Regulations is amended as follows:

PART 404—[AMENDED]

1. The authority citation for subpart P to part 404 continues to read as follows:

Authority: Secs. 202, 205(a), (b), and (d)—(h), 216(i), 221 (a) and (i), 222(c), 223, 225, and 702(a)(5) of the Social Security Act (42 U.S.C. 402, 405 (a), (b), and (d)—(h), 416(i), 421(a) and (i), 422(c), 423, 425, and 902(a)(5)); sec. 211(b), Pub. L. 104–193, 110 Stat. 2105, 2189.

2. Section 404.1520 is amended by revising the last sentence of paragraph (a) to read as follows:

§ 404.1520 Evaluation of disability in general.

(a) * * * Once you have been found entitled to disability benefits, we follow a somewhat different order of evaluation to determine whether your entitlement continues, as explained in § 404.1594(f).

* * * * *

PART 416—[AMENDED]

3. The authority citation for subpart I to part 416 continues to read as follows:

Authority: Secs. 702(a)(5), 1611, 1614, 1619, 1631(a), (c), and (d)(1), and 1633 of the Social Security Act (42 U.S.C. 902(a)(5), 1382, 1382c, 1382h, 1383(a), (c), and (d)(1), and 1383b); secs. 4(c) and 5, 6(c)—(e), 14(a), and 15, Pub. L. 98–460, 98 Stat. 1794, 1801, 1802, and 1808 (42 U.S.C. 421 note, 423 note, 1382h note).

4. Section 416.920 is amended by revising the last sentence of paragraph (a) to read as follows:

§ 416.920 Evaluation of disability of adults, in general.

(a) * * * Once you have been found eligible for Supplemental Security Income benefits based on disability, we follow a somewhat different order of evaluation to determine whether your eligibility continues, as explained in § 416.994(b)(5).

* * * * *

Dated: December 7, 2000.

Georgia E. Myers,

Regulations Officer, Social Security Administration.

[FR Doc. 00–32379 Filed 12–20–00; 8:45 am]

BILLING CODE 4191–02–U

DEPARTMENT OF THE INTERIOR**Office of Surface Mining Reclamation and Enforcement****30 CFR Part 948**

[WV–086–FOR]

West Virginia Regulatory Program

AGENCY: Office of Surface Mining Reclamation and Enforcement (OSM), Interior.

ACTION: Final rule; approval of amendment.

SUMMARY: OSM is announcing its approval, with certain exceptions, of an amendment to the West Virginia regulatory program under the Surface Mining Control and Reclamation Act of 1977 (SMCRA). The program amendment consists of changes to the West Virginia regulations (38 CSR 2) contained in House Bill 4223 concerning Homestead postmining land use. The amendment is intended to comply with the Consent Decree that was agreed to by the plaintiffs and the West Virginia Division of Environmental Protection (WVDEP) and approved by the U.S. District Court for the Southern District of West Virginia on February 17, 2000, in the matter of *Bragg v. Robertson*, Civil Action No. 2:98–0636 (S.D.W.Va.).

EFFECTIVE DATE: December 21, 2000.

FOR FURTHER INFORMATION CONTACT: Mr. Roger W. Calhoun, Director, Charleston Field Office, 1027 Virginia Street East, Charleston, West Virginia 25301. Telephone: (304) 347–7158. E-mail: chfo@osmre.gov.

SUPPLEMENTARY INFORMATION:

- I. Background on the West Virginia Program
- II. Submission of the Amendment
- III. Director's Findings
- IV. Summary and Disposition of Comments
- V. Director's Decision
- VI. Procedural Determinations

I. Background on the West Virginia Program

On January 21, 1981, the Secretary of the Interior conditionally approved the West Virginia program. You can find background information on the West Virginia program, including the Secretary's findings, the disposition of comments, and the conditions of the

approval in the January 21, 1981, **Federal Register** (46 FR 5915–5956). You can find later actions concerning the West Virginia program and previous amendments at 30 CFR 948.10, 948.12, 948.13, 948.15, and 948.16.

II. Submission of the Amendment

By letter dated March 14, 2000 (Administrative Record Number WV–1147) and March 28, 2000 (Administrative Record Number WV–1148), and electronic mail dated April 6, 2000 (Administrative Record Number WV–1149), the WVDEP submitted an amendment to its program. The amendment concerns changes to the West Virginia surface mining reclamation regulations made by the State Legislature in House Bill 4223, and changes made to the Code of West Virginia in Senate Bill 614. Most of the amendment is intended to comply with the Consent Decree that was agreed to by the plaintiffs and the WVDEP and approved by the U.S. District Court for the Southern District of West Virginia on February 17, 2000, in the matter of *Bragg v. Robertson*, Civil Action No. 2:98–0636 (S.D.W.Va.).

We announced receipt of the proposed amendment in the April 25, 2000, **Federal Register** (65 FR 24158–24162), invited public comment, and provided an opportunity for a public hearing on the adequacy of the proposed amendment. The public comment period closed on May 25, 2000. Since no one requested a public hearing, none was held.

To expedite our review of the amendment, we separated the amendment into two parts: (1) Amendments to the proposed rules at new section CSR 38–2–7.5 concerning “homesteading” as a postmining land use for mountaintop removal mining permits that meet the requirements for a variance from the approximate original contour (AOC) provisions at section 22–3–13(c) of the W.Va. Code. These provisions are the subject of this notice; and (2) Changes to the W.Va. Code in Senate Bill 614 and the regulatory changes at CSR 38–2–7.4 concerning commercial forestry postmining land use for mountaintop removal mining operations receiving an AOC variance, and various other regulatory changes. We published our final decision on those amendments in the **Federal Register** on August 18, 2000 (65 FR 50409).

III. Director's Findings

Set forth below, pursuant to SMCRA and the Federal regulations at 30 CFR 732.15 and 732.17, are the Director's findings concerning the proposed

amendment. Any revisions that we do not specifically discuss below concern nonsubstantive wording changes or revised paragraph notations to reflect organizational changes that result from this amendment.

1. CSR 38–2–7.5 Homestead land use.

This subsection is new and contains the following subdivisions.

7.5. The Homestead land use meets the requirements for a variance from the AOC requirements of the Act (W.Va. Code 22–3–13(c)). An appropriately planned Homestead will promote sustainable settlement patterns that protect the environment and support the region's economic development.

7.5.a. Operations receiving a variance from AOC for this use shall establish homesteading on at least one-half (½) of the permit area. The remainder of the permit area shall support an alternate AOC variance use.

The W.Va. Code at section 22–3–13 contains the general environmental protection performance standards for surface mining operations. Specifically, subdivision 13(c)(2) authorizes the Director of the WVDEP to grant approval of AOC variances for mountaintop removal mining operations. Subdivision 13(c)(3) identifies the following postmining land uses that are approvable for mountaintop removal mining operations: industrial, commercial, agricultural, commercial forestry, residential, public facility including recreational uses. Homestead is considered to be a “residential” postmining land use under W. Va. Code 22–3–13(c). It is important to note that Homestead is limited to mountaintop removal mining operations, and does not apply to steep slope mining operations with AOC variances as provided in section 22–3–13(e) of the W.Va. Code and CSR 38–2–14.12.a.1.

SMCRA at section 515(c)(3) and the Federal regulations at 30 CFR 784.14(c)(1) provide for the following postmining land uses for mountaintop removal operations: industrial, commercial, agricultural, residential, and public facility (including recreational facilities). The Federal regulations define “residential” under the definition of “land use” at 30 CFR 701.5 to mean, “land used for single- and multiple-family housing, mobile home parks, or other residential lodgings.” In a similar fashion, the State regulations at CSR 38–2–7.2.d define residential use to be single and multiple-family housing (other than apartment houses) with necessary support facilities. Support facilities may include commercial services incorporated in and comprising less

than five percent (5%) of the total land area of housing capacity, associated open space and minor vehicle parking and recreation facilities supporting the housing.

The proposed Homestead postmining land use is a residential use as defined at 30 CFR 701.5. Therefore, we find that the introductory language at CSR 38–2–7.5 which states that Homestead postmining land use meets the requirements for a variance from the AOC requirements of the W.Va. Code at 22–3–13(c) to be no less stringent than section 515(c)(3) of SMCRA and no less effective than the Federal regulations at 30 CFR 785.14(c)(1) and 701.5 and can be approved. We note that prior to authorizing “homestead” as a postmining land use for a mountaintop removal mining operation, the applicant must submit specific plans and assurances and the State regulatory authority must approve them in accordance with the requirements of W.Va. Code 22–3–13(c)(3) and CSR 38–2–14.10, and 14.12 to the extent that it applies to mountaintop removal mining operations. Therefore, and except as noted below, we are approving the use of Homestead as a postmining land use as provided at CSR 38–2–7.5. to the extent that it supplements or is more stringent than existing State requirements, but is not inconsistent with any existing Federal program requirements.

There is no Federal counterpart to the new language at CSR 38–2–7.5.a. concerning the percentage of the AOC variance land that must contain either the Homestead or an alternate AOC variance postmining land use. We find that this provision is not inconsistent with SMCRA or the Federal regulations and can be approved.

2. CSR 38–2–7.5.b. This provision defines the terms that are applicable only to homestead land use. This subdivision provides the following.

7.5.b. The following terms are applicable only to this subsection of this rule.

7.5.b.1. Building Pad means an accessible, designated, and properly drained area where the soil and/or mine-spoil has been specially placed and compacted to minimize post-mining surface settlement. After the building pad is completed, a registered professional engineer shall certify that the building pad was constructed as designed. This certification shall accompany the deed of conveyance.

7.5.b.2. Civic Parcel means a parcel designated in the Land Plan for public use.

7.5.b.3. Commercial Parcel means a parcel retained by the Landowner of

record and incorporated within the Homestead Area on which the landowner or its designee may develop commercial uses. The size and location of commercial parcels shall comply with the requirements of this regulation.

7.5.b.4. Community Association means an association of all the homesteaders. This association shall receive title to the civic parcels, conservation easements and nurseries at the time of final bond release.

7.5.b.5. Conservation Easement means an area, typically a strip no less than 200 feet wide, designated in the land plan for the purpose of establishing a natural habitat for the development and migration of native species of fauna and flora. These easements shall extend through the mined areas of the land, starting and ending in natural, undisturbed land. These areas shall be permanent easements maintained for conservation and not commercial purposes.

7.5.b.6. Entity Administering The Civic Parcels means the Community Association or its designee shall administer the civic parcels.

7.5.b.7. Escrow Agent means the Attorney General of the State of West Virginia shall be the Escrow Agent.

7.5.b.8. Homesteader means a citizen of the State that fulfills the requirements of this regulation and who is selected by lottery to reside on a designated homestead parcel.

7.5.b.9. Homestead Area means the entire area designated for homestead use, including roads.

7.5.b.10. Homestead Infrastructure means the facilities necessary to sustain residential use, including roads, electricity, telephone, water and sewage or septic systems.

7.5.b.11. Homestead Parcel means an individual segment of a homestead area designated as either a rural or village parcel. The permittee shall assure that each parcel has been surveyed by a licensed land surveyor before Phase I bond release.

7.5.b.12. Homestead Plan means all the required documentation, engineered drawings, authorizations, agreements and schedules which are to be submitted and approved by the Director.

7.5.b.13. Homestead Selection Lottery means a lottery sanctioned by the State, operated under rules established and administered by the Director or the Director's designee as soon as practicable after Phase I bond release.

7.5.b.14. Landowner Of Record means the surface estate owner at the time the mining permit is submitted to the Director. More than one Landowner of Record may be involved in a Homestead Plan. The Landowner of Record shall

transfer the title to the surface estate of the Homestead Area to the Escrow Agent prior to the beginning of mining. The cost of transfer shall be paid by the Landowner of Record.

7.5.b.15. Land Plan means the depiction, with supporting documentation, including surveys and narratives, of the homestead parcels, building pads, roads, easements, civic parcels, commercial parcels, and other features of the Homestead Area.

7.5.b.16. Machine Passable Grade means the maximum grade that can be safely accommodated by commonly used, self-propelled, rubber-tired farming equipment.

7.5.b.17. Rural Parcels means homesteading parcels planned to promote rural uses such as farming, orchard growing, timber management, viticulture, and Morret gardening. The rural parcels shall be an appropriate size for the designated use and may be up to 40 acres. Rural homesteaders may receive title only to that portion of the land that they have improved over the five-year period.

7.5.b.18. Service Drop means the overhead service conductors from the last pole or other aerial support to and including the splices, if any, connecting to the service-entrance conductors at the building or other structure.

7.5.b.19. Service-Entrance Conductors, Overhead System means the service conductors between the terminals of the service equipment and a point usually outside the building, clear of building walls, where joined by tap or splice to the service drop.

7.5.b.20. Service-Entrance Conductors, Underground System means the service conductors between the terminals of the service equipment and the point of connection to the service lateral.

7.5.b.21. Service Lateral means the underground service conductors between the street main, including any risers at a pole or other structure or from transformers, and the first point of connection to the service-entrance conductors in a terminal box or meter or other enclosure with adequate space, inside or outside the building wall. Where there is no terminal box, meter, or other enclosure with adequate space, the point of connection shall be considered to be the point of entrance of the service conductors into the building.

7.5.b.22. Soil Plan means the maps and descriptions of premining and postmining soil included in the Homestead Plan.

7.5.b.23. Village Parcels means homesteading parcels that provide a

higher density of residential population than rural parcels.

There are no specific counterparts to these definitions. We find that, except as noted below, the definitions are not inconsistent with SMCRA at section 515(c)(3) or the Federal regulations at 30 CFR 785.14(c)(1) concerning the approval of AOC variances for proposed postmining land use for mountaintop removal mining operations and can be approved.

The definition of "Commercial Parcel" at CSR 38-2-7.5.b.3. provides that "Commercial Parcel" means a parcel retained by the landowner of record and incorporated within the Homestead area on which the landowner or its designee may develop commercial uses. In addition, the size and location of commercial parcels shall comply with the requirements of this regulation. Under this definition, therefore, a commercial postmining land use may be incorporated within the Homestead postmining land use. SMCRA at section 515(c)(3) and the Federal regulations at 30 CFR 785.14(c)(1) provide that commercial postmining land use may be approved for mountaintop removal mining operations. Therefore, the incorporation of a commercial postmining land use within a homestead (residential) postmining land use does not render the West Virginia program less stringent than SMCRA nor less effective than the Federal regulations and can be approved. However, since the language of this provision states that the landowner "may" develop a parcel for commercial purposes, it is not clear what must be done if a landowner retains a parcel but does not develop that parcel for commercial uses. Therefore, we are requiring that CSR 38-2-7.5.b.3. be amended to clarify that parcels retained by the landowner for commercial development and incorporated within the Homestead area must be developed for commercial uses as provided by subsection CSR 38-2-7.5.g.5.

The definition of "Conservation Easement" at CSR 38-2-7.5.b.5. allows the creation of natural habitat areas within the Homestead postmining land use. Conservation easements are to comprise at least 10 percent of the Homestead area, including commercial parcels. Neither SMCRA at section 515(c)(3) nor the Federal regulations at 30 CFR 785.14(c)(1) specifically authorize conservation easements or the creation of natural habitat areas as approvable postmining land uses for mountaintop removal mining operations. However, such natural areas may play a supporting role in the

developmental plans of a proposed postmining land use that is approvable under SMCRA and the Federal regulations. This is consistent with the Federal regulations at 30 CFR 816.97 which encourages the enhancement of fish and wildlife in postmining land uses. Specifically, 30 CFR 816.97(i) provides that where residential, public service, or industrial uses are to be the postmining land use, and where consistent with the approved postmining land use, the operator shall intersperse reclaimed lands with green belts utilizing species of grass, shrubs and trees useful as food and cover for wildlife. As explained under the definition of "Conservation Easement," the use of natural habitat areas plays an appropriate supporting role in the Homestead postmining land use. Therefore, we find CSR 38-2-7.5.b.5. to be no less stringent than SMCRA and no less effective than the Federal regulations and can be approved.

The definition of "Homestead Area" means the entire area designated for homestead use, including roads. As discussed above at Finding 1., Homestead postmining land use is a residential postmining land use that qualifies for an AOC variance for mountaintop removal mining operations under SMCRA section 515(c)(3) and the Federal regulations at 30 CFR 785.14(c)(1). The definition of "Homestead Area" as meaning the entire area designated for homestead use, including roads is therefore also consistent with the Federal "residential" postmining land use. Therefore, we find that the definition of "Homestead Area" is consistent with and no less stringent than SMCRA section 515(c)(3) and the Federal regulations at 30 CFR 785.14(c)(1) and can be approved.

The definition of "Rural Parcels" at CSR 38-2-7.5.b.17. means homesteading parcels planned to promote rural uses such as farming, orchard growing, timber management, viticulture (grape growing), and Morret gardening. We note that the term "Rural Parcels" includes "timber management" use as one of the uses that are promoted for these rural parcels. Timber management should not be confused with the "commercial forestry and forestry" postmining land use for AOC variances for mountaintop removal mining operations that we recently approved (65 FR 50409). Homesteading postmining land use, which is a residential use under SMCRA section 515(c)(3) and 30 CFR 785.14(c)(1), is an approvable postmining land use. Timber management is one of many uses to which the homeowners of the rural

Homestead parcels may develop their land. In addition, the size of each rural parcel can be up to 40 acres, and the homesteaders may receive title only to that portion of the land that they have improved over the five-year period. Therefore, we find that the definition of "Rural Parcels" is not inconsistent with SMCRA section 515(c)(3) nor with the Federal regulations at 30 CFR 785.14(c)(1) and can be approved. In addition, we recommend that the West Virginia program be amended to define the term "Morret gardening."

3. CSR 38-2-7.5.c. This provision concerns the eligibility requirements and responsibilities for homesteaders. This subdivision provides as follows.

7.5.c. Eligibility Requirements And Responsibilities For Homesteaders;

7.5.c.1. Homesteader shall meet the following eligibility requirements:

7.5.c.1.A. Be a resident of the State of West Virginia and be at least 18 years old;

7.5.c.1.B. Apply for a homestead as required by this rule;

7.5.c.1.C. Abide by the rules of the Homestead Selection Lottery;

7.5.c.1.D. Reside on the subject parcel within 12 months after the property is certified as ready for use. Provided that subject to the approval of the Escrow Agent, occupancy may be delayed up to 6 additional months for good cause shown.

There are no Federal counterparts to the provisions at CSR 38-2-7.5.c. concerning eligibility requirements and responsibilities for homesteaders. However, we find that they are not inconsistent with SMCRA or the Federal regulations and can be approved.

4. CSR 38-2-7.5.d. This provision concerns the rules for the homestead lottery. This subdivision contains the following requirements.

7.5.d. Rules For The Lottery;

7.5.d.1. The rules for the Lottery are as follows:

7.5.d.1.A. Each household may receive no more than one homestead.

7.5.d.1.B. Homestead parcels shall be distributed by anonymous lottery.

7.5.d.1.C. For any given Homestead, the lottery shall first be opened only to West Virginians living within three (3) miles of the permitted area within five years of the date of the filing of the permit application. Provided, however, that if parcels remain after an initial lottery, subsequent lotteries shall be held in the following order. The first subsequent lottery shall be open to any resident of a county (or counties, if more than one) in which the mine is located. Further, lotteries, if necessary, shall be open to any resident of West Virginia,

and shall be held at six (6) month intervals.

7.5.d.1.D. The lottery shall be held as soon as practicable after Phase I bond release is approved. Adequate notice shall be provided at least six (6) months in advance of the lottery.

7.5.d.1.E. The lottery shall be fair, impartial, and open to the public.

7.5.d.1.F. A lottery participant who receives a parcel may decline a parcel, but may not sell the right to homestead on the parcel.

7.5.d.1.G. The right to participate in the lottery is not assignable or saleable.

7.5.d.1.H. Each lottery participant shall, before the lottery, apply for either a rural or a village parcel.

There are no Federal counterparts to the provisions at CSR 38-2-7.5.d. concerning rules for a lottery. However, we find that they are not inconsistent with SMCRA or the Federal regulations and can be approved.

5. CSR 38-2-7.5.e. This provision concerns the homestead plan development. This subdivision contains the following requirements.

7.5.e. Homestead Plan Development.

7.5.e.1. The Director may authorize Homesteading as a post-mining use only if the following conditions have been satisfied.

7.5.e.1.A. The Homestead Plan and any subsequent modifications shall be prepared under the direction of and certified by a professional engineer, a soil scientist, and a design professional that is either a licensed architect, landscape architect, or AICP certified land planner. [Note: AICP means American Institute of Certified Planners].

7.5.e.1.B. The Homestead Plan shall identify each member of a specialty group that contributed to the plan. The Plan shall be sufficiently detailed to ensure success in achieving the designated use of each homestead panel [sic] and to ensure sound future management of the homestead.

7.5.e.1.C. Homestead plan may be used alone or in conjunction with any other alternate land use plan. The Homesteading area, minus commercial parcels, shall occupy at least 50% of the permitted area. In the event that the Homestead use is used in conjunction with another land use, the Landowner of Record shall provide for the Homestead use at least as much land on the mining bench as it retains for alternate land use.

7.5.e.1.D. The Permittee shall submit plans prepared at a preferred scale of at least 1 inch = 200 feet, which include the following:

7.5.e.1.D.1. A Land Plan showing the homestead boundaries, homestead

parcels, building pads, roads, easements, civic parcels, and commercial parcels, as applicable.

7.5.e.1.D.2. A Site Plan and description of the following:

7.5.e.1.D.2.(a) wastewater and sewage systems,

7.5.e.1.D.2.(b) potable water supply,

7.5.e.1.D.2.(c) non-potable water supply (if applicable).

7.5.e.1.D.2.(d) electrical service, and

7.5.e.1.D.2.(e) telephone service.

7.5.e.1.D.3. A grading plan showing contours at an interval appropriate for the map scale and slopes, and including surface drainage and stormwater provisions. The Director shall require maps at specific scales and contour intervals to satisfy the designated uses of the homestead parcels and the land plan.

7.5.e.1.D.4. A map showing all off-bench fill areas and the outcrop of the lowest coal bed.

7.5.e.1.D.5. A Soil Plan showing soil and weathered spoil storage areas. The plan shall describe the methods to be used to distribute, protect, and enhance the stored material upon final regrading of the disturbed surfaces. The plan shall identify the proposed depths of soil and subsoil for each specific use within the Homestead Area. These specific uses may include, but shall not be limited to, the following:

7.5.e.1.D.5.(a) Haul roads;

7.5.e.1.D.5.(b) Conservation

Easements;

7.5.e.1.D.5.(c) Building Pads;

7.5.e.1.D.5.(d) Garden Plots;

7.5.e.1.D.5.(e) Waste Water and

Sewage Disposal Facilities;

7.5.e.1.D.5.(f) Storm Drainage Facilities;

7.5.e.1.D.5.(g) Wetland Facilities;

7.5.e.1.D.5.(h) Utility Easements;

7.5.e.1.D.5.(i) Civic/Public Facilities;

7.5.e.1.D.5.(j) Commercial Areas;

7.5.e.1.D.6. Soil maps.

SMCRA at section 515(c)(3)(B), and the Federal regulations at 30 CFR 785.14(c), like W.Va. Code 22-3-13(c)(3), provide that an applicant for a mountaintop removal mining permit must present specific plans for the proposed postmining land use. SMCRA and the Federal regulations do not, however, contain the same level of specificity as do these regulations with respect to the plans that must be submitted to support a particular authorized postmining land use. The provisions at CSR 38-2-7.5.e. provide detailed requirements concerning the specific plans that must be submitted for a Homesteading postmining land use. The new provisions are not inconsistent with the requirements of SMCRA at section 515(c)(3)(B) and the

Federal regulations at 30 CFR 785.14(c), which require that an applicant for a mountaintop removal mining permit present specific plans for the proposed postmining land use. The new subdivisions at 7.5.e.1.D.3. and D.5. require the submittal of a grading plan (7.5.e.1.D.3.) and a soil plan (7.5.3.1.D.5.). However, these new requirements do not make it clear that the permittee must also submit maps, cross sections and operations plans that comply with CSR 38-2-3.4, 3.5, and 3.6. Therefore, we find that the provisions at CSR 38-2-7.5.e. are no less stringent than SMCRA nor less effective than the Federal regulations and can be approved to the extent that its provisions supplement, but do not supersede, the approved State provisions concerning maps and cross sections, and operation plans at CSR 38-2-3.4, 3.5, and 3.6.

6. CSR 38-2-7.5.f. This subdivision concerns the provisions for financial commitments. This subdivision contains the following requirements.

7.5.f. Financial Commitments.

7.5.f.1. A contract between the Permittee and the Director, binding the Permittee to complete the homestead use as soon as practicable but no later than two years after the completion of mining, shall be required.

7.5.f.2. The contract between the Permittee and the Director shall, at a minimum, require the Permittee to follow the homesteading reclamation plan.

7.5.f.3. To receive approval for a homestead use, the Permittee shall demonstrate that it has the financial capability to achieve the use and carry out the reclamation plan. The Permittee shall submit signed statements containing financial information and data sufficient to demonstrate that the Permittee has the financial capability to achieve the homesteading use.

7.5.f.4. Before approving the Permit, the Director shall find, in writing, that the Permittee has the financial capability to achieve the use.

We find that the provisions at CSR 38-2-7.5.f. are consistent with SMCRA section 515(c)(3)(B)(v), and the Federal regulations at 30 CFR 785.14(c)(1)(iii)(E) which require an applicant for a mountaintop removal permit provide appropriate assurance that the proposed postmining land use is practicable with respect to private financial capability for completion of the proposed use. In addition, new CSR 38-2-7.5.f.1. is consistent with 30 CFR

816.133(c)(3)(iii), which provides that a proposed alternative postmining land use may be approved if, among other requirements, the regulatory authority finds that the proposed use will not

“Involve unreasonable delay in implementation.” Compliance with 30 CFR 816.133(a) through (c) is required by 30 CFR 824.11(a)(4). Therefore, the new provisions at CSR 38-2-7.5.f. can be approved. We note that W.Va. Code section 22-3-13(c)(3), concerning mountaintop removal mining operations, provides that the Director of the WVDEP must make other written findings in addition to a finding concerning financial capability to achieve the proposed postmining land use. Therefore, we are approving CSR 38-2-7.5.f. to the extent that compliance with W.Va. Code section 22-3-13(c)(3) is also required.

7. CSR 38-2-7.5.g. This provision concerns the required elements for all homestead plans and contains the following requirements.

7.5.g. Required Elements For All Homestead Plans.

7.5.g.1. Boundary of the homestead area:

7.5.g.1.A. The Homestead Area shall be defined by a metes and bounds description prepared and certified by a Professional Engineer or Licensed Land Surveyor registered with the State of West Virginia.

7.5.g.1.B. Non-mined areas may be included in the Homestead Area.

7.5.g.1.C. In the event that any portion of the land transferred to the Escrow Agent is not mined, that land may revert to the Landowner of Record.

7.5.g.2. General Requirements of all Parcels:

7.5.g.2.A. Each individual parcel shall be delineated by metes and bounds description prepared by a Professional Engineer or Licensed Land Surveyor registered with the State of West Virginia.

7.5.g.2.B. Parcels shall support their designated land uses.

7.5.g.2.C. Parcels shall be configured and arranged to minimize adverse environmental impacts.

7.5.g.2.D. The Permittee shall provide adequate road frontage for access to each Homestead, Public Nursery, Civic and Commercial Parcel.

7.5.g.2.E. Houses and appurtenant facilities shall be no closer than 50 feet from the edge of a designated Conservation Easement.

7.5.g.3. Homestead parcels:

7.5.g.3.A. Homestead Parcels shall be designated as either rural or village parcels. All parcels shall contain machine passable land appropriate to the designated use.

7.5.g.3.B. Each rural homestead parcel shall be provided with a garden area of at least 5,000 square feet. Each village homestead parcel shall be provided with a garden area of at least 600 square

feet. The garden areas shall be constructed in compliance with the soil requirements set forth in subdivision 7.5.j. of this rule.

7.5.g.3.C. Each rural and village homestead parcel shall contain a building pad of a minimum of 2,500 square feet for a dwelling. Each rural homestead parcel shall also contain a building pad of a minimum of 2,500 square feet for an outbuilding.

7.5.g.4. Civic Parcels:

7.5.g.4.A. The Homestead Plan shall delineate one or more appropriate sites within the total proposed Homestead area for Civic Parcels. These uses may include, but are not limited to, the following: park land, playing fields, schools, post office, and community administrative facilities. This area shall occupy at least 10% of the post-mining permit area.

7.5.g.4.B. The Civic Parcels may be one contiguous parcel or appropriately sized non-contiguous parcels.

7.5.g.4.C. The Civic Parcels shall be deeded at no charge to the duly recognized Community Association.

7.5.g.4.D. The Civic Parcels shall be provided with an access road and utilities that are consistent with the proposed civic land use.

7.5.g.5. Commercial Parcels:

7.5.g.5.A. The Landowner of Record may elect to retain up to 15% of the land in the proposed Homestead Area for the purpose of commercial development; provided that the Landowner of Record may retain no more than 50% of the permitted area.

7.5.g.5.B. The retained commercial area may be comprised of one or more parcels and shall be indicated on the Land Plan.

7.5.g.5.C. In the area for the Commercial Parcel the mine-spoil shall be placed, compacted, and regraded in a manner consistent with the proposed commercial land use.

7.5.g.6. Approval:

7.5.g.6.A. Before approving a homesteading reclamation plan, the Director shall assure that Homestead Plan is reviewed and approved by either a licensed architect, landscape architect, or AICP certified land planner employed by or under contract to the Director. In addition, the Director shall assure that the plans for Rural Parcels are reviewed and approved by an agronomist employed by or under contract with the Director. The applicants shall pay for any review under this subsection.

There are no direct Federal counterparts to the provisions at CSR 38–2–7.5.g. We find that the new provisions are not inconsistent with section 515(c)(3)(B) of SMCRA which

provides that the applicant must provide specific plans for the proposed postmining land use, and can be approved. However, these provisions are only approved to the extent that compliance with the State's approved postmining land use requirements at CSR 38–2–7 is also required. We note that the term "Public Nursery" as used at subdivision CSR 38–2–7.5.g.2.D. is not defined. For clarity, we recommend that the State add a definition of this term.

8. CSR 38–2–7.5.h. This subdivision concerns the construction and conveyance of homestead parcels, and contains the following requirements.

7.5.h. Construction And Conveyance Of Homestead Parcels. All construction projects not performed by the homesteaders on Homestead Areas shall be performed by the Permittee, using a West Virginia licensed contractor.

7.5.h.1. Stabilization of the Homestead Area:

7.5.h.1.A. The Homestead Plan shall describe the methods that will be used during the placement of mine spoil to minimize mine spoil consolidation and its associated ground settlement, where such settlement will adversely affect the use of the homestead. Conditions relating to the placement of structures on the mine-spoil shall be clearly identified in the Plan.

7.5.h.1.B. The Plan must delineate the areas on each parcel where the mine-spoil will be placed in a manner to minimize post-mining land surface settlement on Building Pads, roads and other appropriate areas.

7.5.h.1.C. The placement methodology shall be specified by a qualified engineer. The Plan shall indicate the type and style of structure appropriate for each building pad. The Plan shall include the requirement that a professional engineer will monitor the construction of the building pads to certify compliance with the specifications of the plan.

7.5.h.2. Construction Of The Building Pad:

7.5.h.2.A. Building Pads shall be designed by a registered professional engineer.

7.5.h.2.B. The registered professional engineer shall supervise the placement of the uppermost 20 feet of spoil for Building Pads to minimize consolidation.

7.5.h.2.C. The engineer shall certify the integrity of the Building Pad and that the Building Pads will not settle more than 1/2 inch after the expected structure is in place.

7.5.h.2.D. Building Pads shall be designed to accommodate the type of

building expected to be placed on the pad.

7.5.h.2.E. Building Pads shall not be placed on valley fills.

7.5.h.3. Conveyance Of Homestead Parcels:

7.5.h.3.A. Estimated short and long-term costs to Homesteaders shall be designated in the Homestead Plan and presented to Homesteaders immediately after the Lottery on a parcel specific basis.

7.5.h.3.B. The rights to the surface estate shall be deeded to each Homesteader free and clear of all liens and encumbrances as soon after bond release as the Escrow Agent determines that the property is ready for use. The deeds shall not retain right of entry onto the homestead parcels to conduct future surface mining activities.

7.5.h.3.C. Consistent with State and federal law, the transfer of the surface to the Escrow Agent may be for surface rights only and need not include any minerals, oil or gas and shall be subject to usual and customary mining or extraction rights.

7.5.h.3.D. Before receiving the Homestead Parcel, each homesteader shall:

7.5.h.3.D.1. Install and reside in a dwelling whose structure complies with the Homestead Plan community association rules, and all applicable local, county and state laws;

7.5.h.3.D.2. Reside on the parcel for at least forty-five weeks each year for five (5) consecutive years prior to receipt of title to the land;

7.5.h.3.D.3. Use and improve the parcel by completing a dwelling that complies with this rule, installing an approved septic system and maintaining vegetative cover on all parts of the homestead parcel and plant trees from the Public Nursery in accordance with subdivision 7.5.1.4. of this rule.

7.5.h.3.E. In the event extreme hardship causes a homesteader to be forced to sell his property before the five-year occupancy period has expired, the Escrow Agent shall convey title early. The Escrow Agent's determination of extreme hardship shall be reasonable by the Circuit Court of County in which the homestead parcel is located.

There are no direct Federal counterparts to the provisions at CSR 38–2–7.5.f. However, we find that the new provisions are not inconsistent with section 515(c)(3)(B) of SMCRA which provides that the applicant must provide specific plans for the proposed postmining land use. We note, however, that there is an apparent editorial error at subdivision 7.5.h.2.B. Subdivision 7.5.h.2.B. provides that the registered

professional engineer shall supervise the placement of the uppermost 20 feet of spoil for Building Pads to "minimize" compaction. The term "minimize" should be "maximize." The new rules at both CSR 38-2-7.5.b.1. and 7.5.j.4.A. clearly require that the mine soil under Building Pads must be properly compacted. Without such compaction, the settlement standard for Building Pads at CSR 38-2-7.5.h.2.C. would not be achievable. Therefore, we are approving new CSR 38-2-7.5.h. to the extent that subdivision 7.5.h.2.B. means that consolidation of the uppermost 20 feet of spoil for Building Pads must be maximized. Further, we recommend that the editorial error be corrected to clarify this apparent contradiction, otherwise, it may not be possible to achieve the homestead postmining land use.

9. CSR 38-2-7.5.i. This subdivision concerns required infrastructure, and contains the following requirements.

7.5.i. Required Infrastructure.

7.5.i.1. Roads:

7.5.i.1.A. The Land Plan shall designate an all-weather road connecting the Homestead Area to a public road or highway. The road shall meet State Department of Highways' standards, and shall be certified as safe for passenger car traffic by registered professional engineer.

7.5.i.1.B. The Land Plan shall incorporate adequate road frontage to all parcels. Such roads shall be designated in the plan and referred to as "main roads." Main roads shall meet State Department of Highways standards, and shall be certified as built as safe for passenger car traffic by registered civil engineer.

Before the Director may approve a surface mining application for this use, the County or State road authority shall conditionally agree to accept responsibility for maintaining the all-weather and main roads after mining is complete.

7.5.i.1.C. The Land Plan shall provide an entrance from the main road to each parcel, complete with culvert as needed. The Homesteader shall be responsible for extending the driveway from the entrance to the building pad.

7.5.i.2. Wastewater And Sewage:

7.5.i.2.A. The Homestead Plan shall incorporate a wastewater and sewage disposal plan conditionally approved by the Director, the West Virginia Bureau of Public Health or the public health authority of the county. The wastewater/sewage disposal system shall be approved by the appropriate entities before Phase II bond release shall be authorized. No such approval

may be granted unless the system meets local health department standards.

7.5.i.2.B. A variety of wastewater and sewage disposal systems, including individual septic systems, may be proposed. Alternative/innovative systems shall be consistent with all State and federal regulations. The reclamation, topsoiling, grading, and revegetation plan of each parcel shall be designed to accommodate the proposed wastewater/sewage system.

7.5.i.2.C. The Homestead Plan shall provide a functional wastewater and sewage system for each Civic, Commercial or Homestead Parcel. The system shall describe an approved hookup/cleanout point no more than 50 feet from such homestead and civic Building Pads.

7.5.i.2.D. Each Homesteader shall be responsible for all costs incurred to connect structures on the Homestead parcel to the wastewater and sewage system. Additionally, if necessary, each homesteader shall be responsible for all costs incurred to install an individual septic system.

7.5.i.2.E. The entity administering the Civic Parcel shall be responsible for all costs incurred to connect structures on the Civic Parcel to the wastewater and sewage system.

7.5.i.2.F. The Homestead Plan shall describe the maintenance and upkeep demands of any proposed sewage disposal system, and shall designate the entity responsible for such maintenance. Phase III bond release may not be approved until the designated entity has accepted responsibility for such maintenance.

7.5.i.3. Water Supply:

7.5.i.3.A. The Homestead Plan shall include a potable water supply source or sources adequate for each Homestead Parcel. The supply of water shall be provided by one of the following methods in the following order of priority: a) water piped from an existing public water supply; b) from wells; or c) from reservoirs with catchment basins adequate to supply the homestead area. Before authorizing any system of potable water supply that is not piped from an existing water supply, the Director shall find, in writing, that the higher order methods of delivery of potable water are not feasible. The Director may rely on the sewers if an appropriate Public Health Authority.

7.5.i.3.B. The Permittee shall establish and pay for the potable water supply system.

7.5.i.3.C. The water shall be delivered at a constant rate and at water industry accepted pressure and flow.

7.5.i.3.D. The Homestead Plan shall describe the future maintenance of the

water supply system. If the water system is public, the plan shall designate the entity responsible for its upkeep.

Homesteaders may be required to pay a fair market price for the water.

Homesteaders shall not be charged for water from their own individual well, although Homesteaders shall be responsible for maintenance of their own wells.

7.5.i.3.E. Individual supply systems shall, at a minimum, meet all applicable health standards, comply with all state and federal laws, and be approved by the appropriate public health authority. Appropriate wellhead protection or watershed protection practices shall be incorporated into the Homestead Plan, and shall be protect water from potential vulnerability from future land use.

7.5.i.3.F. The source or sources of potable water must be identified within the Homesteading Plan, along with a demonstration of the adequacy of quantity and quality. Upon completion of the reclamation plan, the Permittee shall install and demonstrate the quality and adequacy of the supply. If the originally proposed water supply system proves to be inadequate or unsuitable, the Permittee shall immediately make application with the Director for approval of alternate supplies or adequate improvements to the water supply system. The resulting improvements and/or alternate supplies shall comply with the requirements in this rule and shall be subject to the approval of the appropriate public health authority. Phase I bond release may not be approved until the Director finds that the installed water supply complies with this rule and applicable State and federal law.

7.5.i.3.G. The Homestead Plan shall describe a water supply plan that is adequate to meet the needs of the Homestead Area. The water supply plan shall address the anticipated future land use of the Homestead Area, and must be reviewed and approved by the Director and the appropriate public health authorities.

7.5.i.3.H. The potable water supply sources shall meet the Federal Primary Drinking Water Maximum Contaminant Level standards. (40 CFR 141, Subpart B). Verification of such quality shall be provided to the appropriate public health authority.

7.5.i.3.I. The supply source means the contiguous water body or contiguous aquifer from which supplies are drawn. If multiple homestead unit supplies are withdrawn from the same source, determination of water quality of the source shall be made at points that are

representative of the water that will be withdrawn from the source.

7.5.i.3.J. The potable water supply shall provide for a minimum quantity of 12,500 gallons per month per homestead unit. The supply may incorporate one or a combination of sources and storage facilities demonstrated to provide an adequate supply for each homestead parcel.

7.5.i.3.K. If a ground water source is to be used, the plan and the confirmation of the installed ground water supply system shall be conducted under the direction of a qualified ground water professional. The locations of drilled wells shall be consistent with appropriate public health requirements.

7.5.i.3.L. The water supply shall be developed (or extended as applicable) free of charge to the homesteader to a point within 50 feet of the designated residence and civic parcel construction pads for each homestead unit.

7.5.i.3.M. After initial establishment of compliant water quality and quantity, responsibility for maintenance of the water supply shall revert to the homesteader or, in the event that the supply is community- or publicly-controlled, to the appropriate and capable public authority.

7.5.i.3.N. When the potable water supply is insufficient to meet the needs of the proposed use for rural homestead parcels, the Homestead Plan shall include nonpotable water supplies for uses that do not require potable water. Before approving Phase I bond release, the Director shall find that the non-potable water supply is sufficient in both quality and quantity for such uses, including agricultural uses. The plan for the system shall indicate the provisions that will be taken to assure that the potable water supply shall not be compromised. The approval of nonpotable water supplies distribution and handling system shall be consistent with State and federal law.

7.5.i.3.O. Each Homesteader shall be responsible for costs incurred to connect dwellings to water facilities.

7.5.i.3.P. The entity administering the civic parcel shall be responsible for costs incurred to connect structures on the civic parcel to water facilities.

7.5.i.3.Q. If a reservoir is used, a registered professional engineer shall certify its integrity. The engineer shall also certify that, taking account of inflow, seepage and evaporation, the reservoir will provide the amount of water and water pressure required by the Homestead use.

7.5.i.4. Electrical Utilities:

7.5.i.4.A. The Homestead Plan shall provide access to electrical power for all

Homestead Parcels and for all Civic Parcels requiring electric power. The quantity of electricity supplied shall be sufficient to support the proposed use. Phase II bond release may not be approved until all the necessary facilities have been rendered operational and extended to a point where the service drop for the Homestead or Civic Parcel can be accomplished in no more than one span. If a service lateral is proposed, access to electrical power shall be deemed to have been satisfactorily provided when the service lateral is no more than 50 feet in length. Such electrical power facilities shall be designated in the plan and referred to as "main electrical power facilities".

7.5.i.4.B. All line work shall conform to the practices of the electric power utility servicing the area. The installed main utilities and associated equipment shall be conveyed to the electric power utility servicing the area.

7.5.i.4.C. Each Homesteader shall be responsible for all costs incurred to install a service drop or service lateral the building pads.

7.5.i.4.D. The entity administering the Civic Parcel shall be responsible for all costs incurred to install a service drop or service lateral to structures on the Civic Parcel.

7.5.i.4.E. Each Homesteader shall be responsible for cost of electrical service.

7.5.i.5. Communication Services:

7.5.i.5.A. The Permittee shall provide access to telephone service for all Homestead Parcels and for all Civic Parcels requiring telephone service. Phase II bond release may not be approved until access to telephone service has been rendered operational and extended to a point within 50 feet of the Parcel's building pads. Such telephone or equivalent utilities shall be designated in the plan and referred to as "main telephone facilities".

7.5.i.5.B. All service line work shall conform to the practices of the telephone service provider of the area. All line work and associated equipment shall be conveyed to the local telephone service provider.

7.5.i.5.C. Each Homesteader shall be responsible for all costs incurred to extend and connect main telephone facilities to the building pads.

7.5.i.5.D. The entity administering the Civic Parcel shall be responsible for all costs incurred to extend and connect main telephone facilities to the Civic Parcels.

7.5.i.5.E. Each Homesteader shall be responsible for the cost of telephone service.

7.5.i.6. Solid Waste:

7.5.i.6.A. The Homestead Plan shall contain a plan for the off-site disposal of solid waste that is acceptable to the Director and the appropriate public health authority.

7.5.i.7. Surface Drainage And Stormwater:

7.5.i.7.A. The Homestead Plan shall contain a detailed surface drainage pattern and stormwater runoff control plan. This plan shall be certified by a registered professional engineer.

7.5.i.7.B. The surface drainage pattern and stormwater plan shall be consistent with a surface drainage pattern that would be found on natural topography similar to the post-mining topography proposed in the Homestead Plan. The beds of the surface and stormwater drainways shall contain material that is as natural as practicable.

7.5.i.8. Reforested Conservation Easements:

7.5.i.8.A. The Homestead Plan shall identify areas within the Homestead Area reserved for reforested Conservation Easements. These areas shall be reforested by the Permittee at no cost to Homesteaders.

7.5.i.8.B. In the event that an isolated forest patch exists as a result of mining activities, the Conservation Easement shall serve as a corridor to establish a wind break and a forested connection with the isolated forest patch and to facilitate the adequate movement of fauna out of and into the isolated forest patch.

7.5.i.8.C. Conservation Easements may serve the purpose of a stormwater management systems. In such case, the technical specifications applicable to the design and construction of the storm water channels and their associated structures shall be satisfied.

7.5.i.8.D. Conservation Easement shall compromise [sic] at least 10% of the Homestead Area, including the Commercial Parcels.

7.5.i.8.E. The Director shall assure that all areas suitable for hardwoods in the Conservation Easement are planted with native hardwoods at a rate of 500 seedlings per acre in continuous mixtures across the conservation easement with at least six (6) species from the following list: white and red oaks, other native oaks, white ash, yellow-poplar, black walnut, sugar maple, black cherry, or native hickories. Plants shall be a minimum of 3/4" in diameter at breast height at planting.

7.5.i.8.F. Each of the species shall not be less than 10% of the total planted composition and at least 75% of the total planted woody plant composition shall be from the above list of species. Species shall be selected based on their

compatibility and expected site-specific long-term dynamics.

7.5.i.8.G. At least 10% of the required number of woody plants shall be a planted continuous mix of three or more nurse tree and shrub species that improve soil quality and habitat for wildlife. They shall consist of black alder, black locust, bristley locust, redbud, or bi-color lespedeza.

7.5.i.8.H. On areas unsuitable for hardwoods, the Director may authorize the following conifers: Virginia pine, red pine, white pine, pitch pine, or pitch x loblolly hybrid pine. Areas unsuitable for hardwoods shall be limited to southwest-facing slopes of greater than 10% or areas where the soil pH is less than 5.5. These conifers shall be planted as single-species stands less than 10 acres in size at the same rate as the hardwood requirements in this rule. The Director shall assure that no Conservation Easement area contains a total of more than 15% conifers.

7.5.i.8.I. The Director shall assure that the specific species and selection of trees and shrubs shall be based on the suitability of the planting site for each species site requirements based on soil type, degree of compaction, ground cover, competition, topographic position, and aspect.

7.5.i.8.J. The Director shall assure that the total planting rate of trees and nurse plants is not less than 500 stems per acre.

7.5.i.9. Perpetual Easements:

7.5.i.9.A. The Homestead Plan shall describe areas within the Homestead reserved for perpetual easements relating to storm water management, protection of outcrops and steep slopes, protection of water sources, public roads of all kinds, and utilities. These areas shall be included within Homesteader's deeded parcels and may have permanent development restrictions included within the Homesteader's deeds of conveyance.

7.5.i.9.B. Fill faces shall be placed under perpetual easements that prohibit activities that may lead to instability or erodability. Trees may be planted on the faces of the fills.

7.5.i.10. Wetlands: Each Homestead Plan may describe areas within the Homestead Area reserved for created wetlands. These created wetlands may be ponds, permanent impoundments or wetlands created during mining. They may be left in place after final bond release.

The provisions at CSR 38-2-7.5.i. provide detailed requirements concerning infrastructure that must be included in a Homesteading postmining land use. SMCRA at section 515(c)(3)(B), and the Federal regulations

at 30 CFR 785.14(c) provide that an applicant for a mountaintop removal mining permit must present specific plans for the proposed postmining land use. SMCRA and the Federal regulations do not, however, contain the same level of specificity as do these regulations with respect to the infrastructure required to support a Homesteading postmining land use. Except as noted below, we find the new provisions are not inconsistent with the requirements of SMCRA at section 515(c)(3)(B) and the Federal regulations at 30 CFR 785.14(c), which require that an applicant for a mountaintop removal mining permit present specific plans for the proposed postmining land use, and can be approved.

CSR 38-2-7.5.i.1.B. provides that main roads shall meet State Department of Highway standards and shall be certified as built as safe for passenger car traffic by a registered civil engineer. However, such main roads that meet the definition of road at CSR 38-2-2.59 and 38-2-4.1 and that are to be retained as part of the postmining land use must be designed and constructed to meet the primary road requirements of CSR 38-2-4. Therefore, we are requiring WVDEP to amend its program to clarify that roads which meet the definition of road at CSR 38-2-2.59 and 38-2-4.1 and that are to be retained as part of the postmining land use must be designed and constructed to meet the primary road requirements of CSR 38-2-4. In addition, we are approving CSR 38-2-7.5.i.1.B. to the extent that the word "conditionally" means that the County or State road authorities will accept responsibility for maintaining the all-weather and main roads after mining and reclamation is complete, and the road(s) is built.

CSR 38-2-7.5.i.2.A. provides that the Homestead Plan shall incorporate a wastewater and sewage disposal plan conditionally approved by the Director, the West Virginia Bureau of Public Health or the public authority of the county. The U.S. Environmental Protection Agency (EPA) stated in its comments concerning this provision (Administrative Record Number WV-1166) that discharges from any wastewater/sewage system must also meet Federal requirements under the Clean Water Act, specifically the NPDES permit requirements which are implemented by the State Office of Water Resources, WVDEP. The EPA recommended, so that there would be no misunderstanding, that either a statement to this effect be included in CSR 38-2-7.5.i.2.A., or, a statement be included which indicates that disposal systems shall be consistent with all

State and Federal regulations. We note that there is nothing in the new provision which indicates that NPDES permit requirements would not be complied with where applicable.

However, for the sake of clarity, we are approving this provision to the extent that the applicable NPDES permit requirements would be complied with.

CSR 38-2-7.5.i.2.B. provides that a variety of wastewater and sewage disposal systems, including individual septic systems, may be proposed in the wastewater and sewage disposal plan. The EPA commented on this provision and stated that since homestead sites are planned to be constructed on somewhat porous backfilled areas, there may be a higher potential for leachate to pass relatively unabsorbed through the fills to streams, presenting possible high fecal coliform levels and associated health risks. The EPA urged close review of this potential when considering any proposals for septic tank systems at homestead sites. We concur with EPA's recommendation.

CSR 38-2-7.5.i.3.A. provides that the Director of the WVDEP may rely on the sewers "if an appropriate Public Health Authority." It appears that the words "approved by" are missing from this provision. The final sentence should read, "The Director may rely on the sewers if approved by an appropriate Public Health Authority." We recommend that this provision be amended to correct this editorial omission.

CSR 38-2-7.5.i.3.H. provides that the potable water supplies shall meet the Federal Primary Drinking Water Maximum Contaminant Level standards of 40 CFR 141 Subpart B. The EPA stated in its comments concerning this provision that "community water systems as defined by 40 CFR 141 (those serving 25 or more people or which have 15 or more service connections) must also comply with all subparts of 40 CFR 141, A. through J." The EPA recommended that, to avoid any misunderstanding, section CSR 38-2-7.5.i.3.H. should be amended to clarify that community water systems must comply with 40 CFR 141 in its entirety. Therefore, we are approving this provision to the extent that the provisions of 40 CFR 141, A. through J. apply to community water systems as defined by 40 CFR 141 (those serving 25 or more people or which have 15 or more service connections).

CSR 38-2-7.5.i.3.Q. provides that if a reservoir is used as a water facility, a registered professional engineer shall certify its integrity. To be no less effective than the Federal regulations concerning permanent impoundments,

CSR 38-2-7.5.i.3.Q. must also require compliance with the West Virginia rules concerning permanent impoundments at CSR 38-2-5.5. Therefore, we are approving CSR 38-2-7.5.i.3.Q. only to the extent that all permanent impoundments approved for Homestead postmining land use must comply with CSR 38-2-3.6.b.1. and 38-2-5.5 concerning permanent impoundments. In addition, we are requiring that the West Virginia program be amended to require that all permanent impoundments approved for Homestead postmining land use must comply with CSR 38-2-3.6.b.1. and 38-2-5.5 concerning permanent impoundments.

CSR 38-2-7.5.i.7.A. provides for a detailed surface drainage pattern and storm water runoff control plan. The EPA commented on this provision and stated that storm water discharges resulting from construction of the homestead sites and supporting streets, depending on the acreage disturbed, may be subject to Federal National Pollutant Discharge Elimination System (NPDES) storm water requirements at 40 CFR 122.26. The EPA recommended that either a statement to this effect be included in section CSR 38-2-7.5.i.7., or a statement be included which indicates that storm water discharges shall be consistent with all State and Federal regulations. The EPA also recommended that the site developers contact the State Office of Water Resources, WVDEP, regarding the applicability of storm water regulations for specific sites. We note that there is nothing in the new provision which indicates that NPDES storm water requirements would not be complied with where applicable. However, for the sake of clarity, we are approving this provision to the extent that the applicable NPDES storm water requirements would be complied with.

CSR 38-2-7.5.i.8.D. concerns conservation easements. This provision contains the word "compromise." It appears that the word should be "comprised." We recommend that this provision be amended to correct this editorial error.

CSR 38-2-7.5.i.10. concerns wetlands. CSR 38-2-7.5.i.10. should be amended to reference CSR 38-2-3.5.d. which requires the submittal of cross sectional areas and profiles of all drainage and sediment control structures including ponds, impoundments, diversions, sumps, etc. which are created during mining and may be left after final bond release. Therefore, we are approving CSR 38-2-7.5.i.10. to the extent that the permit requirements at CSR 38-2-3.5.d. continue to apply. In addition, we are

requiring that CSR 38-2-7.5.i.10. be amended to require compliance with the permit requirements at CSR 38-2-3.5.d.

10. CSR 38-2-7.5.j. This subdivision concerns soils, soil placement and grading, and contains the following requirements.

Subdivision 7.5.j. concerns soils, soil placement and grading.

7.5.j. Soils, Soil Placement And Grading;

7.5.j.1. General Requirements:

7.5.j.1.A. Phase I bond release shall not be approved until a soil scientist certifies and the Director finds that the soil meets the criteria established in this rule and has been placed in accordance with this rule.

7.5.j.1.B. The Homestead Plan shall include a topographic map of the permit area, 1:12000 or finer, showing the location of pre-mining native solids, weathered slightly-acidic brown sandstone and drainages which includes site index for common native tree species. A profile description of each soil mapping unit that includes, at minimum, soil horizons, including the O. horizon depths, soil texture, structure, color, reaction and bedrock type. A certified professional soil scientist shall conduct a detailed on-site survey, create the maps, and provide the written description of the soils and sandstones.

7.5.j.1.C. The Homesteading Plan shall include a description of the present soils and soil substitutes to be used as the plant medium, and a description of the proposed handling, and placement of these materials. The handling plan shall include procedures to:

7.5.j.1.C.1. Protect native soil organisms and the native seed pool;

7.5.j.1.C.2. Include organic debris such as litter, branches, small logs, roots and stumps in the soil;

7.5.j.1.C.3. Inoculate the minesoil with native soil organisms; and

7.5.j.1.C.4. Increase soil fertility.

7.5.j.1.D. A surface preparation plan which includes a description of the methods for replacing and grading the soil and other soil substitutes and their preparation for homesteading.

7.5.j.2. Landscape Criteria:

7.5.j.2.A. The Director shall assure that the postmining landscape is rolling, and diverse. The backfill on the mine bench, shall be configured to create a postmining topography that includes the principles of landforming to reflect the premining irregularities in the land. Postmining landform shall provide a rolling topography with slopes of between 5% and 15%. The elevation change between the ridgeline and the valleys shall be varied. The slope

lengths shall not exceed 500 feet. The minimum thickness of backfill, including minesoil, placed on the pavement of the basal seam mined in any particular area shall be 10 feet.

7.5.j.2.B. At least 3 ponds, permanent impoundments or wetlands totaling at least 3.0 acres shall be created on each 200 acres of permitted area. They shall be dispersed throughout the landscape and each water body shall be no smaller than 0.20 acres. All ponds, permanent impoundments or wetlands shall comply with all requirements of this rule, and shall be left in place after final bond release.

7.5.j.2.C. All ponds and impoundments created during mining shall be left in place after bond release and shall comply with all the requirements of this rule.

7.5.j.2.D. The ponds, permanent impoundments, surface water channels and wetlands on the Permit Area shall be vegetated on the perimeter with at least six native herbaceous species typical of the region at a density of not less than 1 plant per linear foot of edge, and at least 4 native shrub species at a density of not less than 1 shrub per 6 linear feet of edge. No species of herbaceous or shrub species shall be less than 15% of the total for its life form.

7.5.j.2.E. The landscape criteria in this rule do not apply to valley fills.

7.5.j.3. Soil:

7.5.j.3.A. Soil is defined as and shall consist of the O, A, B, C, and Cr horizons.

7.5.j.3.B. The Director shall require the operator to recover and use all the soil on the mined area, as shown on the soil maps, except for those areas with a slope of at least 50%, and other areas from which the applicant affirmatively demonstrates and the Director finds that soil cannot reasonably be recovered. The Director shall assure that all saved soil includes all of the material from the O and A horizons.

7.5.j.3.C. When the Director determines that available soil volume on the permit area is not sufficient to meet the depth requirements, selected overburden materials may be used as soil substitutes. Soil substitutes shall consist of weathered, slightly acid, brown sandstone from within 10 feet of the soil surface if the Director determines that such material is available. Material from this layer maybe removed with the soil and mixed with the soil in order to meet the depth requirement.

7.5.j.3.D. If the applicant affirmatively demonstrates and the Director finds that weathered, slightly acid, brown sandstone from within 10 feet of the soil

surface cannot reasonably be recovered, weathered, slightly acid, brown sandstone taken from below 10 feet of the soil surface from anywhere in the permit area may be substituted. Materials may be suitable for this purpose only if their bulk pH in water is between 5.0 and 7.0. Materials with net potential acidity greater than 5 tons of calcium carbonate equivalence per 1000 tons may not be used.

7.5.j.3.E. Before approving the use of soil substitutes, the Director shall require the permittee to demonstrate that the selected overburden material is suitable for restoring land capability and productivity. This will be demonstrated by the results of chemical and physical analyses, including pH, total soluble salts, phosphorus, potassium, calcium, texture class, acid-base accounting, and other such analyses as necessary.

7.5.j.3.F. The final surface material used on all parts of the permit area except roads, building pads, and valley fill faces shall consist of a minimum of 4 feet of soil, or a mixture of soil and suitable soil substitutes. Homesteading soil depth shall contain at least 33% soil. If the applicant affirmatively demonstrate and the Director finds, that sufficient weathered slightly acid brown sandstone cannot reasonably be recovered from the mined area to satisfy the mine soil depth requirement, then up to one quarter of the total volume of the minesoil may consist of highly-fractured sandstone, as long as it has been demonstrated that the physical and chemical quality of this material is suitable.

7.5.j.3.G. If the applicant does not demonstrate that there is sufficient material available on the permit area to satisfy the requirements of this rule, then the Director may not authorize a Homesteading variance.

7.5.j.3.H. The Director may require the operator to include as part of the minesoil mix organic debris such as forest litter, branches, small logs, roots and stumps in the soil to help reseed the native vegetation, inoculate the minesoil with native soil organisms and increase soil fertility.

7.5.j.3.I. The Director shall require that soil be removed and reapplied in a manner that minimizes stockpiling such that seed pools and soil organisms remain biological viable. No more than 10% of the available soil, described in the Director's findings, may be placed in a long-term stockpile, soil redistribution shall be done within one month of soil removal. Except for soil in a long-term stockpile, soil shall be stored for less than one month in piles less than six feet high and 24 feet wide in a stable area within the permit area where it will

not be disturbed and will be protected from water or wind erosion or contaminants that lessen its capability to support vegetation. Long-term stockpiles shall be seeded with ground cover mixes used for reforestation.

7.5.j.4. Soil Placement And Grading:

7.5.j.4.A. Except for valley fill faces, building pads, roads, and other areas that must be compacted, the Director shall require the Permittee to place minesoil loosely and in a non-compacted manner while meeting static safety factor requirements. Grading the final surface shall be minimized to reduce compaction. Once the material is placed, light grading equipment shall be used to grade the tops of the piles, roughly leveling the area with no more than one or two passes. Tracking in and rubber-tired equipment shall not be used. Non-permanent roads, equipment yards and other trafficked areas shall be deep-ripped (24" to 36") to mitigate compaction.

7.5.j.4.B. Soil physical quality shall be inadequate if it inhibits water infiltration or prevents root penetration or if their physical properties or water-supplying capacities cause them to restrict root growth of trees. Slopes greater than 50% shall be compacted no more is necessary to achieve stability and non-erodability.

7.5.j.4.C. The Director shall require the permittee to leave soil surfaces rough with random depressions across the entire surface to catch seed and sediment, conserve soil water. Organic debris such as forest litter, logs, and stumps may be left on and in the soil.

7.5.j.5. Limiting And Fertilizing: The Permittee shall submit a liming and fertilizing plan. The Director shall assure that the liming and fertilizing plan is appropriate for establishing the ground cover vegetation.

7.5.j.6. Ground Cover Vegetation:

7.5.j.6.A. The Director shall require the permittee to establish a temporary vegetative cover as contemporaneously as practicable with backfilling and grading. This cover shall consist of a combination of native and domesticated non-invasive cool and warm season grasses and other herbaceous vine or shrub species including legume species and ericaceous [sic] shrubs. All species shall be slow growing. The ground cover vegetation shall be capable of stabilizing the soil from excessive erosion. Seeding rates and composition must be in the Homestead Plan. The following ground cover mix and seeding rates (pounds/acre) shall be used: winter wheat (15 lbs/acre, fall seeding), foxtail millet (5 lbs./acre, summer seeding), redtop (2 lbs/acre), perennial ryegrass (2 lbs/acre), orchardgrass (5 lbs/acre), weeping

lovegrass (2 lbs/acre) kobe lespedeza (5 lbs/acre), birdsfoot trefoil (10 lbs./acre), and white clover (3 lbs/acre). Kentucky-31 fescue, sericia [sic] lespedeza, all vetches, clovers (except ladino and white clover) and other aggressive or invasive species shall not be used. On south- and west-facing slopes with a soil pH of 6.0 or greater, the four grasses in the mixture shall be replaced with 20 lbs/acre of warm-season grasses consisting of the following species: Niagara big bluestem (95 lbs/acre), Camper little bluestem (2 lbs/acre), Indian grass (2 lbs/acre), and Shelter switch grass (1 lb/acre), or other varieties of these species approved by the Director. Also, a selection of at least 3 ericaceous shrub species shall be included in the ground cover mix.

7.5.j.6.B. The Permittee may regrade and reseed only those rills and gullies that are unstable.

7.5.j.7. Front Faces Of Valley Fills:

7.5.j.7.A. Front faces of valley fills shall be exempt from the requirements of this rule except that:

7.5.j.7.A.1. They shall be graded and compacted no more than is necessary to achieve stability and non-erodability;

7.5.j.7.A.2. No shales may be present in the upper four feet of surface material;

7.5.j.7.A.3. The upper four feet of surface material shall be composed of soil and weathered brown sandstone when available, unless the Director determines other material is necessary to achieve stability;

7.5.j.7.A.4. The groundcover mixes described in subparagraph shall be used unless the Director requires a different mixture.

7.5.j.7.A.5. Kentucky 31 fescue, sericia [sic] lespedeza, vetches, clovers (except ladino and white clover) or other invasive species may not be used; and

7.5.j.7.B. Although not required by this rule, native, non-invasive trees may be planted on the faces of fills.

There are no specific counterparts to the provisions at CSR 38-2-7.5.j. for Homesteading at SMCRA section 515(c) nor the Federal regulations at 30 CFR 785.14 concerning mountaintop removal mining operations. There is nothing in these provisions that replace the existing State requirements concerning mountaintop removal mining operations at W.Va. Code 22-3-13(c) or the State regulations at CSR 38-2-14.10. Except as noted below, we find that CSR 38-2-7.5.j. is no less stringent than SMCRA and no less effective than the Federal regulations and can be approved.

CSR 38-2-7.5.j.2.C. provides that all ponds and impoundments created during mining shall be left in place after

bond release and shall comply with all the requirements of this rule. In addition to complying with the provisions of CSR 38–2–7.5., all ponds and impoundments created during mining and which will be left in place following mining must comply with the State permanent impoundment rules at CSR 38–2–5.5. Therefore, we are approving CSR 38–2–7.5.j.2.C. to the extent that all ponds and impoundments created during mining and which will be left in place following mining must comply with the State permanent impoundment rules at CSR 38–2–5.5.

CSR 38–2–7.5.j.2.E. provides that the landscape provisions of CSR 38–2–j.2. do not apply to valley fills. The use of the term “valley fills” in this provision does not make it clear that the landscaping provisions of CSR 38–2–7.5.j.2. do not apply to any fills, not just valley fills. Ponds, permanent impoundments or wetlands cannot be allowed on completed fills. Therefore, we are approving CSR 38–2–7.5.j.2.E. to the extent that the landscape criteria of CSR 38–2–7.5.j.2. do not apply to any fills.

CSR 38–2–7.5.j.3.A. defines soil as consisting of the O, A, B, C, and Cr horizons. The Federal regulations at 30 CFR 701.5 define topsoil to mean the A and E soil horizon layers of the four master soil horizons, which include the A, E, B and C horizons. The State rules at CSR 38–2–2.125 defines topsoil to mean the A and E horizons. In addition, the Federal regulations at 30 CFR 816.22(a)(1)(i) require that, prior to mining, all topsoil be removed as a separate layer and segregated. As an alternative, 30 CFR 816.22(a)(2) provides that if the topsoil is less than six inches thick, the operator may remove the topsoil and the unconsolidated materials immediately below the topsoil and treat the mixture as topsoil. The new provisions at subdivision CSR 38–2–7.5.j.3.A., however, lack a reference to the “E” horizon. Therefore, we are requiring the State to add “E” horizon to CSR 38–2–7.5.j.3.A.

The new State provisions at CSR 38–2–7.5.j.3.B. require the operator to recover and use the soil on the mined area, as shown on the soil maps, except for those areas with a slope of at least 50%, and other areas from which the applicant affirmatively demonstrates and the Director of the WVDEP finds that soil cannot reasonably be recovered. The Federal regulations at 30 CFR 816.22, however, like the State rules at CSR 38–2–14.3, require an operator to save and redistribute all topsoil. Therefore, we are not approving

the phrase, “except for those areas with a slope of at least 50%,” and we are not approving the phrase, “and other areas from which the applicant affirmatively demonstrates and the Director of the WVDEP finds that soil cannot reasonably be recovered.” In addition, we are requiring the State to delete these phrases from its regulations at CSR 38–2–7.5.j.3.B.

New CSR 38–2–7.5.j.3.E. provides that, before approving the use of soil substitutes, the Director of the WVDEP shall require the permittee to demonstrate that the selected overburden material is suitable for restoring land capability and productivity on the basis of chemical and physical analyses. In order to be no less effective than the Federal regulations at 30 CFR 816.22(b), the proposed State rule must also provide that the substitute material is equally suitable for sustaining vegetation as the existing topsoil and the resulting medium is the best available in the permit area to support vegetation. Therefore, we are requiring that CSR 38–2–7.5.j.3.E. be amended to provide that the soil substitute material must be equally suitable for sustaining vegetation as the existing topsoil and the resulting medium is the best available in the permit area to support vegetation.

CSR 38–2–7.5.j.3.H. provides that the Director may require the operator to include as part of the soil mix organic debris such as forest litter, branches, small logs, roots and stumps in the soil to help reseed the native vegetation, inoculate the mine soil with native soil organisms and increase soil fertility. The Federal regulations at 30 CFR 816.22(d) provide that topsoil and topsoil substitute materials must be redistributed in a manner that achieves an approximately uniform and stable thickness consistent with the approved postmining land use, contours and surface water drainage systems. These regulations further provide that the regraded land must be treated if necessary to reduce potential slippage of the redistributed material and to promote root penetration. The Federal regulations also address the presence of organic materials in both backfills and excess spoil fills. For example, the Federal regulations at 30 CFR 816.102(d) concerning backfilling and grading require the removal of all organic material before placement of spoil on slope areas. Likewise, 30 CFR 816.71(e) concerning the placement of excess spoil provides that all vegetative and organic materials shall be removed from the disposal area prior to placement of the excess spoil. 30 CFR 816.107(d)

concerning the backfilling and grading of steep slopes provides that woody materials may not be placed in the backfill of steep slope areas unless the regulatory authority determines that the proposed method for placing woody material within the backfill will not deteriorate the stable condition of the backfilled area. 30 CFR 816.71(e) also provides that organic material may be included in the topsoil to control erosion, promote growth of vegetation, or increase the moisture retention of the soil. Because the proposed and existing State rules will limit the placement of organic material, such as branches, roots, and stumps, in the soil mix for redistribution, while still requiring compliance with the static safety factor (see CSR 38–2–7.5.j.4.A.), we find that proposed CSR 38–2–7.5.j.3.H. is consistent with and no less effective than the Federal soil redistribution and stability requirements at 30 CFR 816.22(d), 816.71(e), 816.102(d), 816.107(d) and can be approved.

CSR 38–2–7.5.j.4.A. provides that, except for valley fill faces, building pads, and other areas that must be compacted, mine soil shall be placed loosely and in a non-compacted manner while meeting static factor requirements. Subdivision 7.5.j.4.B. provides that soil physical quality shall be inadequate if it inhibits water infiltration or prevents root penetration or restricts root growth of trees. Slopes greater than 50 percent shall be compacted no more than is necessary to achieve stability and non-erodability. Subdivision 7.5.j.4.C. provides that the soil surface shall be left rough with random depressions across the entire surface to catch seed and sediment, and conserve soil water. Organic debris such as forest litter, logs, and stumps may be left on and in the soil.

These provisions are consistent with the Federal requirements for soil redistribution at 30 CFR 816.22(d) and the final grading requirements at 30 CFR 816.102(h) and (j) which allow for the construction of small depressions to retain moisture, minimize erosion and assist revegetation and for the preparation of the final graded surfaces in a manner that minimizes erosion and provides a surface for replacement of topsoil that will minimize slippage. The emphasis in the State provisions toward minimizing compaction is consistent with the requirements at 30 CFR 816.22(d). In addition, the provisions at CSR 38–2–7.5.j.4.A. require compliance with the static safety requirements for stability of the replaced soil. Therefore, we are approving the new provisions at CSR 38–2–7.5.j.4. to the extent that these provisions do not supersede the

State's general backfilling and grading requirements at CSR 38-2-14.15.a. which are no less effective than the Federal requirements at 30 CFR 816.102(a).

SCR 38-2-7.5.j.5 provides for a liming and fertilizing plan. The Federal revegetation regulations at 30 CFR 816.111 do not contain specific liming or fertilization standards. The Federal regulations do require that the permittee establish a diverse, effective, and permanent vegetative cover that is in accordance with the approved permit and reclamation plan. The State must use its technical judgement to determine the appropriate rate of fertilizer application. We find that the proposed provisions at CSR 38-2-7.5.j.5. are not inconsistent with the Federal revegetation standards and can be approved.

CSR 38-2-7.5.j.6. provides for ground cover vegetation. The Federal regulations at 30 CFR 816.111 require that the permittee establish a diverse, effective, and permanent vegetative cover that is capable of stabilizing the soil from erosion. Furthermore, the Federal requirements at 30 CFR 816.114 provide that mulch and other soil stabilizing practices must be used on all areas that have been regraded and covered by topsoil or topsoil substitutes. The proposed provisions at CSR 38-2-7.5.j.6. are not inconsistent with these Federal revegetation standards with the following exceptions.

CSR 38-2-7.5.j.6.A. provides that ground cover vegetation shall be capable of stabilizing the soil from excessive erosion. SMCRA at section 515(b)(10)(B)(i) provides that coal mining operations must be conducted so as to prevent, to the extent possible using the best technology currently available, additional contributions of suspended solids to streamflow, or runoff outside the permit area, but in no event shall contributions be in excess of requirements set by applicable State or Federal law. Therefore, to be no less stringent than SMCRA, the term "excessive erosion" may not be interpreted to allow additional contributions of suspended solids to streamflow, or runoff outside the permit area in excess of requirements set by applicable State or Federal law. We note that, except for the phrase, "excessive erosion," there is nothing in new CSR 38-2-7.5.j.6 that supersedes or negates the approved State provisions at CSR 38-2-14.5.b. concerning effluent limitations. However, under the proposed State rule, erosion could be allowed as long as it was not excessive, even though the erosion might provide sediment to streams that could violate

State or Federal water quality standards. CSR 38-2-14.5.b., like 30 CFR 816.42, provides that discharge from areas disturbed by surface mining shall not violate effluent limitations or cause a violation of applicable water quality standards.

As proposed, CSR 38-2-7.5.j.6.A. is less effective than the Federal requirements at 30 CFR 816.111 because the proposed standard to stabilize the soil from erosion is modified by the undefined phrase, "excessive erosion." To be no less effective than the Federal requirements, the Director can only be allowed to approve ground cover vegetation that is sufficient to control erosion and air pollution attendant to erosion. Therefore, we are not approving the word "excessive" in the phrase "excessive erosion" at CSR 38-2-7.5.j.6.A. Furthermore, we are requiring the deletion of the word "excessive" from the State rule at CSR 38-2-7.5.j.6.A. to ensure compliance with State water quality requirements at CSR 38-2-14.5.b.

CSR 38-2-7.5.j.6.B. only authorizes the regrading and reseeding of rills and gullies that are unstable. Normally, the presence of unstable rills and gullies indicates that excessive erosion has occurred. The Federal regulations at 30 CFR 816.95(b) require the regrading of all rills and gullies that disrupt the approved postmining land use or the establishment of vegetative cover or cause or contribute to a violation of water quality standards for the receiving stream. Therefore, we are approving CSR 38-2-7.5.j.6.B. only to the extent that it is interpreted to require the repair of all rills and gullies that disrupt the approved postmining land use or the establishment of vegetative cover or cause or contribute to a violation of water quality standards for the receiving stream. In addition, we are requiring that CSR 38-2-7.5.j.6.B. be amended to require the repair of all rills and gullies that disrupt the approved postmining land use or the establishment of vegetative cover or cause or contribute to a violation of water quality standards for the receiving stream.

The new provisions at CSR 38-2-7.5.j.7. concerning the front faces of valley fills do not add any provisions to the West Virginia program that render the State program less stringent than the Federal provisions concerning excess spoil disposal fills in SMCRA at section 515(b)(22) and the Federal regulations at 30 CFR 816.71 and 816.72. However, new CSR 38-2-7.5.j.7. does not make it clear that the proposed State standards are in addition to the excess spoil disposal requirements at W.Va. Code 22-3-13(b)(22) and CSR 38-2-14.14

which apply to all fills, including valley fills. We are approving new CSR 38-2-7.5.j.7. to the extent that the proposed State standards are in addition to the excess spoil disposal requirements at W.Va. Code 22-3-13(b)(22) and CSR 38-2-14.14 and apply to all fills, including valley fills.

11. CSR 38-2-7.5.k. This subdivision concerns requirements for reclamation maps, and contains the following requirements.

7.5.k. Requirements For Reclamation Maps. An appropriately scaled, "as-built" topographic map of the Homestead Area shall be prepared and submitted as part of the permit application. An identically scaled *overlay* map showing the elevation contours at the base of all mined areas as well as the original ground contour of all excess mine spoil storage areas shall accompany the as-built map. The overlay map shall identify all backfilled mine sites and excess mine-spoil storage areas. The overlay map shall depict the boundaries of all parcels, areas of mine spoil specifically compacted for the placement of structures, easements, and areas that the Director may designate for special or limited uses. All post-reclamation maps shall be prepared under the direction of and certified by a registered professional engineer and shall be recorded with the county within one year following the final reclamation of the proposed Homestead Area.

There are no Federal counterparts to the provisions at CSR 38-2-7.5.k. concerning the requirements for reclamation maps for the homestead postmining land use. Except as follows, we find that they are not inconsistent with SMCRA or the Federal regulations and can be approved. The proposed rule does not require that all maps, including "as-built" or post reclamation maps, be approved by the Director as required by CSR 38-2-3.4 and 38-2-3.28.c.

Therefore, we are approving CSR 38-2-7.5.k. to the extent that any as-built or post reclamation maps that depict reclamation which varies from that approved by the Director in the permit application shall be submitted to and approved by the Director under CSR 38-2-3.28.c.

12. CSR 38-2-7.5.l. This subdivision concerns homestead village. This subdivision contains the following requirements.

7.5.l. Homestead Village:

7.5.l.1. Homestead Village: The Homestead Village provides for a residential development at a higher density than in rural Homestead parcels. The Village is intended to:

7.5.l.1.A. Encourage mixed residential and commercial land uses, and 7.5.l.1.B. At least 20% of the Homestead Area shall be composed of Village parcels.

7.5.l.2. Village Parcel Requirements:

7.5.l.2.A. Each Village homestead parcel shall be no larger than one acre in size.

7.5.l.2.B. Each parcel shall have a minimum road frontage of 40 feet. No pipe stem parcel arrangements are permitted.

7.5.l.2.C. Each parcel shall be graded evenly to 5% maximum.

7.5.l.3. Common Lands: In addition to the Civic Parcels and Conservation Easements, each Homestead Area shall include a reserve of 10% of the land as a common area. The Common Land shall be conveyed to the Community Association. The planning and maintenance of the Common Land shall be the responsibility of the Community Association.

7.5.l.4. Public Nursery: Each Village Homestead shall designate an area for a Public Nursery constructed and planted by the Permittee at no cost to the Homesteaders. The nursery may be located adjacent to the Common Land but shall not constitute the required Common Land area. The Nursery shall provide woody plants of high quality and appearance for the use of the Homesteaders as specified below.

7.5.l.4.A. The nursery shall be 1 acre per 30 acres of Homestead Area. The Public Nursery shall be a civil [sic] parcel. The Permittee shall plant the nursery with the same species and to the same standards as required in the Conservation Easement. Once bond is released, the Community Association shall be responsible for maintaining the nursery. Success standards shall be the same as for the conservation easements.

7.5.l.4.B. The nursery plants shall consist of at least six species from the following list: White oak, red oak, other native oaks, white ash, yellow poplar, black walnut, sugar maple, black cherry, or native hickories.

7.5.l.4.C. Adequate water supply shall be provided for the nursery. This may be achieved through any of the water supply means specified or through the stormwater drainage system.

7.5.l.4.D. The nursery shall be maintained in manner consistent with the healthy development of the plants. The nursery plants shall meet the following criteria upon conveyance: (1) In regular form for the species, (2) 80% live branches, and (3) color consistent with the species. Materials not meeting the specifications shall be replaced with like species by the permittee. After final bond release, the nursery shall be

conveyed to the Community Association.

7.5.l.4.E. Each Homesteader shall be allowed to take trees from the nursery as determined by the Community Association. The remainder of the trees shall be for the common landscapes.

There are no direct Federal counterparts to the provisions at CSR 38-2-7.5.l. concerning homestead village. However, we find that they are not inconsistent with SMCRA or the Federal regulations and can be approved because Homestead is a residential postmining land use consistent with SMCRA section 515(c)(3).

13. CSR 38-2-7.5.m. concerns community association. This subdivision contains the following requirements.

7.5.m. Community Association:

7.5.m.1. At the completion of the lottery, a Community Association shall be established among the designated Homesteaders for each Homestead Area. The Association shall maintain and administer the public areas, Conservation Easements and Civic Parcels of the Homestead and may levy membership fees.

7.5.m.2. By-laws for the Community Association shall be developed by the Escrow Agent, working with the Homesteaders and a qualified design professional as defined by this rule. The permittee shall pay the qualified land designer for such services. The by-laws may establish rules for building standards and other Homestead Area rules, as appropriate.

7.5.m.3. Membership in the association is mandatory for all Homesteaders and their successors.

7.5.m.4. The association shall obtain liability insurance for its property and shall be responsible for maintenance of insurance and taxes on undivided open space. The association may place liens on the homes or houselots of its members who fail to pay their association dues in a timely manner. Such liens may require the imposition of penalty interest charges.

7.5.m.5. The association shall administer common facilities and pay for maintaining and developing such facilities.

There are no Federal counterparts to the provisions at CSR 38-2-7.5.m. concerning community association. However, we find that they are not inconsistent with SMCRA or the Federal regulations and can be approved.

14. CSR 38-2-7.5.n. This subdivision concerns interim homestead management. This subdivision contains the following requirements.

7.5.n. Interim Homestead Management

7.5.n.1. The Director or the Director's designee shall administer the Homestead Selection Lotteries.

7.5.n.2. The Escrow Agent shall monitor the 5-year occupancy requirement for each Homestead Parcel and transfer of the titles of the surface estates to the qualified Homesteaders.

7.5.n.3. The Escrow Agent shall manage and administer the homestead between final bond release and the time when all of the titles to the Homestead Parcels have been transferred and duly recorded with the Clerk of the County.

7.5.n.4. Funding these services shall be guaranteed by an insured Bank account established by the Permittee.

7.5.n.5. Before approving any Homestead variance, the Director shall find, in writing, that the funds in the account are sufficient to pay for these services.

7.5.n.6. After final bond release, this account shall be administered by the Escrow Agent.

7.5.n.7. The Escrow Agent shall receive the surface rights to the entire Homestead Area and all-weather and main roads before mining begins.

7.5.n.8. The Escrow Agent shall be charged with responsibility for transferring the surface rights in escrow to the Homesteaders, the Community Association, or the State or county road authority.

7.5.n.9. Such transfers shall promptly occur upon certification by the Escrow Agent that the Homesteader has met the requirements of this rule.

7.5.n.10. Before the homesteader receives title, property may revert to the Escrow Agent, when after notice and hearing, the Escrow Agent determines that the homesteader has not abided by this rule. The Escrow Agent's determination shall be reviewable by the Circuit Court of the County in which the homestead parcel is located.

7.5.n.11. If developed property reverts to Escrow, the Escrow Agent shall promptly sell the property and remit proceeds, less costs, to the homesteader, up to the value of the homesteader's investment.

7.5.n.12. Because deeds to Homestead Parcels will not be transferred to Homesteaders before a Homesteader has lived on a parcel for five years, lending institutions may be reluctant to make loans to Homesteaders before the five-year period has expired. Accordingly, to assure that lending institutions are willing to make loans to Homesteaders during this period, the Escrow Agent shall establish a system to provide mortgage insurance to homesteaders so that lenders will be able to finance private development of homestead parcels. The Escrow Agent shall have all

powers necessary to structure loans and other necessary transactions so lenders are reasonably secure.

There are no Federal counterparts to the provisions at CSR 38-2-7.5.n. concerning interim homestead management. However, we find that they are not inconsistent with SMCRA or the Federal regulations and can be approved.

15. CSR 38-2-7.5.o. This subdivision concerns bond release, and contains the following requirements.

7.5.o. Bond Release:

7.5.o.1. Before approving Phase I bond release, the Director shall assure that the soil is in place, the vegetative cover has been established, that the water system has been completed, that the roads have been completed and transferred to the State or county road authority, and that the main electricity transmission line is in place.

7.5.o.2. Phase II bond release may not occur before two years have passed since Phase I bond release. Before approving Phase II bond release, the Director shall assure that the vegetative cover is still in place. The Director shall further assure that the tree survival on the Conservation Easements and Public Nurseries are no less than 300 trees per acre (80% of which must be species from the approved list). Furthermore, in the Conservation Easement and Public Nursery areas, there shall be a 70% ground cover where ground cover includes tree canopy, shrub and herbaceous cover, organic litter, and rock cover. Trees and shrubs counted in considering success shall be healthy and shall have been in place at least two years, and no evidence of inappropriate dieback. Phase II bond release shall not occur until the service drops for the utilities and communications have been installed to each Homestead Parcel.

7.5.o.3. The Director may authorize Phase III bond release only after all parcels in the Homestead Areas are certified and ready for occupancy.

7.5.o.4. Once final bond release is authorized, the Permittee's responsibility for implementing the Homestead Plan shall cease.

SMCRA at section 519(c) and the Federal regulations at 30 CFR 800.40(c) provide for the release of performance bonds. The approved West Virginia program provisions for bond release are at W.Va. Code 22-3-23 and in the rules at CSR 38-2-12.2.c. Except as follows, the new provisions at CSR 38-2-7.5.o. are consistent with and no less stringent than the revegetation success and bond release provisions of SMCRA at sections 515(b)(19) and (20), and 519(c) and no less effective than the Federal bond release and revegetation success

regulations at 30 CFR 800.40 and 816.116 and can be approved. However, we are approving these provisions to the extent that they supplement but do not conflict the State provisions at CSR 38-2-12.2.

The Federal regulations at 30 CFR 816.97 concern the protection of fish, wildlife, and related environmental values. Subsection (i) at 30 CFR 816.97 provides that where residential, public service, or industrial uses are to be the postmining land use, and where consistent with the approved postmining land use, the operator shall intersperse reclaimed lands with greenbelts utilizing species of grass, shrubs, and trees useful as food and cover for wildlife. The Federal standards for evaluating the success of the revegetation of areas to be developed for fish and wildlife habitat, recreation, shelter belts, or forest products are at 30 CFR 816.116 (b)(3). Subdivision 816.116(b)(3) provides that the minimum stocking and planting arrangements must be specified by the regulatory authority on the basis of local and regional conditions and after consultation with and approval by the State agencies responsible for the administration of forestry and wildlife programs. In addition, subdivision 816.116 (b)(3)(iii) provides that vegetative cover must not be less than that required to achieve the postmining land use. Furthermore, 30 CFR 816.95 requires all exposed surface areas to be protected and stabilized to effectively control erosion and air pollution attendant to erosion.

The West Virginia Division of Forestry has approved the State's existing tree stocking and ground cover standards at CSR 38-2-9.3.g. However, there is no evidence that the West Virginia Division of Forestry has reviewed and approved the proposed tree stocking standards at CSR 38-2-7.5.o.2. as is required by 30 CFR 816.116(b)(3)(i). Nor is there evidence that the Wildlife Resources Section of the Division of Natural Resources has approved the shrub and planting arrangements as is required by 30 CFR 816.116(b)(3)(i). Therefore, we are not approving these planting arrangements and stocking standards at this time. In addition, we are requiring the WVDEP to consult with and obtain the approval of the West Virginia Division of Forestry and the Wildlife Resources Section of the Division of Natural Resources on the new planting arrangements and stocking standards at CSR 38-2-7.5.o.2. Under the Federal regulations, this approval can be on a program-wide or permit-specific basis. Since a program-wide approval has not yet been granted by the

Division of Forestry, the WVDEP must obtain approval on a permit-specific basis until such time that it receives program-wide approval by the Division of Forestry. In addition, the new rules at CSR 38-2-7.5.o.2. do not provide revegetation standards at the time of bond release for Commercial Parcels, Village Parcels, Rural Parcels, Civic Parcels and Common Lands. Therefore, we are requiring that CSR 38-2-7.5.o.2. be amended, or the West Virginia program otherwise be amended, to identify the applicable revegetation success standards for each phase of bond release on Commercial Parcels, Village Parcels, Rural Parcels, Civic Parcels and Common Lands. In the meantime, no bond release for Commercial Parcels, Village Parcels, Rural Parcels, Civic Parcels or Common Lands can be approved until a revegetation standard is approved.

The new provision at CSR 38-2-7.5.o.2. defines ground cover to include tree canopy, shrub and herbaceous cover, organic litter, and rock cover. Under the Federal definition of ground cover at 30 CFR 701.5, ground cover means the area of ground covered by the combined aerial parts of vegetation and the litter that is produced naturally on site. The Federal definition includes only naturally produced organic material, and it does not include "rock cover." In addition, the approved State standards for evaluating vegetative cover at CSR 38-2-9.3 do not refer to either rocks or litter as being included in the term "vegetative cover." Despite these differences, the Federal standard for revegetation success at 30 CFR 816.116(b)(3)(iii) provides that vegetative ground cover shall not be less than that required to achieve the approved postmining land use. At a minimum, the vegetative ground cover must not be less than that required to achieve the approved use whether or not rocks are included within the State's definition of ground cover. Therefore, we are not approving the words "rock cover" as a component of the 70 percent ground cover standard at CSR 38-2-7.5.o.2. In addition, we are requiring that the West Virginia program be further amended to delete the words "rock cover" from CSR 38-2-7.5.o.2.

Summary Finding of the Homestead Requirements

Under the proposed rule, homesteading is a concept which allows for the development of planned communities on mountaintop removal sites that are not returned to approximate original contour (AOC). The homestead area is made up of village and rural parcels primarily for

residential use with other secondary postmining land uses that consist of conservation easements, nurseries, civic parcels, common areas and commercial parcels. The new provisions at CSR 38–2–7.5. provide the details of the Homestead postmining use. However, the details are not perfectly clear, leaving some confusion as to the intended minimum size of these supporting elements. The Homestead and supporting areas are discussed below.

Homestead Area

CSR 38–2–7.5.a. provides that operations receiving a variance from AOC must establish homesteading on at least 50 percent of the permit area, and the remainder of the permit area must support an alternate AOC use. Subsection 7.5.g.5.a. provides that the landowner can retain up to 15 percent of the homestead area for commercial development. This provision appears to be a means for limiting the size of the commercial parcel within the homestead (homestead area $\times$ 15 percent = maximum size of the commercial parcel). It should be noted, however, that subsection 7.5.g.5.A. allows the landowner to retain up to 50 percent of the permitted area for commercial development. Subsection 7.5.e.1.C. provides that the homestead area, minus the commercial parcels, must occupy at least 50 percent of the permitted area. We conclude, therefore, that the commercial area is in addition to the homestead area, and can be no larger than 15 percent of the size of the homestead area (which is at least 50% of the permit area). However, other commercial development can occur within the permitted area outside the homestead area as described above.

Village Parcels

Subsection 7.5.l.1.B. provides that at least 20 percent of the homestead area must be composed of village parcels. Subsection 7.5.l.2.A. provides that village parcels can be no larger than one-acre in size. Subsections 7.5.g.3.B. and C. provide that village parcels must contain a garden area of at least 600 square feet and a building pad of a minimum of 2,500 square feet for a dwelling.

Commercial Parcels

As discussed above, commercial parcels are actually not part of the homestead area, but are in addition to the minimum area to be allotted for Homestead use. Subsection 7.5.g.5.A. also provides that the landowner may not retain more than 50 percent of the permitted area. This provision allows

for additional commercial development outside the homestead area.

Conservation Easements

Subsection 7.5.i.8.D. provides that at least 10 percent of the homestead area, including the commercial parcels, shall be conservation easements. We interpret this to mean that the area for conservation easements shall be 10 percent of the total area of homestead plus commercial parcels. Subsection 7.5.b.5. provides that conservation easements shall typically be a strip no less than 200 feet wide and shall extend through the mined areas of the land, starting and ending in natural, undisturbed land. Such easements are for the purpose of establishing a natural habitat for wildlife, windbreaks, and storm water management.

Common Areas

Subsection 7.5.l.3 provides that 10 percent of the homestead area must be used as common areas.

Civic Parcels

Subsection 7.5.g.4.A. provides that civic parcels consisting of schools, parks and other community facilities must occupy at least 10 percent of the postmining permitted area. We interpret the phrase “postmining permitted area” to mean the entire permit area, and not limited to just the Homestead area plus the commercial parcels.

Rural Parcels

The new rules do not specify a minimum size area for rural parcels. Therefore, Rural parcels must be the remaining acreage of the homestead land after the minimum acreage of the supporting areas (e.g., Civic parcel) have been satisfied. Subsections 7.5.b.17 and 7.5.g.3.B. and C. provide that rural parcels are planned to promote farming or timber management and may be up to 40 acres. Rural parcels must contain a garden area of at least 5,000 square feet and building pads for a dwelling and outbuilding of 2,500 square feet each.

Public Nursery

Subsection 7.5.l.4. provides that each village homestead shall designate an area for a public nursery constructed and planted by the permittee at no cost to the homesteaders. Subsection 7.5.l.4.A. provides that the nursery must be one acre per 30 acres of homestead area. The public nursery shall be a civic parcel. As proposed, it is not clear if the public nursery is limited in size due to the village parcel, the civic parcel or the total homestead area. Given the requirements of subsection 7.5.i.4.A.,

we believe that the public nursery is a separate component of the homestead area, and is not a subcomponent of the village parcel. Furthermore, we believe the reference to civic parcel is merely to clarify that the nursery will be accessible to and used primarily to benefit the homesteaders. However, given the conflicting nature of these requirements, we recommend that the State clarify these provisions.

In summary, a minimum of 20 percent of the Homestead area must be used for one-acre village parcels, and 10 percent for common land. A minimum of 10 percent of the Homestead area plus commercial parcels must be used for conservation easements, and 10 percent of the permitted area for civic parcels. An additional area, equivalent to up to 15 percent of the Homestead area may be retained for commercial development. The remaining area is to be used for 40-acre rural parcels and public nurseries. Our concern is not that the percentages are inconsistent with SMCRA, for they appear not to be, but to demonstrate how we expect implementation of these provisions might work.

To understand how these requirements interrelate, we need to apply them to a typical mountaintop-removal mining situation. For example, in order to permit a 1,000 acre mountaintop removal mining operation with an AOC variance, the operator would have to select one or more of the approvable postmining land uses set forth in Section 22–3–13(c)(3) of the W.Va. Code. If homesteading is selected, the operator would have to establish homesteading on at least 50 percent of the permitted area, or 500 acres. If the operator also plans a commercial development, the commercial parcel could not exceed 75 acres (15 percent of 500 acres). The homestead area would then have to be considered to be 575 acres to ensure that the homestead area minus the commercial parcel is at least 50 percent of the permitted area as is required by Subsection 7.5.e.1.C. The remaining portion of the permitted area would have to support an alternate AOC postmining use as provided in Section 22–3–13(c)(3) of the W.Va. Code.

Under this example, the village parcel would occupy 115 acres of the homestead area (20 percent $\times$ 575 acres). The conservation easement and the common areas would occupy 58 acres each (10 percent $\times$ 575 acres). The civic parcel would occupy 100 acres of the homestead area, which is equal to 10 percent of the 1000-acre permitted area. The public nursery must consist of one acre for every 30 acres of homestead area and would occupy 19 acres

(575÷30). Finally, the rural parcel would occupy the remainder of the homestead area or 150 acres. Therefore, the rural parcel would amount to 26 percent of the homestead area (150 ÷ 575).

Based on these requirements and as shown above in the example, when a landowner chooses to retain a portion of the homestead area for commercial development, the homestead area will have to comprise 58 percent of the permitted area, not 50 percent as provided in Subsection 7.5.a. While the rules provide that the conservation easements, common area, and village parcels are to be a percentage of the homestead area, it is not clear if these calculations are to include or exclude the commercial parcels, which can comprise 15 percent of the homestead area. This is further complicated by the fact that Subsection 7.5.i.8.D. provides that conservation easements are to comprise at least 10 percent of the homestead area, including the commercial parcels, civic parcels are to be 10 percent of the permitted area, and the public nursery could be considered a component of the homestead area, village parcel or civic parcel.

Given the apparent inconsistencies and the resulting difficulty in understanding the intended application of the percentages of the various components of the Homestead Area, the State needs to clarify how the acreage for each of the components of a Homestead Area will be calculated. Specifically, we are requiring that: (1) CSR 38–2–7.5.a. be amended to clarify whether or not the calculated acreage of the Commercial Parcel(s) is to be summed with the total Homestead acreage for the purpose of calculating the acreage of other various components of the Homestead Area (such as Common Lands, Village Parcels, Conservation Easement, etc.); and (2) CSR 38–2–7.5.l.4 be amended to clarify whether or not the acreage for Public Nursery is to be calculated based on the amount of acreage available for the Village Homestead, the Civil Parcel, or the entire Homestead Area.

IV. Summary and Disposition of Comments

Federal Agency Comments

On April 12, 2000, we asked for comments from various Federal agencies that may have an interest in the West Virginia amendment (Administrative Record Number WV–1152). We solicited comments in accordance with section 503(b) of SMCRA and 30 CFR 732.17(h)(11)(i) of the Federal regulations. The U.S. Department of Labor, Mine Safety and

Health Administration responded and stated that it had no comments (Administrative Record Number WV–1162). The U.S. Department of Army, Corps of Engineers responded and stated that they found the amendments to be satisfactory (Administrative Record Number WV–1164). The U.S. Fish and Wildlife Service (USFWS) responded (Administrative Record Number WV–1161), but did not provide any comments concerning CSR 38–2–7.5.

Environmental Protection Agency (EPA)

Pursuant to 30 CFR 732.17(h)(11)(i) and (ii), OSM is required to solicit comments and obtain the written concurrence of the EPA with respect to those provisions of the proposed amendment that relate to air or water quality standards promulgated under the authority of the Clean Water Act (33 U.S.C. 1251 *et seq.*) or the Clean Air Act (42 U.S.C. 7401 *et seq.*). By letter dated April 10, 2000, we requested comments and concurrence from EPA (Administrative Record No. WV–1151) on the State's proposed amendment of March 14, 2000 (Administrative Record Number WV–1147) and March 28, 2000 (Administrative Record Number WV–1148), and electronic mail dated April 6, 2000 (Administrative Record Number WV–1149).

By letter dated June 21, 2000 (Administrative Record Number WV–1166), the EPA responded and stated that it has reviewed the proposed revisions and has determined that they comply with the Clean Water Act. The EPA further stated that its review indicates that the proposed revisions do not appear to relate to air emissions or other issues which EPA would regulate under the Clean Air Act. Therefore, the EPA concurred with the proposed revisions.

In addition, the EPA provided comments and recommendations on several concerns regarding potential water quality impacts. EPA also noted that the State indicated that the new rules are intended to comply with the Consent Decree between WVDEP and the Plaintiff in Civil Action No. 2:98–0636. The EPA stated that it is not a party to that Consent Decree. Accordingly, the EPA stated, its comments are not intended and should not be construed as a determination by EPA as to whether any particular provision does or does not comply with the referenced Consent Decree.

EPA submitted several comments, including comments on the standards applicable to AOC variance operations with a postmining land use of commercial forestry and forestry at CSR

38–2–7.4, and postmining land use of homestead at CSR 38–2–7.5. We addressed EPA's comments which concern the postmining land use of commercial forestry and forestry at CSR 38–2–7.4 in a previous notice in the **Federal Register** (August 18, 2000; 65 FR 50409, 50425–50427) (Administrative Record Number WV–1174). EPA's comments concerning the homestead postmining land use at CSR 38–2–7.5. are addressed below.

1. *Applicable State and Federal laws/regulations*—The EPA stated that there are a number of Federal and State statutes and regulations protective of air and/or water quality which may apply to homesteading activities. For example, a National Pollutant Discharge Elimination System (NPDES) permit may be required for the discharge of pollutants in storm water associated with construction activity related to the homesteading activities. The EPA recommended that the regulations governing each postmining land use include a statement that activities performed in connection with the postmining use must comply with all applicable State and Federal laws and regulations.

In response, we agree that the State regulations governing each postmining land use could be improved by including a statement that the provisions must comply with all applicable State and Federal laws and regulations. However, there is nothing in the new provisions that precludes or prohibits compliance with all applicable State and Federal laws and regulations. Therefore, the lack of such a statement in the State's provisions does not render the new provisions less effective than the Federal regulations.

2. *Erosion and sedimentation control*—The EPA stated that it has concerns about possible excessive erosion and runoff at homestead sites. CSR 38–2–7.5.j.6.B. indicates that at homestead sites, regrading and reseedling may take place only on those rills and gullies which are unstable. While it is understood, the EPA stated, that porous soil must be provided for effective tree growth, the requirement of uncompacted backfills, as well as unseeded rills and gullies, appear to increase the potential for sediment runoff and resulting stream degradation during storm periods. The EPA recommended consideration of options to avoid such situations, including limiting uncompacted areas to just the areas immediately around the tree plantings, maintaining effective sedimentation control ponds below these areas, and providing extensive

vegetative cover in all areas except directly adjacent to tree plantings.

In response, and as noted above in Finding 10., CSR 38–2–7.5.j.6.A., SMCRA at section 515(b)(10)(B)(i) provides that coal mining operations must be conducted so as to prevent, to the extent possible using the best technology currently available, additional contributions of suspended solids to streamflow, or runoff outside the permit area, but in no event shall contributions be in excess of requirements set by applicable State or Federal law. Therefore, to be no less stringent than SMCRA, the term “excessive erosion” may not be interpreted to allow additional contributions of suspended solids to streamflow, or runoff outside the permit area in excess of requirements set by applicable State or Federal law. Except for the phrase, “excessive erosion,” there is nothing in new CSR 38–2–7.5.j.6.A. that supersedes or negates the approved State provisions at CSR 38–2–14.5.b. concerning effluent limitations. It appears that the effluent limitations at CSR 38–2–14.5.b. would continue to apply. However, under the proposed State rule, erosion would be allowed as long as it was not excessive, even though that erosion would be allowed to provide sediment to streams. Subdivision CSR 38–2–14.5.b., like 30 CFR 816.42, provides that discharge from areas disturbed by surface mining shall not violate effluent limitations or cause a violation of applicable water quality standards.

We have determined that as proposed, CSR 38–2–7.5.j.6.A. is less effective than the Federal requirements at 30 CFR 816.111 because the proposed standard to stabilize the soil from erosion is modified by the undefined phrase, “excessive erosion.” To be no less effective than the Federal requirements, the Director can only be allowed to approve ground cover vegetation that is sufficient to control erosion and air pollution attendant to erosion. Therefore, we are not approving the word “excessive” in the phrase “excessive erosion” at CSR 38–2–7.5.j.6. Furthermore, we are requiring the deletion of the word “excessive” from the proposed State rule at CSR 38–2–7.5.j.6.A. to ensure compliance with State water quality requirements at CSR 38–2–14.5.b.

CSR 38–2–7.5.j.6.B. only authorizes the regrading and reseeding of rills and gullies that are unstable. Normally, the presence of unstable rills and gullies indicates that excessive erosion has occurred. The Federal regulations at 30 CFR 816.95(b) require the regrading of all rills and gullies that disrupt the

approved postmining land use or the establishment of vegetative cover or cause or contribute to a violation of water quality standards for the receiving stream. Therefore, we are approving CSR 38–2–7.5.j.6.B. only to the extent that it is interpreted to require the repair of all rills and gullies that disrupt the approved postmining land use or the establishment of vegetative cover or cause or contribute to a violation of water quality standards for the receiving stream. In addition, we are requiring that CSR 38–2–7.5.j.6.B. be further amended to require the repair of all rills and gullies that disrupt the approved postmining land use or the establishment of vegetative cover or cause or contribute to a violation of water quality standards for the receiving stream.

3. *Wastewater and sewage disposal plans*—The EPA stated that section 38–2–7.5.i.2.A. states that wastewater/sewage disposal plans for homestead sites must be approved by the West Virginia Bureau of Public Health or the public health authority of the county, and that the wastewater/sewage systems must meet local health department standards. In addition, the EPA stated, discharges from any wastewater/sewage system must also meet Federal requirements under the Clean Water Act, specifically the NPDES permit requirements which are implemented by the Office of Water Resources, WVDEP. The EPA recommended, so there would be no misunderstanding, that either a statement to this effect be included in section 38–2–7.5.i.2.A., or a statement be included which indicates that disposal systems shall be consistent with all State and Federal regulations. In response, and as we stated above at Finding 9, we are approving the provisions to the extent that the applicable NPDES permitting requirements will be complied with.

4. *Individual septic tanks*—The EPA stated that section 38–2–7.5.i.2.B. indicates that septic tank systems may be proposed for use at homestead sites. Since homestead sites are planned to be constructed on somewhat porous backfilled areas, the EPA stated, there may be a higher potential for leachate to pass relatively unabsorbed through the fills to streams, presenting possible high fecal coliform levels and associated health risks. The EPA urged close review of this potential when considering any proposals for septic tank systems at homestead sites. In response, and as we stated above at Finding 9, we agree with EPA’s recommendation.

5. *Water supply*—The EPA stated that section 38–2–7.5.i.3.A. indicates that

the water supply for a homestead site may be provided by either connecting to an existing public supply, constructing individual wells, or constructing a small reservoir to serve the community. Section 7.5.i.3.H. further states that potable water supply sources shall meet Federal Primary Drinking Water Maximum Contaminant level standards in 40 CFR 141, Subpart B. The EPA stated that community water systems as defined by 40 CFR 141 (those serving 25 or more people or which have 15 or more service connections) also must comply with all subparts of 40 CFR 141, A. through J. The EPA recommended that another sentence be added to section 38–2–7.5.i.3.H. which indicates that community water systems must comply with 40 CFR 141 in its entirety. As discussed above at Finding 9, we are approving this provision to the extent that the provisions of 40 CFR 141, A. through J. apply to community water systems as defined by 40 CFR 141 (those serving 25 or more people or which have 15 or more service connections).

6. *Storm water/surface drainage from homestead sites*—The EPA stated that section 38–2–7.5.i.7. requires that a detailed storm water and surface water drainage plan for homestead sites be certified by a registered engineer. The EPA stated that storm water discharges resulting from construction of the homestead sites and supporting streets, depending on the acreage disturbed, may be subject to Federal NPDES storm water regulations in 40 CFR 122.26. The EPA recommended that either a statement to this effect be included in section 7.5.i.7., or a statement be included which indicates that storm water discharges shall be consistent with all State and Federal regulations. The EPA also recommended that the site developers contact the Office of Water Resources, WVDEP, regarding the applicability of storm water regulations for specific sites. In response, and as stated above at Finding 9, for the sake of clarity, we are approving CSR 38–2–7.5.i.7.A. to the extent that applicable NPDES storm water requirements would be complied with.

Public Comments

We solicited public comments on the amendment. One person responded with comments (Administrative Record Number WV–1163).

The commenter stated that the new homestead rules go far beyond what is in SMCRA. It seems to be true, the commenter stated, that the details would allow the WVDEP to make the necessary findings for higher/better postmining land use on AOC variance areas. We agree with this comment.

The commenter stated that the WVDEP will need extra staff to enforce these requirements. In addition, the commenter stated, OSM must decide if it would provide grant funds for the additional employees. In response, we have no information concerning the likelihood of increased permit applications for homestead postmining land use for mountaintop removal mining operations. Therefore, it is premature to conclude that the WVDEP would need additional staff to process such applications. In our oversight of the West Virginia program, we will monitor the number and processing of such permit applications, and if necessary, we will meet with the State to discuss any need for additional staff.

The commenter stated that CSR 38–2–7.5.b.14. concerning the transfer of title, would require the landowner to transfer title to the Attorney General. Clearly, the commenter stated, this requires compensation. This point should be clarified, the commenter stated. In addition, the purchasing of land for homesteading goes beyond the bounds of SMCRA, the commenter stated, and therefore, OSM could not provide matching Federal grant funds. In response, we agree with the commenter that the rules do not clearly state whether or not the landowner of record will be compensated for the land, and by whom. It is our understanding that the landowner will not be compensated for the land. The fact that the operator will not be required to return the site to AOC may be sufficient compensation under the proposed rule. It is believed that by donating the land for homesteading, the higher or better public use requirements of SMCRA will be better satisfied. Even though some may argue that this provision goes beyond the boundaries of SMCRA, it is not inconsistent with the provisions of SMCRA. Therefore, it can be approved. Finally, we agree with the commenter that Federal funds cannot be used to purchase homestead properties.

The commenter stated that the new rules regarding homesteading appear not to be supported by statutory authority. In response, we disagree with this comment. The W.Va. Code section 22–3–13(c)(3) authorizes residential land uses for AOC variances for mountaintop removal mining operations. Homesteading is primarily a residential use, and is, therefore, approvable for mountaintop removal mining operations. Furthermore, CSR 38–2–7.5.a. provides that the remainder of the permit area (that part of the permit area that will not be Homestead use) shall support an alternate AOC variance use. This means that such areas

shall support postmining uses approvable under the W.Va. Code section 22–3–13(c)(3).

V. Director's Decision

Based on the findings above, and except as noted below, we are approving the use of Homestead as a postmining land use as provided at CSR 38–2–7.5. to the extent that it supplements or is more stringent than existing State requirements, but is not inconsistent with any existing Federal program requirements.

We are requiring that CSR 38–2–7.5.b.3. be amended to clarify that parcels retained by the landowner for commercial development and incorporated within the Homestead area must be developed for commercial uses as provided by subdivision CSR 38–2–7.5.g.5.

CSR 38–2–7.5.e. is approved to the extent that its provisions supplement, but do not supersede, the approved State provisions concerning maps and cross sections, and operations plans at CSR 38–2–3.4, 3.5, and 3.6.

CSR 38–2–7.5.f. is approved to the extent that compliance with W.Va. Code section 22–3–13(c)(3) is also required.

CSR 38–2–7.5.g. is approved to the extent that compliance with the State's approved postmining land use requirements at CSR 38–2–7. is also required.

CSR 38–2–7.5.h. is approved to the extent that subdivision 7.5.h.2.B. means that consolidation of the uppermost 20 feet of spoil for Building Pads must be maximized.

CSR 38–2–7.5.i.1.B. is approved to the extent that the word “conditionally” means that the County or State road authorities will accept responsibility for maintaining the all-weather and main roads after mining and reclamation is complete, and the road(s) is built.

We are requiring that CSR 38–2–7.5.i.1.B. be amended, or the West Virginia program otherwise be amended, to clarify that roads which meet the definition of road at CSR 38–2–2.59 and 38–2–4.1 and that are to be retained as part of the postmining land use must be designed and constructed to meet the primary road requirements of CSR 38–2–4.

CSR 38–2–7.5.i.3.H. is approved to the extent that the provisions of 40 CFR 141, A. through J. apply to community water systems as defined by 40 CFR 141 (those serving 25 or more people or which have 15 or more service connections).

CSR 38–2–7.5.i.3.Q. is approved only to the extent that all permanent impoundments approved for Homestead postmining land use must comply with

CSR 38–2–3.6.b.1. and 38–2–5.5 concerning permanent impoundments. In addition, we are requiring that the West Virginia program be amended to require that all permanent impoundments approved for Homestead postmining land use must comply with CSR 38–2–3.6.b.1. and 38–2–5.5 concerning permanent impoundments.

CSR 38–2–7.5.i.7.A. is approved to the to the extent that the applicable NPDES storm water requirements would be complied with.

CSR 38–2–7.5.i.10. is approved to the extent that the permit requirements at CSR 38–2–3.5.d. continue to apply. In addition, we are requiring that CSR 38–2–7.5.i.10. be amended to require compliance with the permit requirements at CSR 38–2–3.5.d.

CSR 38–2–7.5.j.2.C. is approved to the extent that all ponds and impoundments created during mining and which will be left in place following mining must comply with the State permanent impoundment rules at CSR 38–2–5.5.

CSR 38–2–7.5.j.2.E. is approved to the extent that the landscape criteria at CSR 38–2–7.5.j.2. do not apply to any fills.

We are requiring that CSR 38–2–7.5.j.3.A. be amended to add an “E” horizon.

At CSR 38–2–7.5.j.3.B., the phrase, “except for those areas with a slope of at least 50%” is not approved, and the phrase, “and other areas from which the applicant affirmatively demonstrates and the Director of the WVDEP finds that soil cannot reasonably be recovered” is not approved. In addition, we are requiring the State to delete these phrases from its regulations at CSR 38–2–7.5.j.3.B.

CSR 38–2–7.5.j.3.E. must be amended to provide that the soil substitute material must be equally suitable for sustaining vegetation as the existing topsoil and the resulting medium is the best available in the permit area to support vegetation.

CSR 38–2–7.5.j.4. is approved to the extent that these provisions do not supersede the State's general backfilling and grading requirements at CSR 38–2–14.15.a. which are no less effective than the Federal requirements at 30 CFR 816.102(a).

At CSR 38–2–7.5.j.6.A., the word “excessive” in the phrase “excessive erosion” is not approved. We are requiring the word “excessive” be deleted from CSR 38–2–7.5.j.6.A.

CSR 38–2–7.5.j.6.B. is approved to the extent that it is interpreted to require the repair of all rills and gullies that disrupt the approved postmining land use or the establishment of vegetative cover or cause or contribute to a

violation of water quality standards for the receiving stream. We are requiring that CSR 38–2–7.5.j.6.B. be amended to require the repair of all rills and gullies that disrupt the approved postmining land use or the establishment of vegetative cover or cause or contribute to a violation of water quality standards for the receiving stream.

CSR 38–2–7.5.j.7. is approved to the extent that the proposed State standards are in addition to the excess spoil disposal requirements at W.Va. Code 22–3–13(b)(22) and CSR 38–2–14.14 and apply to all fills, including valley fills.

CSR 38–2–7.5.k. is approved to the extent that any as-built or post reclamation maps that depict reclamation which varies from that approved by the Director in the permit application shall be submitted to and approved by the Director under CSR 38–2–3.28.c.

CSR 38–2–7.5.o. is approved to the extent that it supplements but does not supersede the State provisions at CSR 38–2–12.2.

At CSR 38–2–7.5.o.2., the new planting arrangements and stocking standards are not approved. We are requiring the WVDEP to consult with and obtain the approval of the West Virginia Division of Forestry and the Wildlife Resources Section of the Division of Natural Resources on the new planting arrangements and stocking standards at CSR 38–2–7.5.o.2.

We are requiring that CSR 38–2–7.5.o.2. be amended to, or the West Virginia program otherwise be amended, to identify the applicable revegetation success standards for each phase of bond release on Commercial Parcels, Village Parcels, Rural Parcels, Civic Parcels and Common Lands. In the meantime, no bond release for Commercial Parcels, Village Parcels, Rural Parcels, Civic Parcels or Common Lands can be approved until a revegetation standard is approved.

At CSR 38–2–7.5.o.2., the words “rock cover” are not approved. We are requiring that the words “rock cover” be deleted from CSR 38–2–7.5.o.2.

Finally, we are requiring that: (1) CSR 38–2–7.5.a. be amended to clarify whether or not the calculated acreage of the Commercial Parcel(s) is to be summed with the total Homestead acreage for the purpose of calculating the acreage of other various components of the Homestead Area (such as Common Lands, Village Parcels, Conservation Easement, etc.); and (2) CSR 38–2–7.5.1.4 be amended to clarify whether or not the acreage for Public Nursery is to be calculated based on the amount of acreage available for the

Village Homestead, the Civil Parcel, or the entire Homestead Area.

This final rule is being made effective immediately to expedite the State program amendment process and to encourage States to bring their programs into conformity with the Federal standards without undue delay. Consistency of State and Federal standards is required by SMCRA.

VI. Procedural Determinations

Executive Order 12866—Regulatory Planning and Review

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

Executive Order 12630—Takings

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

Executive Order 13132—Federalism

This rule does not have federalism implications. SMCRA delineates the roles of the federal and state governments with regard to the regulation of surface coal mining and reclamation operations. One of the purposes of SMCRA is to “establish a nationwide program to protect society and the environment from the adverse effects of surface coal mining operations.” Section 503(a)(1) of SMCRA requires that state laws regulating surface coal mining and reclamation operations be “in accordance with” the requirements of SMCRA, and section 503(a)(7) requires that state programs contain rules and regulations “consistent with” regulations issued by the Secretary pursuant to SMCRA.

Executive Order 12988—Civil Justice Reform

The Department of the Interior has conducted the reviews required by section 3 of Executive Order 12988 and has determined that, to the extent allowed by law, this rule meets the applicable standards of subsections (a) and (b) of that section. However, these standards are not applicable to the actual language of state regulatory programs and program amendments since each such program is drafted and promulgated by a specific state, not by OSM. Under sections 503 and 505 of SMCRA (30 U.S.C. 1253 and 1255) and 30 CFR 730.11, 732.15, and 732.17(h)(10), decisions on proposed state regulatory programs and program amendments submitted by the states must be based solely on a determination of whether the submittal is consistent with SMCRA and its implementing

federal regulations and whether the other requirements of 30 CFR Parts 730, 731, and 732 have been met.

National Environmental Policy Act

Section 702(d) of SMCRA (30 U.S.C. 1292(d)) provides that a decision on a proposed state regulatory program provision does not constitute a major federal action within the meaning of section 102(2)(C) of the National Environmental Policy Act (NEPA) (42 U.S.C. 4332(2)(C)). A determination has been made that such decisions are categorically excluded from the NEPA process (516 DM 8.4.A).

Paperwork Reduction Act

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

Regulatory Flexibility Act

The Department of the Interior has determined that this rule will not have a significant economic impact on a substantial number of small entities under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*). The state submittal which is the subject of this rule is based upon counterpart federal regulations for which an economic analysis was prepared and certification made that such regulations would not have a significant economic effect upon a substantial number of small entities. Accordingly, this rule will ensure that existing requirements previously promulgated by OSM will be implemented by the state. In making the determination as to whether this rule would have a significant economic impact, the Department relied upon the data and assumptions for the counterpart federal regulation.

Small Business Regulatory Enforcement Fairness Act

This rule is not a major rule under 5 U.S.C. 804(2), the Small Business Regulatory Enforcement Fairness Act. This rule:

a. Does not have an annual effect on the economy of \$100 million.

b. Will not cause a major increase in costs or prices for consumers, individual industries, federal, state, or local government agencies, or geographic regions.

c. Does not have significant adverse effects on competition, employment, investment, productivity, innovation, or the ability of U.S. based enterprises to compete with foreign-based enterprises.

This determination is based upon the fact that the state submittal which is the

subject of this rule is based upon counterpart federal regulations for which an analysis was prepared and a determination made that the federal regulation was not considered a major rule.

Unfunded Mandates

This rule will not impose a cost of \$100 million or more in any given year on any governmental entity or the private sector.

List of Subjects in 30 CFR Part 948

Intergovernmental relations, Surface mining, Underground mining.

Dated: December 7, 2000.

Allen D. Klein,

Regional Director, Appalachian Regional Coordinating Center.

For the reasons set out in the preamble, Title 30, Chapter VII, Subchapter T of the Code of Federal

Regulations is amended as set forth below:

PART 948—WEST VIRGINIA

1. The authority citation for Part 948 continues to read as follows:

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

2. Section 948.12 is amended by adding new paragraph (c) to read as follows:

§ 948.12 State statutory, regulatory, and proposed program amendment provisions not approved.

* * * * *

(c) We are not approving the following provisions of the proposed program amendment that West Virginia submitted on March 14, 2000, March 28, 2000, and April 6, 2000:

(1) At CSR 38–2–7.5.j.3.B., the phrase, “except for those areas with a slope of at least 50%” is not approved, and the

phrase, “and other areas from which the applicant affirmatively demonstrates and the Director of the WVDEP finds that soil cannot reasonably be recovered” is not approved.

(2) At CSR 38–2–7.5.j.6.A., the word “excessive” in the phrase “excessive erosion” is not approved.

(3) At CSR 38–2–7.5.o.2., the new planting arrangements and stocking standards are not approved.

(4) At CSR 38–2–7.5.o.2., the words “rock cover” are not approved.

* * * * *

3. Section 948.15 is amended by adding a new entry to the table in chronological order by “Date of publication of final rule” to read as follows:

§ 948.15 Approval of West Virginia regulatory program amendments.

* * * * *

Original amendment submission date	Date of publication of final rule	Citation/description of approved provisions
* * * * *	* * * * *	* * * * *
March 14, 2000, March 28, 2000, and April 6, 2000.	12/21/00	CSR 38–2–7.5.(qualified approval), 7.5.a., b., c., d., e. (qualified approval), f. (qualified approval), g. (qualified approval), h. (h.2.B. is a qualified approval), i. (i.1.B., i.3.H., i.3.Q. and i.7.A., and i.10. are qualified approvals), j. (j.2.C. and j.2.E. are qualified approvals; j.3.B. partial approval; j.4. qualified approval, j.6.A. partial approval, j.6.B. qualified approval, j.7. qualified approval), k. (qualified approval), l., m., n., o. (qualified approval; o.2. is a partial approval).

4. Section 948.16 is amended by adding paragraphs (fffff) through (rrrrr) to read as follows:

§ 948.16 Required regulatory program amendments.

* * * * *

(fffff) By February 20, 2001, West Virginia must submit either a proposed amendment or a description of an amendment to be proposed, together with a timetable for adoption to amend CSR 38–2–7.5.b.3., or otherwise amend the West Virginia program to clarify that parcels retained by the landowner for commercial development and incorporated within the Homestead area must be developed for commercial uses as provided by subdivision CSR 38–2–7.5.g.5.

(ggggg) By February 20, 2001, West Virginia must submit either a proposed amendment or a description of an amendment to be proposed, together with a timetable for adoption to amend CSR 38–2–7.5.i.1.B., or to otherwise amend the West Virginia program, to clarify that roads which meet the definition of road at CSR 38–2–2.59 and 38–2–4.1 and that are to be retained as part of the postmining land use must be

designed and constructed to meet the primary road requirements of CSR 38–2–4.

(hhhhh) By February 20, 2001, West Virginia must submit either a proposed amendment or a description of an amendment to be proposed, together with a timetable for adoption to amend CSR 38–2–7.5.i.3.Q., or otherwise amend the West Virginia program, to require that all permanent impoundments approved for Homestead postmining land use must comply with CSR 38–2–3.6.b.1. and 38–2–5.5 concerning permanent impoundments.

(iiiiii) By February 20, 2001, West Virginia must submit either a proposed amendment or a description of an amendment to be proposed, together with a timetable for adoption to amend CSR 38–2–7.5.i.10., or otherwise amend the West Virginia program, to require compliance with the permit requirements at CSR 38–2–3.5.d.

(jjjjj) By February 20, 2001, West Virginia must submit either a proposed amendment or a description of an amendment to be proposed, together with a timetable for adoption to amend CSR 38–2–7.5.j.3.A. by adding an “E” horizon.

(kkkkk) By February 20, 2001, West Virginia must submit either a proposed amendment or a description of an amendment to be proposed, together with a timetable for adoption to amend CSR 38–2–7.5.j.3.B. to delete the phrase, “except for those areas with a slope of at least 50%,” and to delete the phrase, “and other areas from which the applicant affirmatively demonstrates and the Director of the WVDEP finds that soil cannot reasonably be recovered.”

(lllll) By February 20, 2001, West Virginia must submit either a proposed amendment or a description of an amendment to be proposed, together with a timetable for adoption to amend CSR 38–2–7.5.j.3.E., or otherwise amend the West Virginia program, to provide that the soil substitute material must be equally suitable for sustaining vegetation as the existing topsoil and the resulting medium is the best available in the permit area to support vegetation.

(mmmmm) By February 20, 2001, West Virginia must submit either a proposed amendment or a description of an amendment to be proposed, together with a timetable for adoption to delete

the word "excessive" from CSR 38-2-7.5.j.6.A.

(nnnnn) By February 20, 2001, West Virginia must submit either a proposed amendment or a description of an amendment to be proposed, together with a timetable for adoption to amend CSR 38-2-7.5.j.6.B., or otherwise amend the West Virginia program, to require the repair of all rills and gullies that disrupt the approved postmining land use or the establishment of vegetative cover or cause or contribute to a violation of water quality standards for the receiving stream.

(ooooo) By February 20, 2001, West Virginia must submit either a proposed amendment or a description of an amendment to be proposed, together with a timetable for adoption to consult with and obtain the approval of the West Virginia Division of Forestry and the Wildlife Resources Section of the Division of Natural Resources on the new stocking standards and planting arrangements at CSR 38-2-7.5.o.2.

(ppppp) By February 20, 2001, West Virginia must submit either a proposed amendment or a description of an amendment to be proposed, together with a timetable for adoption to amend CSR 38-2-7.5.o.2., or otherwise amend the West Virginia program, to identify the applicable revegetation success standards for each phase of bond release on Commercial Parcels, Village Parcels, Rural Parcels, Civic Parcels and Common Lands. In the meantime, no bond release for Commercial Parcels, Village Parcels, Rural Parcels, Civic Parcels or Common Lands can be approved until a revegetation standard is approved.

(qqqqq) By February 20, 2001, West Virginia must submit either a proposed amendment or a description of an amendment to be proposed, together with a timetable for adoption to delete the words "rock cover" from CSR 38-2-7.5.o.2.

(rrrrr) By February 20, 2001, West Virginia must submit either a proposed amendment or a description of an amendment to be proposed, together with a timetable for adoption to amend: (1) CSR 38-2-7.5.a. to clarify whether or not the calculated acreage of the Commercial Parcel(s) is to be summed with the total Homestead acreage for the purpose of calculating the acreage of other various components of the Homestead Area (such as Common Lands, Village Parcels, Conservation Easement, etc.); and (2) CSR 38-2-7.5.l.4 to clarify whether or not the acreage for Public Nursery is to be calculated based on the amount of acreage available for the Village

Homestead, the Civil Parcel, or the entire Homestead Area.

[FR Doc. 00-32428 Filed 12-20-00; 8:45 am]

BILLING CODE 4310-05-P

DEPARTMENT OF VETERANS AFFAIRS

38 CFR Part 21

RIN 2900-AJ90

Miscellaneous Montgomery GI Bill Eligibility and Entitlement Issues; Correction

AGENCY: Department of Veterans Affairs.

ACTION: Final rule; technical corrections.

SUMMARY: In a document published in the *Federal Register* on November 9, 2000 (65 FR 67265), we amended the regulations concerning eligibility for and entitlement to educational assistance under the Montgomery GI Bill—Active Duty (MGIB). This document makes technical corrections to eliminate duplicate numbering of paragraphs and to correct typographical errors.

DATES: *Effective Date:* This final rule is effective December 21, 2000.

FOR FURTHER INFORMATION CONTACT: William G. Susling, Jr., Assistant Director for Policy and Program Development (225), Veterans Benefits Administration, Department of Veterans Affairs, (202) 273-7187.

SUPPLEMENTARY INFORMATION: This document merely makes technical corrections. Accordingly, there is a basis for dispensing with prior notice-and-comment and a delayed effective date under 5 U.S.C. 552 and 553.

The Catalog of Federal Domestic Assistance number for the program affected by this final rule is 64.124.

List of Subjects in 38 CFR Part 21

Administrative practice and procedure, Armed forces, Civil rights, Claims, Colleges and universities, Conflict of interests, Defense Department, Education, Employment, Grant programs-education, Grant programs-veterans, Health care, Loan programs-education, Loan programs-veterans, Manpower training programs, Reporting and recordkeeping requirements, Schools, Travel and transportation expenses, Veterans, Vocational education, Vocational rehabilitation.

Approved: December 15, 2000.

Thomas O. Gessel,

Director, Office of Regulations Management.

In rule FR Doc. 00-28702 published on November 9, 2000 (65 FR 67265), make the following corrections:

§ 21.7042 [Corrected]

1. On page 67266, in the second column, correct amendatory instruction 3.E. concerning § 21.7042 by removing "(10)" and adding, in its place, "(11)" and by removing "(9)" and adding, in its place, "(10)".

2. On the same page, in the same column, in § 21.7042, in the introductory text of paragraph (b)(2) and in the paragraph number of the paragraph added by amendatory instruction 3.E., remove "(10)" and add, in its place, "(11)".

§ 21.7044 [Corrected]

3. On the same page, in the third column, correct amendatory instruction 4.D. concerning § 21.7044 by removing "paragraph (d)" and adding, in its place, "Paragraph (d)" and by removing "paragraph (c)" and adding, in its place, "Paragraph (c)".

[FR Doc. 00-32599 Filed 12-20-00; 8:45 am]

BILLING CODE 8320-01-P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[WY-001-0006a; FRL-6886-8]

Clean Air Act Approval and Promulgation of State Implementation Plan; Wyoming; Revisions to Air Pollution Regulations

AGENCY: Environmental Protection Agency (EPA).

ACTION: Direct final rule.

SUMMARY: The EPA partially approves and partially disapproves revisions to the State Implementation Plan (SIP) submitted by the Governor of Wyoming on May 21, 1999. The submittal incorporates revisions to the following sections of the Wyoming Air Quality Standards and Regulations (WAQSR): Section 2 Definitions, Section 4 Sulfur oxides, Section 5 Sulfuric acid mist, Section 8 Ozone, Section 9 Volatile organic compounds, Section 10 Nitrogen oxides, Section 14 Control of particulate emissions, and Section 21 Permit requirements for construction, modification and operation. We partially approve these SIP revisions because they are consistent with Federal requirements. We are also partially

disapproving the provisions of the State submittal that allow the Administrator of the Wyoming Air Quality Division (WAQD) to approve alternative test methods to those required in the SIP, (in sections 2, 4, 5, 10, and 14 of the WAQSR) because such provisions are inconsistent with section 110(i) of the Clean Air Act (Act) and the requirement that SIP provisions can only be modified through revisions to the SIP and must be approved by EPA. We are taking this action under section 110 of the Act.

DATES: This rule is effective on February 20, 2001 without further notice, unless we receive adverse comment by January 22, 2001. If we receive adverse comments, we will publish a timely withdrawal of the direct final rule in the **Federal Register** and inform the public that the rule will not take effect.

ADDRESSES: You should mail your written comments to Richard R. Long, Director, Air and Radiation Program, Mailcode 8P-AR, Environmental Protection Agency, Region VIII, 999 18th Street, Suite 300, Denver, Colorado, 80202. Copies of the documents relevant to this action are available for public inspection during normal business hours at the Air and Radiation Program, Environmental Protection Agency, Region VIII, 999 18th Street, Suite 300, Denver, Colorado, 80202-2466. Copies of the Incorporation by Reference material are available at the Air and Radiation Docket (6102), Environmental Protection Agency, 401 M Street, SW, Washington, DC 20460. Copies of the State documents relevant to this action are available for public inspection at the Air Quality Division, Department of Environmental Quality, 122 West 25th Street, Cheyenne, Wyoming, 82002.

FOR FURTHER INFORMATION CONTACT: Kerri Fiedler, EPA Region VIII, (303) 312-6493.

SUPPLEMENTARY INFORMATION:

Throughout this document, wherever "we", "our", or "us" is used, we mean EPA.

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 - C. Section 5 Sulfuric acid mist
 - D. Section 8 Ozone
 - E. Section 9 Volatile organic compounds
 - F. Section 10 Nitrogen oxides
 - G. Section 14 Control of particulate emissions
 - H. Section 21 Permit requirements for construction, modification, and operation
- III. Final Action
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- A. Executive Order 12866
- B. Executive Order 13045
- C. Executive Order 13084
- D. Executive Order 13132
- E. Regulatory Flexibility
- F. Unfunded Mandates
- G. Submission to Congress and the Comptroller General
- H. National Technology Transfer and Advancement Act
- I. Petitions for Judicial Review

I. Summary of EPA's Actions

We are partially approving and partially disapproving revisions to the SIP submitted by the Governor of Wyoming on May 21, 1999. Specifically, we are partially approving and partially disapproving the following sections of the WAQSR: Section 2 Definitions, Section 4 Sulfur oxides, Section 5 Sulfuric acid mist, Section 8 Ozone, Section 9 Volatile organic compounds, Section 10 Nitrogen oxides, Section 14 Control of particulate emissions, and Section 21 Permit requirements for construction, modification and operation. Revisions to sections 2, 4, 5, and 14 represent minor changes to correct cross references. Revisions to the ozone section were designed to comply with revisions to the national 8-hour primary and secondary ambient air quality standards for ozone. Section 9 was revised to remove outdated regulations and clarify requirements for flaring of waste gas. Section 10 was changed to clarify references to combustion equipment. Permitting section 21 was revised to reference additional permitting requirements in the hazardous air pollutant regulations.

We are publishing this rule without prior proposal because we view this as a noncontroversial amendment and anticipate no adverse comments. However, in the "Proposed Rules" section of today's **Federal Register** publication, we are publishing a separate document that will serve as the proposal to approve the SIP revision if adverse comments are filed. This rule will be effective February 20, 2001 without further notice unless the Agency receives adverse comments by January 22, 2001.

If we receive such comments, then we will publish a timely withdrawal of the direct final rule informing the public that the rule will not take effect. All public comments received will then be addressed in a subsequent final rule based on the proposed rule. We will not institute a second comment period on this rule. Any parties interested in commenting on this rule should do so at this time. If no such comments are received, the public is advised that this rule will be effective on February 20,

2001, and no further action will be taken on the proposed rule.

II. Evaluation of the State's Submittal

Section 110(k) of the Act addresses our actions on submissions of SIP revisions. The Act also requires States to observe certain procedures in developing SIP revisions. Section 110(a)(2) of the Act requires that each SIP revision be adopted after reasonable notice and public hearing. We have evaluated the State's submission and determined that the necessary procedures were followed. We also must determine whether a submittal is complete and therefore warrants further review and action (see section 110(k)(1) of the Act). Our completeness criteria for SIP submittals can be found in 40 CFR part 51 appendix V. We attempt to determine completeness within 60 days of receiving a submissions. However, the law considers a submittal complete if we do not determine completeness within six months after we receive it. This submission became complete by operation of law on November 21, 1999 in accordance with section 110(k)(1)(B) of the Act.

A. Section 2 Definitions

The State revised the definition of "particulate matter emissions" in section 2(a)(xxx)(B) of the WAQSR. This revision is a minor change to correct applicable reference methods. This revision is partially approved and partially disapproved, however, because the provision allows the use of an equivalent or alternative method to be approved by the Administrator of the WAQD. In an August 19, 1998 letter to the WAQD, we raised concerns about provisions in the WAQSR where the WAQD has the discretion to approve the use of alternative or equivalent test methods in place of those required in the SIP. Such discretionary authority for the State to change test methods that are included in the SIP, without obtaining prior EPA approval is not consistent with section 110 of the Act. These "director's discretion" provisions essentially allow for a variance from SIP requirements, which is not allowed under section 110(i) of the Act. In our August 19, 1998 letter, we identified the sections in the WAQSR which contain these director's discretion provisions, and informed the State that the provisions needed to be revised to require EPA approval of any alternative or equivalent test methods. In a September 9, 1998 letter responding to our comments, the WAQD committed to address our concerns through revisions to these rules in the near future. In fact, the State recently revised section

2(a)(xxx)(B) of the WAQSR to read, “* * * or an equivalent or alternative method approved by the EPA Administrator.” We anticipate that the revision will be submitted as a SIP revision in the near future. However, until these provisions are revised, we believe it is necessary to disapprove the various “director’s discretion” provisions, to ensure that any alternatives to the test methods required in the SIP are approved by EPA.

B. Section 4 Sulfur Oxides

The State made a minor revision to section 4(h) of the WAQSR to change a reference for the method to measure sulfur oxide emissions. As discussed above, this revision also is partially approved and partially disapproved. This provision allows the Administrator of the WAQD to approve the use of an equivalent test method. For the reasons discussed in section II.B above, we are disapproving the director’s discretion provision in section 4(h) of the WAQSR, because it is inconsistent with section 110(i) of the Act.

C. Section 5 Sulfuric Acid Mist

The State made a minor revision to section 5 of the WAQSR to change the reference for the method to measure sulfuric acid mist. This revision is also partially approved and partially disapproved. This provision allows the Administrator of the WAQD to approve the use of an equivalent method. This provision for director’s discretion has since been revised to require EPA approval of alternative test methods, and the new revision became effective at the State level on October 29, 1999. However, this revision has not yet been submitted to us for approval into the SIP. For the reasons discussed in section II.B above, we are partially disapproving the director’s discretion provision in section 5, because it is inconsistent with section 110(i) of the Act.

D. Section 8 Ozone

The State revised section 8 of the WAQSR by adding the 8-hour primary and secondary ozone National Ambient Air Quality Standards (NAAQS). We are approving this revision as it is consistent with the Federal 8-hour ozone NAAQS, as promulgated in the **Federal Register** on July 18, 1997 (see 62 FR 38856), and also addresses the requirements of 40 CFR part 50 (Appendices D and I) and 40 CFR part 53.

On July 18, 1997, EPA promulgated the new 8-hour ozone NAAQS (see 62 FR 38856). With the promulgation of the new 8-hour standard, and under a Presidential directive dated July 16,

1997, EPA also set into motion the process to revoke the 1-hour standard for areas in the nation that were attaining that standard. The 1-hour ozone standard was revoked for Wyoming on June 5, 1998 (see 63 FR 31014). A May 14, 1999 ruling by the U. S. Court of Appeals for the D.C. Circuit, however undermined the basis for EPA’s June 5, 1998 revocation of the 1-hour ozone standard. As the D.C. Circuit Court ruled that EPA could not enforce the new 8-hour standard, and it may be some time before the Agency’s appeal to the Supreme Court is decided, EPA rescinded its findings that the 1-hour standard no longer applied in certain areas and reinstated the 1-hour ozone standard for all areas of the nation on July 20, 2000 (see 65 FR 45182). The effective date of the July 20, 2000 reinstatement for Wyoming is October 18, 2000.

E. Section 9 Volatile Organic Compounds

The State revised section 9 of the WAQSR to delete a provision regulating hydrocarbon emissions, because the State determined it was unenforceable and replaced it with a provision to control volatile organic compound (VOC) emissions through the application of Best Available Control Technology (BACT) in accordance with Section 21 Permit requirements for construction, modification, and operation. In our comments on this revision, during the State’s public hearing, we expressed concern that the State may be allowing existing sources to relax emission limits as a result of this rule change. However, in a June 23, 2000 letter, the State explained that any existing source that had been regulated under the previous version of this rule would not be able to remove emission controls without triggering the need for a permit to modify, which would require application of BACT. Thus, the State asserts that the new version of this rule is more enforceable and is likely to result in greater control of VOC emissions than the previous rule. We concur with the State and are therefore approving the revision.

F. Section 10 Nitrogen Oxides

The State revised sections 10(b), 10(b)(vii), 10(b)(viii), and 10(b)(ix) of the WAQSR. These revisions are minor editorial corrections that we are partially approving and partially disapproving. Section 10(b) contains a “director’s discretion” provision that allows the Administrator of the WAQD to approve the use of an equivalent test method to measure nitrogen oxide emissions. For the reasons discussed in

section II.B above, we are partially disapproving the director’s discretion provision in section 10(b), because it is inconsistent with section 110(i) of the Act.

G. Section 14 Control of Particulate Emissions

The State made a minor revision to a reference to the method for measuring particulate matter emissions in section 14(h)(iv) of the WAQSR. This revision is partially approved and partially disapproved because it also contains a director’s discretion provision that allows the Administrator of the WAQD to approve the use of variations to the test method. For the reasons discussed in section II.B above, we are partially disapproving the director’s discretion provision in section 14(h)(iv), because it is inconsistent with section 110(i) of the Act.

H. Section 21 Permit Requirements for Construction, Modification and Operation

The State revised section 21(a)(vi) and 21(h) to reference additional permitting requirements in the hazardous air pollutant regulations. Section 21(a)(vi) was revised to include requirements for submitting permit applications under National Emission Standards for Hazardous Air Pollutant Standards and section 21(h) adds an expiration date for permits containing a case-by case Maximum Available Control Technology determination. We have determined both revisions are acceptable.

III. Final Action

In this action, we are granting partial approval and partial disapproval of revisions to sections 2, 4, 5, 8, 9, 10, 14, and 21 of the WAQSR submitted as a SIP revision by the Governor of Wyoming on May 21, 1999. We are publishing this rule without prior proposal because the Agency views this as a noncontroversial amendment and anticipates no adverse comments. However, in the “Proposed Rules” section of today’s **Federal Register** publication, we are publishing a separate document that will serve as the proposal to approve the SIP revisions if adverse comments are filed. This rule will be effective February 20, 2001 without further notice unless the Agency receives adverse comments by January 22, 2001. If we receive adverse comments, then we will publish a timely withdrawal of the direct final rule, in the **Federal Register**, informing the public that the rule will not take effect. All public comments received will then be addressed in a subsequent

final rule based on the proposed rule. We will not institute a second comment period on this action. Any parties interested in commenting must do so at this time. If no such comments are received, the public is advised that this rule will be effective on February 20, 2001, and no further action will be taken on the proposed rule. Please note that if we receive adverse comment on an amendment, paragraph, or section of this rule and if that provision may be severed from the remainder of the rule, we may adopt as final those provisions of the rule that are not the subject of an adverse comment.

IV. Administrative Requirements

A. Executive Order 12866

The Office of Management and Budget (OMB) has exempted this regulatory action from Executive Order 12866, entitled "Regulatory Planning and Review."

B. Executive Order 13045

Protection of Children from Environmental Health Risks and Safety Risks (62 FR 19885, April 23, 1997), applies to any rule that: (1) Is determined to be "economically significant" as defined under Executive Order 12866, and (2) concerns an environmental health or safety risk that EPA has reason to believe may have a disproportionate effect on children. If the regulatory action meets both criteria, the Agency must evaluate the environmental health or safety effects of the planned rule on children, and explain why the planned regulation is preferable to other potentially effective and reasonably feasible alternatives considered by the Agency.

This rule is not subject to Executive Order 13045 because it does not involve decisions intended to mitigate environmental health or safety risks.

C. Executive Order 13084

Under Executive Order 13084, EPA may not issue a regulation that is not required by statute, that significantly affects or uniquely affects the communities of Indian tribal governments, and that imposes substantial direct compliance costs on those communities, unless the Federal government provides the funds necessary to pay the direct compliance costs incurred by the tribal governments, or EPA consults with those governments. If EPA complies by consulting, Executive Order 13084 requires EPA to provide to the Office of Management and Budget, in a separately identified section of the preamble to the rule, a description of the extent of EPA's

prior consultation with representatives of affected tribal governments, a summary of the nature of their concerns, and a statement supporting the need to issue the regulation. In addition, Executive Order 13084 requires EPA to develop an effective process permitting elected officials and other representatives of Indian tribal governments "to provide meaningful and timely input in the development of regulatory policies on matters that significantly or uniquely affect their communities."

Today's rule does not significantly or uniquely affect the communities of Indian tribal governments. This action does not involve or impose any requirements that affect Indian Tribes. Accordingly, the requirements of section 3(b) of Executive Order 13084 do not apply to this rule.

D. Executive Order 13132

Federalism (64 FR 43255, August 10, 1999) revokes and replaces Executive Orders 12612 (Federalism) and 12875 (Enhancing the Intergovernmental Partnership). Executive Order 13132 requires EPA to develop an accountable process to ensure "meaningful and timely input by State and local officials in the development of regulatory policies that have federalism implications." "Policies that have federalism implications" is defined in the Executive Order to include regulations that have "substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government." Under Executive Order 13132, EPA may not issue a regulation that has federalism implications, that imposes substantial direct compliance costs, and that is not required by statute, unless the Federal government provides the funds necessary to pay the direct compliance costs incurred by State and local governments, or EPA consults with State and local officials early in the process of developing the proposed regulation. EPA also may not issue a regulation that has federalism implications and that preempts State law unless the Agency consults with State and local officials early in the process of developing the proposed regulation.

This 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, as specified in Executive Order 13132, because it

merely approves a state rule implementing a federal standard, and does not alter the relationship or the distribution of power and responsibilities established in the Clean Air Act. Thus, the requirements of section 6 of the Executive Order do not apply to this rule.

E. Regulatory Flexibility

The Regulatory Flexibility Act (RFA) generally requires an agency to conduct a regulatory flexibility analysis of any rule subject to notice and comment rulemaking requirements unless the agency certifies that the rule will not have a significant economic impact on a substantial number of small entities. Small entities include small businesses, small not-for-profit enterprises, and small governmental jurisdictions.

This final partial approval rule will not have a significant impact on a substantial number of small entities because SIP approvals under section 110 and subchapter I, part D of the Clean Air Act do not create any new requirements but simply approve requirements that the State is already imposing. Therefore, because the Federal SIP approval does not create any new requirements, I certify that this action will not have a significant economic impact on a substantial number of small entities. Moreover, due to the nature of the Federal-State relationship under the Clean Air Act, preparation of flexibility analysis would constitute Federal inquiry into the economic reasonableness of state action. The Clean Air Act forbids EPA to base its actions concerning SIPs on such grounds. *Union Electric Co., v. U.S. EPA*, 427 U.S. 246, 255-66 (1976); 42 U.S.C. 7410(a)(2).

This final partial disapproval rule will not have a significant impact on a substantial number of small entities because this partial disapproval only affects a limited number of sources. Therefore, I certify that this action will not have a significant economic impact on a substantial number of small entities. Furthermore, as explained in this notice, the request does not meet the requirements of the Clean Air Act and EPA cannot approve the request. EPA has no option but to partially disapprove the submittal.

The partial approval and partial disapproval will not affect an existing state requirements applicable to small entities. Federal disapproval of a state submittal does not affect its state-enforceability.

F. Unfunded Mandates

Under sections 202 of the Unfunded Mandates Reform Act of 1995

("Unfunded Mandates Act"), signed into law on March 22, 1995, EPA must prepare a budgetary impact statement to accompany any proposed or final rule that includes a Federal mandate that may result in estimated costs to State, local, or tribal governments in the aggregate; or to the private sector, of \$100 million or more. Under section 205, EPA must select the most cost-effective and least burdensome alternative that achieves the objectives of the rule and is consistent with statutory requirements. Section 203 requires EPA to establish a plan for informing and advising any small governments that may be significantly or uniquely impacted by the rule.

EPA has determined that the partial approval action promulgated does not include a Federal mandate that may result in estimated costs of \$100 million or more to either State, local, or tribal governments in the aggregate, or to the private sector. This Federal action partially approves pre-existing requirements under State or local law, and imposes no new requirements. Accordingly, no additional costs to State, local, or tribal governments, or to the private sector, result from this action.

G. Submission to Congress and the Comptroller General

The Congressional Review Act, 5 U.S.C. 801 *et seq.*, as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report, which includes a copy of the rule, to each House of the Congress and to the Comptroller General of the United States. EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the **Federal Register**. A major rule cannot take effect until 60 days after it is published in the **Federal Register**. This action is not a "major rule" as defined by 5 U.S.C. 804(2). This rule will be effective February 20, 2001 unless EPA receives adverse written comments by January 22, 2001.

H. National Technology Transfer and Advancement Act

Section 12 of the National Technology Transfer and Advancement Act (NTTAA) of 1995 requires Federal agencies to evaluate existing technical standards when developing a new regulation. To comply with NTTAA, EPA must consider and use "voluntary consensus standards" (VCS) if available

and applicable when developing programs and policies unless doing so would be inconsistent with applicable law or otherwise impractical.

The EPA believes that VCS are inapplicable to this action. Today's action does not require the public to perform activities conducive to the use of VCS.

I. Petitions for Judicial Review

Under section 307(b)(1) of the Clean Air Act, petitions for judicial review of this action must be filed in the United States Court of Appeals for the appropriate circuit by February 20, 2001. Filing a petition for reconsideration by the Administrator of this final rule does not affect the finality of this rule for the purposes of judicial review nor does it extend the time within which a petition for judicial review may be filed, and shall not postpone the effectiveness of such rule or action. This action may not be challenged later in proceedings to enforce its requirements. (See section 307(b)(2).)

List of Subjects in 40 CFR Part 52

Environmental protection, Air pollution control, Hydrocarbons, Incorporation by reference, Intergovernmental relations, Nitrogen dioxide, Ozone, Particulate matter, Reporting and recordkeeping requirements, Sulfur oxides, Volatile organic compounds.

Dated: October 6, 2000.

Jack W. McGraw,

Acting Regional Administrator, Region VIII.

Part 52, Chapter I, title 40 of the Code of Federal Regulations is amended as follows:

PART 52—[AMENDED]

1. The authority citation for Part 52 continues to read as follows:

Authority: 42 U.S.C. 7401 *et seq.*

Subpart ZZ—Wyoming

2. Section 52.2620 is amended by adding paragraph (c)(29) to read as follows:

§ 52.2620 Identification of plan.

* * * * *

(c) * * *

(29) The Governor of Wyoming submitted revisions to sections 2, 4, 5, 8, 9, 10, 14, and 21 of the Wyoming Air Quality Standards and Regulations (WAQSR) on May 21, 1999.

(i) Incorporation by reference.

(A) Revisions to the WAQSR, section 2 Definitions, subsection 2(a)(xxx)(B) excluding the words "or an equivalent

or alternative method approved by the Administrator," effective October 15, 1998.

(B) Revisions to the WAQSR, section 4 Sulfur oxides, subsection 4(h) excluding the words "or an equivalent method," effective October 15, 1998.

(C) Revisions to the WAQSR, section 5 Sulfuric acid mist excluding the words "or an equivalent method," effective October 15, 1998.

(D) Revisions to the WAQSR, section 8 Ozone, effective October 15, 1998.

(E) Revisions to the WAQSR, section 9 Volatile organic compounds, effective October 15, 1998.

(F) Revisions to the WAQSR, section 10 Nitrogen oxides, subsections 10(b), 10(b)(vii), 10(b)(viii), and 10(b)(ix), excluding the words "or by an equivalent method" in subsection 10(b), effective October 15, 1998.

(G) Revisions to the WAQSR, section 14 Control of particulate emissions, subsection 14(h)(iv) excluding the sentence, "Provided that the Administrator may require that variations to said methods be included or that entirely different methods be utilized if he determines that such variations or different methods are necessary in order for the test data to reflect the actual emission rate of particulate matter," effective October 15, 1998.

(H) Revisions to the WAQSR, section 21 Permit requirements for construction, modification and operation, subsections 21(a)(vi) and 21(h), effective October 15, 1998.

(ii) Additional material.

(A) September 1, 1998 letter from Dan Olson, Administrator, Wyoming Air Quality Division, to Richard R. Long, Director, Air and Radiation Program, EPA Region 8.

(B) June 23, 2000 letter from Dan Olson, Administrator, Wyoming Air Quality Division, to Richard R. Long, Program Manager, Air and Radiation, EPA Region VIII.

[FR Doc. 00-32239 Filed 12-20-00; 8:45 am]

BILLING CODE 6560-50-P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP-301092; FRL-6760-7]

RIN 2070-AB78

Avermectin; Extension of Tolerance for Emergency Exemptions

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation re-establishes time-limited tolerances for the combined residues of the insecticide and miticide avermectin a mixture of avermectins containing greater than or equal to 80% avermectin B_{1a} (5-O-demethyl avermectin A₁) and less than or equal to 20% avermectin B_{1b} (5-O-demethyl-25-de(1-methylpropyl)-25-(1-methylethyl) avermectin A₁) and its delta-8,9-isomer in or on avocado and spinach for an additional 2-year period. These tolerances will expire and are revoked on December 31, 2002. Section 408(l)(6) of the Federal Food, Drug, and Cosmetic Act requires EPA to establish a time-limited tolerance or exemption from the requirement for a tolerance for pesticide chemical residues in food that will result from the use of a pesticide under an emergency exemption granted by EPA under section 18 of the Federal Insecticide, Fungicide, and Rodenticide Act.

DATES: This regulation is effective December 21, 2000. Objections and requests for hearings, identified by docket control number OPP-301092, must be received by EPA on or before February 20, 2001.

ADDRESSES: Written objections and hearing requests may be submitted by mail, in person, or by courier. Please follow the detailed instructions for each method as provided in Unit III. of the **SUPPLEMENTARY INFORMATION**. To ensure proper receipt by EPA, your objections and hearing requests must identify docket control number OPP-301092 in the subject line on the first page of your response.

FOR FURTHER INFORMATION CONTACT: By mail: Dan Rosenblatt, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460; telephone number: (703) 308-9375; and e-mail address: rosenblatt.dan@epa.gov.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

You may be affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. Potentially affected categories and entities may include, but are not limited to:

Categories	NAICS codes	Examples of potentially affected entities
Industry	111 112 311	Crop production Animal production Food manufacturing

Categories	NAICS codes	Examples of potentially affected entities
	32532	Pesticide manufacturing

This listing is not intended to be exhaustive, but rather provides a guide for readers regarding entities likely to be affected by this action. Other types of entities not listed in the table could also be affected. The North American Industrial Classification System (NAICS) codes have been provided to assist you and others in determining whether or not this action might apply to certain entities. If you have questions regarding the applicability of this action to a particular entity, consult the person listed under **FOR FURTHER INFORMATION CONTACT**.

B. How Can I Get Additional Information, Including Copies of this Document and Other Related Documents?

1. *Electronically.* You may obtain electronic copies of this document, and certain other related documents that might be available electronically, from the EPA Internet Home Page at <http://www.epa.gov/>. To access this document, on the Home Page select "Laws and Regulations," "Regulations and Proposed Rules," and then look up the entry for this document under the "Federal Register—Environmental Documents." You can also go directly to the **Federal Register** listings at <http://www.epa.gov/fedrgstr/>.

2. *In person.* The Agency has established an official record for this action under docket control number OPP-301092. The official record consists of the documents specifically referenced in this action, and other information related to this action, including any information claimed as Confidential Business Information (CBI). This official record includes the documents that are physically located in the docket, as well as the documents that are referenced in those documents. The public version of the official record does not include any information claimed as CBI. The public version of the official record, which includes printed, paper versions of any electronic comments submitted during an applicable comment period is available for inspection in the Public Information and Records Integrity Branch (PIRIB), Rm. 119, Crystal Mall #2, 121 Jefferson Davis Hwy., Arlington, VA, from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The PIRIB telephone number is (703) 305-5805.

II. Background and Statutory Findings

EPA issued a final rule, published in the **Federal Register** of August 19, 1997 (62 FR 44089) (FRL-5737-1), which announced that on its own initiative under section 408 of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a, as amended by the Food Quality Protection Act of 1996 (FQPA) (Public Law 104-170) it established a time-limited tolerance for the combined residues of avermectin and its delta-8,9-isomer in or on spinach at 0.05 ppm, with an expiration date of July 31, 1998. In the **Federal Register** of August 7, 1998 (63 FR 42246) (FRL-6021-2), this time-limited tolerance was subsequently extended to be effective through January 31, 2000. EPA established the tolerance because section 408(l)(6) of the FFDCA requires EPA to establish a time-limited tolerance or exemption from the requirement for a tolerance for pesticide chemical residues in food that will result from the use of a pesticide under an emergency exemption granted by EPA under section 18 of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). Such tolerances can be established without providing notice or period for public comment. In a separate rule, published in the **Federal Register** of April 7, 1999 (64 FR 16843) (FRL-6070-6), EPA established a time-limited tolerance for the combined residues of avermectin and its delta-8,9-isomer in or on avocado at 0.02 ppm, with an expiration date of September 20, 2000.

EPA received requests to extend the use of avermectin on avocado and spinach for this year's growing seasons for these crops. After having reviewed the submissions, EPA concurs that emergency conditions still exist this year. The nature of the emergency with regard to avocado production involves the continued threat and yield losses posed by thrips. With regard to spinach, this exemption application is submitted in order to respond to the damage posed by leafminers to this crop.

EPA has assessed the potential risks presented by residues of avermectin in or on avocado and spinach. In doing so, EPA considered the safety standard in FFDCA section 408(b)(2), and decided that the necessary tolerance under FFDCA section 408(l)(6) would be consistent with the safety standard and with FIFRA section 18. The data and other relevant material have been evaluated and discussed in the final rules of August 19, 1997 (62 FR 44089) (FRL-5737-1), for spinach and April 7, 1999 (64 FR 16843) (FRL-6070-6) for avocado. Based on that data and information considered, the Agency reaffirms that the re-establishment of the

time-limited tolerances will continue to meet the requirements of section 408(l)(6). Therefore, the time-limited tolerances are re-established for an additional 2-year period. EPA will publish a document in the **Federal Register** to remove the revoked tolerance from the Code of Federal Regulations (CFR). Although this tolerance will expire and is revoked on December 31, 2002, under FFDCA section 408(l)(5), residues of the pesticide not in excess of the amounts specified in the tolerances remaining in or on avocado and spinach after that date will not be unlawful, provided the pesticide is applied in a manner that was lawful under FIFRA and the application occurred prior to the revocation of the tolerance. EPA will take action to revoke these tolerances earlier if any experience with, scientific data on, or other relevant information on this pesticide indicate that the residues are not safe.

III. Objections and Hearing Requests

Under section 408(g) of the FFDCA, as amended by the FQPA, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. The EPA procedural regulations which govern the submission of objections and requests for hearings appear in 40 CFR part 178. Although the procedures in those regulations require some modification to reflect the amendments made to the FFDCA by the FQPA of 1996, EPA will continue to use those procedures, with appropriate adjustments, until the necessary modifications can be made. The new section 408(g) provides essentially the same process for persons to "object" to a regulation for an exemption from the requirement of a tolerance issued by EPA under new section 408(d), as was provided in the old FFDCA sections 408 and 409. However, the period for filing objections is now 60 days, rather than 30 days.

A. What Do I Need to Do to File an Objection or Request a Hearing?

You must file your objection or request a hearing on this regulation in accordance with the instructions provided in this unit and in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket control number OPP-301092 in the subject line on the first page of your submission. All requests must be in writing, and must be mailed or delivered to the Hearing Clerk on or before February 20, 2001.

1. *Filing the request.* Your objection must specify the specific provisions in the regulation that you object to, and the grounds for the objections (40 CFR

178.25). If a hearing is requested, the objections must include a statement of the factual issues(s) on which a hearing is requested, the requestor's contentions on such issues, and a summary of any evidence relied upon by the objector (40 CFR 178.27). Information submitted in connection with an objection or hearing request may be claimed confidential by marking any part or all of that information as CBI. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2. A copy of the information that does not contain CBI must be submitted for inclusion in the public record. Information not marked confidential may be disclosed publicly by EPA without prior notice.

Mail your written request to: Office of the Hearing Clerk (1900), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460. You may also deliver your request to the Office of the Hearing Clerk in Rm. C400, Waterside Mall, 401 M St., SW., Washington, DC 20460. The Office of the Hearing Clerk is open from 8 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Office of the Hearing Clerk is (202) 260-4865.

2. *Tolerance fee payment.* If you file an objection or request a hearing, you must also pay the fee prescribed by 40 CFR 180.33(i) or request a waiver of that fee pursuant to 40 CFR 180.33(m). You must mail the fee to: EPA Headquarters Accounting Operations Branch, Office of Pesticide Programs, P.O. Box 360277M, Pittsburgh, PA 15251. Please identify the fee submission by labeling it "Tolerance Petition Fees."

EPA is authorized to waive any fee requirement "when in the judgement of the Administrator such a waiver or refund is equitable and not contrary to the purpose of this subsection." For additional information regarding the waiver of these fees, you may contact James Tompkins by phone at (703) 305-5697, by e-mail at tompkins.jim@epa.gov, or by mailing a request for information to Mr. Tompkins at Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460.

If you would like to request a waiver of the tolerance objection fees, you must mail your request for such a waiver to: James Hollins, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460.

3. *Copies for the Docket.* In addition to filing an objection or hearing request with the Hearing Clerk as described in

Unit III.A., you should also send a copy of your request to the PIRIB for its inclusion in the official record that is described in Unit I.B.2. Mail your copies, identified by docket control number OPP-301092, to: Public Information and Records Integrity Branch, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460. In person or by courier, bring a copy to the location of the PIRIB described in Unit I.B.2. You may also send an electronic copy of your request via e-mail to: opp-docket@epa.gov. Please use an ASCII file format and avoid the use of special characters and any form of encryption. Copies of electronic objections and hearing requests will also be accepted on disks in WordPerfect 6.1/8.0 or ASCII file format. Do not include any CBI in your electronic copy. You may also submit an electronic copy of your request at many Federal Depository Libraries.

B. When Will the Agency Grant a Request for a Hearing?

A request for a hearing will be granted if the Administrator determines that the material submitted shows the following: There is a genuine and substantial issue of fact; there is a reasonable possibility that available evidence identified by the requestor would, if established resolve one or more of such issues in favor of the requestor, taking into account uncontested claims or facts to the contrary; and resolution of the factual issues(s) in the manner sought by the requestor would be adequate to justify the action requested (40 CFR 178.32).

IV. Regulatory Assessment Requirements

This final rule establishes a time-limited tolerance under FFDCA section 408. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled *Regulatory Planning and Review* (58 FR 51735, October 4, 1993). This final rule does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA), 44 U.S.C. 3501 *et seq.*, or impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) (Public Law 104-4). Nor does it require any prior consultation as specified by Executive Order 13084, entitled *Consultation and Coordination with Indian Tribal Governments* (63 FR 27655, May 19, 1998); special

considerations as required by Executive Order 12898, entitled *Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations* (59 FR 7629, February 16, 1994); or require OMB review or any Agency action under Executive Order 13045, entitled *Protection of Children from Environmental Health Risks and Safety Risks* (62 FR 19885, April 23, 1997). This action does not involve any technical standards that would require Agency consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act of 1995 (NTTAA), Public Law 104-113, section 12(d) (15 U.S.C. 272 note). Since tolerances and exemptions that are established on the basis of a FIFRA section 18 petition under FFDCA section 408, such as the tolerances in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*) do not apply. In addition, the Agency has determined that this action will not have a substantial direct effect on 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, as specified in Executive Order 13132, entitled *Federalism* (64 FR 43255, August 10, 1999). Executive Order 13132 requires EPA to develop an accountable process to ensure "meaningful and timely input by State and local officials in the development of regulatory policies that have federalism implications." "Policies that have federalism implications" is defined in the Executive Order to include regulations that have "substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government." This final rule directly regulates growers, food processors, food handlers and food retailers, not States. This action does not alter the relationships or distribution of power and responsibilities established by Congress in the pre-emption provisions of FFDCA section 408(n)(4).

V. Submission to Congress and the Comptroller General

The Congressional Review Act, 5 U.S.C. 801 *et seq.*, as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report, which includes a copy of the rule, to each House of the

Congress and to the Comptroller General of the United States. EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of this final rule in the **Federal Register**. This final rule is not a "major rule" as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 180

Environmental protection, Administrative practice and procedure, Agricultural commodities, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: December 12, 2000.

James Jones,

Director, Registration Division, Office of Pesticide Programs.

Therefore, 40 CFR chapter I is amended as follows:

PART 180—[AMENDED]

1. The authority citation for part 180 continues to read as follows:

Authority: 21 U.S.C. 321(q), 346(a) and 371.

§ 180.449 [Amended]

2. In § 180.449, amend the table in paragraph (b), by revising the expiration/revocation date for Avocado from "9/20/00" to read "12/31/02" and for Spinach from "1/31/00" to read "1/31/02".

[FR Doc. 00-32572 Filed 12-20-00; 8:45 am]

BILLING CODE 6560-50-S

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP-301095; FRL-6761-7]

RIN 2070-AB78

Clomazone; Pesticide Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes a tolerance for residues of clomazone in or on rice grain and rice straw. FMC Corporation requested this tolerance under the Federal Food, Drug, and Cosmetic Act, as amended by the Food Quality Protection Act of 1996.

DATES: This regulation is effective December 21, 2000. Objections and requests for hearings, identified by docket control number OPP-301095,

must be received by EPA on or before February 20, 2001.

ADDRESSES: Written objections and hearing requests may be submitted by mail, in person, or by courier. Please follow the detailed instructions for each method as provided in Unit VI. of the **SUPPLEMENTARY INFORMATION**. To ensure proper receipt by EPA, your objections and hearing requests must identify docket control number OPP-301095 in the subject line on the first page of your response.

FOR FURTHER INFORMATION CONTACT: By mail: James A. Tompkins, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460; telephone number: (703) 305-5697; and e-mail address: Tompkins.Jim@epamail.epa.gov.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

You may be affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. Potentially affected categories and entities may include, but are not limited to:

Categories	NAICS	Examples of Potentially Affected Entities
Industry	111 112 311 32532	Crop production Animal production Food manufacturing Pesticide manufacturing

This listing is not intended to be exhaustive, but rather provides a guide for readers regarding entities likely to be affected by this action. Other types of entities not listed in the table could also be affected. The North American Industrial Classification System (NAICS) codes have been provided to assist you and others in determining whether or not this action might apply to certain entities. If you have questions regarding the applicability of this action to a particular entity, consult the person listed under **FOR FURTHER INFORMATION CONTACT**.

B. How Can I Get Additional Information, Including Copies of this Document and Other Related Documents?

1. *Electronically.* You may obtain electronic copies of this document, and certain other related documents that might be available electronically, from the EPA Internet Home Page at <http://www.epa.gov/>. To access this

document, on the Home Page select "Laws and Regulations," "Regulations and Proposed Rules," and then look up the entry for this document under the "Federal Register—Environmental Documents." You can also go directly to the **Federal Register** listings at <http://www.epa.gov/fedrgstr/>. To access the OPPTS Harmonized Guidelines referenced in this document, go directly to the guidelines at <http://www.epa.gov/opptsfrs/home/guidelin.htm>.

2. *In person.* The Agency has established an official record for this action under docket control number OPP-301095. The official record consists of the documents specifically referenced in this action, and other information related to this action, including any information claimed as Confidential Business Information (CBI). This official record includes the documents that are physically located in the docket, as well as the documents that are referenced in those documents. The public version of the official record does not include any information claimed as CBI. The public version of the official record, which includes printed, paper versions of any electronic comments submitted during an applicable comment period is available for inspection in the Public Information and Records Integrity Branch (PIRIB), Rm. 119, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA, from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The PIRIB telephone number is (703) 305-5805.

II. Background and Statutory Findings

In the **Federal Register** of February 18, 1999 (64 FR 8087) (FRL-6036-4), EPA issued a notice pursuant to section 408 of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a as amended by the Food Quality

Protection Act of 1996 (FQPA) (Public Law 104-170) announcing the filing of a pesticide petition (PP 7F4896) for tolerance by FMC Corporation, 1735 Market Street, Philadelphia, PA 19103. This notice included a summary of the petition prepared by FMC Corporation, the registrant. There were no comments received in response to the notice of filing.

The petition requested that 40 CFR 180.425 be amended by establishing a tolerance for residues of the herbicide clomazone, (2-(2-chlorophenyl)methyl-4,4-dimethyl-3-isoxazolidinone), in or on the raw agricultural commodities rice grain and rice straw at 0.05 part per million (ppm). Clomazone residues were not detected any rice samples at or above the Level of Quantification (LOQ) of 0.02 ppm. EPA is therefore establishing the tolerances in or on rice grain and rice straw at 0.02 ppm rather than at the proposed tolerance level of 0.05 ppm.

Section 408(b)(2)(A)(i) of the FFDCA allows EPA to establish a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the tolerance is "safe." Section 408(b)(2)(A)(ii) defines "safe" to mean that "there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information." This includes exposure through drinking water and in residential settings, but does not include occupational exposure. Section 408(b)(2)(C) requires EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing a tolerance and to "ensure that there is a reasonable certainty that no harm will result to

infants and children from aggregate exposure to the pesticide chemical residue...."

EPA performs a number of analyses to determine the risks from aggregate exposure to pesticide residues. For further discussion of the regulatory requirements of section 408 and a complete description of the risk assessment process, see the final rule on Bifenthrin Pesticide Tolerances (62 FR 62961, November 26, 1997) (FRL-5754-7).

III. Aggregate Risk Assessment and Determination of Safety

Consistent with section 408(b)(2)(D), EPA has reviewed the available scientific data and other relevant information in support of this action. EPA has sufficient data to assess the hazards of and to make a determination on aggregate exposure, consistent with section 408(b)(2), for a tolerance for residues of clomazone on rice grain and rice straw at 0.02 ppm. EPA's assessment of exposures and risks associated with establishing the tolerance follows.

A. Toxicological Profile

EPA has evaluated the available toxicity data and considered its validity, completeness, and reliability as well as the relationship of the results of the studies to human risk. EPA has also considered available information concerning the variability of the sensitivities of major identifiable subgroups of consumers, including infants and children. The nature of the toxic effects caused by clomazone are discussed in the following Table 1 as well as the no observed adverse effect level (NOAEL) and the lowest observed adverse effect level (LOAEL) from the toxicity studies reviewed.

TABLE 1.— ACUTE, SUBCHRONIC, CHRONIC, AND OTHER TOXICITY

Guideline No.	Study Type	Results
870.1100	Acute oral rat	LD ₅₀ = 2077.0 mg/kg males 1369.0 mg/kg females Toxicity Category III
870.3100	90-Day oral toxicity in rats	No Observed Adverse Effect Level (NOAEL) = 135.2/160.9 mg/kg/day males/females Lowest Observed Adverse Effect Level (LOAEL) = 273/319.3 mg/kg/day males/females based on decreased body weight, body weight gains, food consumption and increased absolute and relative liver weights in females and increased absolute liver weights in males.
870.3100	90-Day oral toxicity in mouse	NOAEL ≥1,200 mg/kg/day (limit dose) LOAEL >1,200 mg/kg/day
870.3700a	Prenatal developmental in rats	Maternal NOAEL = 100 mg/kg/day LOAEL = 300 mg/kg/day based on chromorhinorrhea and/or abdominogenital staining Developmental NOAEL = 100 mg/kg/day

TABLE 1.— ACUTE, SUBCHRONIC, CHRONIC, AND OTHER TOXICITY—Continued

Guideline No.	Study Type	Results
		LOAEL = 300 mg/kg/day based on indications of delayed ossification in the form of either partial ossification or the absence of manubrium, sternbrae 34, xiphoid, caudal, and metcarpals.
870.3700b	Prenatal developmental in rabbits	Maternal NOAEL = 240 mg/kg/day LOAEL = 700 mg/kg/day based on effects seen at 1,000 mg/kg/day, which included mortality, abortions, decreased body wt. gain, and decreased defecation or no feces Developmental NOAEL $\geq$ 700 mg/kg/day highest dose tested (HDT) LOAEL > 700 mg/kg/day
870.3800	Two-Generation Reproduction and Fertility Effects	Parental NOAEL = 50 mg/kg/day LOAEL = 100 mg/kg/day based on statistically significantly decreased body wt. & body wt. gain during premating, and decreased body wt. during gestation & lactation males and females. In addition decreased food consumption in females and hydronephritic kidneys in males. Offspring NOAEL = 50 mg/kg/day LOAEL = 100 mg/kg/day based on decreased body weight in F2a and F2b litters
870.4100b	Chronic toxicity dogs	NOAEL $\geq$ 1,038/1012 mg/kg/day, males/females (HDT) LOAEL > 1,038/1012 mg/kg/day
870.4300	Chronic Toxicity/Carcinogenicity rats	NOAEL = 84.4/112.9 mg/kg/day, males/females (HDT) LOAEL > 84.4/112.9 mg/kg/day, males/females Classified as a "not likely human carcinogen"
870.4300	Carcinogenicity mice	NOAEL = 300 mg/kg/day (HDT) LOAEL = > 300 mg/kg/day Classified as a "not likely human carcinogen"
870.5100	Gene Mutation (<i>Salmonella typhimurium</i> and <i>Escherichia coli</i> reverse gene mutation assay)	The test article was assayed up to cytotoxic concentrations (5,000 μ g/plate), but in no instance were appreciably increased number of revertants to histidine prototrophy (his ⁺) found in any of the tester strains, either in the presence or absence of metabolic activation.
870.5395	Cytogenetics <i>In vivo</i> rat	Negative. The incidence of aberrations and the aberrations/cell were not significantly increased.
870.5550	Other Effects <i>In vitro</i> UDS assay in primary rat hepatocytes	Clomazone was tested up to cytotoxicity (relative toxicity at 0.10 μ L/mL was 88.6%), but in no cultures treated with test article was a significant increase in mean net nuclear counts indicative of UDS recorded.
870.7485	Metabolism and pharmacokinetics	Clomazone is extensively metabolized by the liver and excreted in the urine and feces within 24 hours. Sixteen metabolites, including the parent, were identified; and the predominant route of excretion was in urine.

B. Toxicological Endpoints

The dose at which no adverse effects are observed (the NOAEL) from the toxicology study identified as appropriate for use in risk assessment is used to estimate the toxicological level of concern (LOC). However, the lowest dose at which adverse effects of concern are identified (the LOAEL) is sometimes used for risk assessment if no NOAEL was achieved in the toxicology study selected. An uncertainty factor (UF) is applied to reflect uncertainties inherent in the extrapolation from laboratory animal data to humans and in the variations in sensitivity among members of the human population as well as other unknowns. An UF of 100 is

routinely used, 10X to account for interspecies differences and 10X for intra species differences.

For dietary risk assessment (other than cancer) the Agency uses the UF to calculate an acute or chronic reference dose (acute RfD or chronic RfD) where the RfD is equal to the NOAEL divided by the appropriate UF (RfD = NOAEL/UF). Where an additional safety factor is retained due to concerns unique to the FQPA, this additional factor is applied to the RfD by dividing the RfD by such additional factor. The acute or chronic Population Adjusted Dose (aPAD or cPAD) is a modification of the RfD to accommodate this type of FQPA Safety Factor.

For non-dietary risk assessments (other than cancer) the UF is used to determine the LOC. For example, when 100 is the appropriate UF (10X to account for interspecies differences and 10X for intraspecies differences) the LOC is 100. To estimate risk, a ratio of the NOAEL to exposures (margin of exposure (MOE) = NOAEL/exposure) is calculated and compared to the LOC.

The linear default risk methodology (Q*) is the primary method currently used by the Agency to quantify carcinogenic risk. The Q* approach assumes that any amount of exposure will lead to some degree of cancer risk. A Q* is calculated and used to estimate risk which represents a probability of

occurrence of additional cancer cases (e.g., risk is expressed as 1×10^{-6} or one in a million). EPA's Hazard Identification Assessment Review Committee (HIARC) classified clomazone as a not likely human

carcinogen based on the lack of carcinogenic response in rats and mice and the lack of mutagenic concern. There is no data in the literature or structure activity relationship (SAR) information to indicate carcinogenic

potential. A cancer risk assessment is not required. A summary of the toxicological endpoints for clomazone used for human risk assessment is shown in the following Table 2:

TABLE 2.—SUMMARY OF TOXICOLOGICAL DOSE AND ENDPOINTS FOR CLOMAZONE FOR USE IN HUMAN RISK ASSESSMENT

Exposure scenario	Dose used in risk assessment, UF	FQPA SF* and level of concern for risk assessment	Study and toxicological effects
Acute Dietary (females 13-50 years of age)	Developmental NOAEL = 100 mg/kg/day UF = 100 Acute RfD = 1.0 mg/kg/day	FQPA SF = 1X aPAD = acute RfD/FQPA SF = 1.0 mg/kg/day	Developmental rat Developmental LOAEL = 300 mg/kg/day, based on delayed ossification
Acute Dietary (general population including infants and children)	A dose and endpoint were not selected for this population group because there were no effects observed in oral toxicology studies including maternal toxicity in the developmental toxicity studies in rats and rabbits that are attributable to a single exposure (dose).		
Chronic Dietary (all populations)	NOAEL = 84.4 mg/kg/day UF = 100 Chronic RfD = 0.84 mg/kg/day	FQPA SF = 1X cPAD = cRfD/FQPA SF = 0.84 mg/kg/day	Two year rat feeding study LOAEL $\leq$ 84.4 mg/kg/day (HDT) 90-day oral rat LOAEL = 319.3 mg/kg/day based on based on decreased body weight, body weight gains, food consumption and increased absolute and relative liver weights in females and increased absolute liver weights in males 2-Gen Repro. LOAEL = 100 mg/kg/day based on statistically significantly decreased body wt. & body wt. gain during pre-mating, and decreased body wt. during gestation & lactation M & F. In addition decreased food consumption in females and hydro-nephritic kidneys in males.
Oral, Short-term (1-7 days) (Residential)	No residential uses. An endpoint was not proposed/selected.		
Oral, Intermediate-term (1 week - several months) (Residential)	No residential uses. An endpoint was not proposed/selected.		

*The reference to the FQPA Safety Factor refers to any additional safety factor retained due to concerns unique to the FQPA.

C. Exposure Assessment

1. *Dietary exposure from food and feed uses.* Tolerances have been established (40 CFR 180.425) for the residues of clomazone, in or on a variety of raw agricultural commodities. Risk assessments were conducted by EPA to assess dietary exposures from clomazone in food as follows:

i. *Acute exposure.* Acute dietary risk assessments are performed for a food-use pesticide if a toxicological study has indicated the possibility of an effect of concern occurring as a result of a one day or single exposure. The Dietary Exposure Evaluation Model (DEEMTM) analysis evaluated the individual food consumption as reported by respondents in the USDA 1989–1992 nationwide Continuing Surveys of Food

Intake by Individuals (CSFII) and accumulated exposure to the chemical for each commodity. The following assumptions were made for the acute exposure assessments: An acute analysis was performed for females 1350 years old using existing and recommended tolerance level residues and 100% of the crop treatment information. The aPAD for females 13-50 years old is 1.0 mg/kg/day.

ii. *Chronic exposure.* In conducting this chronic dietary risk assessment the Dietary Exposure Evaluation Model (DEEMTM) analysis evaluated the individual food consumption as reported by respondents in the USDA 1989–1992 nationwide Continuing Surveys of Food Intake by Individuals (CSFII) and accumulated exposure to

the chemical for each commodity. The following assumptions were made for the chronic exposure assessments: A chronic analysis was performed for the general U.S. population using existing and recommended tolerance level residues and 100% of the crop treatment information. The cPAD for the general U.S. population and all population subgroups is 0.84 mg/kg/day.

iii. *Cancer.* Based on the lack of carcinogenic response in rats and mice and the lack of mutagenic effects, and that there is no data in the literature or SAR information to indicate carcinogenic potential, EPA does not consider clomazone to pose a cancer risk.

2. *Dietary exposure from drinking water.*

The Agency lacks sufficient monitoring exposure data to complete a comprehensive dietary exposure analysis and risk assessment for clomazone in drinking water. Because the Agency does not have comprehensive monitoring data, drinking water concentration estimates are made by reliance on simulation or modeling taking into account data on the physical characteristics of clomazone and its major environmental degradate, N-[(2-chlorophenol)methyl]-3-hydroxy-2, 2-dimethyl propanamide.

The Agency uses the Generic Estimated Environmental Concentration (GENEEC) or the Pesticide Root Zone/Exposure Analysis Modeling System (PRZM/EXAMS) to estimate pesticide concentrations in surface water and SCI-GROW, which predicts pesticide concentrations in groundwater. In general, EPA will use GENEEC (a tier 1 model) before using PRZM/EXAMS (a tier 2 model) for a screening level assessment for surface water. The GENEEC model is a subset of the PRZM/EXAMS model that uses a specific highend runoff scenario for pesticides. GENEEC incorporates a farm pond scenario, while PRZM/EXAMS incorporate an index reservoir environment in place of the previous pond scenario. The PRZM/EXAMS model includes a percent crop area factor as an adjustment to account for the maximum percent crop coverage within a watershed or drainage basin.

None of these models include consideration of the impact processing (mixing, dilution, or treatment) of raw water for distribution as drinking water would likely have on the removal of pesticides from the source water. The primary use of these models by the Agency at this stage is to provide a coarse screen for sorting out pesticides for which it is highly unlikely that drinking water concentrations would ever exceed human health levels of concern.

Since the models used are considered to be screening tools in the risk assessment process, the Agency does not use estimated environmental concentrations (EECs) from these models to quantify drinking water exposure and risk as a %RfD or %PAD. Instead drinking water levels of comparison (DWLOCs) are calculated and used as a point of comparison against the model estimates of a pesticide's concentration in water. DWLOCs are theoretical upper limits on a pesticide's concentration in drinking water in light of total aggregate exposure to a pesticide in food, and from residential uses. Since DWLOCs address total aggregate exposure to clomazone

they are further discussed in the aggregate risk sections below.

Based on the GENEEC and SCI-GROW2 models the estimated environmental concentrations (EECs) of both clomazone and N-[(2-chlorophenol)methyl]-3-hydroxy-2, 2-dimethyl propanamide for acute exposures are estimated to be 95 parts per billion (ppb) for surface water and 2.4 ppb for ground water. The EECs for chronic exposures are estimated to be 23 ppb for surface water and 2.4 ppb for ground water.

3. *From non-dietary exposure.* The term "residential exposure" is used in this document to refer to non-occupational, non-dietary exposure (e.g., for lawn and garden pest control, indoor pest control, termiticides, and flea and tick control on pets).

Clomazone is not registered for use on any sites that would result in residential exposure.

4. *Cumulative exposure to substances with a common mechanism of toxicity.* Section 408(b)(2)(D)(v) requires that, when considering whether to establish, modify, or revoke a tolerance, the Agency consider "available information" concerning the cumulative effects of a particular pesticide's residues and "other substances that have a common mechanism of toxicity."

EPA does not have, at this time, available data to determine whether clomazone has a common mechanism of toxicity with other substances or how to include this pesticide in a cumulative risk assessment. Unlike other pesticides for which EPA has followed a cumulative risk approach based on a common mechanism of toxicity, clomazone does not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has not assumed that clomazone has a common mechanism of toxicity with other substances. For information regarding EPA's efforts to determine which chemicals have a common mechanism of toxicity and to evaluate the cumulative effects of such chemicals, see the final rule for Bifenthrin Pesticide Tolerances (62 FR 62961, November 26, 1997).

D. Safety Factor for Infants and Children

1. *In general.* FFDCA section 408 provides that EPA shall apply an additional tenfold margin of safety for infants and children in the case of threshold effects to account for prenatal and postnatal toxicity and the completeness of the data base on toxicity and exposure unless EPA determines that a different margin of

safety will be safe for infants and children. Margins of safety are incorporated into EPA risk assessments either directly through use of a margin of exposure (MOE) analysis or through using uncertainty (safety) factors in calculating a dose level that poses no appreciable risk to humans.

2. *Prenatal and postnatal sensitivity.* There is no quantitative or qualitative evidence of increased susceptibility of rats or rabbit fetuses to in utero exposure in developmental studies. Although there was a suggestion of susceptibility in the rat developmental study based on the presence of delayed ossification in the fetuses, EPA concluded that the fetal effects were no more severe than the maternal effects because there is no dose response relationship for delayed ossification (i.e., absence of increased incidence with increase in dose, low fetal/litter incidences, delayed ossifications were not considered to be severe, and no visceral or skeletal malformations were seen).

3. *Conclusion.* There is a complete toxicity data base for clomazone and exposure data are complete or are estimated based on data that reasonably accounts for potential exposures. Further, there is no indication of quantitative or qualitative increased susceptibility of rats or rabbits to *in utero* and/or postnatal exposure. Therefore, EPA determined that the 10X safety factor to protect infants and children should be removed (reduced to 1X).

E. Aggregate Risks and Determination of Safety

To estimate total aggregate exposure to a pesticide from food, drinking water, and residential uses, the Agency calculates DWLOCs which are used as a point of comparison against the model estimates of a pesticide's concentration in water (EECs). DWLOC values are not regulatory standards for drinking water. DWLOCs are theoretical upper limits on a pesticide's concentration in drinking water in light of total aggregate exposure to a pesticide in food and residential uses. In calculating a DWLOC, the Agency determines how much of the acceptable exposure (i.e., the PAD) is available for exposure through drinking water [e.g., allowable chronic water exposure (mg/kg/day) = cPAD (average food + residential exposure)]. This allowable exposure through drinking water is used to calculate a DWLOC.

A DWLOC will vary depending on the toxic endpoint, drinking water consumption, and body weights. Default body weights and consumption values as used by the USEPA Office of Water

are used to calculate DWLOCs: 2L/70 kg (adult male), 2L/60 kg (adult female), and 1L/10 kg (child). Default body weights and drinking water consumption values vary on an individual basis. This variation will be taken into account in more refined screening level and quantitative drinking water exposure assessments. Different populations will have different DWLOCs. Generally, a DWLOC is calculated for each type of risk assessment used: acute, short-term, intermediate-term, chronic, and cancer.

When EECs for surface water and groundwater are less than the calculated

DWLOCs, OPP concludes with reasonable certainty that exposures to the pesticide in drinking water (when considered along with other sources of exposure for which OPP has reliable data) would not result in unacceptable levels of aggregate human health risk at this time. Because OPP considers the aggregate risk resulting from multiple exposure pathways associated with a pesticide's uses, levels of comparison in drinking water may vary as those uses change. If new uses are added in the future, OPP will reassess the potential impacts of residues of the pesticide in

drinking water as a part of the aggregate risk assessment process.

1. *Acute risk.* Using the exposure assumptions discussed in this unit for acute exposure, the acute dietary exposure from food to clomazone will occupy less than 1% of the aPAD for females 13 years and older. In addition, there is potential for acute dietary exposure to clomazone in drinking water. After calculating DWLOCs and comparing them to the EECs for surface and ground water, EPA does not expect the aggregate exposure to exceed 100% of the aPAD, as shown in the following Table 3:

TABLE 3.— AGGREGATE RISK ASSESSMENT FOR ACUTE EXPOSURE TO CLOMAZONE

Population Subgroup	aPAD (mg/kg)	% aPAD (Food)	Surface Water EEC (ppb)	Ground Water EEC (ppb)	Acute DWLOC (ppb)
Females 13-50 yrs old	1	< 1	95	2.4	30,000

2. *Chronic risk.* Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that exposure to clomazone from food will utilize less than 1% of the cPAD for the U.S. population, less than 1% of the cPAD for all infants (less than 1 year

old) and less than 1% of the cPAD for children 1-6 years old. There are no residential uses for clomazone that result in chronic residential exposure to clomazone. In addition, there is potential for chronic dietary exposure to clomazone in drinking water. After

calculating DWLOCs and comparing them to the EECs for surface and ground water, EPA does not expect the aggregate exposure to exceed 100% of the cPAD, as shown in the following Table 4:

TABLE 4.— AGGREGATE RISK ASSESSMENT FOR CHRONIC (NON-CANCER) EXPOSURE TO CLOMAZONE

Population Subgroup	cPAD mg/kg/day	% cPAD (Food)	Surface Water EEC (ppb)	Ground Water EEC (ppb)	Chronic DWLOC (ppb)
U.S. Population	0.84	<1	23	2.4	29,000
All infants (< 1 year old)	0.84	<1	23	2.4	8,400
Children (1-6 years old)	0.84	<1	23	2.4	8,400
Females (13-50 years old)	0.84	<1	23	2.4	25,000

3. *Short-term risk.* Short-term aggregate exposure takes into account residential exposure plus chronic exposure to food and water (considered to be a background exposure level). Clomazone is not registered for use on any sites that would result in residential exposure. Therefore, the aggregate risk is the sum of the risk from food and water, which do not exceed the Agency's level of concern.

4. *Intermediate-term risk.* Intermediate-term aggregate exposure takes into account residential exposure plus chronic exposure to food and water (considered to be a background exposure level).

Clomazone is not registered for use on any sites that would result in residential exposure. Therefore, the aggregate risk is the sum of the risk from food and water, which do not exceed the Agency's level of concern.

5. *Aggregate cancer risk for U.S. population.* Based on the lack of carcinogenic response in rats and mice and the lack of mutagenic effects, and that there is no data in the literature or SAR information to indicate carcinogenic potential, no cancer risk is posed.

6. *Determination of safety.* Based on these risk assessments, EPA concludes that there is a reasonable certainty that no harm will result to the general population and to infants and children from aggregate exposure to clomazone residues.

IV. Other Considerations

A. Analytical Enforcement Methodology

Adequate enforcement methodology (gas chromatography) is available to enforce the tolerance expression. A confirmatory procedure (GC/MSSIM) is available (Method I, PAM II).

The method may be requested from: Calvin Furlow, PRRIB, IRSD (7502C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW, Washington, DC 20460; telephone number: (703) 305-5229; email address: furlow.calvin@epa.gov.

B. International Residue Limits

There are no Codex Alimentarius Commission (Codex) Maximum Residue Levels (MRLs), nor Canadian or Mexican limits for residues for clomazone in/on rice grain or rice straw.

V. Conclusion

Therefore, the tolerance is established for residues of clomazone, (2-(2-chlorophenyl)methyl-4,4-dimethyl-3-isoxazolidinone), in or on rice grain and rice straw at 0.02 ppm.

VI. Objections and Hearing Requests

Under section 408(g) of the FFDCA, as amended by the FQPA, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. The EPA procedural regulations which govern the submission of objections and requests for hearings appear in 40 CFR part 178. Although the procedures in those regulations require some modification to reflect the amendments made to the FFDCA by the FQPA of 1996, EPA will continue to use those procedures, with appropriate adjustments, until the necessary modifications can be made. The new section 408(g) provides essentially the same process for persons to "object" to a regulation for an exemption from the requirement of a tolerance issued by EPA under new section 408(d), as was provided in the old FFDCA sections 408 and 409. However, the period for filing objections is now 60 days, rather than 30 days.

A. What Do I Need to Do to File an Objection or Request a Hearing?

You must file your objection or request a hearing on this regulation in accordance with the instructions provided in this unit and in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket control number OPP-301095 in the subject line on the first page of your submission. All requests must be in writing, and must be mailed or delivered to the Hearing Clerk on or before February 20, 2001.

1. *Filing the request.* Your objection must specify the specific provisions in the regulation that you object to, and the grounds for the objections (40 CFR 178.25). If a hearing is requested, the objections must include a statement of the factual issues(s) on which a hearing is requested, the requestor's contentions on such issues, and a summary of any evidence relied upon by the objector (40 CFR 178.27). Information submitted in connection with an objection or hearing request may be claimed confidential by marking any part or all of that information as CBI. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2. A copy of the information that does not contain CBI must be submitted for inclusion in the public record. Information not marked confidential may be disclosed publicly by EPA without prior notice. Please mail your written request to: Office of the Hearing Clerk (1900), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460. You may also deliver your request to the Office of the Hearing Clerk in Rm. C400,

Waterside Mall, 401 M St., SW., Washington, DC 20460. The Office of the Hearing Clerk is open from 8 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Office of the Hearing Clerk is (202) 260-4865.

2. *Tolerance fee payment.* If you file an objection or request a hearing, you must also pay the fee prescribed by 40 CFR 180.33(i) or request a waiver of that fee pursuant to 40 CFR 180.33(m). You must mail the fee to: EPA Headquarters Accounting Operations Branch, Office of Pesticide Programs, P.O. Box 360277M, Pittsburgh, PA 15251. Please identify the fee submission by labeling it "Tolerance Petition Fees."

EPA is authorized to waive any fee requirement "when in the judgement of the Administrator such a waiver or refund is equitable and not contrary to the purpose of this subsection." For additional information regarding the waiver of these fees, you may contact James Tompkins by phone at (703) 305-5697, by email at tomkins.jim@epa.gov, or by mailing a request for information to Mr. Tompkins at Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460.

If you would like to request a waiver of the tolerance objection fees, you must mail your request for such a waiver to: James Hollins, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460.

3. *Copies for the Docket.* In addition to filing an objection or hearing request with the Hearing Clerk as described in Unit VI.A., you should also send a copy of your request to the PIRIB for its inclusion in the official record that is described in Unit I.B.2. Mail your copies, identified by docket control number OPP-301095, to: Public Information and Records Integrity Branch, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460. In person or by courier, bring a copy to the location of the PIRIB described in Unit I.B.2. You may also send an electronic copy of your request via e-mail to: opp-docket@epa.gov. Please use an ASCII file format and avoid the use of special characters and any form of encryption. Copies of electronic objections and hearing requests will also be accepted on disks in WordPerfect 6.1/8.0 or ASCII file format. Do not include any CBI in your electronic copy. You may also submit an electronic copy of your

request at many Federal Depository Libraries.

B. When Will the Agency Grant a Request for a Hearing?

A request for a hearing will be granted if the Administrator determines that the material submitted shows the following: There is a genuine and substantial issue of fact; there is a reasonable possibility that available evidence identified by the requestor would, if established resolve one or more of such issues in favor of the requestor, taking into account uncontested claims or facts to the contrary; and resolution of the factual issues(s) in the manner sought by the requestor would be adequate to justify the action requested (40 CFR 178.32).

VII. Regulatory Assessment Requirements

This final rule establishes a tolerance under FFDCA section 408(d) in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled *Regulatory Planning and Review* (58 FR 51735, October 4, 1993). This final rule does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA), 44 U.S.C. 3501 *et seq.*, or impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) (Public Law 104-4). Nor does it require any prior consultation as specified by Executive Order 13084, entitled *Consultation and Coordination with Indian Tribal Governments* (63 FR 27655, May 19, 1998); special considerations as required by Executive Order 12898, entitled *Federal Actions to Address Environmental Justice in Minority Populations and Low Income Populations* (59 FR 7629, February 16, 1994); or require OMB review or any Agency action under Executive Order 13045, entitled *Protection of Children from Environmental Health Risks and Safety Risks* (62 FR 19885, April 23, 1997). This action does not involve any technical standards that would require Agency consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act of 1995 (NTTAA), Public Law 104-113, section 12(d) (15 U.S.C. 272 note). Since tolerances and exemptions that are established on the basis of a petition under FFDCA section 408(d), such as the tolerance in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory

Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*) do not apply. In addition, the Agency has determined that this action will not have a substantial direct effect on 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, as specified in Executive Order 13132, entitled *Federalism* (64 FR 43255, August 10, 1999). Executive Order 13132 requires EPA to develop an accountable process to ensure "meaningful and timely input by State and local officials in the development of regulatory policies that have federalism implications." "Policies that have federalism implications" is defined in the Executive Order to include regulations that have "substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government." This final rule directly regulates growers, food processors, food handlers and food retailers, not States. This action does not alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of FFDCA section 408(n)(4).

VIII. Submission to Congress and the Comptroller General

The Congressional Review Act, 5 U.S.C. 801 *et seq.*, as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report, which includes a copy of the rule, to each House of the Congress and to the Comptroller General of the United States. EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of this final rule in the **Federal Register**. This final rule is not a "major rule" as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 180

Environmental protection, Administrative practice and procedure, Agricultural commodities, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: December 13, 2000.

James Jones,

Director, Registration Division, Office of Pesticide Programs.

Therefore, 40 CFR chapter I is amended as follows:

PART 180—[AMENDED]

1. The authority citation for part 180 continues to read as follows:

Authority: 21 U.S.C. 321(q), 346(a) and 371.

§ 180.425 [Amended]

2. Section 180.425 is amended by alphabetically adding commodities to the table in paragraph (a) to read as follows:

Commodity			Parts per million	
*	*	*	*	*
Rice, grain			0.02	
Rice, straw			0.02	
*	*	*	*	*

[FR Doc. 00-32571 Filed 12-20-01; 8:45 am]

BILLING CODE 6560-50-S

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP-301087; FRL-6758-1]

RIN 2070-AB78

Thiamethoxam; Pesticide Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for combined residues of thiamethoxam and its metabolite in or on barley, canola, cotton, sorghum, wheat, milk, and the meat and meat byproducts of cattle, goats, hogs, horses, and sheep. Novartis Crop Protection, Inc. requested this tolerance under the Federal Food, Drug, and Cosmetic Act, as amended by the Food Quality Protection Act of 1996.

DATES: This regulation is effective December 21, 2000. Objections and requests hearings, identified by docket control number OPP-301087, must be received by EPA on or before February 20, 2001.

ADDRESSES: Written objections and hearing requests may be submitted by mail, in person, or by courier. Please follow the detailed instructions for each method as provided in Unit VI. of the **SUPPLEMENTARY INFORMATION**. To ensure proper receipt by EPA, your objections and hearing requests must identify docket control number OPP-301087 in the subject line on the first page of your response.

FOR FURTHER INFORMATION CONTACT By mail: Dani Daniel, Registration Division

(7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460; telephone number: (703) 305-5409; and e-mail address: daniel.dani@epa.gov.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

You may be affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. Potentially affected categories and entities may include, but are not limited to:

Categories	NAICS codes	Examples of potentially affected entities
Industry	111 112 311 32532	Crop production Animal production Food manufacturing Pesticide manufacturing

This listing is not intended to be exhaustive, but rather provides a guide for readers regarding entities likely to be affected by this action. Other types of entities not listed in the table could also be affected. The North American Industrial Classification System (NAICS) codes have been provided to assist you and others in determining whether or not this action might apply to certain entities. If you have questions regarding the applicability of this action to a particular entity, consult the person listed under **FOR FURTHER INFORMATION CONTACT**.

B. How Can I Get Additional Information, Including Copies of this Document and Other Related Documents?

1. *Electronically.* You may obtain electronic copies of this document, and certain other related documents that might be available electronically, from the EPA Internet Home Page at <http://www.epa.gov/>. To access this document, on the Home Page select "Laws and Regulations", "Regulations and Proposed Rules," and then look up the entry for this document under the "Federal Register—Environmental Documents." You can also go directly to the **Federal Register** listings at <http://www.epa.gov/fedrgstr/>. To access the OPPTS Harmonized Guidelines referenced in this document, go directly to the guidelines at <http://www.epa.gov/opptsfrs/home/guidelin.htm>.

2. *In person.* The Agency has established an official record for this action under docket control number OPP-301087. The official record consists of the documents specifically referenced in this action, and other information related to this action, including any information claimed as Confidential Business Information (CBI). This official record includes the documents that are physically located in the docket, as well as the documents that are referenced in those documents. The public version of the official record does not include any information claimed as CBI. The public version of the official record, which includes printed, paper versions of any electronic comments submitted during an applicable comment period is available for inspection in the Public Information and Records Integrity Branch (PIRIB), Rm. 119, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA, from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The PIRIB telephone number is (703) 305-5805.

II. Background and Statutory Findings

In the *Federal Register* of May 5, 1999 (64 FR 24153) (FRL-6072-7), EPA issued a notice pursuant to section 408 of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a as amended by the Food Quality Protection Act of 1996 (FQPA) (Public Law 104-170) announcing the filing of a pesticide petition (9F5046 and 9F5051) for tolerance by Novartis Crop Protection, P. O. Box 18300 Greensboro, NC 27419-8300. This notice included a summary of the petition prepared by Novartis Crop Protection, the registrant. There were no comments received in response to the notice of filing.

The petitions requested that 40 CFR part 180 be amended by establishing tolerances for the combined residues of the insecticide thiamethoxam, ([3-[(2-chloro-5-thiazolyl)methyl]tetrahydro-5-methyl-*N*-nitro-4*H*-1,3,5-oxadiazin-4-imine) and its CGA-322704 metabolite (*N*-(2-chloro-thiazol-5-ylmethyl)-*N'*-

methyl-*N*-nitro-guanidine) in or on the raw agricultural commodity rapeseed (canola), tuberous and corm vegetables crop subgroup, barley grain, sorghum grain, sorghum forage, sorghum stover, wheat grain, wheat hay, wheat straw, and milk at 0.02 ppm; barley straw at 0.03 ppm; barley hay at 0.05 ppm; undelinted cottonseed at 0.10 ppm; cucurbit vegetables crop group, and pome fruit crop group at 0.20 ppm; fruiting vegetables crop group at 0.25 ppm; wheat forage at 0.50 ppm; tomato paste at 0.80 ppm; head and stem Brassica vegetables crop subgroup at 1.00 ppm; cotton gin byproducts at 1.50 ppm; leafy vegetables crop group, and leafy Brassica greens crop subgroup at 2.00 parts per million (ppm). In addition, meat of cattle, goats, hogs, horses, and sheep at 0.02 ppm and meat byproducts of cattle, goats, hogs, horses, and sheep at 0.02 ppm.

Section 408(b)(2)(A)(i) of the FFDCA allows EPA to establish a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the tolerance is "safe." Section 408(b)(2)(A)(ii) defines "safe" to mean that "there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information." This includes exposure through drinking water and in residential settings, but does not include occupational exposure. Section 408(b)(2)(C) requires EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing a tolerance and to "ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue...."

EPA performs a number of analyses to determine the risks from aggregate exposure to pesticide residues. For further discussion of the regulatory requirements of section 408 and a

complete description of the risk assessment process, see the final rule on Bifenthrin Pesticide Tolerances (62 FR 62961, November 26, 1997) (FRL-5754-7).

III. Aggregate Risk Assessment and Determination of Safety

Consistent with section 408(b)(2)(D), EPA has reviewed the available scientific data and other relevant information in support of this action. EPA has sufficient data to assess the hazards of and to make a determination on aggregate exposure, consistent with section 408(b)(2), for tolerances for the combined residues of thiamethoxam and its metabolite in or on barley grain at 0.02 ppm; barley hay at 0.05 ppm; barley straw at 0.03 ppm; undelinted cottonseed at 0.10 ppm; cotton gin byproducts at 1.5 ppm; sorghum forage at 0.02 ppm; sorghum grain at 0.02 ppm; sorghum stover at 0.02 ppm; wheat forage at 0.50 ppm; wheat grain at 0.02 ppm; wheat hay at 0.02 ppm; wheat straw at 0.02 ppm; milk at 0.02 ppm; meat of cattle, goats, hogs, horses, and sheep at 0.02 ppm; meat byproducts of cattle, goats, hogs, horses, and sheep at 0.02 ppm respectively. EPA's assessment of exposures and risks associated with establishing the tolerance follows.

A. Toxicological Profile

EPA has evaluated the available toxicity data and considered its validity, completeness, and reliability as well as the relationship of the results of the studies to human risk. EPA has also considered available information concerning the variability of the sensitivities of major identifiable subgroups of consumers, including infants and children. The nature of the toxic effects caused by thiamethoxam are discussed in the following Table 1 as well as the no observed adverse effect level (NOAEL) and the lowest observed adverse effect level (LOAEL) from the toxicity studies reviewed.

TABLE 1.—SUBCHRONIC, CHRONIC AND OTHER TOXICITY

Guideline No.	Study Type	Results
870.3100	90-Day oral toxicity - rat	NOAEL = 1.74 (males), 92.5 (females) mg/kg/day LOAEL = 17.64 (males), 182.1 (females) mg/kg/day based on increased incidence of hyaline change of renal tubular epithelium (males), fatty change in adrenal gland of females, liver changes in females, all at the LOAEL.

TABLE 1.—SUBCHRONIC, CHRONIC AND OTHER TOXICITY—Continued

Guideline No.	Study Type	Results
870.3100	90-Day oral toxicity - mouse	NOAEL = 1.41 (males), 19.2 (females) mg/kg/day LOAEL = 14.3 (males), 231 (females) mg/kg/day based on increased incidence of hepatocellular hypertrophy. At higher dose levels: decrease in body weight and body weight gain, necrosis of individual hepatocytes, pigmentation of Kupffer cells, and lymphocytic infiltration of the liver in both sexes; slight hematologic effects and decreased absolute and relative kidney weights in males; and ovarian atrophy, decreased ovary and spleen weights, and increased liver weights in females.
870.3150	90-Day oral toxicity - dog	NOAEL = 8.23 (males), 9.27 (females) mg/kg/day LOAEL = 32.0 (males), 33.9 (females) mg/kg/day based on slightly prolonged prothrombin times and decreased plasma albumin and A/G ratio (both sexes); decreased calcium levels and ovary weights and delayed maturation in the ovaries (females); decreased cholesterol and phospholipid levels, testis weights, spermatogenesis, and occurrence of spermatic giant cells in testes (males).
870.3200	28-Day dermal toxicity - rat	NOAEL = 250 (males), 60 (females) mg/kg/day LOAEL = 1,000 (males), 250 (females) mg/kg/day based on increased plasma glucose, triglyceride levels, and alkaline phosphatase activity and inflammatory cell infiltration in the liver and necrosis of single hepatocytes in females and hyaline change in renal tubules and a very slight reduction in body weight in males. At higher dose levels in females, chronic tubular lesions in the kidneys and inflammatory cell infiltration in the adrenal cortex were observed.
870.3700a	Prenatal developmental - rat	Maternal NOAEL = 30 mg/kg/day LOAEL = 200 mg/kg/day based on decreased body weight, body weight gain, and food consumption. Developmental NOAEL = 200 mg/kg/day LOAEL = 750 mg/kg/day based on decreased fetal body weight and an increased incidence of skeletal anomalies.
870.3700b	Prenatal developmental - rabbit	Maternal NOAEL = 50 mg/kg/day LOAEL = 150 mg/kg/day based on maternal deaths, hemorrhagic uterine contents and hemorrhagic discharge, decreased body weight and food intake during the dosing period. Developmental NOAEL = 50 mg/kg/day LOAEL = 150 mg/kg/day based on decreased fetal body weights, increased incidence of post-implantation loss and a slight increase in the incidence of a few skeletal anomalies/variations.
870.3800	Reproduction and fertility effects - rat	Parental/Systemic NOAEL = 1.84 (males), 202.06 (females) mg/kg/day LOAEL = 61.25 (males), not determined (females) mg/kg/day based on increased incidence of hyaline change in renal tubules in F ₀ and F ₁ males. Reproductive NOAEL = 0.61 (males), 202.06 (females) mg/kg/day LOAEL = 1.84 (males), not determined (females) mg/kg/day based on increased incidence and severity of tubular atrophy observed in testes of the F ₁ generation males. Offspring NOAEL = 61.25 (males), 79.20 (females) mg/kg/day LOAEL = 158.32 (males), 202.06 (females) mg/kg/day based on reduced body weight gain during the lactation period in all litters.
870.4100	Chronic toxicity - dog	NOAEL = 4.05 (males), 4.49 (females) mg/kg/day LOAEL = 21.0 (males), 24.6 (females) mg/kg/day based on increase in creatinine in both sexes, transient decrease in food consumption in females, and occasional increase in urea levels, decrease in ALT, and atrophy of seminiferous tubules in males.
870.4200	Carcinogenicity - mouse	NOAEL = 2.63 (males), 3.68 (females) mg/kg/day LOAEL = 63.8 (males), 87.6 (females) mg/kg/day based on hepatocyte hypertrophy, single cell necrosis, inflammatory cell infiltration, pigment deposition, foci of cellular alteration, hyperplasia of Kupffer cells and increased mitotic activity; also, an increase in the incidence of hepatocellular adenoma (both sexes). At higher doses, there was an increase in the incidence of hepatocellular adenocarcinoma (both sexes) and the number of animals with multiple tumors. Evidence of carcinogenicity.

TABLE 1.—SUBCHRONIC, CHRONIC AND OTHER TOXICITY—Continued

Guideline No.	Study Type	Results
870.4300	Combined chronic carcinogenicity - rat	NOAEL = 21.0 (males), 50.3 (females) mg/kg/day LOAEL = 63.0 (males), 155 (females) mg/kg/day based on increased incidence of lymphocytic infiltration of the renal pelvis and chronic nephropathy in males and decreased body weight gain, slight increase in the severity of hemosiderosis of the spleen, foci of cellular alteration in liver and chronic tubular lesions in kidney in females. No evidence of carcinogenicity.
870.5100 870.5265	Gene mutation in <i>S. typhimurium</i> and <i>E. coli</i>	No evidence of gene mutation when tested up to 5,000 µg/plate. There was no evidence of cytotoxicity.
870.5265	Gene mutation in <i>S. typhimurium</i>	No evidence of gene mutation when tested up to 5,000 µg/plate. The S9 fraction was from non-induced mouse liver, Aroclor 1,254 induced mouse liver, or thiamethoxam induced mouse liver, following dietary administration of thiamethoxam for 14 days at concentrations up to 2,500 ppm.
870.5300	Gene mutation in chinese hamster V79 cells at HGPRT locus	No evidence of gene mutation when tested up to solubility limit.
870.5375	CHO cell cytogenetics	No evidence of chromosomal aberrations when tested up to cytotoxic or solubility limit concentrations.
870.5395	In vivo mouse bone marrow micronucleus	Negative when tested up to levels of toxicity in whole animals; however no evidence of target cell cytotoxicity.
870. 5550	UDS assay	Negative when tested up to precipitating concentrations.
870.6200a	Acute neurotoxicity screening battery - rat	NOAEL = 100 mg/kg/day LOAEL = 500 mg/kg/day based on drooped palpebral closure, decrease in rectal temperature and locomotor activity and increase in forelimb grip strength (males only). At higher dose levels, mortality, abnormal body tone, ptosis, impaired respiration, tremors, longer latency to first step in the open field, crouched-over posture, gait impairment, hypoarousal, decreased number of rears, uncoordinated landing during the righting reflex test, slight lacrimation (females only) and higher mean average input stimulus value in the auditory startle response test (males only).
870.6200b	Subchronic neurotoxicity screening battery - rat	NOAEL = 95.4 (males), 216.4 (females) mg/kg/day, both highest dose tested. LOAEL = not determined. No treatment-related observations at any dose level. LOAEL was not achieved. May not have been tested at sufficiently high dose levels; however, new study not required because the weight of the evidence from the other toxicity studies indicates no evidence of concern.
870.7485	Metabolism and pharmacokinetics - rat	Absorbed rapidly and extensively, widely distributed, followed by very rapid elimination, mostly in urine. Highest tissue concentrations in skeletal muscle: 10–15% of administered dose. Half life times from tissues ranged from 2–6 hours. Tissue residues after 7 days extremely low. Approximately 84–95% of administered dose excreted in urine and 2.5–6% excreted in feces within 24 hours. <0.2% detected in expired air. Most excreted as unchanged parent: 70–80% of dose. The major biotransformation reaction is cleavage of oxadiazine ring to corresponding nitroguanidine compound. Minor pathways: (1) cleavage of nitroguanidine group yielding guanidine derivative, (2) hydrolysis of guanidine group to corresponding urea, (3) demethylation of guanidine group, and (4) substitution of the chlorine of the thiazole ring by glutathione. Cleavage between thiazole- and oxadiazine ring occurs to a small extent. Glutathione derivatives prone to further degradation of the glutathione moiety resulting in various sulfur-containing metabolites (e.g. mercapturates, sulfides, and sulfoxides). Both the thiazole and oxadiazine moiety susceptible to oxidative attack. Small but measurable amounts exhaled, most probably as CO ₂ . Metabolites eliminated very rapidly. Enterohepatic circulation negligible.

TABLE 1.—SUBCHRONIC, CHRONIC AND OTHER TOXICITY—Continued

Guideline No.	Study Type	Results
870.7485	Metabolism and pharmacokinetics - mouse	Approximately 72% of administered dose excreted in the urine; 19% excreted in feces. Small but measurable amount detected in expired air (approximately 0.2% of dose). Predominant metabolites: unchanged parent (33–41% of administered dose; 2 other metabolites: 8–12% and 9–18% of administered dose. These are the same structures that were most commonly observed in rat excreta, however the proportions are quite different in mouse excreta. One additional significant metabolite (mouse R6) was isolated from feces samples. Between 30–60% of the administered dose was excreted as metabolites.
870.7600	Dermal penetration - rat	Estimates of dermal absorption were based on the sum of radioactivity in skin test site, urine, feces, blood, and carcass. Percentage dermal absorption is 27.0, highest mean dermal absorption value across all groups. This value is considered to represent the potential cumulative dermal absorption of test material that might occur after a 10 hour dermal exposure. As the study design did not permit analysis of the fate of skin bound residues, residues at skin site were included in determination of dermal absorption.
	Hepatic cell proliferation study - mouse	NOAEL = 16 (males), 20 (females) mg/kg/day LOAEL = 72 (males), 87 (females) mg/kg/day based on proliferative activity of hepatocytes. At higher dose levels, increases in absolute and relative liver wts, speckled liver, hepatocellular glycogenesis/fatty change, hepatocellular necrosis, apoptosis and pigmentation were observed.
	Replicative DNA synthesis in 28– day feeding study - male rat	NOAEL = 711 mg/kg/day (highest dose tested) LOAEL = not established. Immunohistochemical staining of liver sections from control and high-dose animals for proliferating cell nuclear antigen gave no indication for a treatment-related increase in the fraction of DNA synthesizing hepatocytes in S-phase. CGA 293343 did not stimulate hepatocyte cell proliferation in male rats.
	Special study to assess liver biochemistry in mouse	NOAEL = 17 (males), 20 (females) mg/kg/day LOAEL = 74 (males), 92 (females) mg/kg/day based on marginal to slight increases in absolute and relative liver weights, a slight increase in the microsomal protein content of the livers, moderate increases in the cytochrome P450 content, slight to moderate increases in the activity of several microsomal enzymes, slight to moderate induction of cytosolic glutathione S-transferase activity. Treatment did not affect peroxisomal fatty acid Beta-oxidation.

B. Toxicological Endpoints

The dose at which no adverse effects are observed (the NOAEL) from the toxicology study identified as appropriate for use in risk assessment is used to estimate the toxicological level of concern (LOC). However, the lowest dose at which adverse effects of concern are identified (the LOAEL) is sometimes used for risk assessment if no NOAEL was achieved in the toxicology study selected. An uncertainty factor (UF) is applied to reflect uncertainties inherent in the extrapolation from laboratory animal data to humans and in the variations in sensitivity among members of the human population as well as other unknowns. An UF of 100 is routinely used, 10X to account for interspecies differences and 10X for intraspecies differences.

For dietary risk assessment (other than cancer) the Agency uses the UF to calculate an acute or chronic reference

dose (acute RfD or chronic RfD) where the RfD is equal to the NOAEL divided by the appropriate UF ($RfD = NOAEL / UF$). Where an additional safety factor is retained due to concerns unique to the FQPA, this additional factor is applied to the RfD by dividing the RfD by such additional factor. The acute or chronic Population Adjusted Dose (aPAD or cPAD) is a modification of the RfD to accommodate this type of FQPA Safety Factor.

For non-dietary risk assessments (other than cancer) the UF is used to determine the LOC. For example, when 100 is the appropriate UF (10X to account for interspecies differences and 10X for intraspecies differences) the LOC is 100. To estimate risk, a ratio of the NOAEL to exposures (margin of exposure (MOE) = $NOAEL / \text{exposure}$) is calculated and compared to the LOC.

The linear default risk methodology (Q^*) is the primary method currently

used by the Agency to quantify carcinogenic risk. The Q^* approach assumes that any amount of exposure will lead to some degree of cancer risk. A Q^* is calculated and used to estimate risk which represents a probability of occurrence of additional cancer cases (e.g., risk is expressed as 1×10^{-6} or one in a million). Under certain specific circumstances, MOE calculations will be used for the carcinogenic risk assessment. In this non-linear approach, a “point of departure” is identified below which carcinogenic effects are not expected. The point of departure is typically a NOAEL based on an endpoint related to cancer effects though it may be a different value derived from the dose response curve. To estimate risk, a ratio of the point of departure to exposure ($MOE_{\text{cancer}} = \text{point of departure} / \text{exposures}$) is calculated. A summary of the toxicological endpoints for thiamethoxam used for human risk

assessment is shown in the following
Table 2:

TABLE 2.—SUMMARY OF TOXICOLOGICAL DOSES AND ENDPOINTS FOR THIAMETHOXAM FOR USE IN HUMAN RISK ASSESSMENT

Exposure Scenario	Dose Used in Risk Assessment, UF	FQPA SF* and Level of Concern for Risk Assessment	Study and Toxicological Effects
Acute Dietary general population including infants and children	NOAEL = 100 mg/kg/day UF = 100 Acute RfD = 1 mg/kg/day	FQPA SF = 10 aPAD = acute RfD FQPA SF = 0.1 mg/kg/day	Acute mammalian neurotoxicity study in the rat LOAEL = 500 mg/kg/day based on treatment-related neurobehavioral effects observed in the FOB and LMA testing (drooped palpebral closure, decreased rectal temperature and locomotor activity, increased forelimb grip strength)
Chronic Dietary all populations	NOAEL = 0.6 mg/kg/day UF = 100 Chronic RfD = 0.006 mg/kg/day	FQPA SF = 10 cPAD = chronic RfD FQPA SF = 0.0006 mg/kg/day	2-Generation reproduction study LOAEL = 1.8 mg/kg/day based on increased incidence and severity of tubular atrophy in testes of F ₁ generation males.
Oral Nondietary (all durations)	NOAEL = 0.6 mg/kg/day	LOC for MOE = 1,000 (Residential)	2-Generation reproduction study LOAEL = 1.8 mg/kg/day based on increased incidence and severity of tubular atrophy in testes of F ₁ generation males.
Dermal (all durations) (Residential)	Oral study NOAEL = 0.6 mg/kg/day (dermal absorption rate = 27%)	LOC for MOE = 1,000 (Residential) LOC for MOE = 100 (Occupational)	2-Generation reproduction study LOAEL = 1.8 mg/kg/day based on increased incidence and severity of tubular atrophy in testes of F ₁ generation males.
Inhalation (all durations) (Residential)	Oral study NOAEL = 0.6 mg/kg/day (inhalation absorption rate = 100%)	LOC for MOE = 1,000 (Residential) LOC for MOE = 100 (Occupational)	2-Generation reproduction study LOAEL = 1.8 mg/kg/day based on increased incidence and severity of tubular atrophy in testes of F ₁ generation males.
Cancer (oral, dermal, inhalation)	$Q_1^* \text{ (mg/kg/day)}^{-1}$ is 3.77×10^{-2}	greater than 1×10^{-6}	Likely carcinogen for humans based on increased incidence of hepatocellular adenomas and carcinomas in male and female mice. Quantification of risk based on most potent unit risk: male mouse liver adenoma and/or carcinoma combined tumor rate. The upper bound estimate of unit risk, $Q_1^* \text{ (mg/kg/day)}^{-1}$ is 3.77×10^{-2} in human equivalents.

*The reference to the FQPA Safety Factor refers to any additional safety factor retained due to concerns unique to the FQPA.

C. Exposure Assessment

1. *Dietary exposure from food and feed uses.* The dietary exposure is based on the combined residues of thiamethoxam and its metabolite in or on the following raw agricultural commodities: barley, canola, cotton,

sorghum, wheat, milk, and the meat and meat byproducts of cattle, goats, hogs, horses, and sheep. Risk assessments were conducted by EPA to assess dietary exposures from thiamethoxam and its metabolite in food as follows:

i. *Acute exposure.* Acute dietary risk assessments are performed for a food-use pesticide if a toxicological study has indicated the possibility of an effect of concern occurring as a result of a one day or single exposure. The Dietary Exposure Evaluation Model (DEEM)

analysis evaluated the individual food consumption as reported by respondents in the USDA 1989–1992 nationwide Continuing Surveys of Food Intake by Individuals (CSFII) and accumulated exposure to the chemical for each commodity. The following assumptions were made for the acute exposure assessments: tolerance level residues and 100% crop treated.

ii. *Chronic exposure.* In conducting this chronic dietary risk assessment the Dietary Exposure Evaluation Model (DEEM) analysis evaluated the individual food consumption as reported by respondents in the USDA 1989–1992 nationwide Continuing Surveys of Food Intake by Individuals (CSFII) and accumulated exposure to the chemical for each commodity. The following assumptions were made for the chronic exposure assessments: percent crop treated (based on projected market shares) and anticipated residues (Tier 3).

iii. *Cancer.* The dietary exposure for determining cancer risk is based on the chronic exposure explained in the previous paragraph using the same assumptions.

Section 408(b)(2)(E) authorizes EPA to use available data and information on the anticipated residue levels of pesticide residues in food and the actual levels of pesticide chemicals that have been measured in food. If EPA relies on such information, EPA must require that data be provided 5 years after the tolerance is established, modified, or left in effect, demonstrating that the levels in food are not above the levels anticipated. Following the initial data submission, EPA is authorized to require similar data on a time frame it deems appropriate. As required by section 408(b)(2)(E), EPA will issue a data call-in for information relating to anticipated residues to be submitted no later than 5 years from the date of issuance of this tolerance.

Section 408(b)(2)(F) states that the Agency may use data on the actual percent of food treated for assessing chronic dietary risk only if the Agency can make the following findings: Condition 1, that the data used are reliable and provide a valid basis to show what percentage of the food derived from such crop is likely to contain such pesticide residue; Condition 2, that the exposure estimate does not underestimate exposure for any significant subpopulation group; and Condition 3, if data are available on pesticide use and food consumption in a particular area, the exposure estimate does not understate exposure for the population in such area. In addition, the Agency must provide for periodic

evaluation of any estimates used. To provide for the periodic evaluation of the estimate of percent crop treated (PCT) as required by section 408(b)(2)(F), EPA may require registrants to submit data on PCT.

The Agency used percent crop treated (PCT) information as follows in Table 3.

TABLE 3.—THIAMETHOXAM USES AND ESTIMATES OF PERCENT CROP TREATED

Crop	Percent Crop Treated
Barley	1.0
Wheat	2
Canola	55
Sorghum	9
Cotton	20

The Agency used information provided by the registrant and Agency to determine percent crop treated based on projected percent market share information. The Agency believes that the procedures used were the best available, because thiamethoxam is a new chemical and has never been used. As to Conditions 2 and 3, regional consumption information and consumption information for significant subpopulations is taken into account through EPA's computer-based model for evaluating the exposure of significant subpopulations including several regional groups. Use of this consumption information in EPA's risk assessment process ensures that EPA's exposure estimate does not understate exposure for any significant subpopulation group and regional populations.

2. *Dietary exposure from drinking water.* The Agency lacks sufficient monitoring exposure data to complete a comprehensive dietary exposure analysis and risk assessment for thiamethoxam in drinking water. Because the Agency does not have comprehensive monitoring data, drinking water concentration estimates are made by reliance on simulation or modeling taking into account data on the physical characteristics of thiamethoxam.

The Agency uses the Generic Estimated Environmental Concentration (GENEEC) or the Pesticide Root Zone/Exposure Analysis Modeling System (PRZM/EXAMS) to estimate pesticide concentrations in surface water and SCIGROW, which predicts pesticide concentrations in groundwater. In general, EPA will use GENEEC (a tier 1 model) before using PRZM/EXAMS (a tier 2 model) for a screening-level assessment for surface water. The

GENEEC model is a subset of the PRZM/EXAMS model that uses a specific high-end runoff scenario for pesticides. GENEEC incorporates a farm pond scenario, while PRZM/EXAMS incorporate an index reservoir environment in place of the previous pond scenario. The PRZM/EXAMS model includes a percent crop area factor as an adjustment to account for the maximum percent crop coverage within a watershed or drainage basin.

None of these models include consideration of the impact processing (mixing, dilution, or treatment) of raw water for distribution as drinking water would likely have on the removal of pesticides from the source water. The primary use of these models by the Agency at this stage is to provide a coarse screen for sorting out pesticides for which it is highly unlikely that drinking water concentrations would ever exceed human health levels of concern.

Since the models used are considered to be screening tools in the risk assessment process, the Agency does not use estimated environmental concentrations (EECs) from these models to quantify drinking water exposure and risk as a %RfD or %PAD. Instead drinking water levels of comparison (DWLOCs) are calculated and used as a point of comparison against the model estimates of a pesticide's concentration in water. DWLOCs are theoretical upper limits on a pesticide's concentration in drinking water in light of total aggregate exposure to a pesticide in food, and from residential uses. Since DWLOCs address total aggregate exposure to thiamethoxam they are further discussed in the aggregate risk sections below.

Based on the PRZM/EXAMS and SCIGROW models the estimated environmental concentrations (EECs) of thiamethoxam for acute exposures are estimated to be 8.0 parts per billion (ppb) for surface water and 5.0 ppb for ground water. The EECs for chronic exposures are estimated to be 0.6 ppb for surface water and 5.0 ppb for ground water. These levels are extremely conservative, because they are based on foliar and seed treatment uses. These levels are anticipated to be much lower based on the seed treatment use alone.

3. *From non-dietary exposure.* The term "residential exposure" is used in this document to refer to non-occupational, non-dietary exposure (e.g., for lawn and garden pest control, indoor pest control, termiticides, and flea and tick control on pets).

Thiamethoxam is not registered for use on any sites that would result in residential exposure.

4. *Cumulative exposure to substances with a common mechanism of toxicity.* Section 408(b)(2)(D)(v) requires that, when considering whether to establish, modify, or revoke a tolerance, the Agency consider "available information" concerning the cumulative effects of a particular pesticide's residues and "other substances that have a common mechanism of toxicity."

EPA does not have, at this time, available data to determine whether thiamethoxam has a common mechanism of toxicity with other substances or how to include this pesticide in a cumulative risk assessment. Unlike other pesticides for which EPA has followed a cumulative risk approach based on a common mechanism of toxicity, thiamethoxam does not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has not assumed that thiamethoxam has a common mechanism of toxicity with other substances. For information regarding EPA's efforts to determine which chemicals have a common mechanism of toxicity and to evaluate the cumulative effects of such chemicals, see the final rule for Bifenthrin Pesticide Tolerances (62 FR 62961, November 26, 1997).

D. Safety Factor for Infants and Children

1. *Safety factor for infants and children*—i. *In general.* FFDCA section 408 provides that EPA shall apply an additional tenfold margin of safety for infants and children in the case of threshold effects to account for prenatal and postnatal toxicity and the completeness of the data base on toxicity and exposure unless EPA determines that a different margin of safety will be safe for infants and children. Margins of safety are incorporated into EPA risk assessments either directly through use of a margin of exposure (MOE) analysis or through using uncertainty (safety) factors in calculating a dose level that poses no appreciable risk to humans.

ii. *Prenatal and postnatal sensitivity.* There is not quantitative or qualitative

evidence of increased susceptibility of rat or rabbit fetus to *in utero* exposure based on the fact that the developmental NOAELs are either higher than or equal to the maternal NOAELs. The reproductive studies indicate effects in males in the form of increased incidence and severity of testicular tubular atrophy. These data are considered to be evidence of increased quantitative susceptibility for male pups when compared to the parents.

iii. *Conclusion.* Base on: (1) Effects endocrine organs observed across species (2) the significant decrease in alanine amino transferase levels in the companion animal studies and in the dog studies (3) the mode of action of this chemical in insects (interferes with the nicotinic acetyl choline receptors of the insect's nervous system) thus a developmental neurotoxicity study is required); (4) the transient clinical signs of neurotoxicity in several studies across the species; and (5) the suggestive evidence of increased quantitative susceptibility in the rat reproduction study, the Agency is retaining the FQPA factor which is 10X.

E. Aggregate Risks and Determination of Safety

To estimate total aggregate exposure to a pesticide from food, drinking water, and residential uses, the Agency calculates DWLOCs which are used as a point of comparison against the model estimates of a pesticide's concentration in water (EECs). DWLOC values are not regulatory standards for drinking water. DWLOCs are theoretical upper limits on a pesticide's concentration in drinking water in light of total aggregate exposure to a pesticide in food and residential uses. In calculating a DWLOC, the Agency determines how much of the acceptable exposure (i.e., the PAD) is available for exposure through drinking water e.g., allowable chronic water exposure (mg/kg/day) = cPAD - (average food + residential exposure). This allowable exposure through drinking water is used to calculate a DWLOC.

A DWLOC will vary depending on the toxic endpoint, drinking water consumption, and body weights. Default body weights and consumption values as used by the USEPA Office of Water are used to calculate DWLOCs: 2L/70 kg (adult male), 2L/60 kg (adult female),

and 1L/10 kg (child). Default body weights and drinking water consumption values vary on an individual basis. This variation will be taken into account in more refined screening-level and quantitative drinking water exposure assessments. Different populations will have different DWLOCs. Generally, a DWLOC is calculated for each type of risk assessment used: acute, short-term, intermediate-term, chronic, and cancer.

When EECs for surface water and groundwater are less than the calculated DWLOCs, OPP concludes with reasonable certainty that exposures to the pesticide in drinking water (when considered along with other sources of exposure for which OPP has reliable data) would not result in unacceptable levels of aggregate human health risk at this time. Because OPP considers the aggregate risk resulting from multiple exposure pathways associated with a pesticide's uses, levels of comparison in drinking water may vary as those uses change. If new uses are added in the future, OPP will reassess the potential impacts of residues of the pesticide in drinking water as a part of the aggregate risk assessment process.

1. *Acute risk.* Using the exposure assumptions discussed in this unit for acute exposure, the acute dietary exposure from food to thiamethoxam will occupy 1% of the aPAD for the U.S. population, <1 of the aPAD for females 13 years and older, 1% of the aPAD for all infants <1 year and 2% of the aPAD for children 1–6 years. In addition, there is potential for acute dietary exposure to thiamethoxam in drinking water. The surface water EEC is 8.0 µg/L and the ground water EEC is 5.0 µg/L. The estimated EEC levels are very conservative, because they are based on both foliar uses and seed treatment applications. Since the surface water value is greater than the ground water value, the surface water value will be used for comparison purposes and will protect for any concerns for ground water concentrations. After calculating DWLOCs and comparing them to the EECs for surface water, EPA does not expect the aggregate exposure to exceed 100% of the aPAD, as shown in the following Table 4.

TABLE 4.—AGGREGATE RISK ASSESSMENT FOR ACUTE EXPOSURE TO THIAMETHOXAM

Population Subgroup ^a	aPAD (mg/kg)	%aPAD (Food)	Surface Water DWEC (ppb)	Ground Water DWEC (ppb)	Acute DWLOC (ppb) ^b
U.S. General Population	0.1	1	8	5	3500

TABLE 4.—AGGREGATE RISK ASSESSMENT FOR ACUTE EXPOSURE TO THIAMETHOXAM—Continued

Population Subgroup ^a	aPAD (mg/kg)	%aPAD (Food)	Surface Water DWEC (ppb)	Ground Water DWEC (ppb)	Acute DWLOC (ppb) ^b
All infants (<1 year)	0.1	1	8	5	990
Children (1–6 years)	0.1	2	8	5	980
Children (7–12 years)	0.1	1	8	5	990
Females (13–50 years)	0.1	<1	8	5	3000

2. *Chronic risk.* Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that exposure to thiamethoxam from food will utilize <1% of the cPAD for the U.S. population, <1% of the cPAD for all infants <1 year and 1% of the cPAD for children 1–6 years. Proposed residential uses are not being addressed in this risk assessment. In addition to

chronic dietary exposure, there is potential for chronic dietary exposure to thiamethoxam in drinking water. The surface water EEC is 0.6 µg/L and the ground water EEC is 5.0 µg/L. The estimated EEC levels are very conservative, because they are based on both foliar uses and seed treatment applications. Since the ground water value is greater than the surface water

value, the ground water value will be used for comparison purposes and will protect for any concerns for surface water concentrations. After calculating the DWLOCs and comparing them to the EECs for ground water, EPA does not expect the aggregate exposure to exceed 100% of the cPAD as shown in the following Table 5.

TABLE 5.—AGGREGATE RISK ASSESSMENT FOR CHRONIC (NON-CANCER) EXPOSURE TO THIAMETHOXAM

Population Subgroup	cPAD mg/kg/day	%cPAD (Food)	Surface Water DWEC (ppb)	Ground Water DWEC (ppb)	Chronic DWLOC (ppb)
U.S. Population	0.0006	5	0.6	5	21
All infants (<1 year)	0.0006	13	0.6	5	6
Children (1–6 years)	0.0006	13	0.6	5	6
Children (7–12 years)	0.0006	7	0.6	5	6
Females (13–50 years)	0.0006	3	0.6	5	18

3. *Short-term risk.* Short-term aggregate exposure takes into account residential exposure plus chronic exposure to food and water (considered to be a background exposure level). Thiamethoxam is not registered for use on any sites that would result in residential exposure. Therefore, the aggregate risk is the sum of the risk from food and water, which do not exceed the Agency's level of concern.

4. *Intermediate-term risk.* Intermediate-term aggregate exposure takes into account residential exposure plus chronic exposure to food and water (considered to be a background exposure level). Thiamethoxam is not registered for use on any sites that would result in residential exposure. Therefore, the aggregate risk is the sum of the risk from food and water, which do not exceed the Agency's level of concern.

5. *Aggregate cancer risk for U.S. population.* The cancer risk estimate associated with the use of

thiamethoxam as a seed treatment on barley, canola, cotton, sorghum and wheat is 4.1×10^{-8} for the U.S. population based on an exposure estimate of 0.000001 mg/kg/day. The above cancer risk estimates show that the cancer risk is negligible. Based on modeling estimates, exposure through drinking water will not significantly increase the dietary risk in food.

6. *Determination of safety.* Based on these risk assessments, EPA concludes that there is a reasonable certainty that no harm will result to the general population, and to infants and children from aggregate exposure to thiamethoxam residues.

IV. Other Considerations

A. Analytical Enforcement Methodology

Adequate enforcement methodology (HPLC/UV or MS) is available to enforce the tolerance expression. The method may be requested from: Calvin Furrow, PRRIB, IRSD (7502C), Office of Pesticide Programs, Environmental Protection

Agency, 1200 Pennsylvania Ave., NW, Washington, DC 20460; telephone number: (703) 305-5229; e-mail address: furrow.calvin@epa.gov.

B. International Residue Limits

There are no international residue limits for thiamethoxam.

C. Conditions

Developmental neurotoxicity (Guideline #870.6300) and soil residue dissipation (Guideline #875.2200) studies are required as conditions of registration.

V. Conclusion

Therefore, the tolerance is established for combined residues of thiamethoxam ([3-[(2-chloro-5-thiazolyl)methyl]tetrahydro-5-methyl-N-nitro-4H-1,3,5-oxadiazin-4-imine) and its metabolite (N-(2-chloro-thiazol-5-ylmethyl)-N'-methyl-N'-nitro-guanidine) in or on barley grain at 0.02 ppm; barley hay at 0.05 ppm; barley straw at 0.03 ppm; undelinted cottonseed at 0.10

ppm; cotton gin byproducts at 1.5 ppm; sorghum forage at 0.02 ppm; sorghum grain at 0.02 ppm; sorghum stover at 0.02 ppm; wheat forage at 0.50 ppm; wheat grain at 0.02 ppm; wheat hay at 0.02 ppm; wheat straw at 0.02 ppm; milk at 0.02 ppm; meat of cattle, goats, hogs, horses, and sheep at 0.02 ppm; meat byproducts of cattle, goats, hogs, horses, and sheep at 0.02 ppm respectively.

VI. Objections and Hearing Requests

Under section 408(g) of the FFDCA, as amended by the FQPA, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. The EPA procedural regulations which govern the submission of objections and requests for hearings appear in 40 CFR part 178. Although the procedures in those regulations require some modification to reflect the amendments made to the FFDCA by the FQPA of 1996, EPA will continue to use those procedures, with appropriate adjustments, until the necessary modifications can be made. The new section 408(g) provides essentially the same process for persons to "object" to a regulation for an exemption from the requirement of a tolerance issued by EPA under new section 408(d), as was provided in the old FFDCA sections 408 and 409. However, the period for filing objections is now 60 days, rather than 30 days.

A. What Do I Need to Do to File an Objection or Request a Hearing?

You must file your objection or request a hearing on this regulation in accordance with the instructions provided in this unit and in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket control number OPP-301087 in the subject line on the first page of your submission. All requests must be in writing, and must be mailed or delivered to the Hearing Clerk on or before February 20, 2001.

1. *Filing the request.* Your objection must specify the specific provisions in the regulation that you object to, and the grounds for the objections (40 CFR 178.25). If a hearing is requested, the objections must include a statement of the factual issues(s) on which a hearing is requested, the requestor's contentions on such issues, and a summary of any evidence relied upon by the objector (40 CFR 178.27). Information submitted in connection with an objection or hearing request may be claimed confidential by marking any part or all of that information as CBI. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2. A copy of the

information that does not contain CBI must be submitted for inclusion in the public record. Information not marked confidential may be disclosed publicly by EPA without prior notice.

Mail your written request to: Office of the Hearing Clerk (1900), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460. You may also deliver your request to the Office of the Hearing Clerk in Rm. C400, Waterside Mall, 401 M St., SW., Washington, DC 20460. The Office of the Hearing Clerk is open from 8 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Office of the Hearing Clerk is (202) 260-4865.

2. *Tolerance fee payment.* If you file an objection or request a hearing, you must also pay the fee prescribed by 40 CFR 180.33(i) or request a waiver of that fee pursuant to 40 CFR 180.33(m). You must mail the fee to: EPA Headquarters Accounting Operations Branch, Office of Pesticide Programs, P.O. Box 360277M, Pittsburgh, PA 15251. Please identify the fee submission by labeling it "Tolerance Petition Fees."

EPA is authorized to waive any fee requirement "when in the judgement of the Administrator such a waiver or refund is equitable and not contrary to the purpose of this subsection." For additional information regarding the waiver of these fees, you may contact James Tompkins by phone at (703) 305-5697, by e-mail at tompkins.jim@epa.gov, or by mailing a request for information to Mr. Tompkins at Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460.

If you would like to request a waiver of the tolerance objection fees, you must mail your request for such a waiver to: James Hollins, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460.

3. *Copies for the Docket.* In addition to filing an objection or hearing request with the Hearing Clerk as described in Unit VI.A., you should also send a copy of your request to the PIRIB for its inclusion in the official record that is described in Unit I.B.2. Mail your copies, identified by docket control number OPP-301087, to: Public Information and Records Integrity Branch, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460. In person or by courier, bring a copy to the location of the PIRIB described in Unit

I.B.2. You may also send an electronic copy of your request via e-mail to: opp-docket@epa.gov. Please use an ASCII file format and avoid the use of special characters and any form of encryption. Copies of electronic objections and hearing requests will also be accepted on disks in WordPerfect 6.1/8.0 file format or ASCII file format. Do not include any CBI in your electronic copy. You may also submit an electronic copy of your request at many Federal Depository Libraries.

B. When Will the Agency Grant a Request for a Hearing?

A request for a hearing will be granted if the Administrator determines that the material submitted shows the following: There is a genuine and substantial issue of fact; there is a reasonable possibility that available evidence identified by the requestor would, if established resolve one or more of such issues in favor of the requestor, taking into account uncontested claims or facts to the contrary; and resolution of the factual issues(s) in the manner sought by the requestor would be adequate to justify the action requested (40 CFR 178.32).

VII. Regulatory Assessment Requirements

This final rule establishes a tolerance under FFDCA section 408(d) in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled *Regulatory Planning and Review* (58 FR 51735, October 4, 1993). This final rule does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA), 44 U.S.C. 3501 *et seq.*, or impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) (Public Law 104-4). Nor does it require any prior consultation as specified by Executive Order 13084, entitled *Consultation and Coordination with Indian Tribal Governments* (63 FR 27655, May 19, 1998); special considerations as required by Executive Order 12898, entitled *Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations* (59 FR 7629, February 16, 1994); or require OMB review or any Agency action under Executive Order 13045, entitled *Protection of Children from Environmental Health Risks and Safety Risks* (62 FR 19885, April 23, 1997). This action does not involve any technical standards that would require Agency consideration of voluntary

consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act of 1995 (NTTAA), Public Law 104-113, section 12(d) (15 U.S.C. 272 note). Since tolerances and exemptions that are established on the basis of a petition under FFDCA section 408(d), such as the tolerance in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*) do not apply. In addition, the Agency has determined that this action will not have a substantial direct effect on 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, as specified in Executive Order 13132, entitled *Federalism* (64 FR 43255, August 10, 1999). Executive Order 13132 requires EPA to develop an accountable process to ensure "meaningful and timely input by State and local officials in the development of regulatory policies that have federalism implications." "Policies that have federalism implications" is defined in the Executive Order to include regulations that have "substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government." This final rule directly regulates growers, food processors, food handlers and food retailers, not States. This action does not alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of FFDCA section 408(n)(4).

VIII. Submission to Congress and the Comptroller General

The Congressional Review Act, 5 U.S.C. 801 *et seq.*, as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report, which includes a copy of the rule, to each House of the Congress and to the Comptroller General of the United States. EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of this final rule in the **Federal Register**. This final rule is not a "major rule" as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 180

Environmental protection,
Administrative practice and procedure,

Agricultural commodities, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: December 1, 2000.

Joseph J. Merenda,

Acting Director, Office of Pesticide Programs.

Therefore, 40 CFR chapter I is amended as follows:

PART 180—[AMENDED]

1. The authority citation for part 180 continues to read as follows:

Authority: 21 U.S.C. 321(q), (346a) and 371.

2. Section 180.565 is amended by adding text to paragraph (a) to read as follows:

§ 180.565 Thiamethoxam; tolerance for residues.

(a) *General.* A tolerance is established for the combined residues of the insecticide thiamethoxam [3-[(2-chloro-5-thiazolyl)methyl]tetrahydro-5-methyl-N-nitro-4H-1,3,5-oxadiazin-4-imine] (CAS Reg. No. 153719-23-4) and its metabolite [N-(2-chloro-thiazol-5-ylmethyl)-N'-methyl-N'-nitro-guanidine] in or on the following raw agricultural commodities:

Commodity	Parts per million
Barley, grain	0.02
Barley, hay	0.05
Barley, straw	0.03
Canola, seed	0.02
Cattle, mbyb	0.02
Cattle, meat	0.02
Cotton, gin byproducts ...	1.5
Cotton, undelinted seed	0.10
Goat, mbyb	0.02
Goat, meat	0.02
Hog, mbyb	0.02
Hog meat	0.02
Horse, mbyb	0.02
Horse, meat	0.02
Milk	0.02
Sheep, mbyb	0.02
Sheep, meat	0.02
Sorghum, forage	0.02
Sorghum, grain	0.02
Sorghum, stover	0.02
Wheat, forage	0.50
Wheat, grain	0.02
Wheat, hay	0.02
Wheat, straw	0.02

* * * * *

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP-301082; FRL-6755-9]

RIN 2070-78AB

Avermectin B₁; Pesticide Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes a tolerance for combined residues of avermectin B₁ and its delta-8,9-isomer in or on celeriac (roots and tops) at 0.05 parts per million (ppm). The Interregional Research Project Number 4 (IR-4) requested this tolerance under the Federal Food, Drug, and Cosmetic Act, as amended by the Food Quality Protection Act of 1996.

DATES: This regulation is effective December 21, 2000. Objections and requests for hearings, identified by docket control number OPP-301082, must be received by EPA on or before February 20, 2001.

ADDRESSES: Written objections and hearing requests may be submitted by mail, in person, or by courier. Please follow the detailed instructions for each method as provided in Unit VI. of the **SUPPLEMENTARY INFORMATION**. To ensure proper receipt by EPA, your objections and hearing requests must identify docket control number OPP-301082 in the subject line on the first page of your response.

FOR FURTHER INFORMATION CONTACT By mail: Shaja R. Brothers, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460; telephone number: (703) 308-3194; and e-mail address: brothers.shaja@epa.gov.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

You may be affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. Potentially affected categories and entities may include, but are not limited to:

Categories	NAICS codes	Examples of potentially affected entities
Industry	111 112 311 32532	Crop production Animal production Food manufacturing Pesticide manufacturing

This listing is not intended to be exhaustive, but rather provides a guide for readers regarding entities likely to be affected by this action. Other types of entities not listed in the table could also be affected. The North American Industrial Classification System (NAICS) codes have been provided to assist you and others in determining whether or not this action might apply to certain entities. If you have questions regarding the applicability of this action to a particular entity, consult the person listed under **FOR FURTHER INFORMATION CONTACT**.

B. How Can I Get Additional Information, Including Copies of this Document and Other Related Documents?

1. *Electronically.* You may obtain electronic copies of this document, and certain other related documents that might be available electronically, from the EPA Internet Home Page at <http://www.epa.gov/>. To access this document, on the Home Page select "Laws and Regulations", "Regulations and Proposed Rules," and then look up the entry for this document under the "**Federal Register**—Environmental Documents." You can also go directly to the **Federal Register** listings at <http://www.epa.gov/fedrgstr/>.

2. *In person.* The Agency has established an official record for this action under docket control number OPP-301082. The official record consists of the documents specifically referenced in this action, and other information related to this action, including any information claimed as Confidential Business Information (CBI). This official record includes the documents that are physically located in the docket, as well as the documents that are referenced in those documents. The public version of the official record does not include any information claimed as CBI. The public version of the official record, which includes printed, paper versions of any electronic comments submitted during an applicable comment period is available for inspection in the Public Information and Records Integrity Branch (PIRIB), Rm. 119, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA, from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The PIRIB telephone number is (703) 305-5805.

II. Background and Statutory Findings

In the **Federal Register** of September 27, 2000 (65 FR 58081) (FRL-6746-4), EPA issued a notice pursuant to section 408 of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a as amended by the Food Quality

Protection Act of 1996 (FQPA) (Public Law 104-170) announcing the filing of a pesticide petition (PP 0E6118) for tolerance by IR-4, 681 U.S. Highway #1 South, North Brunswick, New Jersey 08902-3390. This notice included a summary of the petition prepared by Novartis Crop Protection, Inc., the registrant. There were no comments received in response to the notice of filing.

The petitions requested that 40 CFR 180.449 be amended by establishing tolerances for combined residues of the insecticide avermectin B₁, (a mixture of avermectins containing greater than or equal to 80% avermectin B_{1a} (5-O-demethyl avermectin A_{1a}) and less than or equal to 20% avermectin B_{1b} (5-O-demethyl-25-de(1-methylpropyl)-25-(1-methylethyl) avermectin A_{1a})) and its delta-8,9-isomer, in or on celeriac roots and tops at 0.05 ppm.

Section 408(b)(2)(A)(i) of the FFDCA allows EPA to establish a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the tolerance is "safe." Section 408(b)(2)(A)(ii) defines "safe" to mean that "there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information." This includes exposure through drinking water and in residential settings, but does not include occupational exposure. Section 408(b)(2)(C) requires EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing a tolerance and to "ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue...."

EPA performs a number of analyses to determine the risks from aggregate exposure to pesticide residues. For further discussion of the regulatory requirements of section 408 and a complete description of the risk assessment process, see the final rule on Bifenthrin Pesticide Tolerances (62 FR 62961, November 26, 1997) (FRL-5754-7).

III. Aggregate Risk Assessment and Determination of Safety

Consistent with section 408(b)(2)(D), EPA has reviewed the available scientific data and other relevant information in support of this action. EPA has sufficient data to assess the hazards of and to make a determination on aggregate exposure, consistent with section 408(b)(2), for tolerances for

combined residues of avermectin B₁ and its delta-8,9-isomer on celeriac roots and tops at 0.05 ppm. EPA's assessment of exposures and risks associated with establishing the tolerances follows.

A. Toxicological Profile

EPA has evaluated the available toxicity data and considered its validity, completeness, and reliability as well as the relationship of the results of the studies to human risk. EPA has also considered available information concerning the variability of the sensitivities of major identifiable subgroups of consumers, including infants and children. The nature of the toxic effects caused by avermectin B₁ are discussed in Unit III A of the Final Rule on Avermectin Pesticide Tolerance published in the **Federal Register** on September 7, 1999 (FRL 6380-7).

B. Toxicological Endpoints

The dose at which no adverse effects are observed (the NOAEL) from the toxicology study identified as appropriate for use in risk assessment is used to estimate the toxicological level of concern (LOC). However, the lowest dose at which adverse effects of concern are identified (the LOAEL) is sometimes used for risk assessment if no NOAEL was achieved in the toxicology study selected. An uncertainty factor (UF) is applied to reflect uncertainties inherent in the extrapolation from laboratory animal data to humans and in the variations in sensitivity among members of the human population as well as other unknowns. An UF of 100 is routinely used, 10X to account for interspecies differences and 10X for intra species differences.

For dietary risk assessment (other than cancer) the Agency uses the UF to calculate an acute or chronic reference dose (acute RfD or chronic RfD) where the RfD is equal to the NOAEL divided by the appropriate UF (RfD = NOAEL/UF). Where an additional safety factor is retained due to concerns unique to the FQPA, this additional factor is applied to the RfD by dividing the RfD by such additional factor. The acute or chronic Population Adjusted Dose (aPAD or cPAD) is a modification of the RfD to accommodate this type of FQPA Safety Factor.

For non-dietary risk assessments (other than cancer) the UF is used to determine the LOC. For example, when 100 is the appropriate UF (10X to account for interspecies differences and 10X for intraspecies differences) the LOC is 100. To estimate risk, a ratio of the NOAEL to exposures (margin of exposure (MOE) = NOAEL/exposure) is calculated and compared to the LOC.

The linear default risk methodology (Q^*) is the primary method currently used by the Agency to quantify carcinogenic risk. The Q^* approach assumes that any amount of exposure will lead to some degree of cancer risk. A Q^* is calculated and used to estimate risk which represents a probability of occurrence of additional cancer cases (e.g., risk is expressed as 1×10^{-6} or one in a million). Under certain specific

circumstances, MOE calculations will be used for the carcinogenic risk assessment. In this non-linear approach, a "point of departure" is identified below which carcinogenic effects are not expected. The point of departure is typically a NOAEL based on an endpoint related to cancer effects though it may be a different value derived from the dose response curve. To estimate risk, a ratio of the point of

departure to exposure ($MOE_{\text{cancer}} = \text{point of departure/exposures}$) is calculated. A summary of the toxicological endpoints for avermectin B₁ used for human risk assessment is as follows:

A summary of the toxicological endpoints for avermectin B₁ used for human risk assessment is shown in the following Table 1:

TABLE 1.—SUMMARY OF TOXICOLOGICAL DOSE AND ENDPOINTS FOR AVERMECTIN B₁ FOR USE IN HUMAN RISK ASSESSMENT

Exposure Scenario	Dose Used in Risk Assessment, UF	FQPA SF* and Level of Concern for Risk Assessment	Study and Toxicological Effects
Acute Dietary U.S. population	NOAEL = 0.25 mg/kg/day UF = 100 Acute RfD = 0.0025 mg/kg/day	FQPA SF = 1 aPAD = acute RfD FQPA SF = 0.0025 mg/kg/day	Chronic toxicity—dog LOAEL = 0.50 mg/kg/day based on dilated pupils seen at week 1 of dosing.
Acute Dietary females 13+ years of age, and infants and children	NOAEL = 0.25 mg/kg/day UF = 100 Acute RfD = 0.0025 mg/kg/day	FQPA SF = 10 aPAD = acute RfD FQPA SF = 0.00025 mg/kg/day	Chronic toxicity—dog LOAEL = 0.50 mg/kg/day based on dilated pupils seen at week 1 of dosing.
Chronic Dietary U.S. population	NOAEL = 0.12 mg/kg/day UF = 100 Chronic RfD = 0.0012 mg/kg/day	FQPA SF = 1 cPAD = chronic RfD FQPA SF = 0.0012 mg/kg/day	2-generation reproduction—rat LOAEL = 0.40 mg/kg/day based on decreased pup weight and viability during lactation, and increased incidence of retinal rosettes in F _{2b} weanlings.
Chronic Dietary females 13+ years of age, and infants and children	NOAEL = 0.12 mg/kg/day UF = 100 Chronic RfD = 0.0012 mg/kg/day	FQPA SF = 10 cPAD = chronic RfD FQPA SF = 0.00012 mg/kg/day	2-generation reproduction—rat LOAEL = 0.40 mg/kg/day based on decreased pup weight and viability during lactation, and increased incidence of retinal rosettes in F _{2b} weanlings.
Short-Term Dermal (1 to 7 days) (Residential)	oral study NOAEL = 0.25 mg/kg/day (dermal absorption rate = 1%)	LOC for MOE = 1,000 (Residential)	chronic toxicity—dog LOAEL = 0.50 mg/kg/day based on dilated pupils at week 1 of dosing
Intermediate-Term Dermal (1 week to several months) (Residential)	oral study NOAEL = 0.25 mg/kg/day (dermal absorption rate = 1%)	LOC for MOE = 1,000 (Residential)	chronic toxicity—dog LOAEL = 0.50 mg/kg/day based on dilated pupils at week 1 of dosing
Long-Term Dermal (several months to lifetime) (Residential)	oral study NOAEL = 0.12 mg/kg/day (dermal absorption rate = 1% when appropriate)	LOC for MOE = 1,000 (Residential)	2-generation reproduction—rat LOAEL = 0.40 mg/kg/day based on decreased pup weight and viability during lactation, and increased incidence of retinal rosettes in F _{2b} weanlings.
Short-Term Inhalation (1 to 7 days) (Residential)	oral study NOAEL = 0.25 mg/kg/day (inhalation absorption rate = 100%)	LOC for MOE = 1,000 (Residential)	chronic toxicity—dog LOAEL = 0.50 mg/kg/day based on dilated pupils at week 1 of dosing
Intermediate-Term Inhalation (1 week to several months) (Residential)	oral study NOAEL = 0.25 mg/kg/day (inhalation absorption rate = 100%)	LOC for MOE = 1,000 (Residential)	chronic toxicity—dog LOAEL = 0.50 mg/kg/day based on dilated pupils at week 1 of dosing
Long-Term Inhalation (several months to lifetime) (Residential)	oral study NOAEL = 0.12 mg/kg/day (inhalation absorption rate = 100%)	LOC for MOE = 1,000 (Residential)	2-generation reproduction—rat LOAEL = 0.40 mg/kg/day based on decreased pup weight and viability during lactation, and increased incidence of retinal rosettes in F _{2b} weanlings.
Cancer (oral, dermal, inhalation)	Not Applicable	Cancer Group E—absence of significant tumor increases in two adequate rodent carcinogenicity studies.	Rodent carcinogenicity study—was negative carcinogens.

* The reference to the FQPA Safety Factor refers to any additional safety factor retained due to concerns unique to the FQPA.

C. Exposure Assessment

1. *Dietary exposure from food and feed uses.* Tolerances have been established (40 CFR 180.449) for the combined residues of avermectin B₁ and its delta-8,9-isomer, in or on a variety of raw agricultural commodities including apples, almonds, citrus, cottonseed, grapes, hops, peppers, potatoes, cattle meat and meat by-products and milk. Risk assessments were conducted by EPA to assess dietary exposures from avermectin B₁ in food as follows:

i. *Acute exposure.* Acute dietary risk assessments are performed for a food-use pesticide if a toxicological study has indicated the possibility of an effect of concern occurring as a result of a one day or single exposure. The following assumptions were made for the acute exposure assessments: The acute dietary exposure assessment was conducted using probabilistic Monte Carlo modeling incorporating anticipated residue and percent of crop treated refinements to calculate the Anticipated Residue Contribution (ARC). Residue Data Files (RDF) and percent crop treated were used on all but a few low consumption food items. Reduction factors for fractionation and processing were utilized for citrus and pome fruit. Monitoring data were not used for mixed/blended commodities. EPA was able to further refine the acute dietary estimate from food by using updated PCT data, resetting the processing factor for dried potatoes to 1 which reflects the non-concentration of avermectin B₁ in potato processed commodities, correcting the residue files above to use one half the level of detection or one half the level of quantification, where appropriate, and using the average field trial residue level and previously established processing factors for blended commodities. In addition, the analysis included residues in pear juice for which no data has been previously required. Since all other juices show reductions in avermectin B₁ residues from the raw agricultural commodity, EPA used the reduction factor for apples in the analysis.

ii. *Chronic exposure.* In conducting this chronic dietary (food only) risk assessment, EPA used anticipated residues and percent crop-treated data for many crops. This chronic dietary (food only) exposure should be viewed as a highly refined risk estimate; further refinement using additional percent crop-treated values would not result in a significantly lower dietary exposure estimate. Thus, in making a safety determination for this tolerance, EPA is taking into account this refined chronic exposure assessment.

iii. *Anticipated residue and percent crop treated information.* Section 408(b)(2)(E) authorizes EPA to use available data and information on the anticipated residue levels of pesticide residues in food and the actual levels of pesticide chemicals that have been measured in food. If EPA relies on such information, EPA must require that data be provided 5 years after the tolerance is established, modified, or left in effect, demonstrating that the levels in food are not above the levels anticipated. Following the initial data submission, EPA is authorized to require similar data on a time frame it deems appropriate. As required by section 408(b)(2)(E), EPA will issue a data call-in for information relating to anticipated residues to be submitted no later than 5 years from the date of issuance of this tolerance.

Section 408(b)(2)(F) states that the Agency may use data on the actual percent of food treated for assessing chronic dietary risk only if the Agency can make the following findings: Condition 1, that the data used are reliable and provide a valid basis to show what percentage of the food derived from such crop is likely to contain such pesticide residue; Condition 2, that the exposure estimate does not underestimate exposure for any significant subpopulation group; and Condition 3, if data are available on pesticide use and food consumption in a particular area, the exposure estimate does not understate exposure for the population in such area. In addition, the Agency must provide for periodic evaluation of any estimates used. To provide for the periodic evaluation of the estimate of percent crop treated (PCT) as required by section 408(b)(2)(F), EPA may require registrants to submit data on PCT.

The Agency used percent crop treated (PCT) information as follows: For each crop in the dietary (food only) model the following percent crop treated values were used for the acute and chronic analyses (respectively): almond 100%, 100%; apple 6.1%, 1.9%; avocado 100%, 100%; basil 100%, 100%; cantaloupe 5%, 1.3%; celeriac 100%, 100%; celery 60%, 49%; citrus, other 43%, 32%; cotton 4.8%, 3.2%; cucumber 100%, 31%; grapefruit, juice and peel 60.9%, 46%; grapefruit, peeled fruit 43%, 46%; grape 14%, 14%; hops 100%, 84%; lemon, juice and peel 34.4%, 17%; lemon, peeled fruit 43%, 17%; head lettuce 28%, 22%; lime, juice and peel 63.2%, 32%; lime, peeled fruit 43%, 32%; melons 5%, 1.3%; orange, juice and peel 36.3%, 28%; orange, peeled fruit 43%, 28%; pear 75%, 56%; peppers 15%, 6.3%; potato

5%, 0.3%; spinach 18%, 8.9%; squash 100%, 31%; strawberry 47%, 42%; tangelo 43%, 57%; tangerine, juice 74.3%, 53%; tangerine, fresh 43%, 53%; tomato 8%, 3.7%; walnut 100%, 100%; watermelon 5%, 1.3%. For fresh, peeled citrus a weighted average (43%) was calculated pooling all types of citrus; this value was used in the analysis of chronic dietary exposure from citrus.

The Agency believes that the three conditions listed above have been met. With respect to Condition 1, PCT estimates are derived from Federal and private market survey data, which are reliable and have a valid basis. EPA uses a weighted average PCT for chronic dietary exposure estimates. This weighted average PCT figure is derived by averaging State-level data for a period of up to 10 years, and weighting for the more robust and recent data. A weighted average of the PCT reasonably represents a person's dietary exposure over a lifetime, and is unlikely to underestimate exposure to an individual because of the fact that pesticide use patterns (both regionally and nationally) tend to change continuously over time, such that an individual is unlikely to be exposed to more than the average PCT over a lifetime. For acute dietary exposure estimates, EPA uses an estimated maximum PCT. The exposure estimates resulting from this approach reasonably represent the highest levels to which an individual could be exposed, and are unlikely to underestimate an individual's acute dietary exposure. The Agency is reasonably certain that the percentage of the food treated is not likely to be an underestimation. As to Conditions 2 and 3, regional consumption information and consumption information for significant subpopulations is taken into account through EPA's computer-based model for evaluating the exposure of significant subpopulations including several regional groups. Use of this consumption information in EPA's risk assessment process ensures that EPA's exposure estimate does not understate exposure for any significant subpopulation group and allows the Agency to be reasonably certain that no regional population is exposed to residue levels higher than those estimated by the Agency. Other than the data available through national food consumption surveys, EPA does not have available information on the regional consumption of food to which avermectin B₁ may be applied in a particular area.

2. *Dietary exposure from drinking water.* Avermectin B₁ is moderately persistent and non-mobile. It is not expected to reach surface or ground

water in significant quantities. It is stable to hydrolysis at pH 5, 7, and 9. It is also moderately persistent in aerobic soil (topsoil) with half-lives of 37–131 days. The major pathways of avermectin B₁ dissipation are binding to soil and sediment, degradation in aerobic soil, and photolysis in water. In shallow, well-mixed surface water with no suspended sediments, avermectin B₁ degraded rapidly with a photodegradation half-life of 3 days. However, in most surface waters, suspended sediments and lack of mixing would decrease the rate of photodegradation significantly. In water, avermectin B₁ residues would be tightly bound to sediment, reducing aqueous concentrations. There are no Maximum Contaminant Levels (MCL) or Health Advisories (HA) established for avermectin B₁ residues in drinking water.

The Agency lacks sufficient monitoring exposure data to complete a comprehensive dietary exposure analysis and risk assessment for avermectin B₁ in drinking water. Because the Agency does not have comprehensive monitoring data, drinking water concentration estimates are made by reliance on simulation or modeling taking into account data on the physical characteristics of avermectin B₁.

The Agency uses the Generic Estimated Environmental Concentration (GENEEC) or the Pesticide Root Zone/Exposure Analysis Modeling System (PRZM/EXAMS) to estimate pesticide concentrations in surface water and SCI-GROW, which predicts pesticide concentrations in groundwater. In general, EPA will use GENEEC (a tier 1 model) before using PRZM/EXAMS (a tier 2 model) for a screening-level assessment for surface water. The GENEEC model is a subset of the PRZM/EXAMS model that uses a specific high-end runoff scenario for pesticides. GENEEC incorporates a farm pond scenario, while PRZM/EXAMS incorporate an index reservoir environment in place of the previous pond scenario. The PRZM/EXAMS model includes a percent crop area factor as an adjustment to account for the maximum percent crop coverage within a watershed or drainage basin.

None of these models include consideration of the impact processing (mixing, dilution, or treatment) of raw water for distribution as drinking water would likely have on the removal of pesticides from the source water. The primary use of these models by the Agency at this stage is to provide a coarse screen for sorting out pesticides for which it is highly unlikely that

drinking water concentrations would ever exceed human health levels of concern.

EPA decided to rely on the strawberry model to assess aggregate risk since strawberries were considered a higher exposure scenario (four applications per season allowed for strawberries). However, EPA noted that the certainty of the concentrations estimated for strawberries is low, due to uncertainty on the amount of runoff from plant beds covered in plastic mulch and uncertainty on the amount of degradation of avermectin B₁ on black plastic compared to soil. In order to refine the model in the future, the Agency has required the registrant, as a condition of product registration, to conduct additional tests on the effects of plastic mulch on surface water pesticide concentrations.

Since the models used are considered to be screening tools in the risk assessment process, the Agency does not use estimated environmental concentrations (EECs) from these models to quantify drinking water exposure and risk as a %RfD or %PAD. Instead drinking water levels of comparison (DWLOCs) are calculated and used as a point of comparison against the model estimates of a pesticide's concentration in water. DWLOCs are theoretical upper limits on a pesticide's concentration in drinking water in light of total aggregate exposure to a pesticide in food, and from residential uses. Since DWLOCs address total aggregate exposure to avermectin B₁ they are further discussed in the aggregate risk sections below.

Based on the PRZM/EXAMS and SCI-GROW models the estimated environmental concentrations (EECs) of avermectin B₁ for acute exposures are estimated to be [0.88] parts per billion (ppb) for surface water and 0.0015 ppb for ground water. The EECs for chronic exposures are estimated to be 0.57 ppb for surface water and 0.002 ppb for ground water.

3. *From non-dietary exposure.* The term "residential exposure" is used in this document to refer to non-occupational, non-dietary exposure (e.g., for lawn and garden pest control, indoor pest control, termiticides, and flea and tick control on pets).

Avermectin B₁ is currently registered for use on the following residential non-dietary sites: residential lawns for fire ant control, and residential indoor crack and crevice for cockroaches. Registered uses may result in short-term to intermediate exposures. However, based on current use patterns, chronic exposure to avermectin B₁ is not expected. The risk assessment was

conducted using the following residential exposure assumptions:

i. *Short and intermediate exposure—residential lawn applications.* For exposure of residential applicators, three scenarios were used: (a) granular bait dispersed by hand, (b) belly grinder-granular open pour-mixer/loader/applicator and (c) push type granular.

For postapplication exposure from treated lawns, EPA default assumptions such as dermal transfer coefficient (TC), exposure time (ET), hand surface area (SA), ingestion frequency (FQ), residue dissipation, and ingestion rates were used. These defaults estimated postapplication exposure to children and adults from treated lawns. The application rate (AR) used for this assessment is based on the label for Affirm Fire Ant Insecticide (0.011% avermectin B₁). The label recommends a broadcast application rate on lawns of 1 lb of product/acre, the maximum rate for all registered lawn uses.

ii. *Short and intermediate exposure—residential indoor crack and crevice uses.* For residential applicators, exposure and risk estimates for homeowners applying crack and crevice baits were estimated using the EPA DRAFT Standard Operating Procedure (SOP) for Residential Exposure Assessments (12/18/97). The amount of active ingredient (ai) handled was based on the assumption that one 30 gram package of Whitmire Avert Prescription Bait Prescription Treatment 310 (0.05% ai) would be applied in a day. The unit exposure from the EPA default wettable powder, open mixing and loading scenarios was used as a surrogate for estimating dermal and inhalation exposure to residential applicators.

For estimating postapplication exposure from indoor treatment, two postapplication exposure studies were conducted with crack and crevice products containing avermectin B₁: (1) Evaluation of Avert Prescription Treatment 310 Residual Study in Air, Food and on Surfaces, dated November 8, 1990 and (2) Evaluation of Indoor Exposure to a Crack and Crevice Application of Whitmire Avert Crack and Crevice Prescription Treatment 310 and Prescription TC 93A Bait, dated October 27, 1995 (see Unit III.C. of the Final Rule on Avermectin Pesticide Tolerance published in the **Federal Register** on September 7, 1999 (FRL 6380-7)).

4. *Cumulative exposure to substances with a common mechanism of toxicity.* Section 408(b)(2)(D)(v) requires that, when considering whether to establish, modify, or revoke a tolerance, the Agency consider "available

information” concerning the cumulative effects of a particular pesticide’s residues and “other substances that have a common mechanism of toxicity.”

EPA does not have, at this time, available data to determine whether avermectin B₁ has a common mechanism of toxicity with other substances or how to include this pesticide in a cumulative risk assessment. Unlike other pesticides for which EPA has followed a cumulative risk approach based on a common mechanism of toxicity, avermectin B₁ does not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has not assumed that avermectin B₁ has a common mechanism of toxicity with other substances. For information regarding EPA’s efforts to determine which chemicals have a common mechanism of toxicity and to evaluate the cumulative effects of such chemicals, see the final rule for Bifenthrin Pesticide Tolerances (62 FR 62961, November 26, 1997).

D. Safety Factor for Infants and Children

1. *Safety factor for infants and children—i. In general.* FFDCA section 408 provides that EPA shall apply an additional tenfold margin of safety for infants and children in the case of threshold effects to account for prenatal and postnatal toxicity and the completeness of the data base on toxicity and exposure unless EPA determines that a different margin of safety will be safe for infants and children. Margins of safety are incorporated into EPA risk assessments either directly through use of a margin of exposure (MOE) analysis or through using uncertainty (safety) factors in calculating a dose level that poses no appreciable risk to humans.

ii. *Prenatal and postnatal sensitivity.* There was evidence of increased susceptibility to the offspring following prenatal and postnatal exposure to avermectin B₁ in the 2-generation reproduction study in rats.

iii. *Conclusion.* There is a complete toxicity data base for avermectin B₁ and exposure data are complete or are estimated based on data that reasonably accounts for potential exposures. The Agency is retaining the 10-fold safety factor for increased susceptibility of infants and children for this pesticide and is applying it to females 13+, infants, and children population subgroups for acute, chronic, and residential exposure.

The 10X Safety Factor is being retained because: (1) There was

evidence of increased susceptibility to the offspring following pre- and postnatal exposure to avermectin B₁ in the 2-generation reproduction study in rats. (2) There is evidence of neurotoxicity manifested as clinical signs of neurotoxicity in mice, rats, and dogs in developmental, reproduction, chronic and/or carcinogenicity studies in mice, rats and/or dogs. (3) There is concern for Structure Activity Relationship: Avermectin induced cleft palate in fetal rats, and cleft palate and clubbed forefoot in fetal rabbits. (4) EPA determined that a developmental neurotoxicity study in rats is required for avermectin B₁. This study could provide additional information on potential increased susceptibility, effects on the development of the fetal nervous system, as well as the functional development of the young. (5) There is concern for post-application exposure to infants and children in treated areas, including incidental hand-to-mouth ingestion of the pesticide.

E. Aggregate Risks and Determination of Safety

To estimate total aggregate exposure to a pesticide from food, drinking water, and residential uses, the Agency calculates DWLOCs which are used as a point of comparison against the model estimates of a pesticide’s concentration in water (EECs). DWLOC values are not regulatory standards for drinking water. DWLOCs are theoretical upper limits on a pesticide’s concentration in drinking water in light of total aggregate exposure to a pesticide in food and residential uses. In calculating a DWLOC, the Agency determines how much of the acceptable exposure (i.e., the PAD) is available for exposure through drinking water [e.g., allowable chronic water exposure (mg/kg/day) = cPAD - (average food + residential exposure)]. This allowable exposure through drinking water is used to calculate a DWLOC.

A DWLOC will vary depending on the toxic endpoint, drinking water consumption, and body weights. Default body weights and consumption values as used by the USEPA Office of Water are used to calculate DWLOCs: 2L/70 kg (adult male), 2L/60 kg (adult female), and 1L/10 kg (child). Default body weights and drinking water consumption values vary on an individual basis. This variation will be taken into account in more refined screening-level and quantitative drinking water exposure assessments. Different populations will have different DWLOCs. Generally, a DWLOC is calculated for each type of risk

assessment used: acute, short-term, intermediate-term, chronic, and cancer.

When EECs for surface water and groundwater are less than the calculated DWLOCs, OPP concludes with reasonable certainty that exposures to the pesticide in drinking water (when considered along with other sources of exposure for which OPP has reliable data) would not result in unacceptable levels of aggregate human health risk at this time. Because OPP considers the aggregate risk resulting from multiple exposure pathways associated with a pesticide’s uses, levels of comparison in drinking water may vary as those uses change. If new uses are added in the future, OPP will reassess the potential impacts of residues of the pesticide in drinking water as a part of the aggregate risk assessment process.

1. *Acute risk.* Using the exposure assumptions discussed in this unit for acute exposure, the acute dietary exposure from food to avermectin will occupy 4% of the aPAD for the U.S. population, 37% of the aPAD for females 13 years and older nursing, 47% of the aPAD for non-nursing infants and 70% of the aPAD for children 1–6 years. In addition, there is potential for acute dietary exposure to avermectin in drinking water. After calculating DWLOCs and comparing them to the EECs for surface and ground water, the acute exposure for aggregate risk slightly exceeds the aPAD for children 1–6 years old. However EPA believes that acute exposure to avermectin from drinking water will not pose an unacceptable risk to human health. Neither surface nor ground water models used by EPA were designed specifically for estimating concentrations in drinking water. There are significant uncertainties in both the toxicology used to derive the DWLOC and the exposure estimate from the PRZM-EXAMS model. EPA has compensated for these uncertainties by using reasonable high-end assumptions. Given this approach, the Agency does not attach great significance to such a small difference. However, EPA may do additional analyses and, as a condition of product registration, the Agency has required the registrant to submit (1) data on the effects of plastic mulch on surface water pesticide concentrations and (2) data characterizing the effectiveness of various types of drinking water treatment on removing avermectin. These data are expected to confirm that the actual concentration of avermectin in drinking water is less than the level of concern for all sub-populations, as shown in the following Table 2:

TABLE 2.—AGGREGATE RISK ASSESSMENT FOR ACUTE EXPOSURE TO AVERMECTIN B₁

Population Subgroup	aPAD (mg/kg)	% aPAD (Food)	Surface Water EEC (ppb)	Ground Water EEC (ppb)	Acute DWLOC (ppb)
U.S. population	0.0025	4	0.88	0.0015	84
Children 1–6 years old	0.00025	70	0.88	0.0015	0.74
Females 13+ nursing	0.00025	37	0.88	0.0015	4.7

2. *Chronic risk.* Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that exposure to avermectin B₁ from food will utilize less than 1% of the cPAD for the U.S. population, 17% of the cPAD for non-nursing infants and

13% of the cPAD for children 1–6 years old. Based on the use pattern, chronic residential exposure to residues of avermectin B₁ is not expected. In addition, there is potential for chronic dietary exposure to avermectin B₁ in drinking water. After calculating

DWLOCs and comparing them to the EECs for surface and ground water, EPA does not expect the aggregate exposure to exceed 100% of the cPAD, as shown in the following Table 3:

TABLE 3.—AGGREGATE RISK ASSESSMENT FOR CHRONIC (NON-CANCER) EXPOSURE TO AVERMECTIN B₁

Population Subgroup	cPAD mg/kg/day	%cPAD (Food)	Surface Water EEC (ppb)	Ground Water EEC (ppb)	Chronic DWLOC (ppb)
U.S. Population	0.0012	<1	0.57	0.002	42
Infant, non-nursing	0.00012	17	0.57	0.002	1
Female 13+, nursing	0.00012	6	0.57	0.002	3

3. *Short-and intermediate-term risk.* Short- and intermediate term aggregate exposure takes into account residential exposure plus chronic exposure to food and water (considered to be a background exposure level).

Avermectin B₁ is currently registered for use that could result in short- and intermediate term residential exposure and the Agency has determined that it is appropriate to aggregate chronic food and water and short-and intermediate term exposures for avermectin B₁.

Short- and intermediate-term total MOEs (dermal + inhalation) are greater than 1,000 and therefore exceeds EPA's level of concern.

A margin of exposure (MOE) of 1,000 or greater is required for the most sensitive subgroups. All lawn postapplication MOEs exceeded this value and therefore is not of concern to EPA. The dermal short- and intermediate-term MOEs for adults and children are 83,000 and 86,000, respectively. The oral hand-to-mouth short- and intermediate-term MOEs for children are 14,000 and 6,500,

respectively. The oral incidental ingestion short- and intermediate-term MOEs for children are 610,000 and 290,000, respectively.

The short- and intermediate-term MOEs for dermal and inhalation exposure are each 12 million, exceeds EPA's level of concern.

The short- and intermediate-term dermal MOE for children's postapplication dermal is 78,000. The short- and intermediate-term oral MOE for children's postapplication oral hand-to-mouth is 12,000. The short- and intermediate-term inhalation MOE for children's postapplication inhalation is 2,400.

The risk from children's post application exposure to crack and crevice products containing avermectin B₁ does not exceed EPA's level of concern. Avert Prescription Treatment 310 is a dust formulation that is intended for the application to crack and crevices only. Other formulations for similar crack and crevice products (i.e., gels, granulars, pressurized liquids, etc.) will have less migration from the

treated area and are expected to result in lower risk from dermal, oral, and inhalation postapplication exposure.

Using the exposure assumptions described in this unit for short- and intermediate term exposures, EPA has concluded that food and residential exposures aggregated result in aggregate MOEs of dermal, inhalation, and oral exposures. These aggregate MOEs do not exceed the Agency's level of concern for aggregate exposure to food and residential uses. In addition, short-and intermediate term DWLOCs were calculated and compared to the EECs for chronic exposure of avermectin B₁ in ground and surface water. After calculating DWLOCs and comparing them to the EECs for surface and ground water, EPA does not expect short-and intermediate term aggregate exposure to exceed the Agency's level of concern as shown in Table 4.

Short-intermediate-term aggregate exposure takes into account residential exposure plus chronic exposure to food and water (considered to be a background exposure level).

TABLE 4.—AGGREGATE RISK ASSESSMENT FOR SHORT-INTERMEDIATE-TERM EXPOSURE TO AVERMECTIN B₁

Population Subgroup	Aggregate MOE Food + Residential	Aggregate Level of Concern (LOC)	Surface Water EEC (ppb)	Ground Water EEC (ppb)	Short-Term DWLOC (ppb)
U.S. population	1,7000	100	0.57	0.00023	87
Infants and children	1400	100	0.57	0.000077	0.77

4. *Aggregate cancer risk for U.S. population.* EPA classified avermectin B₁ as a Cancer Group E (evidence of non-carcinogenicity for humans) chemical based on the absence of significant tumor increases in two adequate rodent carcinogenicity studies.

5. *Determination of safety.* Based on these risk assessments, EPA concludes that there is a reasonable certainty that no harm will result to the general population, and to infants and children from aggregate exposure to avermectin B₁ residues.

IV. Other Considerations

A. Analytical Enforcement Methodology

Adequate enforcement methodology is available to enforce the tolerance expression. Separate analytical methods were employed to quantify residues in celeriac roots and tops: The method used for roots was a modified version of HPLC Fluorescence Determination for Avermectin B₁ and its Delta 8,9 Isomer in Raw Whole Potatoes (Method No. 936-92-4, 25 July 1992). Celeriac tops were analyzed using HPLC Fluorescence Determination for Avermectin B₁ and its Delta 8,9 Isomer in/on Fruits and Vegetables: Commodity - Stone Fruit (Method No. M-073, 15 November 1996). The methods may be requested from: Calvin Furlow, PRRIB, IRSD (7502C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW, Washington, DC 20460; telephone number: (703) 305-5229; e-mail address: furlow.calvin@epa.gov.

B. International Residue Limits

There are no Codex, Canadian, or Mexican Maximum Residue Limits (MRL) for avermectin B₁ on celeriac. Therefore, international harmonization is not an issue for the action.

V. Conclusion

Therefore, the tolerance is established for combined residues of avermectin B₁ and its delta-8,9-isomer in or on celeriac roots and tops at 0.05 ppm.

VI. Objections and Hearing Requests

Under section 408(g) of the FFDCA, as amended by the FQPA, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. The EPA procedural regulations which govern the submission of objections and requests for hearings appear in 40 CFR part 178. Although the procedures in those regulations require some modification to reflect the amendments made to the FFDCA by the FQPA of 1996, EPA will continue to use those procedures, with appropriate adjustments, until the

necessary modifications can be made. The new section 408(g) provides essentially the same process for persons to "object" to a regulation for an exemption from the requirement of a tolerance issued by EPA under new section 408(d), as was provided in the old FFDCA sections 408 and 409. However, the period for filing objections is now 60 days, rather than 30 days.

A. What Do I Need to Do to File an Objection or Request a Hearing?

You must file your objection or request a hearing on this regulation in accordance with the instructions provided in this unit and in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket control number OPP-301082 in the subject line on the first page of your submission. All requests must be in writing, and must be mailed or delivered to the Hearing Clerk on or before February 20, 2001.

1. *Filing the request.* Your objection must specify the specific provisions in the regulation that you object to, and the grounds for the objections (40 CFR 178.25). If a hearing is requested, the objections must include a statement of the factual issues(s) on which a hearing is requested, the requestor's contentions on such issues, and a summary of any evidence relied upon by the objector (40 CFR 178.27). Information submitted in connection with an objection or hearing request may be claimed confidential by marking any part or all of that information as CBI. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2. A copy of the information that does not contain CBI must be submitted for inclusion in the public record. Information not marked confidential may be disclosed publicly by EPA without prior notice.

Mail your written request to: Office of the Hearing Clerk (1900), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460. You may also deliver your request to the Office of the Hearing Clerk in Rm. C400, Waterside Mall, 401 M St., SW., Washington, DC 20460. The Office of the Hearing Clerk is open from 8 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Office of the Hearing Clerk is (202) 260-4865.

2. *Tolerance fee payment.* If you file an objection or request a hearing, you must also pay the fee prescribed by 40 CFR 180.33(i) or request a waiver of that fee pursuant to 40 CFR 180.33(m). You must mail the fee to: EPA Headquarters Accounting Operations Branch, Office of Pesticide Programs, P.O. Box 360277M, Pittsburgh, PA 15251. Please

identify the fee submission by labeling it "Tolerance Petition Fees."

EPA is authorized to waive any fee requirement "when in the judgement of the Administrator such a waiver or refund is equitable and not contrary to the purpose of this subsection." For additional information regarding the waiver of these fees, you may contact James Tompkins by phone at (703) 305-5697, by e-mail at tompkins.jim@epa.gov, or by mailing a request for information to Mr. Tompkins at Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460.

If you would like to request a waiver of the tolerance objection fees, you must mail your request for such a waiver to: James Hollins, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460.

3. *Copies for the Docket.* In addition to filing an objection or hearing request with the Hearing Clerk as described in Unit VI.A., you should also send a copy of your request to the PIRIB for its inclusion in the official record that is described in Unit I.B.2. Mail your copies, identified by docket control number OPP-301082, to: Public Information and Records Integrity Branch, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460. In person or by courier, bring a copy to the location of the PIRIB described in Unit I.B.2. You may also send an electronic copy of your request via e-mail to: opp-docket@epa.gov. Please use an ASCII file format and avoid the use of special characters and any form of encryption. Copies of electronic objections and hearing requests will also be accepted on disks in WordPerfect 6.1/8.0 file format or ASCII file format. Do not include any CBI in your electronic copy. You may also submit an electronic copy of your request at many Federal Depository Libraries.

B. When Will the Agency Grant a Request for a Hearing?

A request for a hearing will be granted if the Administrator determines that the material submitted shows the following: There is a genuine and substantial issue of fact; there is a reasonable possibility that available evidence identified by the requestor would, if established resolve one or more of such issues in favor of the requestor, taking into account uncontested claims or facts to the contrary; and resolution of the factual

issues(s) in the manner sought by the requestor would be adequate to justify the action requested (40 CFR 178.32).

VII. Regulatory Assessment Requirements

This final rule establishes a tolerance under FFDCA section 408(d) in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled *Regulatory Planning and Review* (58 FR 51735, October 4, 1993). This final rule does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA), 44 U.S.C. 3501 *et seq.*, or impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) (Public Law 104-4). Nor does it require any prior consultation as specified by Executive Order 13084, entitled *Consultation and Coordination with Indian Tribal Governments* (63 FR 27655, May 19, 1998); special considerations as required by Executive Order 12898, entitled *Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations* (59 FR 7629, February 16, 1994); or require OMB review or any Agency action under Executive Order 13045, entitled *Protection of Children from Environmental Health Risks and Safety Risks* (62 FR 19885, April 23, 1997). This action does not involve any technical standards that would require Agency consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act of 1995 (NTTAA), Public Law 104-113, section

12(d) (15 U.S.C. 272 note). Since tolerances and exemptions that are established on the basis of a petition under FFDCA section 408(d), such as the tolerance in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*) do not apply. In addition, the Agency has determined that this action will not have a substantial direct effect on 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, as specified in Executive Order 13132, entitled *Federalism* (64 FR 43255, August 10, 1999). Executive Order 13132 requires EPA to develop an accountable process to ensure “meaningful and timely input by State and local officials in the development of regulatory policies that have federalism implications.” “Policies that have federalism implications” is defined in the Executive Order to include regulations that have “substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government.” This final rule directly regulates growers, food processors, food handlers and food retailers, not States. This action does not alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of FFDCA section 408(n)(4).

VIII. Submission to Congress and the Comptroller General

The Congressional Review Act, 5 U.S.C. 801 *et seq.*, as added by the Small Business Regulatory Enforcement

Fairness Act of 1996, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report, which includes a copy of the rule, to each House of the Congress and to the Comptroller General of the United States. EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of this final rule in the **Federal Register**. This final rule is not a “major rule” as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 180

Environmental protection, Administrative practice and procedure, Agricultural commodities, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: December 7, 2000.

James Jones,

Director, Registration Division, Office of Pesticide Programs.

Therefore, 40 CFR chapter I is amended as follows:

PART 180—[AMENDED]

1. The authority citation for part 180 continues to read as follows:

Authority: 21 U.S.C. 321(q), (346a) and 371.

2. Section 180.449 is amended by alphabetically adding commodities to the table in paragraph (a) to read as follows:

§ 180.449 Avermectin B₁ and its delta-8,9-isomer; tolerances for residues.

(a) * * *

Commodity	Parts per million
* * * * *	* *
Celeriac, roots	0.05
Celeriac, tops	0.05
* * * * *	* *

* * * * *

[FR Doc. 00-32569 Filed 12-20-00; 8:45 am]

BILLING CODE 6560-50-S

FEDERAL EMERGENCY MANAGEMENT AGENCY

44 CFR Part 67

Final Flood Elevation Determinations

AGENCY: Federal Emergency Management Agency (FEMA).

ACTION: Final rule.

SUMMARY: Base (1% annual chance) flood elevations and modified base flood elevations are made final for the communities listed below. The base flood elevations and modified base flood elevations are the basis for the floodplain management measures that each community is required either to adopt or to show evidence of being already in effect in order to qualify or remain qualified for participation in the National Flood Insurance Program (NFIP).

EFFECTIVE DATE: The date of issuance of the Flood Insurance Rate Map (FIRM) showing base flood elevations and modified base flood elevations for each community. This date may be obtained by contacting the office where the FIRM is available for inspection as indicated in the table below.

ADDRESSES: The final base flood elevations for each community are available for inspection at the office of the Chief Executive Officer of each community. The respective addresses are listed in the table below.

FOR FURTHER INFORMATION CONTACT: Matthew B. Miller, P.E., Chief, Hazards Study Branch, Mitigation Directorate, 500 C Street SW., Washington, DC 20472, (202) 646-3461, or (e-mail) matt.miller@fema.gov.

SUPPLEMENTARY INFORMATION: The Federal Emergency Management Agency makes final determinations listed below of base flood elevations and modified base flood elevations for each community listed. The proposed base flood elevations and proposed modified base flood elevations were published in newspapers of local circulation and an

opportunity for the community or individuals to appeal the proposed determinations to or through the community was provided for a period of ninety (90) days. The proposed base flood elevations and proposed modified base flood elevations were also published in the **Federal Register**.

This final rule is issued in accordance with Section 110 of the Flood Disaster Protection Act of 1973, 42 U.S.C. 4104, and 44 CFR part 67.

FEMA has developed criteria for floodplain management in floodprone areas in accordance with 44 CFR part 60.

Interested lessees and owners of real property are encouraged to review the proof Flood Insurance Study and FIRM available at the address cited below for each community.

The base flood elevations and modified base flood elevations are made final in the communities listed below. Elevations at selected locations in each community are shown.

National Environmental Policy Act. This rule is categorically excluded from the requirements of 44 CFR part 10, Environmental Consideration. No environmental impact assessment has been prepared.

Regulatory Flexibility Act. The Associate Director for Mitigation certifies that this rule is exempt from the requirements of the Regulatory Flexibility Act because final or modified base flood elevations are required by the Flood Disaster Protection Act of 1973, 42 U.S.C. 4104, and are required to establish and maintain community eligibility in the NFIP. No regulatory flexibility analysis has been prepared.

Regulatory Classification. This final rule is not a significant regulatory action under the criteria of section 3(f) of Executive Order 12866 of September 30, 1993, Regulatory Planning and Review, 58 FR 51735.

Executive Order 12612, Federalism. This rule involves no policies that have federalism implications under Executive Order 12612, Federalism, dated October 26, 1987.

Executive Order 12778, Civil Justice Reform. This proposed rule meets the applicable standards of section 2(b)(2) of Executive Order 12778.

List of Subjects in 44 CFR Part 67

Administrative practice and procedure, Flood insurance, Reporting and recordkeeping requirements.

Accordingly, 44 CFR part 67 is amended to read as follows:

PART 67—[AMENDED]

1. The authority citation for part 67 continues to read as follows:

Authority: 42 U.S.C. 4001 et seq.; Reorganization Plan No. 3 of 1978, 3 CFR, 1978 Comp., p. 329; E.O. 12127, 44 FR 19367, 3 CFR, 1979 Comp., p. 376.

§ 67.11 [Amended]

2. The tables published under the authority of § 67.11 are amended as follows:

Source of flooding and location	# Depth in feet above ground. *Elevation in feet (NGVD).
CALIFORNIA	
Solano County (Unincorporated Areas) (FEMA Docket No. B-7401)	
<i>Gibson Canyon Creek:</i> Approximately 2,250 feet downstream of Byrnes Road	*69
Approximately 100 feet upstream of Browns Valley Road	*143
<i>South Branch Gibson Canyon Creek:</i> Just downstream of Crocker Drive	*102
Just upstream of Browns Valley Road	*142
<i>Horse Creek:</i> Approximately 500 feet downstream of Willow Avenue	*77
Approximately 1,500 feet upstream of Willow Avenue ..	*79
Maps are available for inspection at Solano County Department of Environmental Management, 601 W. Texas Street, Fairfield, California.	
City of Vacaville, Solano County (FEMA Docket No. B-7401)	
<i>Gibson Canyon Creek:</i> Approximately 2,100 feet downstream of Interstate Highway 80 (Eastbound) ...	*78
Approximately 1,200 feet upstream of Eubanks Road ..	*113

Source of flooding and location	# Depth in feet above ground. *Elevation in feet (NGVD).	Source of flooding and location	# Depth in feet above ground. *Elevation in feet (NGVD).	Source of flooding and location	# Depth in feet above ground. *Elevation in feet (NGVD).
<i>South Branch Gibson Canyon Creek:</i> At confluence with Gibson Canyon Creek At intersection with Interstate Highway 505 Approximately 500 feet upstream of Eubanks Road ..	 *98 *103 *121	Approximately 5,670 feet upstream of Borrego Drive <i>Lightner Creek:</i> At confluence with Animas River Approximately 1,800 feet upstream of confluence with Animas River	 *6,873 *6,485 *6,513	Maps are available for inspection at the City Engineer's office, City Hall, 224 Savage Avenue, Raton, New Mexico.	
<i>Horse Creek:</i> Approximately 800 feet downstream of Leisure Town Road Approximately 2,000 feet upstream of Sewer Maintenance Road	 *82 *137	Maps are available for inspection at the Planning Department, 1235 Camino Del Rio, Durango, Colorado.		SOUTH DAKOTA	
<i>Middle Branch Horse Creek:</i> Just upstream of Interstate Highway 80 Approximately 2,200 feet upstream of Interstate Highway 505	 *91 *112	La Plata County (Unincorporated Areas) (FEMA Docket No. B-7401) <i>Animas River:</i> Approximately 2.09 miles downstream of U.S. Highway 155/160 Approximately 2.8 miles upstream of 32nd Street Approximately 3.56 miles upstream of 32nd Street	 *6,337 *6,548 *6,551	City of Deadwood, Lawrence County (FEMA Docket No. B-7401) <i>Whitewood Creek:</i> Approximately 800 feet downstream of U.S. Highway 14-A Approximately 550 feet downstream of U.S. Highway 85	 *4,394 *4,642
<i>Pine Tree Creek:</i> At confluence with Horse Creek At upstream side of Putah South Canal Just downstream of Browns Valley Road At Browns Valley Road Crossing of Southern Pacific Railroad	 *97 *122 *136 #2	<i>Lightner Creek:</i> At confluence with Animas River Approximately 3,525 feet upstream of U.S. Highway 160	 *6,484 *6,699	<i>Deadwood Creek:</i> Approximately 1,225 feet upstream of Shine Street Just upstream of U.S. Highway 14-A Approximately 1,550 feet upstream of U.S. Highway 14-A	 None *4,640 *4,658
<i>South Branch Horse Creek:</i> At confluence with Horse Creek Just downstream of Southern Pacific Railroad Just downstream of Sundance Drive	 *114 *134 # 2	Maps are available for inspection at the Building Department, 1060 E. 2nd Avenue, Durango, Colorado.		<i>Spring Creek:</i> At upstream end of culvert, approximately 400 feet upstream of North Williams Street At western corporate limit, approximately 2,600 feet upstream of North Williams Street	 *4,580 *4,753
<i>Middle Swale to South Branch Horse Creek:</i> At confluence with South Branch Horse Creek Just downstream of Southern Pacific Railroad Just upstream of Southern Pacific Railroad	 *122 *131 # 1	KANSAS		Maps are available for inspection at 102 Sherman Street, Deadwood, South Dakota.	
<i>North Branch Horse Creek:</i> At confluence with Horse Creek At downstream side of Interstate Highway 80	 *83 *88	City of Augusta, Butler County (FEMA Docket No. B-7401) <i>Elm Creek (above Augusta Lake):</i> At mouth at Augusta Lake Approximately 1,900 feet upstream of Augusta Lake Road	 *1,263 *1,269	TEXAS	
<i>Pine Tree Creek Split:</i> At convergence with Pine Tree Creek Approximately 1,100 feet upstream of convergence with Pine Tree Creek	 *122 *125	NEW MEXICO		City of Huntsville, Walker County (FEMA Docket No. B-7401) <i>Alligator Branch:</i> Approximately 4,200 feet upstream of confluence with Prairie Branch Approximately 7,400 feet upstream of confluence with Prairie Branch	 *307 *323
Maps are available for inspection at the Vacaville City Hall, 650 Merchant Street, Vacaville, California.		City of Raton, Colfax County (FEMA Docket No. B-7401) <i>Raton Creek:</i> Approximately 3,360 feet downstream of Frontage Road Approximately 1,560 feet upstream of North Second Street	 *6,541 *6,705	<i>Baldwin Creek:</i> Approximately 36,500 feet above confluence with Nelson Creek Approximately 43,500 feet above confluence with Nelson Creek	 *244 *261
COLORADO		<i>Middle Creek:</i> Approximately 600 feet downstream of Interstate Highway 25 At Atchison, Topeka and Santa Fe Railway Crossing	 *6,527 *6,633	<i>Caney Creek:</i> Approximately 1,900 feet upstream of confluence with Winters Bayou Approximately 24,000 feet upstream of confluence with Winters Bayou	 *354 *374
City of Durango, La Plata County (FEMA Docket No. B-7401) <i>Animas River:</i> Approximately 0.67 mile downstream of U.S. Highway 155/160 Approximately 3.56 miles upstream of 32nd Street	 *6,375 *6,551	<i>South Creek:</i> Approximately 900 feet upstream of confluence with Middle Creek	 *6,520	<i>Crabb Creek:</i> Approximately 17,400 feet upstream of confluence with Nelson Creek Approximately 27,100 feet upstream of confluence with Nelson Creek	 *257 *287
<i>Dry Gulch:</i> Approximately 1,500 feet upstream of confluence with Junction Creek	*6,628	Approximately 120 feet upstream of South Second Street (U.S. Highway 85) ..	*6,552	<i>East Fork:</i> At confluence with Tanyard Branch	*271

Source of flooding and location	# Depth in feet above ground. *Elevation in feet (NGVD).	Source of flooding and location	# Depth in feet above ground. *Elevation in feet (NGVD).	Source of flooding and location	# Depth in feet above ground. *Elevation in feet (NGVD).
Approximately 5,500 feet upstream of confluence with Tanyard Branch	*298	Approximately 2,600 feet upstream of State Highway 190	*363	Approximately 2,100 feet upstream of confluence with Harmony Creek	*259
<i>Ford Branch:</i>		<i>Thompson Branch:</i>		Approximately 12,600 feet upstream of confluence with Harmony Creek	*298
At confluence with Wayne Creek	*272	At confluence with Sixmile Branch	*254	Maps are available for inspection at City Service Center, 448 Highway 75 North, Huntsville, Texas.	
Approximately 2,700 feet upstream of confluence with Wayne Creek	*286	Approximately 1,000 feet upstream of confluence with Sixmile Branch	*260		
<i>Hadley Creek:</i>		<i>Town Branch:</i>		(Catalog of Federal Domestic Assistance No. 83.100, "Flood Insurance.")	
At Rosenwall Road	*250	At confluence with Parker Creek	*260		
Approximately 200 feet north of Huntsville Airport Runway	*292	Approximately 700 feet upstream of Avenue J and 14th Street	*361	Dated: December 6, 2000.	
<i>Horse Branch:</i>		<i>Tributary A:</i>		Michael J. Armstrong,	
At its confluence with Town Branch	*274	At confluence with Town Branch	*322	<i>Associate Director for Mitigation.</i>	
Approximately 450 feet downstream of FM 2821 ...	*285	Approximately 280 feet upstream of its confluence with Town Branch	*324	[FR Doc. 00-32213 Filed 12-20-00; 8:45 am]	
Approximately 3,500 feet upstream of Holly Bend Road	*329	Approximately 300 feet upstream of State Highway 30/190	*338	BILLING CODE 6718-04-P	
<i>Mays Creek:</i>		<i>Tributary B:</i>		FEDERAL EMERGENCY MANAGEMENT AGENCY	
Approximately 2,600 feet upstream of confluence of Shepherd Creek	*320	At confluence with Horse Branch	*307	44 CFR Part 67	
Approximately 13,400 feet upstream of confluence of Shepherd Creek	*355	Approximately 800 feet upstream of Private Dam	*327	Final Flood Elevation Determinations	
<i>McDonald Creek:</i>		<i>Tributary 2:</i>		AGENCY: Federal Emergency Management Agency (FEMA).	
Approximately 2,300 feet downstream of Sunset Lake Dam	*293	At confluence with Tanyard Branch	*225	ACTION: Final rule.	
Approximately 1,900 feet upstream of Spring Lake Dam	*376	Approximately 1,250 feet upstream of Robinson Road	*253	SUMMARY: Base (1% annual chance) flood elevations and modified base flood elevations are made final for the communities listed below. The base flood elevations and modified base flood elevations are the basis for the floodplain management measures that each community is required either to adopt or to show evidence of being already in effect in order to qualify or remain qualified for participation in the National Flood Insurance Program (NFIP).	
<i>McGary Creek:</i>		<i>Tributary 3:</i>			
Approximately 8,050 feet downstream of confluence with Tributary 6	*279	At confluence with Shepherd Creek	*358	EFFECTIVE DATE: The date of issuance of the Flood Insurance Rate Map (FIRM) showing base flood elevations and modified base flood elevations for each community. This date may be obtained by contacting the office where the FIRM is available for inspection as indicated in the table below.	
Approximately 9,700 feet upstream of confluence with Tributary 5	*351	Approximately 1,700 feet upstream of confluence with Shepherd Creek	*364		
<i>Parker Creek:</i>		<i>Tributary 4:</i>		ADDRESSES: The final base flood elevations for each community are available for inspection at the office of the Chief Executive Officer of each community. The respective addresses are listed in the table below.	
Approximately 10,500 feet upstream of confluence with harmon Creek	*212	At confluence with Robinson Creek	*293		
Approximately 1,000 feet upstream of FM 247	*279	Approximately 7,800 feet upstream of confluence with Robinson Creek	*330	FOR FURTHER INFORMATION CONTACT: Matthew B. Miller, P.E., Chief, Hazards Study Branch, Mitigation Directorate, 500 C Street SW., Washington, DC 20472, (202) 646-3461, or (e-mail) matt.miller@fema.gov.	
<i>Prairie Branch:</i>		<i>Tributary 5:</i>			
Approximately 14,800 feet upstream of confluence with East Sandy Creek	*287	At confluence with McGary Creek	*319		
Approximately 800 feet upstream of Broadmoor Drive	*368	Approximately 7,600 feet upstream of confluence with McGary Creek	*347		
<i>Robinson Creek:</i>		<i>Tributary 6:</i>			
Approximately 4,700 feet downstream of confluence with Tributary 4	*283	At confluence with McGary Creek	*292		
Approximately 16,350 feet upstream of confluence with Tributary 4	*362	Approximately 10,500 feet upstream of confluence with McGary Creek	*319		
<i>Shepherd Creek:</i>		<i>Tributary 7:</i>			
Approximately 3,700 feet upstream of confluence of Mays Creek	*317	Approximately 14,800 feet upstream of confluence with Hadley Creek	*256		
Approximately 7,150 feet upstream of confluence with Tributary 3	*381	Approximately 20,400 feet upstream of confluence with Hadley Creek	*275		
<i>Sixmile Branch:</i>		<i>Tributary 8:</i>			
Approximately 400 feet downstream of confluence with Thompson Branch	*253	Approximately 3,700 feet upstream of confluence with Parker Creek	*217		
Approximately 1,400 feet upstream of confluence with Thompson Branch	*261	Approximately 8,000 feet upstream of confluence with Parker Creek	*231		
<i>Tanyard Branch:</i>		<i>Tributary 9:</i>			
Approximately 500 feet upstream of confluence with Harmony Creek	*224	At confluence with Shepherd Creek	*332		
		Approximately 6,700 feet upstream of confluence with Shepherd Creek	*347		
		<i>Wayne Creek:</i>			

SUPPLEMENTARY INFORMATION: The Federal Emergency Management Agency makes final determinations listed below of base flood elevations and modified base flood elevations for each community listed. The proposed base flood elevations and proposed modified base flood elevations were published in newspapers of local circulation and an opportunity for the community or individuals to appeal the proposed determinations to or through the community was provided for a period of ninety (90) days. The proposed base flood elevations and proposed modified base flood elevations were also published in the **Federal Register**.

This final rule is issued in accordance with Section 110 of the Flood Disaster Protection Act of 1973, 42 U.S.C. 4104, and 44 CFR part 67.

FEMA has developed criteria for floodplain management in floodprone areas in accordance with 44 CFR part 60.

Interested lessees and owners of real property are encouraged to review the proof Flood Insurance Study and FIRM available at the address cited below for each community.

The base flood elevations and modified base flood elevations are made final in the communities listed below. Elevations at selected locations in each community are shown.

National Environmental Policy Act. This rule is categorically excluded from the requirements of 44 CFR part 10, Environmental Consideration. No environmental impact assessment has been prepared.

Regulatory Flexibility Act. The Associate Director for Mitigation certifies that this rule is exempt from the requirements of the Regulatory Flexibility Act because final or modified base flood elevations are required by the Flood Disaster Protection Act of 1973, 42 U.S.C. 4104, and are required to establish and maintain community eligibility in the NFIP. No regulatory flexibility analysis has been prepared.

Regulatory Classification. This final rule is not a significant regulatory action under the criteria of section 3(f) of Executive Order 12866 of September 30, 1993, Regulatory Planning and Review, 58 FR 51735.

Executive Order 12612, Federalism. This rule involves no policies that have federalism implications under Executive Order 12612, Federalism, dated October 26, 1987.

Executive Order 12778, Civil Justice Reform. This proposed rule meets the applicable standards of section 2(b)(2) of Executive Order 12778.

List of Subjects in 44 CFR Part 67

Administrative practice and procedure, Flood insurance, Reporting and recordkeeping requirements.

Accordingly, 44 CFR part 67 is amended to read as follows:

PART 67—[AMENDED]

1. The authority citation for part 67 continues to read as follows:

Authority: 42 U.S.C. 4001 *et seq.*; Reorganization Plan No. 3 of 1978, 3 CFR, 1978 Comp., p. 329; E.O. 12127, 44 FR 19367, 3 CFR, 1979 Comp., p. 376.

§ 67.11 [Amended]

2. The tables published under the authority of § 67.11 are amended as follows:

Source of flooding and location	*Depth in feet above ground. *Elevation in feet (NGVD).
ARIZONA	
Yavapai County and Incorporated Areas (FEMA Docket No. B-7404)	
<i>Blue Tank Wash:</i>	
Just upstream of Yavapai-Marcopla County Boundary	*2,176
Approximately 200 feet upstream of Yavapai-Marcopla County Boundary	*2,179
<i>Powerhouse Wash Tributary 1:</i>	
Just upstream of Yavapai-Marcopla County Boundary	*2,262
Approximately 800 feet upstream of Yavapai-Marcopla County Boundary	*2,297
<i>Powerhouse Wash Tributary 2:</i>	
Just upstream of Yavapai-Marcopla County Boundary	*2,280
Approximately 300 feet upstream of Yavapai-Marcopla County Boundary	*2,286
<i>Sols Wash:</i>	
Just downstream of Atchison, Topeka and Santa Fe Railroad	*2,364
Approximately 1,500 feet upstream of Atchison, Topeka and Santa Fe Railroad	*2,401
<i>Wash P:</i>	
Just upstream of Yavapai-Marcopla County Boundary	*2,131
Approximately 600 feet upstream of Yavapai-Marcopla County Boundary	*2,147
<i>Verde River:</i>	
Just downstream of North 5th Street	*3,297
Approximately 800 feet north of Yavapai Street	*3,303
Maps for the unincorporated areas of Yavapai County are available for inspection at 500 Marina Street, Prescott, Arizona 86301.	

Source of flooding and location	*Depth in feet above ground. *Elevation in feet (NGVD).
Maps for the Town of Cottonwood are available for inspection at the Public Works Office, 1490 West Mingus Avenue, Cottonwood, Arizona.	
ARKANSAS	
Mountain Home (City), Baxter County (FEMA Docket No. B-7404)	
<i>Hicks Creek:</i>	
Approximately 3,000 feet upstream of Hicks Road	*682
Just upstream of Arkansas Highway 201	*833
<i>Indian Creek:</i>	
At confluence with Hicks Creek	*753
At Bradley Street	*819
Maps are available at 720 South Hickory, Mountain Home, Arkansas.	
CALIFORNIA	
Madera County (Unincorporated Areas) (FEMA Docket No. B-7404)	
<i>San Josquin River:</i>	
Just upstream of State Highway 99	*245
Just downstream of Friant Dam	*329
Maps are available for inspection at 209 West Yosemite Avenue, Madera, California.	
COLORADO	
Silver Plume (Town), Clear Creek County (FEMA Docket No. B-7404)	
<i>Clear Creek:</i>	
Approximately 800 feet downstream of Interstate 70	*9,002
Approximately 300 feet upstream of Burleigh Street extended	*9,142
Maps are available for inspection at Town Hall, 487 Main Street, Silver Plume, Colorado.	
Summit County (Unincorporated Areas) (FEMA Docket No. B-7404)	
<i>Willow Creek:</i>	
At confluence with Blue River	*8,674
Approximately 400 feet upstream of Ranch Road	*8,864
<i>Blue River:</i>	
Approximately 3,400 feet downstream of Winegard Road	*8,565
Approximately 2,400 feet upstream of Interstate 70	*8,777
Maps are available for inspection at 0037 Summit County Road, #1005, Town of Frisco, Colorado.	

Source of flooding and location	#Depth in feet above ground. *Elevation in feet (NGVD).	Source of flooding and location	#Depth in feet above ground. *Elevation in feet (NGVD).	Source of flooding and location	#Depth in feet above ground. *Elevation in feet (NGVD).
IOWA					
Akron (City), Plymouth County (FEMA Docket No. B-7404)		Approximately 1,700 feet downstream of Burlington Northern Railroad	*2,530	At confluence of 17th and 18th Streets shallow flooding	+3,999
<i>Big Sioux River:</i>		Approximately 350 feet upstream of Park Footbridge	*2,613	<i>17th and 18th Streets shallow Flooding:</i>	
Approximately 400 feet west of the intersection of South Street and Route 12	*1,136	<i>Paradise Creek (University Overflow):</i>		Area bounded by South Main Avenue, West 17th Street, South Avenue A, and West 18th Street	+4,000
Just upstream of Route 48 ...	*1,144	Approximately 1,200 feet downstream of Rayburn Street	*2,552	Area bounded by South Avenue F, West 17th Street, South Avenue G, and West 18th Street	+4,004
Maps are available for inspection at the Akron City Hall, 220 Reed Street, Akron, Iowa 51001.		Approximately 1,500 feet upstream of Third Street	*2,561	<i>Flooding throughout University and Downtown Areas:</i>	
Plymouth County (Unincorporated Areas) (FEMA Docket No. B-7404)		<i>Paradise Creek (Mountain View Road Overflow):</i>		Area bounded by South Main Avenue, West 10th Street, South Avenue A, and West 11th Street	+4,002
<i>Big Sioux River:</i>		Approximately 2,000 feet downstream of Harold Avenue	*2,584	Area bounded by South Avenue B, West Commercial Street, South Avenue C, and West First Street	+4,009
Just upstream of the Plymouth and Woodbury County boundary	*1,111	Just downstream of Mountain View Road	*2,594	<i>Ponding Area:</i>	
Approximately 1,000 feet downstream of Route 48 ...	*1,142	Maps are available for inspection at 122 East 4th Street, Moscow, Idaho.		Upstream of Burlington Northern Santa Fe Railroad from Boulder Avenue to southwest of University Avenue	+4,011
Maps are available for inspection at the Plymouth County Courthouse, 215 - 4th Avenue, Southeast, LeMars, Iowa 51031.		Latah County (Unincorporated Areas) (FEMA Docket No. B-7404)		<i>Ponding Area:</i>	
Sioux City (City), Woodbury County (FEMA Docket No. B-7404)		<i>Paradise Creek:</i>		At the intersection of Industrial Drive and West 18th Street	+4,004
<i>Big Sioux River:</i>		Approximately 1,200 feet downstream of Joseph Street	*2,586	Approximately 700 feet west of the intersection of the Burlington Northern Santa Fe Railroad and West 18th Street	+4,004
Approximately 3,000 feet downstream of intersection of Riverside Boulevard and Interstate 29	*1,090	Approximately 1,600 feet downstream of Darby Road	*2,614	<i>Ponding Area:</i>	
Just upriver of Military Road	*1,103	Maps are available for inspection at 522 South Adams, Moscow, Idaho.		Approximately 4,000 feet northwest of the intersection of Industrial Drive and West 18th Street	+4,010
Just downriver of Interstate 29	*1,094	NEVADA		+Elevation in feet (NAVD)	
Just downstream of the Plymouth and Woodbury County boundary	*1,110	Washoe County (Unincorporated Areas) (FEMA Docket No. B-7407)		Maps are available for inspection at City Hall, 100 West First Street, Portales, New Mexico.	
Maps are available for inspection at the City of Sioux City City Hall, 520 Pierce Street, Sioux City, Iowa 51107.		<i>Galena Creek:</i>		Red River (Town), Toas County (FEMA Docket No. B-7407)	
Westfield (City), Plymouth County (FEMA Docket No. B-7404)		Approximately 12,000 feet downstream of Joy Lake Road	#3	<i>Bitter Creek:</i>	
<i>Big Sioux River:</i>		Approximately 1,950 feet downstream of Joy Lake Road	*5,840	Approximately 220 feet downstream of East River Street	*8,654
Approximately 300 feet downstream of the confluence of Westfield Creek	*1,123	Approximately 1,000 feet upstream of Joy Lake Road ..	*6,830	Approximately 760 feet upstream of East High Street	*8,691
Approximately 4,500 feet upstream of the confluence of Westfield Creek	*1,124	At Mount Rose Highway	#2	<i>Mallette Creek:</i>	
Maps are available for inspection at 233 Union Street, Westfield, Iowa 51062.		<i>Jones Creek:</i>		Approximately 340 feet downstream of West Main Street	*8,632
IDAHO		At confluence with Galena Creek	#3	Approximately 180 feet downstream of Mallette Canyon Park Road	*8,656
Moscow (City), Latah County (FEMA Docket No. B-7404)		At Callahan Ranch Road	*5,450	<i>Red River:</i>	
<i>Paradise Creek:</i>		Approximately 2,600 feet upstream of Bordeaux Drive	*5,888	Approximately 100 feet downstream of High Cost Trail	*8,608
		At Mount Rose Highway	#1	Approximately 1,500 feet upstream of Fishing Pond Bridge	*8,778
		Maps are available for inspection at Washoe County Engineering, 1001 E. 9th Street, Reno, Nevada.		Maps are available for inspection at 100 East Main Street, Red River, New Mexico.	
		NEW MEXICO			
		Portales (City), Roosevelt County (FEMA Docket No. B-7404)			
		<i>Globe Ditch:</i>			
		Approximately 400 feet downstream of confluence of 17th and 18th Streets shallow flooding	+3,998		

(Catalog of Federal Domestic Assistance No. 83.100, "Flood Insurance.")

Dated: December 6, 2000.

Michael J. Armstrong,

Associate Director for Mitigation.

[FR Doc. 00-32212 Filed 12-20-00; 8:45 am]

BILLING CODE 6718-04-P

FEDERAL COMMUNICATIONS COMMISSION

47 CFR CH. 1

[FCC 00-401]

Development of Secondary Markets

AGENCY: Federal Communications Commission.

ACTION: Policy statement.

SUMMARY: This document outlines in general terms a series of initiatives that the Commission intends to undertake to promote secondary markets for spectrum. The Commission's current policies concerning transfer, assignment, disaggregation and partitioning of licenses allow certain licensees to market portions of their spectrum to others. In this effort, the Commission seeks to significantly expand and enhance the existing secondary markets for spectrum and radio communications services to permit spectrum to flow more freely among users and uses in response to economic demand, to the extent consistent with our other statutory mandates and public interest objectives.

FOR FURTHER INFORMATION CONTACT: Lisa Gaisford, Office of Engineering and Technology, (202) 418-7280.

SUPPLEMENTARY INFORMATION: This is a summary of the Commission's *Policy Statement*, FCC 00-401, adopted November 9, 2000, and released December 1, 2000. The full text of this Commission decision is available on the Commission's Internet site, at www.fcc.gov. It is also available for inspection and copying during normal business hours in the FCC Reference Information Center, Room CY-A257, 445 12th Street, SW., Washington, DC, and also may be purchased from the Commission's duplication contractor, International Transcription Service, (202) 857-3800, 1231 20th Street, NW, Washington, DC 20036.

Summary of the Policy Statement

The Commission adopted a Policy Statement setting forth the Commission's plans for facilitating secondary markets for radio spectrum that will allow and encourage licensees to make all or portions of their

frequencies and/or service areas available to other entities and uses. The Commission envisions that secondary markets can flourish by facilitating arrangements such as leasing, franchising, and joint operating agreements, and improving the conditions for transferability of spectrum through, for example, partitioning or disaggregation. The Policy Statement outlines in general terms a series of initiatives that the Commission intends to undertake to promote secondary markets for spectrum. The Commission's current policies concerning transfer, assignment, disaggregation and partitioning of licenses allow certain licensees to market portions of their spectrum to others. In this new effort, the Commission seeks to significantly expand and enhance the existing secondary markets for spectrum and radio communications services to permit spectrum to flow more freely among users and uses in response to economic demand, to the extent consistent with our other statutory mandates and public interest objectives.

Federal Communications Commission.

Magalie Roman Salas,

Secretary.

[FR Doc. 00-32467 Filed 12-20-00; 8:45 am]

BILLING CODE 6712-01-P

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Part 73

[DA 00-2710; MM Docket No. 98-29; RM-9190, RM-9275]

Radio Broadcasting Services; Indian Wells, Indio, CA

AGENCY: Federal Communications Commission.

ACTION: Final rule.

SUMMARY: The Commission, at the request of Professional Broadcasting, Inc. allots Channel 238A at Indian Wells, California, as the community's first local aural transmission service. See 63 FR 12426 (March 13, 1998). The Commission considers comparatively and denies a petition filed by Elia Tawil proposing to allot Channel 238A at Indio, California, as the community's fourth aural transmission service, and to reserve the channel as a noncommercial educational channel. It also dismisses as technically and procedurally defective a pleading filed by Playa Del Sol Broadcasters, permittee of an unbuilt station on Channel 249A in Mecca, California, requesting the allotment of Channel 238A at Mecca, California,

reallotment of Channel 249A from Mecca to Indian Wells, California, and modification of its permit for unbuilt station in Mecca to reflect the new community. Channel 238A can be allotted to Indian Wells in compliance with the Commission's minimum distance separation requirements, with respect to domestic allotments, at a site 6 kilometers (3.7 miles) east, at coordinates 33-42-04 North Latitude and 116-14-47 West Longitude. A filing window for Channel 238A at Indian Wells, California, will not be opened at this time. Instead, the issue of opening filing windows for this channel will be addressed by the Commission in a subsequent Order. With this Order, this proceeding is terminated.

DATES: Effective January 22, 2000.

FOR FURTHER INFORMATION CONTACT:

Victoria M. McCauley, Mass Media Bureau, (202) 418-2180.

SUPPLEMENTARY INFORMATION: This is a synopsis of the Commission's Report and Order, MM Docket No. 98-29, adopted November 22, 2000, and released December 1, 2000. The full text of this Commission decision is available for inspection and copying during normal business hours in the FCC Reference Center (Room 239), 445 12th Street, SW, Washington, DC. The complete text of this decision may also be purchased from the Commission's copy contractor, International Transcription Services, Inc., (202) 857-3800, 1231 20th Street, NW, Washington, DC 20036.

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, 334 and 336.

§ 73.202 [Amended]

2. Section 73.202(b) the FM Table of Allotments under California is amended by adding Indian Wells, Channel 238A.

Federal Communications Commission.

John A. Karousos,

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

[FR Doc. 00-32330 Filed 12-20-00; 8:45 am]

BILLING CODE 6712-01-P

DEPARTMENT OF COMMERCE**National Oceanic and Atmospheric Administration****50 CFR Part 229****[Docket No. 001128334-0334-01; I.D. 101800A]****RIN 0648-AN88****Taking of Marine Mammals Incidental to Commercial Fishing Operations; Atlantic Large Whale Take Reduction Plan Regulations****AGENCY:** National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.**ACTION:** Interim final rule.

SUMMARY: NMFS is issuing an interim final rule to amend the regulations implementing the Atlantic Large Whale Take Reduction Plan (ALWTRP). The Atlantic Large Whale Take Reduction Team (ALWTRT) recommended modifications to the ALWTRP to further reduce whale entanglement. The intent of this interim final rule is to implement the recommendations of the ALWTRT.

DATES: This interim final rule is effective January 22, 2001. Comments on this interim final rule must be postmarked or transmitted via facsimile by 5 p.m., Eastern Standard Time, on February 20, 2001. Comments transmitted via e-mail will not be accepted.

ADDRESSES: Send comments on this interim final rule to the Chief, Marine Mammal Division, NMFS, Office of Protected Resources, 1315 East-West Highway, Silver Spring, MD 20910. Copies of the Environmental Assessment, ALWTRT meeting summaries, progress reports on implementation of the ALWTRP, and a map and table of the changes to the ALWTRP may be obtained by writing Douglas Beach, NMFS/Northeast Region, 1 Blackburn Dr., Gloucester, MA 01930 or Katherine Wang, NMFS/Southeast Region, 9721 Executive Center Dr., St. Petersburg, FL 33702-2432.

Send comments regarding any ambiguity or unnecessary complexity arising from the language used in this interim final rule to the Marine Mammal Division Chief at the previously listed address. See **SUPPLEMENTARY INFORMATION** for Internet addresses pertaining to this interim final rule.

FOR FURTHER INFORMATION CONTACT: Douglas Beach, NMFS, Northeast Region, 978-281-9254; Katherine Wang, NMFS, Southeast Region, 727-570-5312;

or Patricia Lawson, NMFS, Office of Protected Resources, 301-713-2322.

SUPPLEMENTARY INFORMATION:**Electronic Access**

Several of the background documents for this interim final rule and the take reduction planning process can be downloaded from the ALWTRP web site at <http://www.nero.nmfs.gov/whaletrp/>. Copies of the most recent marine mammal Stock Assessment Reports may be obtained by writing to Richard Merrick, NMFS, 166 Water St., Woods Hole, MA 02543 or can be downloaded from the Internet at <http://www.nmfs.noaa.gov/prot-res/mammals/sa-rep/sar.html>.

Background

The ALWTRP was developed pursuant to the Marine Mammal Protection Act (MMPA) to reduce the level of serious injury/mortality of all whales in four East Coast lobster trap and finfish gillnet fisheries. The background for the take reduction planning process and development of the ALWTRP is set out in the preamble to the proposed (62 FR 16519, April 7, 1997), interim final (62 FR 39157, July 22, 1997), and final (64 FR 7529, February 16, 1999) rules implementing the ALWTRP. Additional information is available in the report from the ALWTRT after its initial series of meetings in 1996 and 1997. Copies of these documents and supporting Environmental Assessments are available from the NMFS/Northeast Region contact in the **ADDRESSES** section of this document.

Since the ALWTRP final rule was published in February 1999, entanglements of whales have continued to occur. The four whale species protected by the ALWTRP are the northern right whale, the humpback whale, and the fin whale which are listed as endangered pursuant to the Endangered Species Act (ESA), and the minke whale. Because of the critical status of the right whale population, there is an urgent need to reduce entanglement. The impacts of the gear modifications required by this rule (buoy line weak links, net panel weak links with anchoring systems, restrictions on number of buoy lines, and gear marking) were analyzed in the 1997 proposed and 1999 final rules and were available for public comment. In addition, through the ALWTRT process, representatives of all stakeholder groups directly affected by the ALWTRP participated in development of the consensus recommendations implemented by this interim final rule. Because of the continued entanglements

of whales, the Assistant Administrator for Fisheries, NOAA (AA) has determined that it would be contrary to the public interest to delay this interim final rule to provide prior notice and an opportunity for public comments. However, rather than issuing a final rule the AA is issuing an interim final rule to allow public comments to be received and considered before this rule is made final. The final rule will be incorporating the most current gear technology that has been tested and confirmed to be valid for reducing whale entanglements.

Recent Information on Entanglement and Right Whale Population Status

Section 118 of the MMPA requires NMFS to monitor the incidental take of U.S. marine mammal stocks. Through the monitoring process, NMFS obtains data on annual serious injury/mortality of these stocks which is then analyzed and prepared in accordance with the Stock Assessment Report (SAR) process established in Section 117 of the MMPA. Data presented in the SARs are then used for establishing take reduction teams, preparing take reduction plans, and monitoring the progress of those plans. A copy of the most recent SAR can be obtained from the mail or web site contacts listed in the **ADDRESSES** section.

NMFS prepared a summary of the 1999 entanglement events for the ALWTRT's February 2000 meeting. The most recent summary of the 1999 events is available on the ALWTRP web site listed in the **ADDRESSES** section. A summary of the 2000 events will be provided to the ALWTRT at its next meeting. Information on some of the 1999 and 2000 events is also available on the web page of NMFS' whale disentanglement contractor, the Center for Coastal Studies, at <http://www.coastalstudies.org/>.

In 1999, six confirmed right whale entanglements, nine confirmed humpback whale entanglements, three confirmed fin whale entanglements, and four confirmed minke whale entanglements were reported by the Center for Coastal Studies. NMFS has determined that one of the right whale entanglements resulted in mortality which is attributable to gillnet gear regulated by the ALWTRP; this entanglement is described in greater detail here.

As of September 8, 2000, six confirmed right whale entanglements, 11 confirmed humpback whale entanglements, zero confirmed fin whale entanglements, and five confirmed minke whale entanglements have been reported for 2000.

Information Specific to Right Whales

The northern right whale is the rarest of all large cetaceans and one of the most endangered species in the world. The size of the Western North Atlantic population has most recently been estimated at 291 animals (Kraus et al., In press). In October 1999, the Scientific Committee of the International Whaling Commission (IWC) hosted a workshop on the status and trends in this population (IWC In press) and concluded that survival has declined. Due to the decline in survival resulting from continuing mortality coupled with poor reproduction (as evidenced by the decline in calving rates and increase in calving interval), the Atlantic Scientific Review Group recommended that the potential biological removal (PBR) level for this population be reduced from 0.4 individuals per year to zero in the 2000 SAR.

Approximately one-third of all known right whale mortality is caused by human activities (Kraus, 1990), the most significant of which are ship strikes and fishing gear entanglements. Furthermore, the small population size and low annual reproductive rate suggest that human sources of mortality may have a greater effect on population growth rates of the right whale than on those of other whales (IWC In press).

NMFS implemented a Mandatory Ship Reporting System to help protect right whales on July 1, 1999. Commercial ships 300 tons and greater are required to report to a shore-based station when entering designated right whale critical habitats. When the officers of the ship report in, they are provided with the latest whale sightings and advice on how to avoid a collision with the right whales.

With regard to assessing the effectiveness of the ALWTRP, two recent right whale entanglements are particularly significant. The first involves an adult female that was first sighted entangled in sink gillnet gear in the Cultivator Shoals area off Massachusetts on May 10, 1999. Attempts to remove the gear were made several times in September 1999 in Canada, and some gear was removed. However, the animal's injuries were substantial and it was found floating dead off New Jersey in October 1999.

Another right whale was sighted floating dead, entangled in fishing gear (type not determined) on January 19, 2000, off Rhode Island. The carcass could not be recovered and examined due to inclement weather, therefore the agency could not determine whether the entanglement caused the death.

Take Reduction Planning Activities in 1999 and 2000

The ALWTRP creates a regulatory (e.g., gear restrictions, closures) and non-regulatory (e.g., disentanglement, gear research) framework for reaching the MMPA take reduction goals, including the short-term goal of achieving the PBR level and the long-term goal of reaching a zero mortality rate. The regulatory elements of the ALWTRP implemented by the 1999 final rule included time/area closures in right whale critical habitats and a series of gear modifications for lobster and gillnet gear.

Pursuant to Section 118(f)(7)(E) and (F) of the MMPA, NMFS has reconvened the ALWTRT periodically to monitor progress of the ALWTRP and to make recommendations for improvements. The ALWTRT met on February 8-10, 1999, to review gear modifications, gear research progress, and entanglements that occurred since the publication of the 1997 interim final rule. On April 9, 1999 (64 FR 17292), NMFS published a partial stay for the gear marking requirements in the northeast U.S. fisheries until November 1, 1999, to allow time for modifications to the requirements to be developed. On December 30, 1999 (64 FR 73434), NMFS extended the suspension until November 1, 2000 to allow for additional developmental time. On November 22, 2000 (65 FR 70316), NMFS removed and reserved the gear marking system indefinitely. The removal did not apply to required gear marking regimes in the Southeast U.S., which remains in effect. The gear marking system implemented by this interim final rule replaces the one in the final rule for northeast fisheries and is described later in this document.

At the February 2000 meeting, the ALWTRT reached consensus on a number of improvements to the final rule which could be implemented without further research as well as more advanced concepts that require additional research and field-testing prior to implementation. The ALWTRT provided detailed recommendations for short-term measures, which are the subject of this interim final rule, and an outline for long-term measures. For more information on the range of options discussed by the ALWTRT, readers should refer to the February 2000 meeting summary which is available from the NMFS Northeast Regional Office contact provided in the ADDRESSES section. To facilitate more thorough discussion of area-specific issues, the ALWTRT split into three

sub-groups covering the New England, Mid-Atlantic, and Southeast Areas.

The ALWTRT did not fully discuss gillnet measures for the Mid-Atlantic and Southeast areas at the February 2000 meeting. However, the sub-groups for these areas met subsequently (August 25, 2000, and July 24, 2000, respectively) and have provided recommendations to the whole ALWTRT for its review. The Northeast subgroup of the ALWTRT also met on April 11, 2000, and May 22-23, 2000, to discuss modification to the time/area closure component of the ALWTRP for the New England area.

Although NMFS intends to consider the recommendations of the three sub-groups after they have been fully vetted by the whole ALWTRT, this information was not available at the time this interim final rule and supporting analyses were prepared. NMFS has decided to move forward with the consensus recommendations from the February 2000 meeting without waiting for the additional sub-group recommendations in order to address the urgent need for additional protection for the northern right whale. Recommendations from the April-August 2000 sub-group meetings will be addressed in future rulemaking.

Thus, this interim final rule only implements the ALWTRT's recommendations for lobster trap gear in New England and the Mid-Atlantic and for anchored gillnet gear in New England. These measures are described in detail here. Readers should refer to the Environmental Assessment prepared for this interim final rule for a discussion of impacts of this action on the environment.

Changes Recommended by the Atlantic Large Whale Take Reduction Team for Lobster Trap Gear

The ALWTRT reached consensus on the following amendments to the ALWTRP lobster trap gear restrictions for each time/area combination outlined here. Further discussion on the rationale for many of the changes recommended by the ALWTRT is provided in the Rationale section.

Northern Inshore State Lobster Waters

The ALWTRT establishes an area called the "Northern Inshore State Lobster Waters Area" that includes the state-water portions of Management Areas 1 and 2 in the American Lobster Fishery regulations (64 FR 68228, December 6, 1999) not otherwise included in the right whale critical habitat. This area does not include the portions of Rhode Island waters that are currently exempted from the ALWTRP

regulations. Based on the best available information, the ALWTRT believes that the threat of entanglement of right whales in New England state waters, with the exception of CCB in the winter, is small enough that no additional gear restrictions are needed at this time.

The ALWTRT recommended that state-water vessels comply with the Lobster Gear Take Reduction Technology List from the February 1999 final rule (one option), with the following exceptions: (1) the buoy line weak link option maximum breaking strength changed from 1100 lbs (489.8 kg) to 600 lbs (272.4 kg), and (2) buoy line weak links must break to produce a knotless end. No gear marking was recommended by the ALWTRT for lobster trap gear in the Northern Inshore State Lobster Waters Area.

The ALWTRT also suggested that fishers be encouraged to maintain the buoy lines as knot-free as possible, with splices preferable to knots.

Cape Cod Bay Restricted Area

The ALWTRT recommended measures for the CCB Restricted Area, which is the same as the area of CCB designated as right whale critical habitat. As in the final rule, these measures are divided into two categories; the peak and off-peak periods of right whale abundance.

The ALWTRT did not recommend additional measures for the peak period of right whale abundance (January 1 - May 15) in the CCB Restricted Area. For monitoring purposes, a gear marking system was recommended to be implemented. Thus, all buoy lines must be marked with a red mark midway along all lobster trap buoy lines; this is the same color required for the Northern Nearshore Lobster Waters Area. The gear marking system is discussed in greater detail here.

For the off-peak period (May 16 - December 31), the ALWTRT divided the CCB Restricted Area into state and Federal waters. For the state-water portion, the ALWTRT recommended that the Lobster Take Reduction Technology List in the February 1999 final rule be maintained, but that the number of requirements from the list be reduced from two to one so that the requirements would be similar to those for the Northern Inshore State Lobster Waters Area during the off-peak period. Changes to the Lobster Take Reduction Technology List described in this document also apply to lobster gear set in the state-water portion of the CCB Restricted Area during the off-peak period. For consistency with requirements for Northern Inshore State Lobster Waters, no gear marking is

required for the state-water portion of CCB during the off-peak period.

For the Federal-water portion of the CCB Restricted Area during the off-peak period, the ALWTRT recommended that lobster trap gear set in this area be required to comply with the requirements for the Northern Nearshore Lobster Waters Area. The ALWTRT recommended different measures for the Federal-water portion because, although all four whale species protected by the ALWTRP might occasionally enter the state-water portion of the area during the off-peak period for right whales, the best available information suggests that most sightings of all whale species in this time/area have been in the Federal-water portion. The ALWTRT also recognized that the Commonwealth of Massachusetts monitors concentrations of whales that are sighted in the state-water portion of the area during the off-peak period and notifies NMFS and fishermen of the whales' locations. Gear marking (red) midway on buoy lines is required for lobster trap gear set in the Federal-water portion of CCB during the off-peak period.

Great South Channel Restricted Lobster Area

Management of the GSC Restricted Lobster Area for lobster trap gear maintains the right whale critical habitat area as one unit. For monitoring purposes, the ALWTRT recommended that all lobster trap buoy lines set in this time/area be marked with a black mark midway along each buoy line. This is the same mark required for the Offshore Lobster Waters Area.

The ALWTRT did not make any recommendations for adjustments in the GSC Restricted Lobster Area during the peak right whale period. Therefore, the area remains closed to lobster trap gear until NMFS "determines that alternative fishing practices or gear modifications have been developed that reduce the risk of serious injury or mortality to whales to acceptable levels" (64 FR 7534).

For the off-peak period (July 1 - March 31) of right whale abundance in the GSC Restricted Lobster Area, the ALWTRT recommended that requirements for this time/area (choosing two options from the Lobster Gear Technology List) be replaced with a mandatory requirement for knotless buoy line weak links. The maximum breaking strength of 3780 lb (1714.3 kg) for this buoy line weak link requirement is the same as in the technology list from the final rule.

The ALWTRT also recommended, and NMFS is currently undertaking, research on the actual operational forces

experienced in the offshore lobster fishery to determine options for reduced breaking strength.

Stellwagen Bank/Jeffreys Ledge Restricted Area

Readers should refer to the Northern Nearshore Lobster Waters Area discussion below for new measures applicable to the Stellwagen Bank/Jeffreys Ledge Restricted Area. NMFS also maintains the Stellwagen Bank/Jeffreys Ledge Restricted Area designation from the final rule because of its significance as a high-use habitat for whales and the need to maintain the flexibility to implement protective measures in the future.

Northern Nearshore Lobster Waters Area

The ALWTRT recommended that NMFS establish an area called the "Northern Nearshore Lobster Waters Area" to encompass the federal-water portion of EEZ Nearshore Management Area 1, Area 2, and the Outer Cape Lobster Management Area as defined in the lobster fishery management plan, excluding the critical habitat areas and the Stellwagen Bank/Jeffreys Ledge Restricted Area. This area does not include the Area 2/3 Overlap from the lobster fishery management plan; instead Area 2/3 is included in the Offshore Lobster Waters Area.

For reduction of entanglement risk from lobster trap gear set in the Northern Nearshore Lobster Waters Area, the ALWTRT recommended that the technology list strategy from the final rule (one option required) be replaced with the following mandatory modifications: (1) Breaking strength of the weak link at the buoy is decreased from 1100 lb (498.8 kg) to 600 lbs (272.4 kg); (2) the weak link must break to produce a knotless end; (3) no single traps are prohibited; and (4) multiple-trap trawls with two to five traps can only have one buoy line. For monitoring purposes, the ALWTRT recommended marking all vertical lines midway in the water column with a red mark. The ALWTRT also suggested that fishers be encouraged to maintain the buoy lines as knot-free as possible, with splices preferable to knots.

The ALWTRT determined that requiring this new set of gear modifications in areas where whales may not be concentrated, but are likely to be transiting, would significantly reduce the risk of serious injury/mortality to these animals due to entanglement in lobster trap gear.

Southern Nearshore Lobster Waters

The ALWTRT recommended that NMFS change the name of the area designated as "Southern Inshore Lobster Waters" in the February 1999 final rule to "Southern Nearshore Lobster Waters Area" and revise the boundaries to be consistent with the American Lobster Fishery regulations. The Southern Nearshore Lobster Waters Area encompasses both the state- and Federal-water portions of EEZ Nearshore Management Areas 4 and 5 (as defined in the American Lobster Fishery regulations), excluding the waters currently exempted from regulation under the ALWTRP.

The ALWTRT did not recommend splitting the Southern Nearshore Lobster Waters Area into state and Federal waters because it did not recommend different modifications for these zones at this time. The only change the ALWTRT recommended for reduction of entanglement risk in this area is that the lobster trap gear must comply with one option from the technology list. For monitoring purposes, the ALWTRT recommended marking of buoy lines of lobster trap gear set in this area with an orange mark midway along the length of the buoy line.

Offshore Lobster Waters Area

The ALWTRT recommended the area designated as the "Offshore Lobster Waters Area" to encompass both the area represented by EEZ Offshore Management Area 3 and the Area 2/3 Overlap as defined in the American Lobster Fishery regulations. However, for the purposes of the ALWTRP, the GSC Restricted Lobster Area is maintained as a separate area.

The February 1999 final rule required that lobster trap gear set in this area comply with one option from the technology list. The ALWTRT recommended the following changes for entanglement risk reduction in this area: (1) The 3780 lb (1714.3 kg) buoy line weak link is now mandatory, and (2) the weak link must break to produce a knotless end. The ALWTRT also recommended that research be done by using load cells to test actual strain on offshore gear with the intent to provide options for lowering the breaking strength of the buoy line weak link. For monitoring purposes, the ALWTRT also recommended that buoy lines be marked with a black mark midway along the buoy line. For voluntary measures, the ALWTRT recommended that fishers be encouraged to maintain buoy lines as knot-free as possible, with splices preferable to knots.

Changes Recommended by Atlantic Large Whale Take Reduction Team for Northeast Anchored Gillnet Gear

The ALWTRT recommended that NMFS amend the ALWTRP restrictions applicable to anchored gillnet gear in the Northeast. In changing the gear restrictions for the Northeast anchored gillnet fisheries, the ALWTRT replaced the gillnet technology list options with mandatory items. Unlike the strategy for lobster pot gear, the ALWTRT did not recommend a distinction between state and Federal waters in the Northeast for gillnet gear. The ALWTRT did recommend establishing an area called the "Other Northeast Gillnet Waters Area" to encompass Northeast waters other than the critical habitats and the Stellwagen Bank/Jeffreys Ledge Restricted Area, which was formerly designated as "Other Northeast Waters Area". The ALWTRT also recommended that the gillnet gear restrictions for the right whale critical habitat areas and Stellwagen Bank/Jeffreys Ledge Restricted Area be the same as those recommended for the Other Northeast Gillnet Waters Area.

Although new measures for anchored gillnet gear in the Mid-Atlantic and Southeast were discussed by the ALWTRT at the February 2000 meeting, the ALWTRT did not reach consensus. The Southeast subgroup met on July 24, 2000, and the Mid-Atlantic subgroup met on August 25, 2000. NMF S will incorporate their recommendations into future rulemaking for the ALWTRP.

The following is a discussion of the changes for each combination of time/area closures. Further discussion of the rationale for many of the changes recommended by the ALWTRT is provided in a following section entitled "General Rationale for Gear Modification Changes".

Cape Cod Bay Restricted Area

The ALWTRT recommended measures for anchored gillnet gear set in the CCB Restricted Area, which is the area of CCB designated as right whale critical habitat. These measures are divided into two categories for peak and off-peak periods of right whale abundance.

The peak period in this area, or spring restricted period, is January 1 - May 15. The closure for anchored gillnet gear in this time/area is unchanged from the February 1999 final rule.

For the off-peak period (May 16 - December 31), the ALWTRT recommended replacing the technology list option strategy from the final rule (two options required) with the mandatory gear requirements for

entanglement risk reduction described below in the Other Northeast Gillnet Waters Area section. For monitoring purposes, the ALWTRT also recommended that all anchored gillnet gear set in this area be marked with a green marking midway along each buoy line. This is the same marking required for the Other Northeast Gillnet Waters Area.

Great South Channel Restricted Gillnet Area

The GSC Restricted Gillnet Area is the area designated as right whale critical habitat with the exception of the "Sliver" along the western boundary. The ALWTRT recommended that this separation be maintained. The Sliver recommendations are discussed here. The ALWTRT did not recommend changes to the area boundaries; however, ALWTRT members did recommend criteria for modification of closure timing.

During the spring restricted period (April 1 - June 30), anchored gillnet gear is prohibited in this area under the ALWTRP until NMFS "determines that alternative fishing practices or gear modifications have been developed that reduce the risk of serious injury or mortality to whales to acceptable levels" (64 FR 7529, February 16, 1999). The area is also currently closed under Framework Adjustment 23 to the Northeast Multispecies Fishery Management Plan (FMP) as discussed here.

During its 1999 and 2000 deliberations, the ALWTRT agreed upon criteria, based on right whale sightings, which the AA could use to open the area early or extend the closure through July 7. The additional flexibility was requested by the ALWTRT for this time/area, which is currently heavily restricted by other measures for groundfish conservation under the Multispecies FMP. The ALWTRT recommended that consideration be given to relaxing the closure to allow access to the fishing grounds if NMFS determines that right whales have left the area. Conversely, if observations from surveys indicate that the right whales are remaining in the closure area longer than anticipated, the closure could be extended through July 7.

After reviewing the ALWTRT's recommendations, the Biological Opinion requirements, and the requirements still effective under Framework 23, NMFS has chosen not to incorporate the closure modification criteria recommended by the ALWTRT for the GSC Restricted Gillnet Area. This decision is based in part on the significance that NMFS has placed on

the GSC right whale critical habitat area pursuant to the ESA review and also on the concern that closure modification criteria should be considered in a consistent manner for all closures in the ALWTRP. Accordingly, NMFS prefers to address criteria for modifying the GSC Restricted Gillnet Area closure in the context of an ongoing examination of the administration of all closures currently in place in the ALWTRP or which may be developed in the future under such measures as dynamic area management (in-season modifications) recently discussed by the ALWTRT.

For the off-peak period (July 1 - March 31), the ALWTRT recommended that the technology list strategy from the final rule (two options required) be replaced with the mandatory gear requirements for entanglement risk reduction described below in the Other Northeast Gillnet Waters Area. For monitoring purposes, the ALWTRT also recommended that all anchored gillnet gear set in this area be marked with a green mark midway along each buoy line. This is the same marking required for the Other Northeast Gillnet Waters Area.

Great South Channel Sliver Restricted Area

The ALWTRT did not recommend any additional risk reduction modifications for anchored gillnet gear exclusive to this area. Readers should refer to the Other Northeast Gillnet Waters Area discussion below for new measures that apply to the GSC Sliver Restricted Area. Gear marking requirements (green) for this area are the same as for the Other Northeast Gillnet Waters Area.

Stellwagen Bank/Jeffreys Ledge Restricted Area

The ALWTRT did not recommend any additional risk reduction modifications for anchored gillnet gear exclusive to this area. Readers should refer to the Other Northeast Gillnet Waters Area discussion for new measures that apply to the Stellwagen Bank/Jeffreys Ledge area. NMFS also maintains the Stellwagen Bank/Jeffreys Ledge Restricted Area designation because of its significance as a high-use habitat for whales. Gear marking requirements (green) are the same as for the Other Northeast Gillnet Waters Area.

Other Northeast Gillnet Waters Area

The Other Northeast Gillnet Waters Area, previously included as the "Other Northeast Waters Area" in the February 1999 final rule, encompasses those waters of the Northeast Region (Maine through and including Virginia) not

otherwise included in the CCB Restricted Area, GSC Restricted Gillnet Area, GSC Sliver Restricted Area, Stellwagen Bank/Jeffreys Ledge Restricted Area, Mid-Atlantic Coastal Waters Area, or exempted waters. For this area, the ALWTRT recommended reducing entanglement risk by replacing the technology list strategy from the final rule (one option required) with mandatory gear modifications. The new mandatory gear requirements for anchored gillnet gear set in this area are: (1) knotless buoy line weak links with a breaking strength no greater than 1100 lb (498.8 kg); (2) net panel weak links, with a breaking strength no greater than 1100 lb (498.8 kg), placed in the center of the headrope section on each net panel; and (3) for strings of 20 or fewer nets, each end of the string must be anchored with either a Danforth-style anchor with the holding power of at least 22 lb (10.0 kg), dead weights weighing at least 50 lb (22.7 kg), or a lead line weighing at least 100 lb (45.4 kg) per 300 feet (91.4 m). For monitoring purposes, the ALWTRT recommended that all anchored gillnet buoy lines set in this area be marked with a green marking midway in the water column. The ALWTRT also suggested that fishers be encouraged to maintain buoy lines as knot-free as possible, with splices preferable to knots.

The weak link-breaking strength is the same as the buoy line and net panel weak link options in the technology list in the February 1999 final rule. The ALWTRT requested that stress load research be conducted by the end of 2000 with the intent of providing options for lowering the maximum weak link breaking strength. Results from ongoing testing are expected in late 2000. The placement of the net panel weak link at the center of each panel is a change from the February 1999 final rule, which required that the weak link be placed between net panels.

General Rationale for Gear Modification Changes

Buoy Line Weak Links

The weak link at the buoy increases the likelihood that a line sliding through a whale's mouth will break away quickly at the buoy before the whale begins to thrash and become more entangled. It is also expected to reduce risk in cases where a whale gets line wrapped around an appendage at a point close to the buoy. The weak link would only be effective when sufficient resistance is created by the weight and drag of the gear to exceed the breaking strength of the weak link.

The 1100 lb (498.8 kg) breaking strength in the 1997 interim final rule was recommended by the Gear Advisory Group (GAG) at its original meeting in June 1997 as a "best available practice" which could be used in the gear technology lists. The decrease in the buoy line weak link breaking strength for nearshore lobster trap gear is based on information collected by the ALWTRP gear research program which suggests that the 1100 lb (498.8 kg) breaking strength required in the previous rule is higher than necessary for the nearshore lobster fishery.

The required breaking strength of 3780 lb (1714.3 kg) for the offshore lobster buoy line weak links is the same as that specified in the Lobster Take Reduction Technology List in the February 1999 final rule. This option was developed based on a recommendation from the GAG at its June 1997 meeting for 0.5 in (1.27 cm) polypropylene line, which has a breaking strength of approximately 3780 lb (1714.3 kg). Initial testing conducted by NMFS suggests that this breaking strength can be lowered for these gear types while still allowing the gear to be effectively used. However, the ALWTRT requested further testing for extreme conditions. In response to the ALWTRT's request, NMFS is conducting further testing to investigate loads encountered in offshore gear to determine if a lower breaking strength may be effectively used in the fishery.

The required breaking strength of 1100 lb (498.9 kg) for the anchored gillnet gear buoy line weak links is the same as that specified in the Gillnet Take Reduction Technology List in the February 1999 final rule. This option was developed based on a recommendation from the GAG at its June 1997 meeting. The NMFS gear research staff is conducting further testing of gillnet weak links along with the offshore lobster testing mentioned above.

The NMFS gear research staff has tested various types of buoy line weak links and provided fishers with a list of tested devices that include swivels, plastic weak links, rope of appropriate diameter, hog rings, and rope stapled to a buoy stick. Fishers must use one of these options or request approval of another option in writing from the AA. NMFS gear staff will assist fishers in determining whether alternative devices will work as a weak link and provide them with feedback on whether the breaking strength is in compliance with current ALWTRP regulations.

Buoy line weak links are required to be knotless when the weak link fails because a weak link that breaks but

leaves a knot or other obstruction at the end of the line leading down to the gear would have reduced effectiveness. A knot or piece of a broken link could become lodged in the whale's baleen or around an appendage and prevent the line from slipping through.

Observations of right whale jaw anatomy suggest that even a knotless line would be difficult to pull through a whale's mouth when the jaw is clamped shut. Testing on baleen obtained from stranded whale carcasses has shown that knots hinder the passage of line through the baleen. This interim final rule does not require buoy line weak links for lobster trap gear during the peak period of right whale abundance in the CCB Restricted Area to be knotless because such a requirement would conflict with the Commonwealth of Massachusetts regulations for lobster trap gear in this time/area. The Massachusetts regulations currently allow certain types of knots as part of one of the weak link options.

Buoy Lines

The ALWTRT initially recommended requiring knot-free buoy lines, but changed to the recommendation to voluntary because fishers need to repair and re-tie buoy lines frequently at sea. The knot-free buoy line concept is similar to the breakaway buoy concept, where the objective is to keep knots from hanging up in a whale's baleen or around an appendage and preventing the line from sliding out.

In some cases, fishers prefer splices to knots because splices are stronger. NMFS is also recommending the use of splices wherever possible because splices are not likely to increase entanglement threat. However, connecting lines using a splice is not practicable while gear is being hauled, so splicing, if used at all, is preferentially done on land during seasonal overhaul or as new gear is added. Although concepts for devices to join lines quickly at sea have been proposed, none are yet developed; therefore, there is currently no feasible way to join lines quickly other than knotting. NMFS will continue to investigate line connecting alternatives and may require knotless buoy lines in the future if a reasonable substitute for knots is developed.

Net Panel Weak Links and Anchoring Requirements

Weak links in the center of each 50-fathom (300 ft = 91.4 m) net panel floatline (headrope) are expected to break when a whale exerts pressure in opposition to the resistance provided by

the anchoring system and weight of the gear. The weak link would allow the floatline to part and unravel from the net mesh when a whale encounters any section of the gear. The net mesh would then be free of the stronger floatline and a large whale would have a better chance of breaking free of the weaker monofilament mesh.

The net panel weak link requirement contained in this interim final rule specifies a breaking strength of no more than 1100 lb (498.8 kg). This breaking strength is a significant reduction from the floatline strength typically used in sink gillnet gear, which ranges from 1700 lb (771.8 kg) to 2500 lb (1135 kg). The use of weak links is not expected to hinder retrieval of the gear, as gillnetters will be able to haul their gear by the lead line in each net panel and the full-strength bridles between the net panels.

When a whale encounters a net panel, the pressure exerted by the whale will not necessarily be right at the weak link, and the part of the headrope containing the weak link will not necessarily be in the whale's mouth. Therefore, these weak links do not need to be knotless.

The anchoring requirement is intended to create sufficient resistance to allow the net panel weak links to break when at least 1100-lb (498.8 kg) of pressure is exerted by a whale on net strings of 20 or fewer net panels. The specified anchoring system is only required for net strings of 20 or fewer nets because NMFS gear research has shown that, for strings of greater than 20 net panels, the 1100 lb (498.8 kg) force necessary to break the weak link is reached solely by the weight and resistance of the gear itself, rendering additional resistance from anchors unnecessary.

The net panel weak links are required in the center of each net panel floatline, rather than between net panels as was specified for the gillnet technology list option in the February 1999 final rule. The ALWTRT recommended changing the placement of the net panel weak links because a weak link placed at the bridle might cause a failure at a point in the gear which is critical for safe hauling of the gear and would reduce chances of lost gear. Furthermore, in cases where a whale hits the gear near a weak link in the floatline, a breaking point within that floatline would maximize the chance for the whale to break away from the net as soon as possible, before becoming entangled in the mesh. Once a whale becomes entangled in the mesh, there is a greater chance that other parts of the gear, including the heavier lines will contribute to the seriousness of the

entanglement. This theory is also based on observations of the flexibility and mobility of net strings along the ocean floor, where the nets become bowed with the current rather than remain in a rigid straight line. A whale exerting force on a net string would move the net before breaking it. During that period of movement, a net without weak links is likely to wrap along either side of the whale. With a weak link at the bridle, which is much shorter than the net panel sections, there is a greater chance that a whale would come away wrapped in sections of the net.

At this time, information is not available on the ideal breaking strength for different locations along a string of nets, the ideal number of weak links, or for all oceanographic conditions. The ALWTRT requested further testing on these parameters for New England waters and to determine appropriate configurations for the Mid Atlantic.

Single Traps and Multiple-trap Trawls

Prohibiting single pots in Federal waters reduces the number of buoy lines in the water column. Trap trawls of up to, and including, five traps have only one buoy line, which accomplishes the goal of reducing the number of lines in the water column. The ALWTRT recommended this consensus measure as a reasonable means of reducing the entanglement risk represented by vertical lines in nearshore waters where large whale movements predominantly occur in summer and fall. Although NMFS has limited information on the number of single traps in use in Federal waters at this time, it is known that single traps are used in some areas. Therefore, lobster trap vessels operators who decide to continue fishing in federal waters must reconfigure the gear into multiple-trap trawls, thereby reducing the number of buoy lines in the water.

Gear Marking

As noted earlier, on April 9, 1999 (64 FR 17292), NMFS published a partial stay suspending the gear marking requirements for the northeast U.S. fisheries until November 1, 1999 to allow time for developing modifications to the requirements. On December 30, 1999 (64 FR 73434), the suspension was extended until November 1, 2000 to allow for additional developmental time. On November 22, 2000 (65 FR 70316), a final rule was published removing and reserving the gear marking system indefinitely. The system provided in the February 16, 1999, final rule (64 FR 7529) involved two-part color markings (one for fishery and one for area) placed in two places on each

buoy line but did not provide individual vessel identification. NMFS agreed to the ALWTRT's request for a suspension of the gear marking requirements to allow for further study of alternative systems which would provide identification of individual vessels and be less complex. Individual identification is still preferred to maximize information on when and where gear was set as well as to provide a description of the modification in use. However, it has proven difficult to find a marking material that can be placed on lines without interfering with fishing operations or creating a safety hazard. Therefore, the ALWTRT recommended a simpler system involving a one-color marking placed in one location, midway on each buoy line for all lobster trap gear (except lobster trap gear in Northern Inshore State Lobster Waters and in the state-water portion of the CCB Restricted Area during the off-peak period) and for all Northeast anchored gillnet gear. The one-color marking indicates both area and gear type, where previously a two-color code was required. For example, lobster trap gear set in the Northern Nearshore Lobster Waters Area must have a red mark, and, by contrast, lobster trap gear in the Southern Nearshore Lobster Waters Area must have an orange mark.

With regard to markings which yield individual vessel information, many of the state and Federal fishery management plans currently require marking of buoys and/or traps with individual vessel identification. Additionally, some plans require tags for gillnet gear when there are caps on the number of net sets in a certain area for effort reduction. NMFS plans to work with state fisheries agencies to investigate the plans coastwide and identify gaps in marking of surface gear, gillnets, and traps. This information will be presented to the ALWTRT and GAG for future consideration.

The ALWTRT had originally discussed the need to mark gear in such a way that there would be enough markings on the buoy lines and groundlines that the sections of line likely to be found on a whale would be marked with individual vessel identification. However, at the February 2000 meeting, the ALWTRT recognized that a marking system extensive enough to meet those requirements had not yet been developed. Consequently, the ALWTRT recommended requiring only one marking per buoy line and did not recommend markings for groundlines at this time.

The NMFS gear research program has provided options for marking or affixing the gear marking color code that include

dye, paint, thin colored line whipped around the buoy line or woven through it, thin colored plastic, or heat shrink tubing.

Other Entanglement Reduction Measures not Specified in this Plan

Several fishery management plans affect the level of fixed gear effort and, therefore, the level of entanglement risk to large whales protected by the ALWTRP. These plans and several specific actions are described in the preamble to the February 16, 1999, final rule (64 FR 7529). NMFS has also implemented the Harbor Porpoise Take Reduction Plan (63 FR 66464) which contains additional gillnet fishing effort reduction in New England and the Mid-Atlantic.

Changes from the February 1999 Final Rule

With this interim final rule, NMFS is implementing the recommendations of the ALWTRT described for lobster trap gear throughout the range of the American lobster fishery and for anchored gillnet gear in the Northeast. Specifically, these changes are:

1. *Removal of definitions for "Inshore Lobster Waters", "Northeast Waters", "Offshore Lobster Waters", "Southeast Waters", and "Stellwagen Bank/Jeffreys Ledge Area"*. These terms are removed from the definitions section of the rule in favor of describing the areas in the area-specific sections of this interim final rule. This practice is consistent with the manner in which areas are described in the FMP regulations.

2. *Lobster area changes*. The generic lobster areas are replaced with designations which are consistent with the area descriptions in the American Lobster Fishery regulations (64 FR 68228, December 6, 1999). In addition, the ALWTRT recommended that the nearshore lobster fishery in waters off New England states be further split into state and Federal waters. Thus, the north/south division line of 41° 30' N. lat. has been removed, and the following inshore and nearshore area descriptions are added to be consistent with the American Lobster Fishery regulations: (a) the "Northern Inshore State Lobster Waters Area" includes the state waters of Maine, New Hampshire, Massachusetts, and Rhode Island, which fall within the Exclusive Economic Zone (EEZ) Nearshore Management Area 1 and/or Area 2; (b) the "Northern Nearshore Lobster Waters Area" includes the Federal waters of EEZ Nearshore Management Areas 1 and 2 as well as the EEZ Nearshore Outer Cape Lobster Management Area; and (c) the "Southern Nearshore Lobster Waters

Area" includes both state and Federal waters of EEZ Nearshore Management Areas 4 and 5. Management measures for these waters do not affect the exempted waters listed in § 229.32 (a)(2). Separate areas for right whale critical habitat and the Stellwagen Bank/Jeffreys Ledge area are maintained. The "Offshore Lobster Waters Area" is modified to correct Points C and ZA and to add Point ZB to be consistent with the American Lobster Fishery regulations. It is also clarified that the Area 2/3 Overlap in the lobster plan is encompassed by the Offshore Lobster Waters Area in the ALWTRP.

3. Prohibitions.

The Prohibitions listed in § 229.2 are modified to incorporate changes made with this interim final rule.

4. *Gear marking for lobster trap gear and Northeast gillnet gear*. The gear marking system implemented for lobster trap gear (in the New England and Mid-Atlantic areas) and anchored gillnet gear (in New England areas) replaces that specified in the February 1999 final rule. Gear marking is required for anchored gillnet gear in the CCB Restricted Area, Stellwagen Bank/Jeffreys Ledge Restricted Area, GSC Restricted Gillnet Area, GSC Sliver Restricted Area, and Other Northeast Gillnet Waters Area. Gear marking is also required for lobster trap gear in the Stellwagen Bank/Jeffreys Ledge Restricted Area, GSC Restricted Lobster Area, Northern Nearshore Lobster Waters Area, Southern Nearshore Lobster Waters Area, Offshore Lobster Waters Area, and CCB Restricted Area (whole area during the winter restricted period and Federal waters only during the other restricted period). For the above gear/area combinations, gear marking of buoy lines is changed from a two-color code on each buoy line to a one-color code midway along the buoy line. Gear marking is not required for lobster gear in the Northern Inshore State Lobster Waters Area or for the state-water portion of the CCB Restricted area during the other restricted period.

5. *Gear marking in the Southeast U.S. Observer Area*. Requirements for markings of buoy lines and net panels in this area have been in effect since the publication of the February 1999 final rule. Therefore, NMFS has added paragraph (b) of § 229.32 to maintain the provisions of that paragraph that were applicable to the Southeast, which uses a different system than that implemented with this interim final rule.

6. *Structural changes to the regulations*. The gear modification

requirement paragraphs are re-organized to bring all requirements for a given area closer together. Paragraph headings reflecting the differences between "universal" and "area-specific" requirements are provided, and cross-references to both gear marking and universal gear modification requirements are provided in a complete set of measures for each area.

7. Lobster Take Reduction Technology List. Because measures for offshore lobster gear are now mandatory rather than optional, the two options in the Lobster Take Reduction Technology List specific to offshore lobster gear have been removed. The technology list is now only applicable to nearshore lobster trap gear. In addition, two of the remaining options have been changed. The buoy line weak link option has been changed to lower the breaking strength of the weak link from 1100 lb (498.8 kg) to 600 lb (272.4 kg), and the weak link is now required to be knotless.

8. Measures for lobster trap gear in the "Northern Inshore State Lobster Waters Area". The Northern Inshore State Lobster Waters Area is now treated as a separate area as described in change number 2. Lobster trap gear in this area must still comply with one option from the Lobster Take Reduction Technology List; however, the nature of the available options has changed as described in change number 7.

9. Measures for lobster trap gear in the Cape Cod Bay Restricted Area. The division of measures for the CCB Restricted Area (right whale critical habitat area) into peak and off-peak requirements is maintained. However, the off-peak section is further subdivided into state and federal waters. Changes for the peak period of right whale abundance (January 1 - May 15) include mandatory gear marking (red) midway on all buoy lines. Changes to the off-peak period (May 16 - December 31) for state waters include reducing the number of technology list options required from two to one. Because the technology list has changed, the option list requirement is affected by the changes described in change number 7. For the Federal-water portion of the CCB Restricted Area during the off-peak period, technology list options strategy is replaced with the mandatory requirements described in change number 12, and gear marking (red) on buoy lines is required throughout the year.

10. Measures for lobster trap gear in the Great South Channel Restricted Lobster Area. Changes to the lobster trap requirements for the off-peak (April 1 - June 30) period for this area include (1)

replacing the technology list options strategy (two items required) with mandatory knotless buoy line weak links with a breaking strength of no more than 3780 lb (1714.3 kg) and (2) mandatory gear marking (black) midway on all buoy lines.

11. Measures for lobster trap gear in the Stellwagen Bank/Jeffreys Ledge Restricted Area. Changes for lobster trap gear in this area include (1) Replacing the technology list options strategy (two items required) with the mandatory modifications described in change number 12 and (2) mandatory marking (red) midway on all buoy lines.

12. Measures for lobster trap gear in the "Northern Nearshore Lobster Waters Area". For this area, the technology list options strategy (one item required) is replaced with the following mandatory gear modification requirements: (1) Knotless buoy line weak links with a breaking strength of no more than 600 lb (272.4 kg), (2) prohibition on single traps, and (3) only one buoy line permitted for trawls of up to five traps. In addition, gear marking (red) midway on all buoy lines is required.

13. Measures for lobster trap gear in the "Southern Nearshore Lobster Waters Area". The number of technology list options required (one) is unchanged; however, the nature of available options is changed as described in change number 7. In addition, lobster trap gear set in this area must be marked (orange) midway along all buoy lines.

14. Measures for lobster trap gear in the Offshore Lobster Waters Area. The technology list options strategy (one item required) is replaced with a requirement for a knotless buoy line weak link with breaking strength of no more than 3780 lb (1714.3 kg). In addition, marking (black) of all lobster trap buoy lines midway along the buoy line is required.

15. Measures for anchored gillnet gear in the Cape Cod Bay Restricted Area. The gillnet technology list options strategy (two items required) for the off-peak period (May 16 - December 31) is replaced with the following requirements: (1) A knotless buoy line weak link; (2) the buoy line and net panel weak link breaking strength of no more than 1100 lb (498.8 kg) is now mandatory; (3) the placement of floatline (headrope) weak link is changed from bridles to the center of each net panel; and (4) an anchoring system consisting of either (a) dead weights weighing at least 50 lb (22.7 kg) at each end of the net string, (b) anchors with the holding power of at least a 22 lb (10.0 kg) Danforth-style anchor at each end of the net string, or (c) a lead line weighing at least 100 lb (45.4 kg)

per 300 ft (91.4 m) for each net panel in the net string is required for net strings of 20 or fewer nets. In addition, marking (green) of all buoy lines midway along the buoy line is required.

16. Measures for anchored gillnet gear in the Great South Channel Restricted Gillnet Area. The separation of the bulk of the right whale critical habitat area from the "Sliver" along the western boundary is maintained. (See change number 17 for changes to Sliver Area requirements.) For the off-peak (July 1 - March 31) period, the technology list options strategy (two items required) is replaced with the mandatory gear modifications as described in change number 15 for CCB. Gear marking (green) is also now required midway along all buoy lines.

17. Measures for anchored gillnet gear in the Great South Channel Sliver Restricted Area. For the off-peak period (July 1 - March 31), the technology list options strategy (two items required) is replaced with the mandatory gear modifications described in change number 15 for CCB. Gear marking (green) is also required midway along all buoy lines.

18. Measures for anchored gillnet gear in the Stellwagen Bank/Jeffreys Ledge Restricted Area. The technology list options strategy (two items required) is replaced with the mandatory gear modifications described in change number 15 for CCB. Gear marking (green) is also required midway along all buoy lines.

19. Measures for anchored gillnet gear in the Other Northeast Gillnet Waters Area. The technology list options strategy (one item required) is replaced with the mandatory gear modifications described in change number 15 for CCB. Gear marking (green) is also required midway along all buoy lines.

Classification

An Environmental Assessment (EA) describing the impacts to the environment that would result from the implementation of the ALWTRP was prepared for the July 22, 1997, interim final rule (62 FR 39157). Supplemental EAs were also prepared for the April 9, 1999, final rule (64 FR 17292) and subsequent gear marking suspensions. The conclusion of those EAs was that the actions would pose no significant adverse environmental impact. NMFS prepared an EA for this interim final rule and has concluded that these regulations would pose no significant adverse environmental impact.

The actions implemented by this interim final rule are expected to impact approximately 7,539 lobster trap fishing operations and 316 gillnet operations.

Four alternatives were evaluated in the EA prepared for this interim final rule, including a status quo or "no action" alternative as represented by the 1999 final rule, the present interim final rule, and two other alternatives. For a description and a detailed economic analysis of the alternatives analyzed for the lobster fleet and gillnet fleet, readers should refer to the EA prepared for this interim final rule. The total cost to the lobster industry resulting from the time/area closures and gear restrictions in this interim final rule is expected to fall between \$191K and \$539K. The total cost to the gillnet industry under this interim final rule, based on a point estimate, is expected to be approximately \$109K. Adding the lobster trap and gillnet costs, the total cost to the combined fleets is expected to fall between \$300K and \$648K.

Notwithstanding any other provision of the law, no person is required to respond to, nor shall any person be subject to a penalty for failure to comply with, a collection of information subject to the requirements of the PRA, unless that collection of information displays a currently valid Office of Management and Budget (OMB) control number.

This interim final rule contains collection-of-information requirements subject to the (PRA) which has been approved by the (OMB) under control number 0648-0364. Public reporting burden for marking fishing gear, using the whipping line option, is estimated to average .5 minutes per line. This estimate includes the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate, or any other aspect of this data collection, including suggestions for reducing the burden to the NMFS, Office of Protected Resources, Marine Mammal Division Chief (see ADDRESSES) and to OMB at the Office of Information and Regulatory Affairs, Office of Management and Budget, Washington, DC 20503 (Attention: NOAA Desk Officer).

This interim final rule has been determined to be not significant for purposes of Executive Order 12866.

Pursuant to 15 CFR 930.35(d)(2), NMFS has determined that preparation of a consistency determination for this interim final rule is unnecessary because the action falls within the scope of past ALWTRP actions for which consistency determinations were made. Therefore, this action does not change the determination that the ALWTRP will be implemented in a manner that is consistent to the maximum extent

practicable with the approved coastal zone management programs of the U.S. Atlantic coastal states. This determination has been submitted for review by the responsible state agencies under Section 307 of the Coastal Zone Management Act.

A biological opinion (BO) on the ALWTRP was finalized on July 15, 1997. That opinion concluded that implementation of the ALWTRP and continued operation of fisheries conducted under the American Lobster, Northeast Multispecies, and Shark FMPs, as modified by the ALWTRP, may adversely affect, but are not likely to jeopardize the continued existence of any listed species or adversely modify critical habitat. A further determination was made that the February 16, 1999, final rule (64 FR 7529) did not change the basis for that BO. This interim final rule implements additional gear restrictions for lobster trap and anchored gillnet gear which will provide additional protection for endangered whales. NMFS has determined that this interim final rule does not change the basis for the 1997 and 1999 ESA determinations. In addition, NMFS has reinitiated ESA section 7 consultation on the FMPs listed to consider new information on endangered whale entanglements, new fishery management actions, and ESA listing actions. Since the ALWTRP is the Reasonable and Prudent Alternative for several of the FMPs, future modification of the ALWTRP may be necessary in response to the outcome of these consultations.

Several species of non-endangered marine mammals protected by the MMPA, including cetacean and pinniped species that are not the focus of this plan are known to become entangled in gillnet and/or lobster trap gear. This action benefits large whales and other marine mammals by implementing restrictions to lobster trap and gillnet gear which are designed to reduce adverse impacts of entanglement in those gear types. Therefore, the changes in the ALWTRP made by this interim final rule will have no adverse impacts on marine mammals.

Given the status of the species to be protected and the fact that entanglements are continuing to occur under the existing regulations the AA, for good cause, under U.S.C. 553 (b)(B) finds that delaying this action to allow for prior notice and an opportunity for public comment would be contrary to the public interest. Because prior notice and an opportunity for public comment are not required to be provided for this interim final rule by 5 U.S.C. 553 or by any other law, the analytical

requirements of the Regulatory Flexibility Act, 5 U.S.C. 601 *et seq.*, are inapplicable.

This interim final rule does not contain policies with federalism implications sufficient to warrant preparation of a federalism assessment under Executive Order 12612.

Plain Language Requirement for Rulemaking

The President has directed Federal agencies to use plain language in their communications with the public, including regulations. To comply with this directive, we seek public comment on any ambiguity or unnecessary complexity arising from the language used in this rule. Send comments to the NMFS Marine Mammal Division Chief (see ADDRESSES).

References

- International Whaling Commission (IWC). In press. Report of the IWC Workshop on the Status and Trends of the Western North Atlantic Right Whale.
- Kraus, S.D. 1990. Rates and potential causes of mortality in North Atlantic right whales (*Eubalaena glacialis*). *Mar. Mamm. Sci.* 6(4):278-291.
- Kraus, S.D., P.K. Hamilton, R. D. Kenney, A.R. Knowlton, and C.K. Slay. In press. Reproductive parameters of the North Atlantic Right Whale.
- Waring, G.T., D.L. Palka, P.J. Clapham, S. Swartz, M.C. Rossman, T.V.N. Cole, L.J. Hansen, K.D. Bisack, K.D. Mullin, R.S. Wells, D.K. Odell, and N.B. Barros. 1999. U.S. Atlantic and Gulf of Mexico Marine Mammal Stock Assessments - 1999. NOAA Technical Memorandum NMFS-NE-153. U.S. Department of Commerce, Northeast Fisheries Science Center, Woods Hole, MA. 196 pp.

List of Subjects in 50 CFR Part 229

Administrative practice and procedure, Confidential business information, Fisheries, Marine mammals, Reporting and record keeping requirements.

Dated: December 6, 2000.

William T. Hogarth,
Deputy Assistant Administrator for Fisheries,
National Marine Fisheries Service.

For the reasons set out in the preamble, 50 CFR part 229 is amended to read as follows:

PART 229—AUTHORIZATION FOR COMMERCIAL FISHERIES UNDER THE MARINE MAMMAL PROTECTION ACT OF 1972

1. The authority citation for part 229 continues to read as follows:

Authority: 16 U.S.C. 1361 *et seq.*

§ 229.2 [Amended]

2. In § 229.2, the definitions of “Inshore Lobster waters”, “Northeast waters”, “Offshore lobster waters”, “Southeast waters”, and “Stellwagen Bank/Jeffreys Ledge area” are removed.

3. In § 229.3, paragraphs (h) through (k) are revised to read as follows:

§ 229.3 Prohibitions.

* * * * *

(h) It is prohibited to fish with lobster trap gear in the areas and for the times specified in § 229.32 (b)(2) and (c)(2) through (c)(8) unless the lobster trap gear complies with the closures, marking requirements, modifications, and restrictions specified in § 229.32 (b)(3)(i), (b)(3)(ii), and (c)(1) through (c)(9).

(i) It is prohibited to fish with anchored gillnet gear in the areas and for the times specified in § 229.32(b)(2) and (d)(2) through (d)(7) unless that gillnet gear complies with the closures, marking requirements, modifications, and restrictions specified in § 229.32(b)(3)(i), (b)(3)(ii), and (d)(1) through (d)(8).

(j) It is prohibited to fish with drift gillnet gear in the areas and for the times specified in § 229.32 (d)(7) and (e)(1) unless the drift gillnet gear complies with the restrictions specified in § 229.32 (e)(1).

(k) It is prohibited to fish with shark gillnet gear in the areas and for the times specified in § 229.32(b)(2), (f)(1)(i), and (f)(1)(ii) unless the gear complies with the closures, marking requirements, modifications, and other restrictions specified in § 229.32(b)(3)(i), (b)(3)(ii), and (f)(2) through (f)(3)(iii)(D).

* * * * *

4. In subpart C, § 229.32, paragraphs (b)(1) through (d)(6)(ii) are revised to read as follows:

* * * * *

§ 229.32 Atlantic large whale take reduction plan regulations.

* * * * *

(b) *Gear marking requirements.* (1) Specified gear consists of lobster trap gear and gillnet gear set in specified areas.

(2) *Specified areas.* The following areas are specified for gear marking purposes: CCB Restricted Area, Stellwagen Bank/Jeffreys Ledge Restricted Area, Northern Nearshore Lobster Waters Area, GSC Restricted Lobster Area, GSC Restricted Gillnet Area, GSC Sliver Restricted Area, Southern Nearshore Lobster Waters Area, Offshore Lobster Waters Area, Other Northeast Gillnet Waters Area, and Southeast U.S. Observer Area.

(3) *Requirements for Southeast U.S. Observer Area.* Any person who owns or fishes with specified fishing gear in the Southeast U.S. Observer Area must mark that gear in accordance with (b)(3)(i) and (b)(3)(ii) of this section, unless otherwise required by the Assistant Administrator under paragraph (g) of this section.

(i) *Color code.* Specified gear in the Southeast U.S. Observer Area must be marked with the appropriate color code to designate gear types and areas as follows:

(A) *Gear type code—Gillnet gear.* Gillnet gear must be marked with a green marking.

(B) *Area code.* Gear set in the Southeast U.S. Observer Area must be marked with a blue marking.

(ii) *Markings.* All specified gear in specified areas must be marked with two color codes, one designating the gear type, the other indicating the area where the gear is set. Each color of the two-color code must be permanently marked on or along the line or lines specified under (f)(2) of this section. Each color mark of the color codes must be clearly visible when the gear is hauled or removed from the water. Each mark must be at least 4 inches (10.2 cm) long. The two color marks must be placed within 6 inches (15.2 cm) of each other. If the color of the rope is the same as or similar to a color code, a white mark may be substituted for that color code. In marking or affixing the color code, the line may be dyed, painted, or marked with thin colored whipping line, thin colored plastic, or heat-shrink tubing, or other material; or a thin line may be woven into or through the line; or the line may be marked as approved in writing by the Assistant Administrator (AA).

(4) *Requirements for other specified areas.* Any person who owns or fishes with specified gear in the other specified areas must mark that gear in accordance with (b)(4)(i) and (b)(4)(ii) of this section, unless otherwise required by the Assistant Administrator under paragraph (g) of this section. For the purposes of the following gear marking requirements only, lobster trap gear set in the CCB Restricted Area during the winter restricted period, the Federal-water portion of the CCB Restricted Area during the off-peak period, and the Stellwagen Bank/Jeffreys Ledge Restricted Area shall comply with the requirements for the Northern Nearshore Lobster Waters Area. Lobster gear set in the GSC Restricted Lobster Area shall comply with the requirements for the Offshore Lobster Waters Area. Similarly, anchored gillnet gear set in the CCB Restricted area,

Stellwagen Bank/Jeffreys Ledge Restricted Area, GSC Restricted Gillnet Area, and GSC Silver Restricted Area shall comply with the requirements for gillnet gear in the Other Northeast Gillnet Waters Area.

(i) *Color code.* Specified gear must be marked with the appropriate colors to designate gear-types and areas as follows:

(A) Lobster trap gear in the Northern Nearshore Lobster Waters Area must be marked with a red marking.

(B) Lobster trap gear in the Southern Nearshore Lobster Waters Area must be marked with an orange marking.

(C) Lobster trap gear in the Offshore Lobster Waters Area must be marked with a black marking.

(D) Gillnet gear in the Other Northeast Gillnet Waters Area must be marked with a green marking.

(ii) *Markings.* All specified gear in specified areas must be marked with one color code (see paragraph (4)(i) of this section) which indicates the gear type and general area where the gear is set. Each color code must be permanently affixed on or along the line or lines. Each color code must be clearly visible when the gear is hauled or removed from the water. Each mark must be at least 4 inches (10.2 cm) long. The mark must be placed along the buoy line midway in the water column.

(5) *Changes to requirements.* If the Assistant Administrator revises the gear marking requirements in accordance with paragraph (g) of this section, the gear must be marked in compliance with those requirements.

(c) *Restrictions applicable to lobster trap gear in regulated waters—*(1) Universal lobster trap gear requirements. In addition to the area-specific measures listed in (c)(2) through (c)(8) of this section, all lobster trap gear in regulated waters, including the Northern Inshore State Lobster Waters Area, must comply with the universal gear requirements listed here¹. The Assistant Administrator may revise these requirements in accordance with paragraph (g) of this section.

(i) *No line floating at the surface.* No person may fish with lobster trap gear that has any portion of the buoy line that is directly connected to the gear at the ocean bottom floating at the surface at any time. If more than one buoy is attached to a single buoy line or if a high flyer and a buoy are used together on a single buoy line, floating line may be used between these objects.

¹ Fishers are also encouraged to maintain their buoy lines to be as knot-free as possible. Splices are not considered to be an entanglement threat and are thus preferable to knots.

(ii) *No wet storage of gear.* Lobster traps must be hauled out of the water at least once every 30 days.

(2) *Cape Cod Bay Restricted Area—(i) Area.* The CCB restricted area consists of the CCB right whale critical habitat area specified under 50 CFR 226.203(b) unless the Assistant Administrator changes that area in accordance with paragraph (g) of this section.

(ii) *Area-specific gear requirements during the winter restricted period.* No person may fish with lobster trap gear in the CCB Restricted Area during the winter restricted period unless that person's gear complies with the gear marking requirements in paragraph (b) of this section, the universal lobster trap gear requirements in (c)(1) of this section, and the area-specific requirements listed below for the winter restricted period. The Assistant Administrator may revise these requirements in accordance with paragraph (g) of this section.

(A) *Winter restricted period.* The winter restricted period for the CCB Restricted Area is from January 1 through May 15 of each year unless the Assistant Administrator changes that area in accordance with paragraph (g) of this section.

(B) *Weak links.* All buoy lines shall be attached to the main buoy with a weak link meeting the following specifications:

(1) The breaking strength of the weak link must not exceed 500 lb (226.7 kg).

(2) The weak link must be chosen from the following list of combinations approved by the NMFS gear research program: swivels, plastic weak links, rope of appropriate diameter, hog rings, rope stapled to a buoy stick, or other materials or devices approved in writing by the Assistant Administrator.

(C) *Single traps and multiple-trap trawls.* Single traps and three-trap trawls are prohibited. All traps must be set in either a two-trap string or in a trawl of four or more traps. A two-trap string must have no more than one buoy line.

(D) *Sinking buoy lines.* All buoy lines must be comprised of sinking line except the bottom portion of the line, which may be a section of floating line not to exceed one-third the overall length of the buoy line.

(E) *Sinking ground line.* All ground lines must be comprised entirely of sinking line.

(iii) *Area-specific gear requirements during the other restricted period.* No person may fish with lobster trap gear in the CCB Restricted Area during the other restricted period unless that person's gear complies with the gear marking requirements in paragraph (b) of this section and the universal lobster

trap gear requirements in (c)(1) of this section as well as the area-specific requirements listed below for the other restricted period. The Assistant Administrator may revise these requirements in accordance with paragraph (g) of this section.

(A) *Other restricted period.* The other restricted period for the CCB Restricted Area is from May 16 through December 31 of each year unless the Assistant Administrator revises that period in accordance with paragraph (g) of this section.

(B) *Gear requirements—(1) State-water portion.* No person may fish with lobster trap gear in the state-water portion of the CCB Restricted Area during the other restricted period unless that person's gear complies with the requirements for the Northern Inshore State Lobster Waters Area listed in (c)(6) of this section. The Assistant Administrator may revise these requirements in accordance with paragraph (g) of this section.

(2) *Federal-water portion.* No person may fish with lobster trap gear in the federal-water portion of the CCB Restricted Area during the other restricted period unless that person's gear complies with the requirements for the Northern Nearshore Lobster Waters Area in (c)(7) of this section. The Assistant Administrator may revise these requirements in accordance with paragraph (g) of this section.

(3) *Great South Channel Restricted Lobster Area—(i) Area.* The GSC Restricted Lobster Area consists of the GSC right whale critical habitat area specified under 50 CFR 226.203(a) unless the Assistant Administrator changes that area in accordance with paragraph (g) of this section.

(ii) *Closure during the spring restricted period—(A) Spring restricted period.* The spring restricted period for the GSC Restricted Lobster Area is from April 1 through June 30 of each year unless the Assistant Administrator revises this period in accordance with paragraph (g) of this section.

(B) *Closure.* During the spring restricted period, no person may fish with or set lobster trap gear in this Area unless the Assistant Administrator specifies gear modifications or alternative fishing practices in accordance with paragraph (g) of this section and the gear or practices comply with those specifications.

(iii) *Area-specific gear requirements for the other restricted period.* No person may fish with lobster trap gear in the GSC Restricted Lobster Area unless that person's gear complies with the gear marking requirements in paragraph (b) of this section, the

universal lobster trap gear requirements in (c)(1) of this section, and the area-specific requirements listed here for the other restricted period. The Assistant Administrator may revise these requirements in accordance with paragraph (g) of this section.

(A) *Other restricted period.* The other restricted period for the GSC Restricted Lobster Area is July 1 through March 31, unless the Assistant Administrator revises the timing in accordance with paragraph (g) of this section.

(B) *Weak links.* All buoy lines must be attached to the main buoy with a weak link meeting the specifications listed in subparagraph (c)(5)(ii)(A) below for the Offshore Lobster Waters Area.

(4) *Stellwagen Bank/Jeffreys Ledge Restricted Area—(i) Area.* The Stellwagen Bank/Jeffreys Ledge Restricted Area includes all federal waters of the Gulf of Maine, except those designated as right whale critical habitat under 50 CFR 226.203(b), that lie south of 43°15' N. lat. and west of 70° W long.. The Assistant Administrator may change that area in accordance with paragraph (g) of this section.

(ii) *Area-specific gear requirements.* No person may fish with lobster trap gear in the Stellwagen Bank/Jeffreys Ledge Restricted Area unless that person's gear complies with the gear marking requirements in paragraph (b) of this section, the universal lobster trap gear requirements in (c)(1) of this section, and the requirements listed for the Northern Nearshore Lobster Waters Area in (c)(7) of this section. The Assistant Administrator may revise these requirements in accordance with paragraph (g) of this section.

(5) *Offshore Lobster Waters Area—(i) Area.* The Offshore Lobster Waters Area includes all waters bounded by straight lines connecting the following points in the order stated (including the area known as the Area 2/3 Overlap in the American Lobster Fishery regulations at 50 CFR 697.18 but not including the GSC Restricted Lobster Area):

Point	Latitude (°N)	Longitude (°W)
A	43° 58'	67° 22'
B	43° 41'	68° 00'
C	43° 12'	69° 00'
D	42° 49'	69° 40'
E	42° 15.5'	69° 40'
F	42° 10'	69° 56'
K	41° 10'	69° 6.5'
N	40° 45.5'	71° 34'
M	40° 27.5'	72° 14'
U	40° 12.5'	72° 48.5'
V	39° 50'	73° 01'
X	38° 39.5'	73° 40'
Y	38° 12'	73° 55'
Z	37° 12'	74° 44'
ZA	35° 34'	74° 51'

Point	Latitude (°N)	Longitude (°W)
ZB	35° 14.5'	75° 31' ¹

¹From Point ZB east to the EEZ boundary, thence along the seaward EEZ boundary to Point A.

(ii) *Area-specific gear requirements.* No person may fish with lobster trap gear in the Offshore Lobster Waters Area unless that person's gear complies with the gear marking requirements in paragraph (b) of this section, the universal lobster trap gear requirements in (c)(1) of this section, and the gear requirements listed here. The Assistant Administrator may revise these requirements in accordance with paragraph (g) of this section.

(A) *Weak Links.* All buoy lines must be attached to the main buoy with a weak link meeting the following specifications:

(1) The weak link must be chosen from the following list of combinations approved by the NMFS gear research program: swivels, plastic weak links, rope of appropriate diameter, hog rings, rope stapled to a buoy stick, or other materials or devices approved in writing by the Assistant Administrator.

(2) The breaking strength of these weak links must not exceed 3780 lb (1714.3 kg).

(3) Weak links must be designed such that the bitter end of the buoy line is clean and free of any knots when the link breaks. Splices are not considered to be knots for the purposes of this provision.

(B) [Reserved]

(6) *Northern Inshore State Lobster Waters Area*—(i) *Area.* The Northern Inshore State Lobster Waters Area includes the state waters of Rhode Island, Massachusetts, New Hampshire, and Maine but does not include waters exempted under (a)(2) of this section.

(ii) *Area-specific gear requirements.* No person may fish with lobster trap gear in the Northern Inshore State Lobster Waters Area unless that person's gear complies with the universal lobster trap gear requirements in (c)(1) of this section and at least one of the options on the Lobster Take Reduction Technology List in (c)(9) of this section. The Assistant Administrator may revise this requirement in accordance with paragraph (g) of this section.

(7) *Northern Nearshore Lobster Waters Area*—(i) *Area.* The Northern Nearshore Lobster Waters Area includes all Federal waters of EEZ Nearshore Management Area 1, Area 2, and the Outer Cape Lobster Management Area as defined in the American Lobster Fishery regulations at 50 CFR 697.18, with the

exception of the CCB Restricted Area and the Stellwagen Bank/Jeffreys Ledge Restricted Area.

(ii) *Area-specific gear requirements.* No person may fish with lobster trap gear in the Northern Nearshore Lobster Waters Area unless that person's gear complies with the gear marking requirements in paragraph (b) of this section, the universal lobster trap gear requirements in (c)(1) of this section, and the gear requirements listed below for this area. The Assistant Administrator may revise these requirements in accordance with paragraph (g) of this section.

(A) *Weak Links.* All buoy lines must be attached to the main buoy with a weak link meeting the following specifications:

(1) The weak link must be chosen from the following list of combinations approved by the NMFS gear research program: swivels, plastic weak links, rope of appropriate diameter, hog rings, rope stapled to a buoy stick, or other materials or devices approved in writing by the Assistant Administrator.

(2) The breaking strength of these weak links must not exceed 600 lb (272.4 kg).

(3) Weak links must be designed such that the bitter end of the buoy line is clean and free of any knots when the link breaks. Splices are not considered to be knots for the purposes of this provision.

(B) *Single traps and multiple-trap trawls.* Single traps are prohibited. All traps must be set in trawls of two or more traps. All trawls up to and including five traps must have no more than one buoy line.

(8) *Southern Nearshore Lobster Waters Area*—(i) *Area.* The Southern Nearshore Lobster Waters Area includes all state and federal waters which fall within EEZ Nearshore Management Area 4 and EEZ Nearshore Management Area 5 as described in the American Lobster Fishery regulations in 50 CFR 697.18.

(ii) *Area-specific gear requirements for the restricted period*—(A) *Restricted period.* The restricted period for Southern Nearshore Lobster Waters is from October 1 through April 30 unless the AA revises this period in accordance with paragraph (g) of this section.

(B) *Gear requirements.* No person may fish with lobster trap gear in the Southern Nearshore Lobster Waters Area during the restricted period unless that person's gear complies with the gear marking requirements specified in paragraph (b) of this section, the universal lobster trap gear requirements in (c)(1) of this section, and at least one of the options on the Lobster Take

Reduction Technology List in (c)(9) of this section. The AA may revise these requirements in accordance with paragraph (g) of this section.

(9) *Lobster Take Reduction Technology List.* The following gear modification options comprise the Lobster Take Reduction Technology List:

(i) All buoy lines must be 7/16 inches (1.11 cm) or less in diameter.

(ii) All buoys must be attached to the buoy line with a weak link meeting the following specifications:

(A) The weak link must be chosen from the following list of combinations approved by the NMFS gear research program: swivels, plastic weak links, rope of appropriate diameter, hog rings, rope stapled to a buoy stick, or other materials or devices approved in writing by the Assistant Administrator.

(B) The breaking strength of these weak links must not exceed 600 lb (272.4 kg).

(C) Weak links must be designed such that the bitter end of the buoy line is clean and free of any knots when the link breaks. Splices are not considered to be knots for the purposes of this provision.

(iii) All buoy lines must be comprised entirely of sinking line.

(iv) All ground lines must be comprised entirely of sinking line.

(d) *Restrictions applicable to anchored gillnet gear*—(1) *Universal anchored gillnet gear requirements.* In addition to the area-specific measures listed in (d)(2) through (d)(7) of this section, all anchored gillnet gear in regulated waters must comply with the universal gear requirements listed here². The AA may revise these requirements in accordance with paragraph (g) of this section.

(i) *No line floating at the surface.* No person may fish with anchored gillnet gear that has any portion of the buoy line that is directly connected to the gear on the ocean bottom floating at the surface at any time. If more than one buoy is attached to a single buoy line or if a high flyer and a buoy are used together on a single buoy line, floating line may be used between these objects.

(ii) *No wet storage of gear.* Anchored gillnet gear must be hauled out of the water at least once every 30 days.

(2) *Cape Cod Bay Restricted Area*—(i) *Area.* The CCB Restricted Area consists of the CCB right whale critical habitat area specified under 50 CFR 226.203(b), unless the AA changes the boundaries

² Fishers are also encouraged to maintain their buoy lines to be as knot-free as possible. Splices are not considered to be an entanglement threat and are thus preferable to knots.

in accordance with paragraph (g) of this section.

(ii) *Closure during the winter restricted period*—(A) *Winter restricted period*. The winter restricted period for this area is from January 1 through May 15 of each year, unless the AA revises the timing in accordance with paragraph (g) of this section.

(B) *Closure*. During the winter restricted period, no person may fish with anchored gillnet gear in the CCB Restricted Area unless the AA specifies gear restrictions or alternative fishing practices in accordance with paragraph (g) of this section and the gear or practices comply with those specifications. The AA may waive this closure for the remaining portion of the winter restricted period in any year through a notification in the Federal Register if NMFS determines that right whales have left the critical habitat and are unlikely to return for the remainder of the season.

(iii) *Area-specific gear requirements for the other restricted period*—(A) *Other restricted period*. The other restricted period for the CCB Restricted Area is from May 16 through December 31 of each year unless the AA revises that period in accordance with paragraph (g) of this section.

(B) No person may fish with anchored gillnet gear in the CCB Restricted Area during the other restricted period unless that person's gear complies with the gear marking requirements specified in paragraph (b) of this section, the universal anchored gillnet gear requirements specified in (d)(1) of this section, and the area-specific requirements listed in (d)(6)(ii) of this section for the Other Northeast Gillnet Waters Area. The AA may revise these requirements in accordance with paragraph (g) of this section.

(3) *Great South Channel Restricted Gillnet Area*—(i) *Area*. The GSC Restricted Gillnet Area consists of the area bounded by lines connecting the following four points: 41°02.2' N/69°02' W, 41°43.5' N/69°36.3' W, 42°10' N/68°31' W, and 41°38' N/68°13' W. This area includes most of the GSC right whale critical habitat area specified under 50 CFR 226.203(a), with the exception of the sliver along the western boundary described in (d)(4)(i) here. The AA may revise these boundaries in accordance with paragraph (g) of this section.

(ii) *Closure during the spring restricted period*—(A) *Spring restricted period*. The spring restricted period for the GSC Restricted Gillnet Area is from April 1 through June 30 of each year unless the AA revises that period in

accordance with paragraph (g) of this section.

(B) *Closure*. During the spring restricted period, no person may set or fish with anchored gillnet gear in the GSC Restricted Gillnet Area unless the AA specifies gear restrictions or alternative fishing practices in accordance with paragraph (g) of this section and the gear or practices comply with those specifications.

(iii) *Area-specific gear requirements for the other restricted period*—(A) *Other restricted period*. The other restricted period for the GSC Restricted Gillnet Area is from July 1 through March 31 of each year unless the AA revises that period in accordance with paragraph (g) of this section.

(B) During the other restricted period, no person may fish with anchored gillnet gear in the GSC Restricted Gillnet Area unless that person's gear complies with the gear marking requirements specified in paragraph (b) of this section, the universal anchored gillnet gear requirements specified in (d)(1) of this section, and the area-specific requirements listed in (d)(6)(ii) of this section for the Other Northeast Gillnet Waters Area. The AA may revise these requirements in accordance with paragraph (g) of this section.

(4) *Great South Channel Sliver Restricted Area*—(i) *Area*. The GSC Sliver Restricted Area consists of the area bounded by lines connecting the following points: 41°02.2' N/69°02' W, 41°43.5' N/69°36.3' W, 41°40' N/69°45' W, and 41°00' N/69°05' W. The AA may revise these boundaries in accordance with paragraph (g) of this section.

(ii) *Area-specific gear requirements*. No person may fish with anchored gillnet gear in the GSC Sliver Restricted Area unless that gear complies with the gear marking requirements specified in paragraph (b) of this section, the universal anchored gillnet gear requirements specified in (d)(1) of this section, and the area-specific requirements listed in subparagraph (d)(6)(ii) of this section for the Other Northeast Gillnet Waters Area. The AA may revise these requirements in accordance with paragraph (g) of this section.

(5) *Stellwagen Bank/Jeffreys Ledge Restricted Area*—(i) *Area*. The Stellwagen Bank/Jeffreys Ledge Restricted Area includes all Federal waters of the Gulf of Maine, except those designated as right whale critical habitat under 50 CFR 226.203(b), that lie south of 43°15' N. lat. and west of 70° W long. The AA may change these boundaries in accordance with paragraph (g) of this section.

(ii) *Area-specific gear requirements*. No person may fish with anchored gillnet gear in the Stellwagen Bank/Jeffreys Ledge Restricted Area unless that gear complies with the gear marking requirements specified in paragraph (b) of this section, the universal anchored gillnet gear requirements specified in (d)(1) of this section, and the area-specific requirements listed in (d)(6)(ii) of this section for the Other Northeast Gillnet Waters Area. The AA may revise these requirements in accordance with paragraph (g) of this section.

(6) *Other Northeast Gillnet Waters Area*—(i) *Area*. The Other Northeast Gillnet Waters Area consists of all U.S. waters west of the U.S./Canada border and north of a line extending due east from the Virginia/North Carolina border with the exception of the CCB Restricted Area, Stellwagen Bank/Jeffreys Ledge Restricted Area, GSC Restricted Gillnet Area, GSC Sliver Restricted Area, Mid-Atlantic Coastal Waters Area, and exempted waters listed in (a)(2) of this section.

(ii) *Area-specific gear requirements*. No person may fish with anchored gillnet gear in the Other Northeast Gillnet Waters Area unless that person's gear complies with the gear marking requirements specified in paragraph (b) of this section, the universal anchored gillnet gear requirements specified in (d)(1) of this section, and the area-specific requirements listed below. The AA may revise these requirements in accordance with paragraph (g) of this section.

(A) *Buoy line weak links*. All buoy lines must be attached to the main buoy with a weak link meeting the following specifications:

(1) The weak link must be chosen from the following list of combinations approved by the NMFS gear research program: swivels, plastic weak links, rope of appropriate diameter, hog rings, rope stapled to a buoy stick, or other materials or devices approved in writing by the AA.

(2) The breaking strength of these weak links must not exceed 1100 lb (498.8 kg).

(3) Weak links must be designed such that the bitter end of the buoy line is clean and free of any knots when the link breaks. Splices are not considered to be knots for the purposes of this provision.

(B) *Net panel weak links*. All net panels must contain weak links meeting the following specifications:

(1) Weak links must be inserted in the center of the floatline (headrope) of each net panel in a net string.

(2) The breaking strength of these weak links must not exceed 1100 lb (498.8 kg).

(C) Anchoring System. All anchored gillnet strings containing 20 or fewer net panels must be securely anchored with one of the following anchoring systems:

(1) Anchors with the holding power of at least a 22 lb (10.0 kg) Danforth-style anchor at each end of the net string,

(2) Dead weights weighing at least 50 lb (22.7 kg) at each end of the net string, or

(3) A lead line weighing at least 100 lb (45.4 kg) per 300 ft (91.4 m) for each net panel in the net string.

* * * * *

[FR Doc. 00-32050 Filed 12-20-00; 8:45 am]

BILLING CODE 3510-22-S

DEPARTMENT OF COMMERCE

National Oceanic Atmospheric Administration

50 CFR Part 679

[Docket No. 001023289-0289-01; I.D. 083000C]

RIN 0648-AO25

Fisheries of the Exclusive Economic Zone Off Alaska; Extension of the Interim Groundfish Observer Program through December 31, 2002

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic Atmospheric Administration (NOAA), Commerce.

ACTION: Final rule.

SUMMARY: NMFS issues a final rule to extend through 2002 the regulations implementing the Interim North Pacific Groundfish Observer Program (Interim Observer Program), which otherwise would expire December 31, 2000. This action is necessary to ensure uninterrupted observer coverage through December 31, 2002. The intention is to advance the management objectives of the Fishery Management Plan for the Groundfish Fishery of the Bering Sea and Aleutian Islands Area and the Fishery Management Plan for Groundfish of the Gulf of Alaska (FMPs). This final rule does not amend the existing regulations, except to extend the certifications of observer contractors who are currently certified by NMFS.

DATES: Effective January 1, 2001.

ADDRESSES: Copies of the Environmental Assessment/Regulatory Impact Review/Final Regulatory Flexibility Analysis (EA/RIR/FRFA) prepared for the 1997 Interim

Groundfish Observer Program, the RIR/FRFA prepared for the 1998 Interim Groundfish Observer Program, the RIR/FRFA prepared for the 1999-2000 Interim Groundfish Observer Program, and the RIR/FRFA prepared for this final regulatory action may be obtained from the Alaska Region, NMFS, P.O. Box 21668, Juneau, AK 99802, Attn: Lori Gravel. Send comments on any ambiguity or unnecessary complexity arising from the language used in this final rule to the Administrator, Alaska Region, P.O. Box 21668, Juneau, AK 99802-1668.

FOR FURTHER INFORMATION CONTACT: Bridget Mansfield, 907-586-7228.

SUPPLEMENTARY INFORMATION: NMFS manages the U.S. groundfish fisheries of the Gulf of Alaska (GOA) and the Bering Sea and Aleutian Islands Management Area (BSAI) in the Exclusive Economic Zone under the FMPs. The North Pacific Fishery Management Council (Council) prepared the FMPs pursuant to the Magnuson-Stevens Fishery Conservation and Management Act (Magnuson-Stevens Act). Regulations implementing the FMPs appear at 50 CFR part 679. General regulations that pertain to U.S. fisheries appear at subpart H of 50 CFR part 600.

The Council adopted and NMFS implemented the Interim Observer Program in 1996, which superseded the North Pacific Fisheries Research Plan (Research Plan). The regulations implementing the Interim Program were extended through 1997 (61 FR 56425, November 1, 1996), again through 1998 (62 FR 67755, December 30, 1997), and again through 2000 (63 FR 69024, December 15, 1998). The Interim Observer Program provides the framework for the collection of data by observers to obtain information necessary for the conservation and management of the groundfish fisheries managed under the FMPs. Further, it authorizes mandatory observer coverage requirements for vessels and shoreside processors and establishes vessel, processor and contractor responsibilities relating to the observer program. NMFS intends that by 2003 a long-term program will be developed and implemented that addresses several current concerns. These include data integrity, observer compensation, working conditions for observers, and equitable distribution of observer costs.

NMFS is working with the Council and the Council's Observer Advisory Committee (OAC) to address these concerns and to develop new options for an alternative infrastructure for an Observer Program. A new infrastructure would be expected to ensure the

continued collection of quality observer data and address observer coverage cost distribution issues through a fee system or alternate funding mechanism.

The development of a new infrastructure will require extensive time and coordination among NMFS staff, the OAC, and representatives of the industry sectors and observer interests. NMFS and the Council intend to implement a replacement structure for the program prior to the expiration of the Interim Observer Program on December 31, 2002.

A description of the regulatory provisions of the Interim Groundfish Observer Program was provided in the proposed and final rules implementing this program (61 FR 40380, August 2, 1996; 61 FR 56425, November 1, 1996, respectively) as well as the proposed and final rules extending this program through 1998 and again through 2000 (62 FR 49198, September 19, 1997; 62 FR 67755, December 30, 1997; 63 FR 47462, September 8, 1998; 63 FR 69024, December 15, 1998, respectively).

A proposed rule to extend the Interim Observer Program through 2002 was published in the **Federal Register** on November 3, 2000 (65 FR 66223), for a 17-day public comment and review period that ended on November 20, 2000. No written comments were received. This final rule does not change the existing regulations, except to extend certification of observer contractors who are currently certified by NMFS under the terms and conditions set forth in the regulations at § 679.50(i).

Changes From the Proposed Rule

No changes are made in this final rule from the proposed rule published in the **Federal Register** (65 FR 66223 November 3, 2000).

Small Entity Compliance Guide

The following information satisfies the Small Business Regulatory Enforcement Act of 1996, which requires a plain language guide to compliance with this final rule by affected small entities.

How much observer coverage do I need?

Observer coverage requirements for vessels over 60 ft (18.3 m) length overall (LOA) and up, other than motherships, that fish for groundfish in the BSAI or the GOA are applicable each calendar quarter and are specific to vessel type and length. Coverage requirements also vary according to the gear used and the directed fishery in which the vessel participates. Vessels under 60 ft (18.3 m) LOA are exempt from observer coverage under this final rule.

Coverage requirements for shoreside processors and motherships are specified according to projected landings in a given month. Additional coverage requirements for vessels and shoreside processors are specified under the Community Development Quota Program (CDQ) and American Fisheries Act (AFA).

The regulations found at 50 CFR 679.50 should be referenced for specific coverage requirements.

Who is responsible for ensuring that observer coverage is met?

The operator of the vessel or shoreside processor is responsible for obtaining appropriate coverage levels as specified by regulation. The owner of a vessel must ensure the operator complies and is liable with the operator for compliance.

How do I obtain an observer?

Vessel owner/operators are required to procure observers directly through a NMFS-certified observer provider company (contractor). A list of contractors is available from the NMFS Alaska Regional Office (see **ADDRESSES**) or from the North Pacific Groundfish Observer Program at (206) 526-4078.

What if an observer is not available when I need one?

In general, a vessel may not fish for groundfish and a shoreside processor may not process groundfish without a required observer. NMFS encourages vessels and shoreside processors that anticipate the need for an observer to contact, as early as possible and in writing, the contractors that provide observers to allow enough time to ensure the availability of an observer when needed. A written contract regarding the terms of agreement with the contractor for providing observer coverage also is encouraged. If an observer also is not available when the vessel or shoreside processor has requested one, the vessel or shoreside processor may need to adjust operations. For a vessel or shoreside processor requiring 100 percent observer coverage, if an observer is not available when scheduled operations would require one, the vessel or shoreside processor would be in violation of coverage regulations should the vessel continue to fish for groundfish, or, in the case of a mothership or shoreside processor, continue to receive and process groundfish. Vessels or shoreside processors that require 30 percent observer coverage in a given calendar quarter or month may have some latitude to obtain observer coverage later

that quarter or month. However, the vessels or shoreside processors requiring 30 percent observer coverage will be considered in violation of coverage regulations if, by the close of the calendar quarter or month, they do not obtain the appropriate level of coverage for that period.

What are my responsibilities to the Observer aboard my vessel or at my shoreside processor?

At no cost to the observers or the U.S. Government, vessels must provide food and accommodation equivalent to that of the vessels' officers or other management-level personnel of the vessel. Vessels and shoreside processors must maintain safe conditions, and vessels must adhere to U.S. Coast Guard rules for safe operation of the vessel and display a valid Commercial Fishing Vessel Safety Decal issued by the Coast Guard. Vessels and shoreside processors must facilitate the transmission of observer data by providing the appropriate computer and communications hardware equipped with NMFS-supplied software. Observers must have free and unobstructed access to equipment and areas of a vessel or shoreside processor, as outlined in the regulations, that are necessary for observers to complete their work. Such access must also be available to records such as the Daily Fishing Log, Daily Catch Processing Log, product transfer forms, scale information or production records, or any logs or documents required by regulation. Observers must be notified in advance of fish being brought aboard the vessel or a delivery being received at a shoreside processor, unless the observer requests otherwise. Observers must be reasonably assisted in carrying out their duties, including being provided with a safe work area. The Community Development Quota Program and American Fisheries Act programs have additional requirements outlined in regulations implementing those programs.

What are the responsibilities of an observer provider company?

The observer provider (specified in the regulations as the contractor) must be certified by NMFS to provide observer services to vessels and shoreside processors operating in the BSAI and GOA. Contractors are required to provide a NMFS-certified observer to a shoreside processor or vessel upon request. This means that they are responsible for recruiting and hiring qualified candidates; providing observers' salaries; benefits and personnel services in a timely manner;

providing all logistics, including travel and per diem costs to get an observer to place of deployment. Contractors must meet requirements of deployment length and assignment criteria and must replace an observer or prospective observer under specified conditions. Contractors must maintain communication with deployed observers with an employee on call 24 hours a day for observer emergencies and must ensure observer data, biological samples, and other communication are transmitted or transferred to NMFS within the specified time frames. Contractors must also ensure that observers meet all NMFS training, briefing, and debriefing requirements, as well as all equipment maintenance and replacement requirements. Contractors are responsible to monitor observers' performance to ensure satisfactory conformance to NMFS standards. Contractors are responsible to provide NMFS with information as specified in regulations under § 679.50(i)(2)(xiv). Finally, contractors must conform with conflict-of-interest standards as set out in § 679.50(i)(3).

Classification

This final rule has been determined to be not significant for purposes of Executive Order 12866.

This final rule extends without change existing collection-of-information requirements subject to the Paperwork Reduction Act (PRA). The collection of this information has been approved by the Office of Management and Budget (OMB) under OMB control numbers 0648-0307 and 0648-0318.

Notwithstanding any other provision of the law, no person is required to respond to, nor shall any person be subject to a penalty for failure to comply with, a collection of information subject to the requirements of the PRA, unless that collection of information displays a currently valid OMB control number.

The extension of the regulations implementing the Interim Observer Program through December 31, 2002, is consistent with the intent and purpose of the Interim Observer Program. The extension will provide the same benefits as listed in the EA/RIR/FRFA for the Interim Observer Program dated August 27, 1996, the RIR/FRFA for the extension of the Interim Observer Program through 1998 dated October 28, 1997, and the RIR/FRFA for the extension of the Interim Observer Program through 2000, dated June 4, 1998. Copies of these analyses are available from NMFS (see **ADDRESSES**).

NMFS prepared an FRFA, which describes the impact this final rule

would have on small entities. A copy of this analysis is also available from NMFS (see **ADDRESSES**). No comments on the Initial Regulatory flexibility Analysis were received during the public comment period on the proposed rule. NMFS has determined that this final rule could have a significant impact on a substantial number of small entities. Alternatives that addressed modifying reporting requirements for small entities or the use of performance standards rather than design standards for small entities were not included in the analysis, because such alternatives are not relevant to this final action and would not mitigate impacts on small entities. Allowing exemptions for small entities would not be appropriate because the objective to ensure uninterrupted observer coverage requirements through 2002 would not be achieved would undermine the collection of information needed to effectively manage the Alaska groundfish fisheries.

Under the definition of small entity for the fisheries harvesting and processing industry, 6 companies certified by NMFS to supply observers and 19 shoreside processors that would be impacted by this action are considered small entities with fewer than 500 employees. With the exception of Anchorage, 17 Alaskan communities impacted by this rule qualify as "small jurisdictions", under Regulatory Flexibility Act definitions. None of these communities is directly regulated by this action, and there are no anticipated indirect effects associated with the action that would accrue to this group of "small entities".

Approximately 1,315 vessels that caught groundfish off Alaska while fishing Federal total allowable catch amounts in 1997 were provisionally considered to be small entities. Most persons operating in the fisheries impacted by the action are small entities given their expected gross annual revenues less than \$3 million. The ownership characteristics of vessels operating in the fisheries have not been thoroughly analyzed to determine if they are independently owned and operated or affiliated with a larger parent company.

This may represent an overestimate of vessels considered to be small entities, because in 1997, the most recent year for which data on the number of vessels considered to be large entities is available, 59 vessels were considered large entities based solely on their

Alaska groundfish fishery ex-vessel value and product value. This is considered to be an underestimate of large entities for the following reasons: (1) earnings from other fisheries and activities were not included; (2) a vessel's owner's earnings from other sources were not included; (3) ex-vessel value of a delivery by a catcher vessel to an at-sea processor was included only when a fish ticket with value was submitted for the delivery; (4) vessel-specific fish ticket landings weight and value data are used to estimate ex-vessel value for catcher vessels, but such data are not available for all deliveries to inshore processors.

However, this action does include measures that will minimize the significant economic impacts of observer coverage requirements on at least some small entities. Vessels less than 60 ft (18.3 m) LOA are not required to carry an observer while fishing for groundfish. Vessels 60 ft (18.3 m) and greater, but less than 125 ft (38.1 m) LOA, have lower levels of observer coverage than those 125 ft (38.1 m) and above. Recently, NMFS proposed reductions in observer coverage for some CDQ vessels and shoreside processors. Since the inception of the North Pacific Groundfish Observer Program in 1989, NMFS has strived to mitigate the economic impacts of the observer program on small entities. In doing so, NMFS has not significantly adversely affected the implementation of the conservation and management responsibilities imposed by the FMPs prepared under the Magnuson-Stevens Fishery Conservation and Management Act.

The Assistant Administrator for Fisheries, NOAA, (AA) finds for good cause under 5 U.S.C. 553(d) that delaying the effectiveness of this rule for 30 days would be contrary to the public interest. Such a delay would cause the Observer Program to expire. For conservation and management reasons, NMFS could not allow fishing in 2001 without requiring observer coverage necessary to monitor and manage the Alaska groundfish fisheries. Also, this final rule is not establishing any new requirements with which affected parties must come into compliance. For these reasons, a delay in the effective date is not warranted. Accordingly, the AA makes the extension effective on January 1, 2001.

The President has directed Federal agencies to use plain language in their communications with the public,

including regulations. To comply with this directive, we seek public comment on any ambiguity or unnecessary complexity arising from the language used in this proposed rule. Such comments such be sent to the Administrator, Alaska Region (see **ADDRESSES**).

List of Subjects in 50 CFR Part 679

Alaska, Fisheries, Reporting and recordkeeping requirements.

Dated: December 14, 2000

William T. Hogarth,

Deputy Assistant Administrator for Fisheries, National Marine Fisheries Service.

For the reasons set out in the preamble, 50 CFR part 679 is amended as follows:

PART 679—FISHERIES OF THE EXCLUSIVE ECONOMIC ZONE OFF ALASKA

1. The authority citation for 50 CFR part 679 continues to read as follows:

Authority: 16 U.S.C. 773 *et seq.*, 1801 *et seq.*, and 3631 *et seq.*

2. In § 679.50, the section heading, and paragraphs (i)(1)(i) and (i)(1)(iii) are revised to read as follows:

§ 679.50 Groundfish Observer Program applicable through December 31, 2002.

* * * * *

(i) * * *

(1) * * *

(i) *Application.* An applicant seeking to become an observer contractor must submit an application to the Regional Administrator describing the applicant's ability to carry out the responsibilities and duties of an observer contractor as set out in paragraph (i)(2) of this section and the arrangements to be used. Observer contractors certified for the year 2000 to provide observers through the North Pacific Groundfish Observer Program, are exempt from this requirement to submit an application and are certified for the term specified in paragraph (i)(1)(iii) of this section.

* * * * *

(iii) *Term.* Observer contractors will be certified through December 31, 2002. NMFS can decertify or suspend observer contractors pursuant to paragraph (j) of this section.

* * * * *

[FR Doc. 00-32424 Filed 12-20-00; 8:45 am]

BILLING CODE 3510-22-S

Proposed Rules

Federal Register

Vol. 65, No. 246

Thursday, December 21, 2000

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.

FEDERAL RESERVE SYSTEM

12 CFR Part 225

[Regulation Y; Docket No. R-1092]

Bank Holding Companies and Change in Bank Control

AGENCY: Board of Governors of the Federal Reserve System.

ACTION: Proposed rule with request for public comment.

SUMMARY: The Board invites public comment on a proposal to amend its Regulation Y to change the conditions that govern the conduct of financial data processing activities previously found to be closely related to banking in order to permit all bank holding companies to conduct a greater amount of nonfinancial data processing in connection with processing financial data, and to allow financial holding companies, as an activity that is complementary to financial activities, to own companies engaged in certain types of data storage, Internet and portal hosting activities, and broad advisory activities involving data processing activities, so long as the companies also provide financial data processing or other financial products and services. In addition, the Board seeks comment on whether it should permit financial holding companies to make investments in companies that engage in developing new technologies that might support the sale and availability of financial products and services, companies that provide communication links for the delivery of financial products and services and/or companies that engage in the electronic sale and delivery of products and services that include, but are not limited to, financial products and services.

DATES: Comments must be received by February 16, 2001.

ADDRESSES: Comments should refer to docket number R-1092 and should be mailed to Ms. Jennifer J. Johnson, Secretary, Board of Governors of the Federal Reserve System, 20th Street and

Constitution Avenue, NW, Washington, DC, 20551, or mailed electronically to regs.comments@federalreserve.gov. Comments addressed to Ms. Johnson also may be delivered to the Board's mailroom between 8:45 a.m. and 5:15 p.m. and, outside those hours, to the Board's security control room. Both the mailroom and the security control room are accessible from the Eccles Building courtyard entrance, located on 20th Street between Constitution Avenue and C Street, NW. Members of the public may inspect comments in room MP-500 of the Martin Building between 9:00 a.m. and 5:00 p.m. on weekdays.

FOR FURTHER INFORMATION CONTACT: Scott G. Alvarez, Associate General Counsel (202/452-3583), or Adrienne G. Threatt, Senior Attorney (202/452-3554), Legal Division; Board of Governors of the Federal Reserve System, 20th Street and Constitution Avenue, NW., Washington, DC, 20551. For users of Telecommunications Device for the Deaf ("TDD") only, contact Janice Simms at 202/872-4984.

SUPPLEMENTARY INFORMATION:

Background

A number of financial holding companies, represented by the New York Clearing House, the American Bankers Association and the Financial Services Roundtable, have requested that the Board permit financial holding companies (FHCs) to engage in and make investments in companies engaged in broad data processing and e-commerce activities. The requested activities involve:

1. Acting as a finder;
2. Operating an electronic marketplace;
3. Purchasing aggregation and marketing access arrangements;
4. Conducting nonfinancial data processing activities in connection with financial data processing activities;
5. Data collection, processing, imaging, storage and retrieval for financial and nonfinancial data;
6. Providing web and portal hosting services, electronic links to Internet and Intranet sites (including serving as an Internet Service Provider), data transmission security and authentication, software and ongoing support and maintenance for third party web sites and portals;
7. Advisory and consulting services related to the development,

implementation and operation of Internet and Intranet sites and web portals;

8. Owning communication linkages;

9. Owning companies engaged in developing new technologies that might in the future support the sale and provision of financial products and services; and

10. Owning companies engaged in the electronic marketing and sale of nonfinancial products and services for the purpose of allowing the FHC to market and provide financial products and services.¹

The FHCs argue that recent dramatic changes in technology and in the manner in which products and services are sold over the Internet make these types of activities and investments either financial in nature, incidental to financial activities or complementary to financial activities. They argue in particular that there is no practical distinction between processing financial data (a permissible activity for bank holding companies) and processing nonfinancial data (an activity permitted for bank holding companies only in limited amounts). FHCs also contend that the experience that they have gained over the years conducting data processing activities for financial, banking and economic data is readily transferable to other types of data processing. For example, FHCs contend that activities such as the storage, imaging and retrieval of nonfinancial data are a natural extension of permissible activities already conducted by bank holding companies and banks.

FHCs also argue that, while in the past a banking organization could make contractual arrangements with a nonfinancial firm to market financial products and services of the banking organization along with products and services of the nonfinancial firm, today companies that market products and services over the Internet or intranets typically seek equity partners rather than contractual partners in order to share the equity risk of these ventures and to raise equity capital. Consequently, banking organizations

¹ Several companies also requested that the Board permit FHCs to provide identity certification services, including digital certification services. The Board has already permitted these activities for all bank holding companies, including financial holding companies. See *Bayerische Hypo- und Vereinsbank AG*, 86 Federal Reserve Bulletin 56 (January 2000).

contend that they must be in a position to make equity investments in companies that have found innovative methods of reaching the same customers that the banking organizations seek to reach for their own financial products and services.

In addition, FHCs argue that they must be able to participate in the development of new technologies that in the future may be useful in delivering financial products and services. They contend that FHCs must be able to participate in the development of the standards and industry protocols for new technology and in the development of delivery systems and equipment to be sure that these standards and equipment will be capable of delivering banking products and services.

Again, FHCs contend that the paradigm of the past—where financial products and services were largely delivered over uniquely designed systems developed by or under contract to banking organizations—has changed. Today, technology is designed to accommodate a series of partners that bind together to develop a number of simultaneous uses for the new technology. FHCs argue that, unless they are permitted to be partners in the development of new technologies and standards, FHCs risk being required to comply with standards and limitations imposed by other industries that will tailor new delivery systems to their own products and services. Similarly, FHCs contend that they must be permitted to own delivery systems, such as communication lines and systems, in order to assure that these broad technologies for the delivery of products and services remain available to them.

Legal Framework

The Gramm-Leach-Bliley Act broadened in two ways the authority of the Board to determine the scope of activities permissible for FHCs. First, FHCs may conduct any activity that the Board, in consultation with the Secretary of the Treasury, determines to be “financial in nature or incidental to a financial activity.”² This new authority was specifically designed to create a test that is broader than the “closely related to banking” test that applied previously. The closely related test has been construed over the years by the Board and the courts to allow bank holding companies to conduct activities that are permissible for banks to conduct, are operationally similar to activities conducted by banks, or are activities that bank holding companies are particularly well equipped to

conduct because of their other activities. The new “financial in nature” test was intended to allow activities to be authorized in response to technological and other developments that more broadly affect the market for financial products and services.³

In addition, the Board may allow an FHC to engage in any nonfinancial activity that the Board determines to be “complementary to a financial activity.”⁴ The activity must be complementary to a financial activity. That is, the activity must in some way complement or enhance a financial activity or there must be a relationship or connection between the complementary activity and a financial activity. In considering whether an activity is complementary, the Board must also consider whether the activity poses a substantial risk to the safety and soundness of depository institutions or the financial system generally.⁵

The authority to engage in complementary activities was included as a mechanism for allowing some amount of commercial or nonfinancial activities so long as there is a connection between the complementary activity and a financial activity conducted by the FHC and the activity does not pose unacceptable risks to the safety and soundness of the FHC, its banks or the banking system. At the same time, Congress rejected the invitation to allow depository institutions to affiliate in an unrestricted manner with commercial companies and determined not to permit FHCs to engage in a basket of purely commercial activities that have no connection to financial activities.

The requesting FHCs have indicated that some of the investments they have requested authority to make are similar to investments that could be made under the merchant banking authority granted to FHCs under the Gramm-Leach-Bliley Act. However, that authority does not permit cross-

marketing between the depository institutions owned by the FHC and the portfolio company, and it is precisely this cross-marketing opportunity that motivates many of the requested investments.

Proposal

In response to the requests described above, the Board proposes several steps. As an initial matter, items 1, 2 and 3 in the list above involve various aspects of a finder proposal that the Board, in consultation with the Secretary of the Treasury, has already published for public comment and recently adopted as a final rule.⁶

The Board proposes several additional amendments to Regulation Y to address other aspects of the requests. First, the Board, under the closely related to banking test, has already allowed bank holding companies to engage in processing financial, economic and banking data (and providing limited amounts of general purpose data processing hardware). In connection with those activities, the Board authorized bank holding companies to own a company engaged in processing any type of data so long as the revenues generated by the company from processing nonfinancial data do not exceed 30 percent of the company's total data processing revenues.

The Board proposes to expand from 30 to 49 percent the amount of revenues that may be derived from nonfinancial data processing. This would allow bank holding companies, including FHCs, to make more efficient use of their data processing expertise and equipment and recognizes that processing nonfinancial data is in many cases operationally and functionally indistinguishable from processing financial, economic and banking data. At the same time, the revenue test assures that a majority of the business of each data processing subsidiary would be financial data processing. This would address item 4 in the above list.

The Board proposes this change as a change in the conditions that govern the conduct of financial data processing activities under section 4(c)(8) of the Bank Holding Company Act (BHC Act) and the Board's Regulation Y. Accordingly, this change, if adopted, would allow all bank holding companies and financial holding companies to engage in broader data processing activities. The Board has authority to modify the conditions that

³ In considering whether an activity is financial in nature or incidental to a financial activity, the Board is directed to consider (1) the purposes of the Bank Holding Company Act and the Gramm-Leach-Bliley Act; (2) changes and reasonably expected changes in the marketplace in which financial holding companies compete and in the technology for delivering financial services; and (3) whether the activity is necessary or appropriate to allow a FHC to compete effectively with other companies providing financial services, to deliver efficiently information and services that are financial in nature through the use of technological means, including any application necessary to protect the security or efficacy of systems for the transmission of data or financial transactions, and to offer customers any available or emerging technological means for using financial services or for the document imaging of data. 12 U.S.C. 1843(k)(3).

⁴ 12 U.S.C. 1843(k)(1)(B).

⁵ *Id.*

⁶ This rule received Board approval on December 13, 2000, and will be published in a later issue of the **Federal Register**.

² 12 U.S.C. 1843(k)(1)(A).

govern activities that were previously found to be closely related to banking.⁷

Second, to address items 5, 6 and 7 listed above, the Board proposes to amend Regulation Y to authorize FHCs, as an activity that is complementary to related financial activities, to invest up to an aggregate of 5 percent of the FHC's Tier 1 capital in the following types of companies:

(1) *Data storage.* Companies that act as custodian of files that involve *any type of data, including financial and nonfinancial data, so long as* the custodian provides these services for financial data. This activity would include data imaging, data storage and data retrieval for data in any form, including in electronic, paper, microfiche or other form.

(2) *General data processing.* Companies that provide general data processing and data transmission services, including data processing and data transmission hardware, software, documentation and operating personnel, data bases, advice and facilities, *without limit as to the type of data processed or transmitted, so long as* at least 20 percent of the total revenues of the company conducting these activities are derived from providing data processing services to depository institutions and their affiliates and/or processing financial data and/or the sale of other financial products and services. This authority would be in addition to investments permitted above in companies that engage primarily in financial data processing, and would be available only to FHCs.

(3) *Electronic information portal services.* Companies that provide or facilitate information search, exchange, consolidation, screening, filtering or aggregation services over electronic networks. This activity would include providing on-line search engines that display sites meeting criteria selected by the user, bulletin boards, newsgroup services on general or specific topics, "chat" rooms, Internet web sites or portals that contain links to other web sites, and aggregation services that accumulate and display any type of data selected by the user on a customized web page. This activity would also include acting as an Internet Service Provider. It would be expected that FHCs would market and provide financial products and services through these companies.

Each of these proposed investments involves investing in companies engaged in some degree of commercial activities. Consequently, the Board proposes to find that investments in

these companies are *complementary* to a financial activity.

As explained above, in order to determine that an activity is permissible as a complementary activity, the Board must determine that the activity is related to or complements a financial activity. In each case, the proposal includes a connection with a previously approved financial activity or with the marketing and delivery of financial products and services.

The Board seeks comment on whether the connections to financial activities described above are appropriate and sufficient to indicate that each of the types of investments or activities described above is complementary to a financial activity within the meaning of the BHC Act. In addition, comment is invited on whether the Board should adopt other requirements to assure that the investment or activity is related to or complements a financial activity. For example, the Board requests comment on whether the Board should require that some amount of revenues of the target company be derived from financial data processing or from marketing financial products and services of the FHC in order to satisfy the complementary test.

The Board does not propose that any restrictions be placed on the FHC's ability to be involved in managing these companies or cross-marketing or delivering financial products and services through these companies. In fact, as noted above, in each case it is expected that financial products and services, such as storing and processing financial data or providing access to financial advice or home banking services, would be provided as an integral part of the activities of the company.

In order to limit the potential risk of these investments and activities to the safety and soundness of the FHC, its depository institutions and the financial system generally as required by section 4(k)(1)(B) of the BHC Act,⁸ the proposal would limit the total carrying value of all investments permitted under the 3 categories listed above to an aggregate of 5 percent of the FHC's Tier 1 capital. The Board believes that this limitation will also help to ensure that the proposed investments and activities remain complementary to the FHC's overall financial activities.

The Board requests comment on whether an investment limit is an appropriate way to limit the potential risk to the safety and soundness of affiliated depository institutions and to the financial system generally and

whether the limit proposed is the appropriate level given the potential risks of these activities and the nature of the activities. The Board also requests comment on whether a stronger connection between the activity and a related financial activity may justify a higher or different type of limit. In addition, the Board requests comment on whether, either as an alternative to the limit described above or as a supplement to that limit, the Board should require that additional capital be maintained by FHCs against investments made in the three types of companies listed above.

Section 4(j) of the BHC Act as amended by the Gramm-Leach-Bliley Act requires that a financial holding company provide notice to the Board at least 60 days prior to conducting any activity or acquiring any company that conducts any activity that is complementary to a financial activity.⁹ At least initially, the Board proposes that each investment under any of the complementary authorities would be subject to review by the Board on a case-by-case basis pursuant to section 4(j) of the BHC Act. In this process, the FHC would be expected to explain the connection between its proposed complementary investment or activity and a related financial activity. The Board proposes that its review be focused on a review of the permissibility of the investment under the appropriate category and a brief review of the public benefits. This notice would satisfy the approval process in the Gramm-Leach-Bliley Act. After the System has gained more experience with these types of investment activities, the Board would revisit whether a more streamlined process (e.g., a one-time approval to make investments in companies engaged in the listed activities) is appropriate.

In addition to these activities, FHCs have requested authority to make investments in companies engaged in developing new technologies, in providing communication links or in e-commerce (Items 8, 9 and 10 above). The Board requests comment on whether conducting or investing in companies that conduct any of these activities would be financial in nature, incidental to a financial activity or complementary to a financial activity. In particular, the Board requests comment on how these types of activities or investments should be defined or identified. Commenters favoring a finding regarding these activities or investments should provide detailed

⁷ 12 U.S.C. 1843(c)(8).

⁸ 12 U.S.C. 1843(k)(1)(B).

⁹ 12 U.S.C. 1843(j)(1)(A) and (E).

arguments and information supporting their recommended action. In particular, to the extent that an activity or investment would be financial in nature or incidental to a financial activity, commenters are requested to provide detailed arguments and data explaining and supporting how the activity or investment is financial or incidental. Similarly, to the extent that an activity or investment is considered to be complementary to a financial activity, detailed information is sought on what connection exists between these activities/investments and financial activities that are conducted by FHCs or how the proposed activity or investment would otherwise complement a financial activity.

In addition, comment is sought on how investing in companies engaged in developing new technologies, providing communication links or selling products electronically might be conducted in a manner consistent with the separation of banking and commerce. Comment is also sought on whether any supervisory limits, such as those discussed above for data processing activities, might be appropriate to address potential risks to affiliated depository institutions and the financial system generally.

The Board also seeks comment on whether it should permit FHCs to make noncontrolling investments in companies engaged in developing new technologies, providing communication links or selling products electronically. The Board already permits bank holding companies to acquire up to 25 percent of the equity, in the form of nonvoting shares, of any company so long as the bank holding company does not have the ability to exercise control over the portfolio company. Under this proposal, the Board would permit FHCs to invest in up to 25 percent of the voting stock of these companies and engage in cross-marketing activities through these companies so long as the FHC does not exercise control over the companies and there is another person or group of persons that owns more voting shares than the FHC. As an alternative, the Board could permit FHCs to make equity investments that represent in the aggregate more than 25 percent of the equity of the portfolio company, such as the levels permitted for portfolio investments overseas under Regulation K (that is, in up to 20 percent of the voting shares and up to another 20 percent of equity in the form of nonvoting shares). In this event, it would be particularly important that another person or control group, such as the management of the company, control more shares of the portfolio company than the FHC and have

responsibility for actively managing the company.

The Board invites comment on all aspects of the proposed rule, and particularly on the items specifically identified in the foregoing discussion.

Section 722 of the GLB Act requires the Board to use "plain language" in all proposed and final rules published after January 1, 2000. In light of this requirement, the Board has sought to present the proposed rule in a simple and straightforward manner. The Board invites comment on whether the Board could take additional steps to make the proposed rule easier to understand.

Regulatory Flexibility Act

In accordance with section 3(a) of the Regulatory Flexibility Act (5 U.S.C. 603(a)), the Board must publish an initial regulatory flexibility analysis with this proposed rulemaking. The proposed rule, if adopted, would: (1) Change the conditions that govern the conduct of data processing activities that already are permissible for a bank holding company; and (2) allow a bank holding company or foreign bank that qualifies as an FHC, on a case by case basis, to own companies engaged in certain types of data processing and web hosting activities as an activity that is complementary to its financial activities. A description of the reasons for the Board's consideration of this action and a statement of the objectives of and legal basis for the proposed rule are contained in the supplementary material provided above.

The proposed rule would apply to bank holding companies and FHCs regardless of their size and should enhance the ability of all such companies, including small ones, to compete with other providers of financial services in the United States and to respond to technological and other changes in the marketplace in which banking organizations compete. The Board specifically seeks comment on the likely burden the proposed rule would have on bank holding companies, including FHCs.

Paperwork Reduction Act

In accordance with the Paperwork Reduction Act of 1995 (44 U.S.C. 3506; 5 CFR part 1320 Appendix A.1), the Board has reviewed the proposed rule under authority delegated to the Board by the Office of Management and Budget. If the proposal is adopted, bank holding companies and financial holding companies, including foreign banks, would be required by statute to file notice with the Board prior to making the investments or conducting the activities addressed in the proposal

(12 U.S.C. 1843(j)). The applicable notice procedures, which already are in place, are described at sections 225.22 to 225.24 and section 225.89 of the Board's Regulation Y. In addition, the Board would be required to monitor the compliance of a bank holding company or financial holding company with the 49 percent revenue limitation on nonfinancial data processing and the 5 percent of Tier I capital limitation on the proposed complementary activity, which are described in more detail above. The Board intends to monitor compliance with these limitations through existing financial reports filed by bank holding companies and financial holding companies. Because all paperwork collection procedures associated with this proposed rule already are in place, the Board anticipates that no additional burden will be imposed as a result of this proposal. The Board specifically requests comment on the likely burden that would result from implementation of this rule.

List of Subjects in 12 CFR Part 225

Administrative practice and procedures, Banks, banking, Federal Reserve System, Holding companies, Reporting and recordkeeping requirements, Securities.

Authority and Issuance

For the reasons set forth in the preamble, Title 12, Chapter II, of the Code of Federal Regulations is proposed to be amended as follows:

PART 225—BANK HOLDING COMPANIES AND CHANGE IN BANK CONTROL (REGULATION Y)

1. The authority citation for part 225 continues to read as follows:

Authority: 12 U.S.C. 1817(j)(13), 1818, 1828(o), 1831i, 1831p-1, 1843(c)(8), 1843(k), 1844(b), 1972(l), 3106, 3108, 3310, 3331-3351, 3907, and 3909.

2. Section 225.28(b)(14) is revised to read as follows:

§ 225.28 List of Permissible Nonbanking Activities.

* * * * *

(b) * * *

(14) *Data processing.* (i) Providing data processing and data transmission services, facilities (including data processing and data transmission hardware, software, documentation, or operating personnel), data bases, advice, and access to such services, facilities, or data bases by any technological means, if:

(A) The data to be processed or furnished are financial, banking, or economic; and

(B) The hardware provided in connection therewith is offered only in conjunction with software designed and marketed for the processing and transmission of financial, banking, or economic data, and where the general purpose hardware does not constitute more than 30 percent of the cost of any packaged offering.

(ii) A company conducting data processing and data transmission activities may conduct data processing and data transmission activities not described in paragraph (b)(14)(i) of this section if the total annual revenue derived from those activities does not exceed 49 percent of the company's total annual revenues derived from data processing and data transmission activities.

3. Section 225.89 is amended by adding a new paragraph (d) to read as follows:

§ 225.89 How to request approval to engage in an activity that is complementary to a financial activity?

* * * * *

(d) *What activities have been determined to be complementary to a financial activity?* The following activities are complementary to the described financial activity

(1) *Expanded data processing and related activities.* (i) When conducted in accordance with the limitation in paragraph (d)(1)(ii) of this section—

(A) *Data storage.* Acting as custodian of files that involve any type of data, including financial and nonfinancial data, so long as the custodian provides these services for financial data. This activity includes data imaging, data storage and data retrieval for data in any form, including in electronic, paper, microfiche or other form.

(B) *General data processing.* Providing general data processing and data transmission services, including data processing and data transmission hardware, software, documentation and operating personnel, data bases, advice and facilities, without limit as to the type of data processed or transmitted, so long as at least 20 percent of the total revenues of the company conducting these activities are derived from providing data processing services to depository institutions and their affiliates and/or processing financial, banking and economic data and/or the sale of other financial products and services.

(C) *Electronic information portal services.* Providing or facilitating information search, exchange, consolidation, screening, filtering or aggregation services over electronic networks. This activity includes acting

as an Internet Service Provider, providing on-line search engines that display sites meeting criteria selected by the user, bulletin boards, newsgroup services on general or specific topics, "chat" rooms, Internet web sites or portals that contain links to other web sites, and aggregation services that accumulate and display any type of data selected by the user on a customized web page. These activities must be provided in connection with the marketing and delivery of financial products and services.

(ii) The aggregate carrying value of all investments in companies engaged in activities described in paragraph (d)(1)(i) of this section may not exceed 5 percent of the Tier 1 capital of the financial holding company.

(2) [Reserved]

Dated: December 13, 2000.

By order of the Board of Governors of the Federal Reserve System, December 13, 2000.

Jennifer J. Johnson,

Secretary of the Board.

[FR Doc. 00-32505 Filed 12-20-00; 8:45 am]

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DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. 2000-NM-354-AD]

RIN 2120-AA64

Airworthiness Directives; Boeing Model 747-100, 747-200, 747-300, 747SP, and 747SR Series Airplanes Powered by Pratt & Whitney JT9D-3 and JT9D-7 Series Engines

AGENCY: Federal Aviation Administration, DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: This document proposes the superseding of an existing airworthiness directive (AD), applicable to certain Boeing Model 747-100, 747-200, 747-300, 747SP, and 747SR series airplanes powered by Pratt & Whitney JT9D-3 or JT9D-7 series engines. That AD currently requires inspections of the vertical chords of the aft torque bulkhead of the outboard nacelle struts, and corrective action, if necessary. That AD also gives an optional modification of the vertical chords, which ends the inspections. This action would require the previously optional modification. The actions specified by the proposed AD are intended to prevent cracking of the vertical chords adjacent to the lower

spar fitting, which could result in separation of the diagonal brace load path. Continued operation with a separated diagonal brace load path increases loads on the upper link, midspar fitting, and dual side links, which could result in separation of the strut and engine from the airplane. This action is intended to address the identified unsafe condition.

DATES: Comments must be received by February 5, 2001.

ADDRESSES: Submit comments in triplicate to the Federal Aviation Administration (FAA), Transport Airplane Directorate, ANM-114, Attention: Rules Docket No. 2000-NM-354-AD, 1601 Lind Avenue, SW., Renton, Washington 98055-4056.

Comments may be inspected at this location between 9:00 a.m. and 3:00 p.m., Monday through Friday, except Federal holidays. Comments may be submitted via fax to (425) 227-1232. Comments may also be sent via the Internet using the following address: 9-anm-nprmcomment@faa.gov. Comments sent via fax or the Internet must contain "Docket No. 2000-M-354-AD" in the subject line and need not be submitted in triplicate. Comments sent via the Internet as attached electronic files must be formatted in Microsoft Word 97 for Windows or ASCII text.

The service information referenced in the proposed rule may be obtained from Boeing Commercial Airplane Group, P.O. Box 3707, Seattle, Washington 98124-2207. This information may be examined at the FAA, Transport Airplane Directorate, 1601 Lind Avenue, SW., Renton, Washington.

FOR FURTHER INFORMATION CONTACT: Tamara Anderson, Aerospace Engineer, Airframe Branch, ANM-120S, FAA, Seattle Aircraft Certification Office, 1601 Lind Avenue, SW., Renton, Washington 98055-4056; telephone (425) 227-2771; fax (425) 227-1181.

SUPPLEMENTARY INFORMATION:

Comments Invited

Interested persons are invited to participate in the making of the proposed rule by submitting such written data, views, or arguments as they may desire. Communications shall identify the Rules Docket number and be submitted in triplicate to the address specified above. All communications received on or before the closing date for comments, specified above, will be considered before taking action on the proposed rule. The proposals contained in this action may be changed in light of the comments received.

Submit comments using the following format:

- Organize comments issue-by-issue. For example, discuss a request to change the compliance time and a request to change the service bulletin reference as two separate issues.

- For each issue, state what specific change to the proposed AD is being requested.

- Include justification (e.g., reasons or data) for each request.

Comments are specifically invited on the overall regulatory, economic, environmental, and energy aspects of the proposed 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 summarizing each FAA-public contact concerned with the substance of this proposal will be filed in the Rules Docket.

Commenters wishing the FAA to acknowledge receipt of their comments submitted in response to this action must submit a self-addressed, stamped postcard on which the following statement is made: "Comments to Docket Number 2000-NM-354-AD." The postcard will be date stamped and returned to the commenter.

Availability of NPRMs

Any person may obtain a copy of this NPRM by submitting a request to the FAA, Transport Airplane Directorate, ANM-114, Attention: Rules Docket No. 2000-NM-354-AD, 1601 Lind Avenue, SW., Renton, Washington 98055-4056.

Discussion

On November 14, 2000, the FAA issued AD 2000-23-25, amendment 39-11998 (65 FR 70781, November 28, 2000), applicable to certain Boeing Model 747-100, 747-200, 747-300, 747SP, and 747SR series airplanes powered by Pratt & Whitney JT9D-3 or JT9D-7 series engines; to require inspections of the vertical chords of the aft torque bulkhead of the outboard nacelle struts, and corrective action, if necessary. That AD also gives optional terminating action for the inspections. That action was prompted by reports of fatigue cracking of the vertical chords of the aft torque bulkhead of the outboard nacelle struts. The requirements of that AD are intended to detect and correct cracking of the vertical chords adjacent to the lower spar fitting, which could result in separation of the diagonal brace load path. Continued operation with a separated diagonal brace load path increases loads on the upper link, midspar fitting, and dual side links,

which could result in separation of the strut and engine from the airplane.

Actions Since Issuance of Previous Rule

In the preamble to AD 2000-23-25, the FAA indicated that the actions required by that AD were considered "interim action" and that further rulemaking action was being considered to require the modification of the vertical chords of the aft torque bulkhead of the outboard nacelle struts in Boeing Alert Service Bulletin 747-54A2201, dated September 28, 2000, which AD 2000-23-25 references as optional terminating action. The FAA has determined that further rulemaking is needed, and this proposed AD follows from that determination.

Explanation of Change Made to Requirements of Existing AD

The FAA has added a note to this proposed rule to clarify the definition of a detailed visual inspection, as specified in paragraph (a)(1) of this AD.

Explanation of Requirements of Proposed Rule

Since an unsafe condition has been identified that is likely to exist or develop on other products of this same type design, the proposed AD would supersede AD 2000-23-25 to continue to require inspections of the vertical chords of the aft torque bulkhead of the outboard nacelle struts, and corrective action, if necessary. The proposed AD would also require modification of the vertical chords, which would end the inspections. The actions would be required to be accomplished in accordance with Boeing Alert Service Bulletin 747-54A2201, which was described in AD 2000-23-25, except as discussed below.

Difference Between Service Bulletin and This Proposed AD

Operators should note that, although the service bulletin says to contact the manufacturer for certain repairs, this proposed AD would require those repairs to be accomplished by a method approved by the FAA, or according to data meeting the type certification basis of the airplane approved by a Boeing Company Designated Engineering Representative authorized by the FAA to make such findings.

Cost Impact

There are approximately 366 airplanes of the affected design in the worldwide fleet. The FAA estimates that 115 airplanes of U.S. registry would be affected by this proposed AD.

The detailed visual inspections that are currently required by AD 2000-23-

25 take approximately 18 work hours per airplane, at an average labor rate of \$60 per work hour. Based on these figures, the FAA estimates that the cost impact of these inspections on U.S. operators is \$124,200, or \$1,080 per airplane, per inspection cycle.

The ultrasonic and eddy current inspections that are currently required by AD 2000-23-25 take approximately 18 work hours per airplane, at an average labor rate of \$60 per work hour. Based on these figures, the FAA estimates that the cost impact of these inspections on U.S. operators is \$124,200, or \$1,080 per airplane, per inspection cycle.

The new modification that is proposed in this AD action would take approximately 48 work hours per airplane, at an average labor rate of \$60 per work hour. Required parts would cost approximately \$10,000 per airplane. Based on these figures, the FAA estimates that the cost impact of the proposed modification on U.S. operators is \$1,481,200, or \$12,880 per airplane.

The cost impact figures discussed above are based on assumptions that no operator has yet accomplished any of the proposed requirements of this AD action, and that no operator would accomplish those actions in the future if this proposed AD were not adopted. The cost impact figures discussed in AD rulemaking actions represent only the time necessary to perform the specific actions actually required by the AD. These figures typically do not include incidental costs, such as the time required to gain access and close up, planning time, or time necessitated by other administrative actions.

Regulatory Impact

The regulations proposed herein would not have a substantial direct effect on the States, on the relationship between the national Government and the States, or on the distribution of power and responsibilities among the various levels of government. Therefore, it is determined that this proposal would not have federalism implications under Executive Order 13132.

For the reasons discussed above, I certify that this proposed regulation (1) is not a "significant regulatory action" under Executive Order 12866; (2) is not a "significant rule" under the DOT Regulatory Policies and Procedures (44 FR 11034, February 26, 1979); and (3) if promulgated, 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 draft regulatory 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, Safety.

The Proposed Amendment

Accordingly, pursuant to the authority delegated to me by the Administrator, the Federal Aviation Administration proposes to amend 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. 106(g), 40113, 44701.

§ 39.13 [Amended]

2. Section 39.13 is amended by removing amendment 39–11998 (65 FR 70781, November 28, 2000), and by adding a new airworthiness directive (AD), to read as follows:

Boeing: Docket 2000–NM–354–AD.

Supersedes AD 2000–23–25,

Amendment 39–11998.

Applicability: Model 747–100, 747–200, 747–300, 747SP, and 747SR series airplanes powered by Pratt & Whitney JT9D–3 or JT9D–7 series engines; as listed in Boeing Alert Service Bulletin 747–54A2201, dated September 28, 2000; certificated in any category.

Note 1: This AD applies to each airplane identified in the preceding applicability provision, regardless of whether it has been modified, altered, or repaired in the area subject to the requirements of this AD. For airplanes that have been modified, altered, or repaired so that the performance of the requirements of this AD is affected, the owner/operator must request approval for an alternative method of compliance in accordance with paragraph (e) of this AD. The request should include an assessment of the effect of the modification, alteration, or repair on the unsafe condition addressed by this AD; and, if the unsafe condition has not been eliminated, the request should include specific proposed actions to address it.

Compliance: Required as indicated, unless accomplished previously.

To prevent cracking of the vertical chords adjacent to the lower spar fitting, which could result in separation of the diagonal brace load path and lead to separation of the strut and engine from the airplane, accomplish the following:

Restatement of Requirements of AD 2000–23–25:

Inspections

(a) Except as provided by paragraph (b) of this AD, prior to the accumulation of 14,000

total flight cycles, or within 90 days after December 13, 2000 (the effective date of AD 2000–23–25), whichever occurs later: Accomplish paragraphs (a)(1) and (a)(2) of this AD.

(1) Perform a detailed visual inspection to detect cracking of the vertical chords of the aft torque bulkhead of the outboard nacelle struts, in accordance with Part 2 of the Accomplishment Instructions of Boeing Alert Service Bulletin 747–54A2201, dated September 28, 2000. Thereafter, repeat this inspection at intervals not to exceed 600 flight cycles until paragraph (d) of this AD is accomplished.

(2) Perform surface eddy current and ultrasonic inspections to detect cracking of the vertical chords of the aft torque bulkhead of the outboard nacelle struts, in accordance with Part 3 of the Accomplishment Instructions of Boeing Alert Service Bulletin 747–54A2201, dated September 28, 2000. Thereafter, repeat these inspections at intervals not to exceed 1,200 flight cycles until paragraph (d) of this AD is accomplished.

Note 2: For the purposes of this AD, a detailed visual inspection is defined as: “An intensive visual examination of a specific structural area, system, installation, or assembly to detect damage, failure, or irregularity. Available lighting is normally supplemented with a direct source of good lighting at intensity deemed appropriate by the inspector. Inspection aids such as mirror, magnifying lenses, etc., may be used. Surface cleaning and elaborate access procedures may be required.”

Optional Compliance Time

(b) If Boeing Service Letter 747–54–055, dated April 24, 1998, was accomplished on the airplane during the modification of the nacelle strut in accordance with AD 95–10–16, amendment 39–9233: Accomplishment of the initial inspection in paragraph (a) of this AD may be deferred until 3,000 flight cycles after accomplishment of the service letter.

Repair

(c) If any cracking is detected during any inspection or modification required by this AD: Prior to further flight, repair in accordance with a method approved by the Manager, Seattle Aircraft Certification Office (ACO), FAA; or in accordance with data meeting the type certification basis of the airplane approved by a Boeing Company Designated Engineering Representative who has been authorized by the Manager, Seattle ACO, to make such findings. For a repair method to be approved by the Manager, Seattle ACO, as required by this paragraph, the approval letter must specifically reference this AD.

New Requirements of This AD

Modification (Terminating Action)

(d) Within 4 years after the effective date of this AD, do the modification of the vertical chords of the aft torque bulkhead of the outboard nacelle struts according to Part 4 of Boeing Alert Service Bulletin 747–54A2201, dated September 28, 2000. After this modification, stop the repetitive inspections required by paragraph (a) of this AD.

Alternative Methods of Compliance

(e) 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, Seattle ACO. Operators shall submit their requests through an appropriate FAA Principal Maintenance Inspector, who may add comments and then send it to the Manager, Seattle ACO.

Note 3: Information concerning the existence of approved alternative methods of compliance with this AD, if any, may be obtained from the Seattle ACO.

Special Flight Permits

(f) 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.

Issued in Renton, Washington, on December 15, 2000.

Dorenda D. Baker,

Acting Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 00–32576 Filed 12–20–00; 8:45 am]

BILLING CODE 4910–13–U

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. 2000–NM–296–AD]

RIN 2120–AA64

Airworthiness Directives; Boeing Model 767–200 and –300 Series Airplanes

AGENCY: Federal Aviation Administration, DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: This document proposes the adoption of a new airworthiness directive (AD) that is applicable to certain Boeing Model 767–200 and –300 series airplanes. This proposal would require replacement of the existing potable water fill line tube with a new hose. This action is necessary to prevent fracture of a clamshell coupling on the potable water fill line, which could cause water to flow into the aft cargo compartment. A large amount of water in the cargo compartment could cause large shifts in the airplane's center of gravity, which could result in reduced controllability of the airplane. This action is intended to address the identified unsafe condition.

DATES: Comments must be received by February 5, 2001.

ADDRESSES: Submit comments in triplicate to the Federal Aviation

Administration (FAA), Transport Airplane Directorate, ANM-114, Attention: Rules Docket No. 2000-NM-296-AD, 1601 Lind Avenue, SW., Renton, Washington 98055-4056. Comments may be inspected at this location between 9:00 a.m. and 3:00 p.m., Monday through Friday, except Federal holidays. Comments may be submitted via fax to (425) 227-1232. Comments may also be sent via the Internet using the following address: 9-anm-nprmcomment@faa.gov. Comments sent via fax or the Internet must contain "Docket No. 2000-NM-296-AD" in the subject line and need not be submitted in triplicate. Comments sent via the Internet as attached electronic files must be formatted in Microsoft Word 97 for Windows or ASCII text.

The service information referenced in the proposed rule may be obtained from Boeing Commercial Airplane Group, P.O. Box 3707, Seattle, Washington 98124-2207. This information may be examined at the FAA, Transport Airplane Directorate, 1601 Lind Avenue, SW., Renton, Washington.

FOR FURTHER INFORMATION CONTACT: Don Eiford, Aerospace Engineer, Systems and Equipment Branch, ANM-130S, FAA, Seattle Aircraft Certification Office, 1601 Lind Avenue, SW., Renton, Washington 98055-4056; telephone (425) 227-2788; fax (425) 227-1181.

SUPPLEMENTARY INFORMATION:

Comments Invited

Interested persons are invited to participate in the making of the proposed rule by submitting such written data, views, or arguments as they may desire. Communications shall identify the Rules Docket number and be submitted in triplicate to the address specified above. All communications received on or before the closing date for comments, specified above, will be considered before taking action on the proposed rule. The proposals contained in this action may be changed in light of the comments received.

Submit comments using the following format:

- Organize comments issue-by-issue. For example, discuss a request to change the compliance time and a request to change the service bulletin reference as two separate issues.
- For each issue, state what specific change to the proposed AD is being requested.
- Include justification (e.g., reasons or data) for each request.

Comments are specifically invited on the overall regulatory, economic, environmental, and energy aspects of the proposed 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 summarizing each FAA-public contact concerned with the substance of this proposal will be filed in the Rules Docket.

Commenters wishing the FAA to acknowledge receipt of their comments submitted in response to this action must submit a self-addressed, stamped postcard on which the following statement is made: "Comments to Docket Number 2000-NM-296-AD." The postcard will be date stamped and returned to the commenter.

Availability of NPRMs

Any person may obtain a copy of this NPRM by submitting a request to the FAA, Transport Airplane Directorate, ANM-114, Attention: Rules Docket No. 2000-NM-296-AD, 1601 Lind Avenue, SW., Renton, Washington 98055-4056.

Discussion

The FAA has received reports of fractures of clamshell couplings used on the potable water fill line on certain Boeing Model 767-200 and -300 series airplanes. A fractured coupling may allow water to flow into the bilge areas of the aft cargo compartment. If an airplane operates with a large amount of water in the cargo compartment, large shifts in the airplane's center of gravity could occur. This condition, if not corrected, could result in reduced controllability of the airplane.

Explanation of Relevant Service Information

The FAA has reviewed and approved Boeing Alert Service Bulletin 767-38A0057, dated July 13, 2000, which describes procedures for replacement of the existing potable water fill line tube with a new hose. The existing fill line is a metal tube, which, combined with the normal expansion and contraction of the fuselage, puts stress on the clamshell couplings on the fill line, causing them to fracture. The replacement potable water fill line tube is a flexible hose, which will reduce the stress on the clamshell couplings. Accomplishment of the actions specified in the service bulletin is intended to adequately address the identified unsafe condition.

Explanation of Requirements of Proposed Rule

Since an unsafe condition has been identified that is likely to exist or develop on other products of this same type design, the proposed AD would require accomplishment of the actions

specified in the service bulletin described previously, except as discussed below.

Difference Between Proposed Rule and Service Bulletin

The service bulletin recommends accomplishing the actions in the service bulletin "as soon as the airplane and manpower are available." The FAA finds that the proposed AD needs a definite compliance time to ensure that all airplanes are modified in a timely manner. Thus, this proposed AD would require the replacement to be done within 12 months after the effective date of this AD.

Cost Impact

There are approximately 159 airplanes of the affected design in the worldwide fleet. The FAA estimates that this proposed AD would affect 18 airplanes of U.S. registry. The proposed replacement would take approximately 1 work hour per airplane, at an average labor rate of \$60 per work hour. Required parts would cost approximately \$482 per airplane. Based on these figures, the cost impact of the proposed AD on U.S. operators is estimated to be \$9,756, or \$542 per airplane.

The cost impact figure discussed above is based on assumptions that no operator has yet accomplished any of the proposed requirements of this AD action, and that no operator would accomplish those actions in the future if this proposed AD were not adopted. The cost impact figures discussed in AD rulemaking actions represent only the time necessary to perform the specific actions actually required by the AD. These figures typically do not include incidental costs, such as the time required to gain access and close up, planning time, or time necessitated by other administrative actions.

Regulatory Impact

The regulations proposed herein would not have a substantial direct effect on the States, on the relationship between the national Government and the States, or on the distribution of power and responsibilities among the various levels of government. Therefore, it is determined that this proposal would not have federalism implications under Executive Order 13132.

For the reasons discussed above, I certify that this proposed regulation (1) is not a "significant regulatory action" under Executive Order 12866; (2) is not a "significant rule" under the DOT Regulatory Policies and Procedures (44 FR 11034, February 26, 1979); and (3) if

promulgated, 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 draft regulatory 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, Safety.

The Proposed Amendment

Accordingly, pursuant to the authority delegated to me by the Administrator, the Federal Aviation Administration proposes to amend 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. 106(g), 40113, 44701.

§ 39.13 [Amended]

2. Section 39.13 is amended by adding the following new airworthiness directive:

Boeing: Docket 2000–NM–296–AD.

Applicability: Model 767–200 and –300 series airplanes, as listed in Boeing Alert Service Bulletin 767–38A0057, dated July 13, 2000; certificated in any category.

Note 1: This AD applies to each airplane identified in the preceding applicability provision, regardless of whether it has been modified, altered, or repaired in the area subject to the requirements of this AD. For airplanes that have been modified, altered, or repaired so that the performance of the requirements of this AD is affected, the owner/operator must request approval for an alternative method of compliance in accordance with paragraph (c) of this AD. The request should include an assessment of the effect of the modification, alteration, or repair on the unsafe condition addressed by this AD; and, if the unsafe condition has not been eliminated, the request should include specific proposed actions to address it.

Compliance: Required as indicated, unless accomplished previously.

To prevent fracture of a clamshell coupling on the potable water fill line, which could cause a large amount of water to flow into the aft cargo compartment, and result in large shifts in the airplane's center of gravity and consequent reduced controllability of the airplane, accomplish the following:

Replacement

(a) Within 12 months after the effective date of this AD, replace the existing potable water fill line tube with a new flexible hose, in accordance with Boeing Alert Service Bulletin 767–38A0057, dated July 13, 2000.

Spares

(b) As of the effective date of this AD, no person shall install a potable water fill line tube, part number 417T2021–179, on any airplane.

Alternative Methods of Compliance

(c) 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, Seattle Aircraft Certification Office (ACO), FAA. Operators shall submit their requests through an appropriate FAA Principal Maintenance Inspector, who may add comments and then send it to the Manager, Seattle ACO.

Note 2: Information concerning the existence of approved alternative methods of compliance with this AD, if any, may be obtained from the Seattle ACO.

Special Flight Permits

(d) 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.

Issued in Renton, Washington, on December 15, 2000.

Dorenda D. Baker,

Acting Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 00–32575 Filed 12–20–00; 8:45 am]

BILLING CODE 4910–13–U

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. 2000–NM–222–AD]

RIN 2120–AA64

Airworthiness Directives; Saab Model SAAB SF340A and SAAB 340B Series Airplanes

AGENCY: Federal Aviation Administration, DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: This document proposes the adoption of a new airworthiness directive (AD) that is applicable to certain Saab Model SAAB SF340A and SAAB 340B series airplanes. This proposal would require installation of a new circuit breaker and related wiring, and relocation of circuit breaker 12FG, if applicable. This action is necessary to prevent loss of the nose wheel steering and reduced controllability of the airplane on the ground. This action is intended to address the identified unsafe condition.

DATES: Comments must be received by January 22, 2001.

ADDRESSES: Submit comments in triplicate to the Federal Aviation Administration (FAA), Transport Airplane Directorate, ANM–114, Attention: Rules Docket No. 2000–NM–222–AD, 1601 Lind Avenue, SW., Renton, Washington 98055–4056. Comments may be inspected at this location between 9:00 a.m. and 3:00 p.m., Monday through Friday, except Federal holidays. Comments may be submitted via fax to (425) 227–1232. Comments may also be sent via the Internet using the following address: 9-anm-nprmcomment@faa.gov. Comments sent via fax or the Internet must contain “Docket No. 2000–NM–222–AD” in the subject line and need not be submitted in triplicate. Comments sent via the Internet as attached electronic files must be formatted in Microsoft Word 97 for Windows or ASCII text.

The service information referenced in the proposed rule may be obtained from Saab Aircraft AB, SAAB Aircraft.. Product Support, S–581.88, Linköping, Sweden. This information may be examined at the FAA, Transport Airplane Directorate, 1601 Lind Avenue, SW., Renton, Washington.

FOR FURTHER INFORMATION CONTACT: Roseanne Ryburn, Aerospace Engineer, International Branch, ANM–116, FAA, Transport Airplane Directorate, 1601 Lind Avenue, SW., Renton, Washington 98055–4056; telephone (425) 227–2139; fax (425) 227–1149.

SUPPLEMENTARY INFORMATION:

Comments Invited

Interested persons are invited to participate in the making of the proposed rule by submitting such written data, views, or arguments as they may desire. Communications shall identify the Rules Docket number and be submitted in triplicate to the address specified above. All communications received on or before the closing date for comments, specified above, will be considered before taking action on the proposed rule. The proposals contained in this action may be changed in light of the comments received.

Submit comments using the following format:

- Organize comments issue-by-issue. For example, discuss a request to change the compliance time and a request to change the service bulletin reference as two separate issues.
- For each issue, state what specific change to the proposed AD is being requested.
- Include justification (e.g., reasons or data) for each request.

Comments are specifically invited on the overall regulatory, economic,

environmental, and energy aspects of the proposed 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 summarizing each FAA-public contact concerned with the substance of this proposal will be filed in the Rules Docket.

Commenters wishing the FAA to acknowledge receipt of their comments submitted in response to this action must submit a self-addressed, stamped postcard on which the following statement is made: "Comments to Docket Number 2000-NM-222-AD." The postcard will be date stamped and returned to the commenter.

Availability of NPRMs

Any person may obtain a copy of this NPRM by submitting a request to the FAA, Transport Airplane Directorate, ANM-114, Attention: Rules Docket No. 2000-NM-222-AD, 1601 Lind Avenue, SW., Renton, Washington 98055-4056.

Discussion

The Luftfartsverket (LFV), which is the airworthiness authority for Sweden, notified the FAA that an unsafe condition may exist on certain Saab Model SAAB SF340A and SAAB 340B series airplanes. The LFV advises that it has received reports in which an emergency extension of the landing gear was necessary due to a popped or non-resettable circuit breaker, which resulted in loss of the nose wheel steering and reduced controllability of the airplane on the ground. This circuit is also common for the locked-down signals of the weight-on-wheel and landing gear to other systems (i.e., nose wheel steering and flight idle stop). The circuit breaker failure has been attributed to the lack of another circuit breaker that would supply 28 volts direct current (VDC) to the relays. This condition, if not corrected, could result in loss of the nose wheel steering and reduced controllability of the airplane on the ground.

Explanation of Relevant Service Information

Saab has issued Service Bulletin 340-32-120, Revision 01, dated August 29, 2000, which describes procedures for installation of a new circuit breaker and related wiring. Accomplishment of the actions specified in the service bulletin is intended to adequately address the identified unsafe condition. The LFV classified this service bulletin as mandatory and issued Dutch airworthiness directive (SAD) 1-155, dated February 28, 2000, in order to

assure the continued airworthiness of these airplanes in Sweden.

FAA's Conclusions

These airplane models are manufactured in Sweden and are type certificated for operation in the United States under the provisions of § 21.29 of the Federal Aviation Regulations (14 CFR 21.29) and the applicable bilateral airworthiness agreement. Pursuant to this bilateral airworthiness agreement, the LFV has kept the FAA informed of the situation described above. The FAA has examined the findings of the LFV, reviewed all available information, and determined that AD action is necessary for products of this type design that are certificated for operation in the United States.

Explanation of Requirements of Proposed Rule

Since an unsafe condition has been identified that is likely to exist or develop on other airplanes of the same type design registered in the United States, the proposed AD would require accomplishment of the actions specified in the service bulletin described previously.

Cost Impact

The FAA estimates that 312 Saab Model SAAB SF340A and SAAB 340B series airplanes of U.S. registry would be affected by this proposed AD.

It would take approximately 7 work hours per airplane to accomplish the proposed installation, at an average labor rate of \$60 per work hour. Required parts would cost approximately \$177 per airplane. Based on these figures, the cost impact of the proposed AD on U.S. operators is estimated to be \$186,264, or \$597 per airplane.

The cost impact figure discussed above is based on assumptions that no operator has yet accomplished any of the proposed requirements of this AD action, and that no operator would accomplish those actions in the future if this AD were not adopted. The cost impact figures discussed in AD rulemaking actions represent only the time necessary to perform the specific actions actually required by the AD. These figures typically do not include incidental costs, such as the time required to gain access and close up, planning time, or time necessitated by other administrative actions.

Regulatory Impact

The regulations proposed herein would not have a substantial direct effect on the States, on the relationship between the national Government and

the States, or on the distribution of power and responsibilities among the various levels of government. Therefore, it is determined that this proposal would not have federalism implications under Executive Order 13132.

For the reasons discussed above, I certify that this proposed regulation (1) is not a "significant regulatory action" under Executive Order 12866; (2) is not a "significant rule" under the DOT Regulatory Policies and Procedures (44 FR 11034, February 26, 1979); and (3) if promulgated, 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 draft regulatory 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, Safety.

The Proposed Amendment

Accordingly, pursuant to the authority delegated to me by the Administrator, the Federal Aviation Administration proposes to amend 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. 106(g), 40113, 44701.

§ 39.13 [Amended]

2. Section 39.13 is amended by adding the following new airworthiness directive:

Saab Aircraft AB: Docket 2000-NM-222-AD.

Applicability: The following airplanes, certificated in any category:

Model	Serial numbers
SAAB SF340A ...	-004 through -159 inclusive
SAAB 340B	-160 through -459 inclusive, except -342, -379, -395, -409, -431, and -455

Note 1: This AD applies to each airplane identified in the preceding applicability provision, regardless of whether it has been modified, altered, or repaired in the area subject to the requirements of this AD. For airplanes that have been modified, altered, or repaired so that the performance of the requirements of this AD is affected, the owner/operator must request approval for an

alternative method of compliance in accordance with paragraph (b) of this AD. The request should include an assessment of the effect of the modification, alteration, or repair on the unsafe condition addressed by this AD; and, if the unsafe condition has not been eliminated, the request should include specific proposed actions to address it.

Compliance: Required as indicated, unless accomplished previously.

To prevent loss of the nose wheel steering and reduced controllability of the airplane on the ground, accomplish the following:

Installation of Circuit Breaker and Related Wiring and Relocation of the Circuit Breaker, if Applicable

(a) Within 6 months after the effective date of this AD, install a new circuit breaker and related wiring, per Saab Service Bulletin 340-32-120, Revision 01, dated August 29, 2000.

Alternative Methods of Compliance

(b) 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, International Branch, ANM-116, FAA. Operators shall submit their requests through an appropriate FAA Principal Maintenance Inspector, who may add comments and then send it to the Manager, International Branch, ANM-116.

Note 2: Information concerning the existence of approved alternative methods of compliance with this AD, if any, may be obtained from the International Branch, ANM-116.

Special Flight Permits

(c) 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.

Note 3: The subject of this AD is addressed in Dutch airworthiness directive (SAD) 1-155, dated February 28, 2000.

Issued in Renton, Washington, on December 15, 2000.

Dorenda D. Baker,

Acting Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 00-32574 Filed 12-20-00; 8:45 am]

BILLING CODE 4910-13-U

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 2

[FRL-6921-2]

Public Information and Confidentiality: Advance Notice of Proposed Rulemaking; Withdrawal of 1994 Proposed Rule

AGENCY: Environmental Protection Agency (EPA).

ACTION: Advance notice of proposed rulemaking (ANPRM); withdrawal of 1994 proposed rule.

SUMMARY: EPA is providing advance notice of proposed rulemaking regarding revisions of its regulations dealing with the handling of confidential business information (CBI). We refer to these as "the CBI regulations." As part of this process, we are planning to revise the current CBI regulations so they will be in plain language and will reflect current case law and recent technological developments. In revising the CBI regulations, we also intend to improve our processing of requests for CBI while ensuring appropriate protection of confidential business information. We are seeking comments as to the extent of additional revisions. EPA is also withdrawing its November 23, 1994 Proposed Rulemaking (59 FR 60445).

DATES: Comments on this advance notice of proposed rulemaking must be submitted by March 21, 2001. EPA will be holding a public meeting on the potential revision of the CBI regulations on January 18, 2001 from 9:00 a.m. to 4:30 p.m. in the EPA Auditorium, 401 M Street, SW Washington, DC. Please direct all correspondence to the addresses shown below.

ADDRESSES: Written comments should be submitted (in duplicate if possible) to Docket Number EC-2000-004, Enforcement and Compliance Docket and Information Center (ECDIC), U.S. Environmental Protection Agency, 1200 Pennsylvania Ave., NW, Room 4033, Mail Code 2201A, Washington, DC 20460; Phone, 202-564-2614 or 202-564-2119; Fax, 202-501-1011 EMail, doCKET.oeca@epa.gov. Written, but not oral, comments for the official record will also be accepted at the public meeting. Documents related to this advance notice of proposed rulemaking are available for public inspection and viewing by contacting the ECDIC at this same address. The ECDIC is open from 8:00 a.m. to 4:00 p.m., Monday through Friday, excluding Federal holidays.

Comments in an electronic format also should reference docket number EC-2000-004. All electronic comments must be submitted as an ASCII file and should avoid the use of special characters and any form of encryption. Commenters should not submit any CBI electronically. To the extent a comment contains CBI, commenters must submit an original and one copy of CBI under separate cover to: Alan Margolis, Office of Information Collection, Office of Environmental Information, U.S.

Environmental Protection Agency, 1200 Pennsylvania Ave., NW, Mail Code 2822, Washington, DC 20460.

FOR FURTHER INFORMATION CONTACT: Alan Margolis, Office of Information Collection, Office of Environmental Information, U.S. Environmental Protection Agency, 1200 Pennsylvania Ave., NW, Mail Code 2822, Washington, DC 20460; Phone, 202-260-9329; Fax, 202-401-4544; Email, margolis.alan@epa.gov.

SUPPLEMENTARY INFORMATION:

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I. Purpose and Background of ANPRM

In this ANPRM, we provide advance notice of proposed rulemaking regarding revisions of our CBI regulations. Our intent is to ensure that the regulations are in plain language, and that they adequately protect CBI in light of current caselaw and recent technological developments. Additionally, EPA is reviewing its current regulations to determine whether there are ways the Agency could reduce the burden on the regulated community while also ensuring the adequate protection of CBI and streamlining the Agency's processes for handling CBI. The ANPRM sets forth existing problems with current policies and suggests possible options for improving the efficiency of the Agency's CBI operations.

Under the Freedom of Information Act (FOIA), any person has a right to obtain federal agency records, except to the extent that such records (or portions thereof) are protected from disclosure by one of nine exemptions or three exclusions. Exemption 4 of FOIA, 5 U.S.C. 552(b)(4), protects "trade secrets and commercial or financial information obtained from a person and privileged or confidential." In 1976, EPA first promulgated its comprehensive CBI regulations, which are codified as 40 CFR part 2, subpart B. EPA's CBI regulations are part of its public information regulations and implement Exemption 4 of FOIA. In addition to

implementing FOIA Exemption 4, the CBI regulations also generally address issues outside of the FOIA context that involve the handling, processing, and disclosure of CBI under specific EPA-administered statutes. The CBI regulations set out procedures for EPA to make confidentiality determinations for information claimed as confidential.

II. Withdrawal of 1994 Proposal

On November 23, 1994, EPA published a proposed rule on Public Information and Confidentiality ("the 1994 proposal"), which proposed amendments to the CBI regulations (59 FR 60445). The intent of the proposed rule was to eliminate unnecessary procedures and to streamline and expedite activities involving CBI. Major changes raised in 1994 included up-front assertion of CBI claims, up-front substantiation, sunset provisions, different options for changing the manner of processing FOIA requests, and clarification regarding the release of aggregated data. Over 60 comments were received from the public. The rule was not finalized due to the complexity of the issues raised in the public comments. EPA is withdrawing this proposed rule on December 21, 2000. EPA will initiate a new and separate rulemaking based on the issues raised in the comments to this ANPRM and at the public meeting.

III. Major CBI Topics

EPA intends to revise its CBI regulations to make them less burdensome on EPA and the submitters of CBI, while preserving the public's right to obtain publicly available information and ensuring the adequate protection of CBI. For each idea presented below, we discuss some existing problems with current policies and suggest possible options for improving the policies. EPA welcomes comments on any of the topics discussed below. We are not proposing any specific action regarding the CBI regulations at this time but are providing background information and requesting additional information that we should consider.

A. Submissions of Confidential Business Information

EPA receives a large number of submissions of various types of information claimed as CBI. Many of the claims received are very broad, and the Agency has limited resources to deal with this stream of information. As a result, large amounts of information claimed as CBI are retained by the Agency longer than necessary, and broad or non-specific CBI claims may

limit public access to information that is not actually CBI. We are considering the following options to facilitate EPA's examination and, if appropriate, protection of this material, as well as the Agency's responses to those who request the information under FOIA.

1. Up-front Substantiation of CBI Claims

An option that a number of other agencies have used to reduce the number of overly-broad or non-specific CBI claims is the use of up-front substantiation. Up-front substantiation would require the submission of statements setting forth the basis of business confidentiality at the time the information is first submitted and claimed confidential. Our current CBI regulations require that when EPA is determining whether information claimed as confidential is entitled to confidential treatment, it must notify affected businesses that they may submit comments substantiating their claims of confidentiality (see section 2.204(e)). The CBI regulations generally do not require a business to submit a substantiation until disclosure becomes an issue.

Although EPA realizes that seeking complete up-front substantiations may increase the burden on submitters of information, we are exploring options to permit the reduction of overly-broad or non-specific CBI claims, while requiring less handling and storage of the information claimed as confidential. One possible option would be to require that certain elements of a CBI substantiation be provided when the information is submitted and claimed as confidential. A more comprehensive substantiation would be required only if disclosure becomes an issue. We believe this would help reduce the number of overly-broad or non-specific claims, while providing only an incremental burden on submitters. Additionally, EPA is interested in comments concerning whether it should require up-front substantiation when only portions of documents are claimed as CBI. The Agency is interested in other suggestions for facilitating the initial CBI determination process.

2. Submission of Redacted Copies

An additional method of streamlining the CBI process would be to require that a copy of the document from which information claimed to be confidential has been deleted (hereinafter "redacted copy") be submitted along with a copy of the material claimed as confidential. The submission of redacted copies would enable the Agency to respond in a timely fashion to FOIA requests for CBI by releasing the redacted copy of

the information to the FOIA requester. Certain submitters to the Agency already submit redacted copies of information as a matter of practice. EPA is soliciting comments concerning the effect of requiring businesses to submit redacted copies whenever they submit information claimed as confidential.

B. EPA Treatment of Information Claimed as CBI

EPA often finds it necessary to make final confidentiality determinations as a result of FOIA requests or rulemaking. Final determinations are written by the EPA legal office in consultation with the appropriate EPA program staff. EPA is interested in improving the efficiency of this process. In addition, the Agency has relied on class determinations and the aggregation of data in order to maximize Agency resources, ensure the timely release of information to the public, and appropriately protect information that is claimed to be confidential. We are seeking comments and suggestions on the use of class determinations and data aggregation.

The Agency is also considering adding language to the CBI regulations concerning the disposition of records containing CBI in accordance with the appropriate records management schedules. We are seeking comments on the possible addition of this language to the CBI regulations.

1. Class Determinations

Title 40 CFR section 2.207 permits EPA to use class determinations to make known its position regarding the manner in which information within a class will be treated by EPA under the CBI regulations. EPA relies on class determinations to permit efficient processing of numerous FOIA requests for the same types of CBI. Certain affected businesses have expressed concern over the Agency's reliance on class determinations, arguing that decisions about whether specific information is entitled to be treated as CBI are best made on a case-by-case basis. We are soliciting comments on the benefits or the harm resulting from EPA's use of class determinations.

2. Aggregation of Data

EPA uses several mechanisms to ensure that public records in rulemaking adequately allow for meaningful public comment and effective judicial review, while at the same time complying with the Agency's CBI obligations. These mechanisms include using summaries or aggregations of data as well as identity-masking strategies, to develop a public rulemaking record from information

claimed as CBI while avoiding the disclosure of such information.

EPA does not have general guidelines for aggregating CBI data, and we are seeking comments on whether such guidelines are needed. We are also interested in suggestions concerning the form such guidelines could take, given the diversity of data submitted to the Agency.

3. Mosaic Effect

Since the 1976 regulations were promulgated, the information landscape has changed. The rapid growth of the Internet and other electronic means of disseminating information, the increasing use of competitive intelligence measures by private industry, and the perceived potential for environmental terrorist attacks have heightened concerns about the public release of information. The main challenge to the Agency is to achieve an appropriate balance between disclosing information to the public and withholding information that could cause competitive harm.

In response to the growth of the Internet, the regulated community has made the argument that multiple pieces of data which may not qualify individually to be treated as CBI and are made publicly available can be pieced together to reveal a trade secret. EPA held discussions with stakeholders about the potential for such a "mosaic effect" as part of the EPA/State Stakeholder Forum on Public Information Policies, in Chicago on November 15–16, 1999 (for summary see EPA's web site at www.epa.gov/oei/issuepapers). No consensus was reached on whether the "mosaic effect" exists, how extensive or serious it is, or how EPA could address it. This lack of consensus was also reflected in the General Accounting Office's report "Environmental Information, EPA Could Better Address Concerns About Disseminating Sensitive Business Information" (GAO/RCED–99–156, General Accounting Office, June 1999), citing the range of views expressed by industry representatives and competitive intelligence professionals.

In several lawsuits, courts have recognized the mosaic approach in sustaining a finding that the disclosure of information that was not in and of itself harmful, would be harmful when combined with information already available to the requestor. These courts, however, made their decisions on a case-by-case basis by examining the facts that would lead to such an

outcome.¹ EPA is not aware of any general government policy or regulation that attempts to regulate the dissemination or disclosure of information based on the concept of a mosaic effect. Our current policy is to continue treating such claims on an individual case-by-case basis, as required by FOIA. In doing so, we would also consider any concerns raised by the submitter of the information regarding its potential to be combined with other information in a way that could result in competitive harm.

We are soliciting comments on this issue, particularly specific examples of the harm resulting from the mosaic effect and ideas to prevent harm while also preserving the public's right to obtain government-held information that is not exempt from disclosure under FOIA.

In addition to the issues listed above, we are dealing with other issues concerning CBI. These issues are driven by legal concerns. We describe them below.

4. Disposition of CBI

EPA's current CBI regulations do not address the disposition of CBI records. Retention of all records (including CBI records) is governed by records schedules approved by the Archivist of the United States. National Archives and Records Administration (NARA) regulations at 36 CFR Part 1256 allow for the transfer of CBI records to the Federal Records Centers and the National Archives. The Agency is considering adding language to the CBI regulations referencing the appropriate retirement of records containing CBI in accordance with NARA-approved records schedules. The purpose of this addition is to encourage compliance with the NARA regulations and EPA records schedules by the various EPA offices responsible for handling CBI. EPA is soliciting comments on the addition of this language to the CBI regulations.

5. Definition of "voluntarily submitted information"

Since the promulgation of the CBI regulations, the definition of "voluntarily submitted information" used in our CBI regulations has been called into question by the decision in *Critical Mass Energy Project v. NRC*, 975

F.2d 871 (D.C. Cir. 1992). *Critical Mass* held that "voluntarily" submitted information should be categorically protected as confidential, provided it is not "customarily" disclosed to the public by the submitter. Cases subsequent to *Critical Mass* have clarified the meaning of "voluntary" pursuant to the holding in *Critical Mass*.

The Department of Justice, in accordance with recent case law, has concluded that a submitter's voluntary participation in an activity does not govern whether any submissions made in connection with that activity are likewise "voluntary." Submissions that are required to realize the benefits of a voluntary program are considered to be mandatory.² EPA's current regulations defining voluntary are located at 2.201(i)(2) and 2.208 and predate the *Critical Mass* decision. EPA is considering revision of the regulatory language to reflect the decision in *Critical Mass* and the subsequent case law defining "voluntarily submitted."

6. Legal Challenge to 40 CFR 2.205(c)

Under section 2.205(c) of our CBI regulations, EPA will automatically treat as CBI a substantiation marked as confidential by the submitter in accordance with section 2.203(b) if the information in the substantiation is not otherwise possessed by EPA. When EPA receives a FOIA request for such a substantiation, we do not request that the affected business submit comments substantiating why the information in its previous CBI substantiation should be treated as confidential, and we automatically deny the FOIA request for the substantiation on the basis of section 2.205(c). The result is that information submitted to EPA in a CBI substantiation and claimed as CBI is treated differently than all other business information submitted to EPA and claimed as CBI. This special treatment has been challenged in United States District Court (*Northwest Coalition for Alternatives to Pesticides (NCAP) v. EPA*, D.D.C., Civil Action No. 99–437) on the grounds that it violates FOIA.

EPA has currently repropose a rule to eliminate the automatic protection of CBI substantiations (65 FR 52684, Aug. 30, 2000). This rule was originally published in the **Federal Register** in October 1999, in response to a lawsuit from NCAP. EPA is repropose the rule to explain in more detail why the proposed change in its CBI regulations

¹ See, e.g., *Trans-Pacific Policing Agreement v. United States Customs Service*, 1998 U.S. Dist. LEXIS 7800 (D.D.C. 1998), reversed and remanded, 177 F.3d 1022 (D.C. Cir. 1999); *Timken Co. v. United States Customs Service*, 491 F. Supp. 557 (D.D.C. 1980); *Department of Justice Freedom of Information Act Guide & Privacy Act Overview*, p. 201 (May 2000 Edition).

² See *Public Citizen Health Research Group v. FDA*, 964 F. Supp. 413, 414 (D.D.C. 1997); *Lykes Bros. Steamship Company v. Pena*, 1993 WL 786064 (D.D.C. 1993); *Department of Justice Freedom of Information Act Guide & Privacy Act Overview*, pp. 173–174 (May 2000 Edition).

is needed. EPA has proposed that the rule be applied prospectively, but we are soliciting further comments on this issue.

List of Subjects in 40 CFR Part 2

Environmental protection, Administrative practice and procedure, Confidential business information, Freedom of information, Government employees.

Dated: December 15, 2000.

Carol M. Browner,
Administrator.

[FR Doc. 00-32565 Filed 12-20-00; 8:45 am]

BILLING CODE 6560-50-U

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[WY-001-0006b; FRL-6886-9]

Clean Air Act Approval and Promulgation of State Implementation Plan; Wyoming; Revisions to Air Pollution Regulations

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: The EPA is proposing to partially approve and partially disapprove revisions to the State Implementation Plan (SIP) submitted by the Governor of Wyoming on May 21, 1999. The submittal incorporates revisions to the following sections of the Wyoming Air Quality Standards and Regulations (WAQSR): Section 2 Definitions, Section 4 Sulfur oxides, Section 5 Sulfuric acid mist, Section 8 Ozone, Section 9 Volatile organic compounds, Section 10 Nitrogen oxides, Section 14 Control of particulate emissions, and Section 21 Permit requirements for construction, modification and operation. EPA is proposing to partially disapprove the provisions that allow the Administrator of the Wyoming Air Quality Division to approve alternative test methods to those required in the SIP (sections 2, 4, 5, 10, and 14 of the WAQSR) because such provisions are inconsistent with section 110(i) of the Clean Air Act (Act) and the requirement that SIP provisions can only be modified through revision to the SIP and approval by EPA. The intended effect of this action, once final, is to make federally enforceable those provisions that EPA is approving. EPA is proposing this action under section 110 of the Act.

In the "Rules and Regulations" section of this **Federal Register**, EPA is acting on the State's SIP revision as a

direct final rule without prior proposal because the Agency views this as a noncontroversial SIP revision and anticipates no adverse comments. A detailed rationale for the approval is set forth in the preamble to the direct final rule. If EPA receives no adverse comments, EPA will not take further action on this proposed rule. If EPA receives adverse comments, EPA will withdraw the direct final rule and it will not take effect. EPA will address all public comments in a subsequent final rule based on this proposed rule. EPA will not institute a second comment period on this action. Any parties interested in commenting must do so at this time. Please note that if EPA receives adverse comment on an amendment, paragraph, or section of this rule and if that provision may be severed from the remainder of the rule, EPA may adopt as final those provisions of the rule that are not the subject of an adverse comment.

DATES: Comments must be received in writing on or before January 22, 2001.

ADDRESSES: Written comments may be mailed to Richard R. Long, Director, Air and Radiation Program, Mailcode 8P-AR, Environmental Protection Agency, Region VIII, 999 18th Street, Suite 300, Denver, Colorado, 80202. Copies of the documents relevant to this action are available for public inspection during normal business hours at the Air and Radiation Program, Environmental Protection Agency, Region VIII, 999 18th Street, Suite 300, Denver, Colorado, 80202-2466. Copies of the State documents relevant to this action are available for public inspection at the Air Quality Division, Department of Environmental Quality, 122 West 25th Street, Cheyenne, Wyoming, 82002.

FOR FURTHER INFORMATION CONTACT: Kerri Fiedler, EPA Region VIII, (303) 312-6493.

SUPPLEMENTARY INFORMATION: See the information provided in the Direct Final action of the same title which is located in the Rules and Regulations section of this **Federal Register**.

Authority: 42 U.S.C. 7401 *et seq.*

Dated: October 6, 2000.

Jack W. McGraw,

Acting Regional Administrator, Region VIII.

[FR Doc. 00-32240 Filed 12-20-00; 8:45 am]

BILLING CODE 6560-50-P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 81

[Docket Id-00-01; FRL-6920-8]

Finding of Attainment for PM-10; Portneuf Valley PM-10 Nonattainment Area, Idaho

AGENCY: Environmental Protection Agency (EPA or we).

ACTION: Proposed rule; extension of comment period.

SUMMARY: EPA is extending the public comment period on EPA's notice of proposed rulemaking "Finding of Attainment for PM-10; Portneuf Valley PM-10 Nonattainment Area, Idaho," published on December 6, 2000 at 65 FR 76203. The comment period was originally scheduled to close on December 26, 2000. The comment period is being extended until January 19, 2001.

DATES: All comments regarding EPA's proposed rulemaking published on December 6, 2000 must be received by EPA in writing on or before close of business on January 19, 2001.

ADDRESSES: Written comments should be mailed to Debra Suzuki, SIP Manager, Office of Air Quality, Mailcode OAQ-107, EPA Region 10, 1200 Sixth Avenue, Seattle, Washington, 98101. Copies of documents relevant to this action are available for public review during normal business hours (8:00 AM to 4:30 PM) at this same address.

FOR FURTHER INFORMATION CONTACT: Steven K. Body, Office of Air Quality, EPA Region 10, 1200 Sixth Avenue, Seattle Washington, 98101, (206) 553-0782.

SUPPLEMENTARY INFORMATION: On December 6, 2000, we solicited public comment on a proposal to find that the Portneuf Valley nonattainment area in Idaho has attained the National Ambient Air Quality Standard (NAAQS) for particulate matter with an aerodynamic diameter of less than, or equal to a nominal ten micrometers (PM-10) as of December 31, 1996. See 65 FR 76203. In the proposal, we stated that EPA would accept public comments on the proposal until December 26, 2000.

EPA has received a request to extend the public comment period. In light of this request, we are extending the public comment period to January 19, 2001, resulting in a public comment period of 44 days. All written comments received by EPA by January 19, 2001, will be considered in our final action.

List of Subjects in 40 CFR Part 81

Environmental protection, Air pollution control, Intergovernmental relations, Particulate matter.

Dated: December 15, 2000.

Ronald A. Kreizenbeck,

Acting Regional Administrator, Region 10.

[FR Doc. 00-32563 Filed 12-20-00; 8:45 am]

BILLING CODE 6560-50-U

ENVIRONMENTAL PROTECTION AGENCY**40 CFR Part 97**

[FRL-6919-7]

Findings of Significant Contribution and Rulemaking on Section 126 Petitions for Purposes of Reducing Interstate Ozone Transport—Federal NO_x Budget Trading Program, Rule Revision

AGENCY: Environmental Protection Agency.

ACTION: Proposed rule.

SUMMARY: The Environmental Protection Agency (EPA) is proposing to amend the Federal NO_x Budget Trading Program regulations to revise the allowance allocations for certain NO_x Budget units subject to the program. In January 2000, EPA took final action (the January 2000 final rule) under section 126 of the Clean Air Act (CAA) on petitions filed by eight Northeastern States seeking to mitigate interstate transport of nitrogen oxides (NO_x), one of the precursors of ground-level ozone. EPA determined that a number of large electric generating units (EGUs) and large industrial boilers and turbines (non-EGUs) named in the petitions emit in violation of the CAA prohibitions against significantly contributing to nonattainment or maintenance problems in the petitioning States. EPA also established the Federal NO_x Budget Trading Program as the control remedy for these sources, determined allowable emissions for the sources, and allocated authorizations to emit NO_x (*i.e.*, NO_x allowances) to the sources.

After promulgation of EPA's January 2000 final rule, some owners, or associations of owners, of EGUs or non-EGUs filed petitions with the U.S. Court of Appeals for the District of Columbia Circuit (D.C. Circuit) challenging, among other things, the allowance allocations for certain units under the rule. Subsequently, EPA entered into settlements with these owners or associations of owners. Today's action proposes to revise the allocations in the January 2000 final rule for these units in

a manner consistent with the settlements.

In addition, after promulgation of the January 2000 final rule, owners of non-EGUs requested EPA to correct allowance allocations for two other units under the rule. EPA responded that it was treating the requests as requests for reconsideration of the two units' allocations under the rule and would propose to revise the allocations. Today's action includes such a proposal for these units.

DATES: If you want to submit any written comments on this proposed rule, EPA must receive the written comments by January 30, 2001.

Public Hearing: A public hearing will be held at 9:30 a.m. on January 2, 2001.

ADDRESSES: *Comments:* If you submit any written comments on this proposed rule, the comments must reference Docket No. A-97-43 and must be submitted in duplicate to Air and Radiation Docket and Information Center (6102), Attention: Docket No. A-97-43, U.S. Environmental Protection Agency, 401 M Street, SW, Room M-1500, Washington, DC 20460.

Docket: Docket No. A-97-43, containing supporting information used in developing the proposed rule, is available for public inspection and copying between 8 a.m. and 4 p.m., Monday through Friday, at EPA's Air and Radiation Docket and Information Center at the above address. EPA may charge a reasonable fee for copying.

Public Hearing: The public hearing will be held at the EPA Auditorium, 401 M Street, SW., Washington, DC.

FOR FURTHER INFORMATION CONTACT: Dwight C. Alpern, at (202) 564-9151, U.S. Environmental Protection Agency, 1200 Pennsylvania Ave., NW., (6204J), Washington, DC 20460; or the Acid Rain Hotline at (202) 564-9089.

SUPPLEMENTARY INFORMATION:**Availability of Related Information**

The official record for this rulemaking, as well as the public version, has been established under Docket No. A-97-43 (including comments and data submitted electronically as described below). A public version of this record, including printed, paper versions of electronic comments, that does not include any information claimed as confidential business information, is available for inspection from 8 a.m. to 4 p.m. Monday through Friday, excluding legal holidays. The official rulemaking record is located at the address in the **ADDRESSES** section. In addition, the **Federal Register** rulemaking actions under section 126 and the associated

documents are located at <http://www.epa.gov/ttn/rto/126>.

The EPA has issued a separate rule on NO_x transport entitled, "Finding of Significant Contribution and Rulemaking for Certain States in the Ozone Transport Assessment Group Region for Purposes of Reducing Regional Transport of Ozone" (the NO_x State implementation plan call (NO_x SIP call)). The rulemaking docket for that rule contains information and analyses that were relied on in the January 2000 final rule. Therefore, EPA is incorporating by reference the entire NO_x SIP call record for purposes of today's rulemaking. Documents related to the NO_x SIP call are available for inspection in Docket No. A-96-56 at the address and times given above. In addition, the documents associated with the NO_x SIP call are located at <http://www.epa.gov/ttn/oarpg/otagsip.html>.

Outline

The information in this preamble is organized as follows:

- I. Background
- II. Proposed Rule Revisions
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 - 1. "Stranded units".
 - 2. West Virginia non-EGUs.
 - 3. Blue Ridge Paper Products Company, Riley Bark Boiler, Plant 0159.
 - 4. Michigan State University, Unit 0056, Plant K3249.
 - B. Proposed sources of NO_x allowances for revised allocations.
 - 1. Sources of allowances under part 97.
 - a. Allocations in Appendices A and B to part 97.
 - b. Allocation set-aside.
 - c. Compliance supplement pool.
 - 2. Proposed approach for obtaining allowances for units' revised allocations.
 - a. Proposed approach for West Virginia non-EGUs.
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 - i. Use of allocations to non- NO_x Budget units.
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 - C. Proposed amount of allowances for units' revised allocations.
 - D. Proposed changes to regulatory text.
 - III. Administrative Requirements
 - A. Executive Order 12866: Regulatory Impacts Analysis
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 - C. Unfunded Mandates Reform Act
 - D. Paperwork Reduction Act
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 - F. Executive Order 12898: Environmental Justice
 - G. Executive Order 13132: Federalism
 - H. Executive Order 13084: Consultation and Coordination with Indian Tribal Governments

I. National Technology Transfer and Advancement Act

I. Background

In January 2000, EPA took final action (the January 2000 final rule) under section 126 of the CAA on petitions filed by eight Northeastern States seeking to mitigate interstate transport of NO_x.¹ 65 FR 2674 (January 18, 2000). Section 126 of the CAA authorizes a downwind State to petition EPA for a finding that an existing or new (or modified) major stationary source or a group of such sources emits or would emit in violation of section 110(a)(2)(D)(i) by contributing significantly to nonattainment of a National Ambient Air Quality Standard or interfering with maintenance of such a standard in a downwind State. EPA determined that certain large electric generating units (EGUs) and large industrial boilers and turbines (non-EGUs) named in the petitions emit in violation of the CAA prohibitions against significantly contributing to nonattainment or maintenance problems in the petitioning States. The EGUs and non-EGUs covered by the January 2000 final rule are in the following States or portions of States and the District of Columbia: Delaware; Indiana; Kentucky; Maryland; Michigan; North Carolina; New Jersey; New York; Ohio; Pennsylvania; Virginia; and West Virginia. 65 FR 2675.

EPA established the Federal NO_x Budget Trading Program as the control remedy for these sources. EPA determined allowable emissions for the sources and allocated authorizations to emit NO_x (*i.e.*, NO_x allowances) to the sources. Under this program, an affected unit (referred to as a "NO_x Budget unit") may buy or sell allowances but must hold, after the end of the ozone season, a number of allowances at least equal to the number of tons of NO_x that the unit emitted during that ozone season.

For purposes of allocating allowances, EPA set for each State (or portion of State) NO_x emission budgets (in tons of NO_x) for EGUs and non-EGUs. EPA then allocated allowances to each existing unit, based on the unit's historical heat input. For EGUs, the average of the two highest ozone season heat inputs from 1995–1998 was used as the historical heat input. For non-EU's, the 1995 ozone season heat input or, if data were available, the average of the two highest

ozone season heat inputs from 1995–1998 was used as the historical heat input. 40 CFR 97.42(a). EPA also adjusted each unit's allocations so that the total number of allowances allocated to EGUs and the total number of allowances allocated to non-EGUs in a given State equaled 95 percent of the EGU budget and of the non-EU budget respectively for that State. 40 CFR 97.42(b) and (c). Five percent of the budget was reserved for allocations to new units.

After EPA promulgated the January 2000 final rule, owners, or associations of owners, of EGUs or non-EGUs filed petitions with the D.C. Circuit challenging, among other things, the allowance allocations for certain units in the Federal NO_x Budget Trading Program regulations. Subsequently, EPA entered into settlements with some of these owners and associations of owners. Today's action proposes to revise the allowance allocations in the January 2000 rule for these units, in a manner consistent with the settlements.

In addition, after promulgation of the January 2000 final rule, owners of non-EGUs submitted letters to EPA requesting correction of the allowance allocations for two other units under the rule. EPA responded that it was treating the letters as requests for reconsideration of the two units' allocations under the rule and would propose to revise the allocations. Today's action includes such a proposal for these units.

II. Proposed Rule Revisions

EPA is proposing to make specific, limited revisions to provisions of the Federal NO_x Budget Trading Program rule, *i.e.*, part 97, in order to change the NO_x allowance allocations for certain NO_x Budget units. In today's proposal, EPA is specifying which units will receive revised allocations, how EPA will obtain the additional allowances used for the revised allocations, and what will be the amount of each unit's revised allocation. For the reasons discussed below, EPA proposes to revise the allocations for units discussed in section II.A of today's preamble. To provide the revised allocations, EPA proposes to use first allowances that were allocated initially to units that EPA has subsequently determined are not NO_x Budget units and therefore not subject to the Federal NO_x Budget Trading Program. If an insufficient amount of allowances are available from such units, EPA proposes to then use allowances from the compliance supplement pool. This approach to obtaining allowances for the revised allocations is discussed in section II.B.

In section II.C, EPA proposes the amount of each unit's revised allocation.

The specific rule revisions necessary to implement the above-described approach are discussed in section II.D of today's preamble. EPA is proposing to revise Appendices A and B to part 97 in order to include revised allocations for the units identified in section II.A and remove allocations for some other units that EPA has previously determined not to be NO_x Budget units. EPA is also proposing changes to § 97.43 (compliance supplement pool provisions) in order to provide, where necessary, allowances that supplement the allocation change proposed in Appendix A or B.

Further, EPA is proposing revisions to § 97.42 (allocation procedures) to provide the Administrator general authority to issue orders to correct other units' allocations, where appropriate, using allowances allocated initially to units determined not to be NO_x Budget units. EPA is also proposing revisions to § 97.43 to provide the Administrator general authority to issue orders to correct units' allocations, where appropriate, using allowances from the compliance supplement pool.

EPA has not considered, and is not requesting comment on, any other changes to part 97 or the January 2000 final rule. This proposal is limited to changes to part 97 that are necessary either: to correct the allocations for the units specifically identified here; or to provide the Administrator general authority to address similar allocation-quantity issues that may arise in the future.

A. Rationale for Proposing To Revise Units' Allocations

The units for which EPA is proposing revised allocations are discussed below.

1. "Stranded" Units

EPA is proposing revised allocations for a group of identified units referred to here as "stranded" units. These are units that commenced operation after May 1, 1995 and before May 1, 1997. In the October 21, 1998 proposed rule for the Federal NO_x Budget Trading Program (October 1998 proposed rule), EPA did not propose any allocations for these units for 2003–2007. *See, e.g.*, 63 FR 56292, 56377–87 (October 21, 1998). However, the proposed rule included a provision that established an allocation set-aside for allocating allowances to new units for 2003–2007. New units were the units commencing operation "on or after May 1 of period used to calculate [historical] heat input" for determining allocations for existing units for 2003–2007. 63 FR 56347

¹ This background is for the convenience of the reader to understand better the proposed revisions in sections II.B.2.C, and D below. EPA is not reconsidering or requesting comment on any of the provisions in part 97, except to the extent discussed in the proposals in sections II.B.2.C, and D.

(§ 97.42(d)). For existing EGUs, the historical heat input for 2003–2007 allocations was “the average of the two highest amounts of the unit’s heat input for the control periods in 1995, 1996, and 1997.” *Id.* (§ 97.42(a)(1)(i)). For existing non-EGUs, the historical heat input for 2003–2007 allocations was “the control period in 1995.” *Id.* (§ 97.42(a)(1)(i)). In light of these provisions, owners of units commencing operation on or after May 1, 1995 could reasonably have assumed that their units would be treated as new units to be allocated allowances under § 97.42(d). They therefore had no reason to be concerned about the failure to include their units in the allocations tables in the October 1998 proposed rule or in a subsequent Notice of Data Availability (64 FR 43124 (September 9, 1999)) requesting comment on units’ heat input.

In the January 2000 final rule, EPA changed the periods used for historical heat input and the cutoff date for distinguishing between existing units receiving allocations under § 97.42(b) or (c) and new units receiving allocations under § 97.42(d). For purposes of 2003–2007 allocations, new units are defined as units commencing operation on or after May 1, 1997. 40 CFR 97.42(d). Consequently, the final rule makes units commencing operation on or after May 1, 1995 but before May 1, 1997 ineligible for the allocation set-aside.

However, as in the proposed rule, such units are still not listed as existing units with allocations in Appendix A or B in the January 2000 final rule. EPA has identified three such units: Unit 0B7, plant 00003, Union Carbide—South Charleston Plant, Kanawha County, West Virginia; and the Package Boiler at Weyerhaeuser Paper Company Plymouth, plant 0069, Martin County and Power Boiler No. 2 at Weyerhaeuser Paper Company New Bern Mill, plant 0104, Craven County in North Carolina. As noted above, the owners of such units had no reason to comment on the absence of their units in EPA’s notices requesting comment on allocations or heat input data. Under these circumstances, EPA believes that the owners did not have a reasonable opportunity to comment on the lack of allocations for their units. Therefore, EPA proposes to provide allocations for these units.

In addition, there is another unit with circumstances analogous to those of the “stranded” units. SEI Birchwood, plant 12 (Birchwood) commenced operation after the ozone season in 1996 and so would have been a new unit under the October 1998 proposed rule. Subsequently, in the Notice of Data

Availability, EPA requested comment on heat input data provided by the State of Virginia on Birchwood for 1996–1998. These data turned out to be erroneous. The owners had little or no reason to comment on the data since, under the October 21, 1998 proposed rule, the unit seemed to be a new unit that would receive allocations under § 97.42(d) based on maximum design heat input, not any actual heat input data. 40 CFR 97.42(d)(3) and (4). Under these circumstances, EPA believes that, as in the case of the “stranded” units, there was not a reasonable opportunity for the Birchwood owners to comment. Therefore, EPA proposes to provide allocations for this unit as well.

2. West Virginia Non-EGUs

EPA is also proposing revised allocations for the non-EQU units in West Virginia. One of these units (Unit 006, plant 00001, Elkem Metals Company—Alloy L.P. Plant in Fayette County, West Virginia (Elkem Metals)) was allocated 58 allowances in the October 1998 proposed rule. Subsequently, EPA received comments from a State agency mistakenly indicating that the unit had a significantly higher heat input than the heat input on which the proposed allocation was based. The owners of the non-EGUs in West Virginia did not realize that erroneous data had been submitted and so did not submit comments on the data. Unaware that the data was erroneous, EPA increased the unit’s allocation to 701 allowances and adjusted downward the allocations for the other non-EGUs in West Virginia so that the total non-EQU allocations would not exceed the non-EQU budget for the State. As a result, the allocations for West Virginia non-EGUs were distorted, with Elkem Metals receiving a significantly overstated allocation and the other non-EGUs receiving significantly understated allocations.

However, the owners of all of the units affected by the erroneous data, including the owner of the unit with the overstated allocation, agree on what are the correct data and the correct resulting allocations. Further, one “stranded” non-EQU in West Virginia (discussed above) did not receive any allowances. EPA therefore proposes to revise the non-EQU allocations in West Virginia to correct these errors.

3. Blue Ridge Paper Products Company, Riley Bark Boiler, Plant 0159

EPA is proposing revised allocations for the Blue Ridge Paper Products Company, Riley Bark Boiler, Plant 0159 in Haywood County, North Carolina. The unit burns primarily coal,

supplemented by some bark, and so qualifies as a fossil fuel fired unit. The unit’s prior owner submitted comments in hardcopy and in electronic format to EPA. The comments stated that the unit was fossil fuel fired, and thus a NO_x Budget unit, and that the unit had been erroneously excluded from the non-EQU inventory for North Carolina.

However, the hardcopy and electronic versions of the comments were inconsistent. The electronic version indicated that the unit burned primarily bark, which would mean the unit would not actually qualify as fossil fuel fired, while the hardcopy version indicated that the unit burned primarily coal, which would mean the unit would qualify as fossil fuel fired. Apparently for this reason, EPA misinterpreted the comments and did not include the unit in allocations in either the October 1998 proposed rule or the January 2000 final rule and thereby allocated zero allowances for the unit. EPA therefore proposes to provide allocations for the unit.

4. Michigan State University, Unit 0056, Plant K3249

EPA is proposing revised allocations for Michigan State University, Unit 0056, Plant K3249 in Ingham County, Michigan (Michigan State). In the October 1998 proposed rule, EPA allocated 168 allowances to the unit. Subsequently, EPA received comments from the State of Michigan and attached comments from Michigan State University. The comments replaced the information on the unit’s NO_x emissions for 1995 with blanks and suggested using 1997 information on the unit instead. EPA misinterpreted the comments as indicating that the unit was not operating at all. EPA allocated the unit zero allowances in the January 2000 final rule. EPA therefore proposes to provide allocations for the unit.

B. Proposed Sources of NO_x Allowances for Revised Allocations

This section discusses the proposed sources of NO_x allowances for revised allocations for the units identified above. EPA maintains that, to ensure that the overall environmental goals of the section 126 rulemaking are met and to provide finality concerning the State EGU and non-EQU budgets set by EPA rulemakings,² the quantity of NO_x

² The State EGU and non-EQU budgets are the result of extensive rulemaking proceedings. *See, e.g.*, 62 FR 60318 (November 7, 1997) (proposing State EGU and non-EQU budgets), 63 FR 57356 (October 27, 1998) (setting EGU and non-EQU budgets), 63 FR 71220 (December 24, 1998) (extending comment period on EGU and non-EQU budgets), 64 FR 26298 (May 14, 1999) (technical

emissions allowed from all units in a particular State should not change under today's proposed rule from the amount allowed from such units under the January 2000 final rule. Therefore, the proposed rule revisions must revise the identified units' allocations in a way that holds constant the total number of allowances available in each State.

Under the January 2000 final rule, allowances may be allocated to units in a State from several pools of allowances: a pool consisting of 95% of the State EGU or non-EGU budget and used for allocations to existing units in Appendix A or B; a pool (the allocation set-aside) consisting of 5% of the State EGU and non-EGU budgets used for allocations to new units; and the compliance supplement pool for the State established to address electric reliability concerns. Part 97 includes provisions addressing allocations from each of these pools of allowances. In today's rulemaking, EPA is considering using allowances from one or more of these pools to provide revised allocations for the units identified in today's proposal.

With regard to the West Virginia non-EGUs (including one of the "stranded" units), EPA believes that the revised allocations can be implemented by redistributing among the units the allowances allocated to West Virginia non-EGUs in Appendix B of the January 2000 final rule. EPA is proposing today such a redistribution of the allowances for West Virginia non-EGUs.

For the remaining units identified as warranting revised allocations (*i.e.*, two "stranded" units and the Birchwood, Blue Ridge, and Michigan State units), EPA is proposing today to use the allowances that were allocated in the January 2000 final rule to other units subsequently determined not to be NO_x Budget units. To the extent an insufficient amount of allowances are available from such non-NO_x Budget units, EPA is proposing to use allowances from the compliance supplement pool.

1. Sources of A allowances Under Part 97

The discussion below summarizes the existing provisions of part 97 that establish several pools of allowances that may be allocated to units.³

amendment to EGU and non-EGU budgets in response to comments), 65 FR 11222 (March 2, 2000) (second technical amendment to EGU and non-EGU budgets in response to comments).

³ This background information is for the convenience of the reader to understand better the proposed revisions in sections II.B.2, C, and D below. EPA is not reconsidering or requesting comment on any of the provisions of part 97, except

a. *Allocations in Appendices A and B to part 97.* First, part 97 establishes pools consisting of 95% of the State EGU or non-EGU budgets respectively and uses these allowances for allocations to existing units each year during 2003–2007, as listed in Appendices A and B. Section 97.42(b) and (c) set forth the procedures for determining allocations from the pools for EGUs and non-EGUs respectively. See 40 CFR 97.42(b)(2) and (c)(2) (providing for adjustment of unit allocations to ensure that the total amount of allocations equal 95% of the EGU or non-EGU budget for the State). Further, § 97.42(g) establishes procedures for handling allocations provided in Appendix A or B to a recipient that is not actually a NO_x Budget unit and that therefore is not subject to part 97.⁴ In particular, if the Administrator determines that the recipient is not a NO_x Budget unit, the Administrator will not generally record in the NO_x Allowance Tracking System the recipient's allocation listed in Appendix A or B. 40 CFR 97.42(g)(1)(i). Instead, the Administrator will transfer the unrecorded allowances to the allocation set-aside for new units for the State. 40 CFR 97.42(g)(2).

b. *Allocation Set-Aside.* A second pool of allowances established by part 97 is the allocation set-aside, consisting of 5% of the sum of the State EGU and non-EGU budgets. 40 CFR 97.42(d)(1). As noted above, the rule uses the allocation set-aside to allocate allowances to new units, *i.e.*, units that began operating after the period whose heat input values are used to allocate to existing units under § 97.42(b) or (c). New units are initially allocated allowances year-by-year based on the unit's maximum design heat input. 40 CFR 97.42(d)(3) and (4). After the ozone season, the Administrator deducts an amount of allowances equal to the difference between the initial allocation and an allocation based on the unit's actual ozone season heat input. 40 CFR 97.42(e)(1). The deducted allowances are transferred back to the allocation set-aside, whose unallocated allowances are distributed to the existing units. 40 CFR 97.42(e)(2) and (f).

c. *Compliance Supplement Pool.* The third pool of allowances established by

to the extent discussed in the proposals in sections II.B.2, C, and D.

⁴ As discussed in section II.D.1 below, EPA has issued letters determining that 31 units allocated allowances in Appendix A or B to part 97 are not actually NO_x Budget units and that the allowances will therefore not be recorded. Generally, a unit was misidentified as a NO_x Budget unit due to an error concerning the size, type, fuel, or location of the unit.

part 97 is the compliance supplement pool, as set forth for each State in Appendix D to part 97. Compliance supplement pool allowances may be used in 2003 or 2004 to meet the requirement to hold allowances at least equal to NO_x emissions. These allowances expire after 2004. 40 CFR 97.43(c)(7). The purpose of the compliance supplement pool is to provide additional allowances above and beyond the State EGU and non-EGU budgets for 2003 and 2004 for units "that are unable to meet the compliance deadline" during those years. 63 FR 57356, 57428 (October 27, 1998) (explaining purpose of pool in NO_x SIP call); see also 64 FR 28250, 28310 (May 25, 1999) (adopting pool in Federal NO_x Budget Trading Program for same reasons as in NO_x SIP call). EPA explained that it believed that the compliance deadline is feasible without the compliance supplement pool. However, the additional allowances in this pool will ensure that any unit unable to install NO_x control equipment (*e.g.*, because of concerns for electric reliability during a shutdown for installation) in the first two years of the Federal NO_x Budget Trading Program are able to obtain allowances until they can install the equipment. See 63 FR 57428.

Owners and operators of units that reduce the units' NO_x emissions below a specified level after 2000 and before 2003, the year when the control requirements of the Federal NO_x Budget Trading Program first take effect, may apply for compliance supplement pool allowances. 40 CFR 97.43(a). Owners and operators of units in the Ozone Transport Commission NO_x Budget Program may also apply for compliance supplement pool allowances to the extent the units have banked allowances for 2000 or 2001 under that program. 40 CFR 97.43(b). Although the compliance supplement pool is distributed to units with early reductions or with banked allowances under the Ozone Transport Commission NO_x Budget Trading Program, units "that need extra allowances for compliance will have access to them through the allowance market." 65 FR 2714; see also Responses to Significant Comments on the Proposed Findings of Significant Contribution and Rulemaking on Section 126 Petitions for Purposes of Reducing Interstate Ozone Transport, Docket No. A–97–43, XI–C–01 (December 1999) (Response to Comment for January 2000 rule), section II.F.1 at 65 (stating that any unit unable to install controls by 2003 "may buy allowances from other sources" and therefore

rejecting claim that “additional allowances [e.g., compliance supplement pool allowances] * * * need to be distributed via a mechanism other than the allowance market to ensure that all sources will be in compliance”).

If the total amount of compliance supplement pool allowances requested for units in a State exceeds the total amount of allowances in the State’s compliance supplement pool, the Administrator adjusts the amounts allocated so that the allocations are limited by the amount in the pool. 40 CFR 97.43(c)(4). If the total amount requested is less than the amount in the pool, the unrequested amount is not allocated to any unit.

2. Proposed Approach for Obtaining Allowances for Units’ Revised Allocations

EPA’s general approach to obtaining allowances for revised allocations is to adopt a methodology that will result in the least disruption to the Federal NO_x Budget Trading Program, while maintaining unchanged the environmental benefits of the program. In particular, EPA believes it should minimize the disruption to NO_x Budget units not involved in the issues giving rise to the need for revised allocations.

a. *Proposed Approach for West Virginia Non-EGUs.* Since the issues concerning the West Virginia non-EGUs (including one “stranded” unit) involve the entire West Virginia non-EGU budget sector, EPA proposes to obtain allowances for the non-EGUs’ revised allocations by redistributing the allocations for that sector. The redistribution will not affect any units other than those needing revised allocations. Further, the redistribution is the least disruptive approach for revising the units’ allocations. In fact, since the owners of all the West Virginia non-EGUs have agreed on the amounts of the revised allocations for the units, the owners could have accomplished this redistribution on their own at any time, simply by using the unrestricted trading allowed under the Federal NO_x Budget Trading Program to transfer allowances among the units. Nonetheless, EPA is proposing to redistribute the allocations, as requested by the owners, through today’s rulemaking.

b. *Proposed approach for other units.* For the other units identified above, EPA is proposing to use first the allowances that were allocated in the January 2000 final rule to units that EPA subsequently determined not to be NO_x Budget units. To the extent an insufficient amount of allowances are

available from such non-NO_x Budget units, EPA proposes to use allowances from the compliance supplement pool.

If the two “stranded” units⁵ and the Birchwood, Blue Ridge, and Michigan State units had been provided the proper number of allowances in the January 2000 final rule, the allocations for all units in their respective budget sectors in their respective States would have been affected. This is because, under § 97.42(b) and (c), each existing unit is allocated its proportionate share of the budget for its respective sector (EGU or non-EGU) for its respective State. For example, allocations for an EGU in a given State are determined by: multiplying an emission rate (0.15 lb/mmBtu) times each unit’s historical heat input; totaling the results for all EGUs in the State; and adjusting each EGU’s allocation proportionately until the total number of allowances allocated to the EGUs in the State equals 95 percent of the State’s EGU budget. Non-EGU allocations are determined in the same way except that the emission rate (0.17 lb/mmBtu) is different and the allocations must equal 95 percent of the non-EGU budget.

One approach to providing revised allocations for the “stranded”, Birchwood, Blue Ridge, and Michigan State units would be to recreate the allocations that would have resulted if those units had been properly handled in the January 2000 rule. This would require reallocating allowances for each, entire budget sector (*i.e.*, the EGU or non-EGU sector for a given State) that includes one or more of these five units. EPA believes that approach would result in disruption of the Federal NO_x Budget Trading Program, and for the units in the program, far out of proportion to the scope of the problem. Consequently, EPA is proposing an approach that appears to be less disruptive to the Federal NO_x Budget Trading Program and the units in the program.

i. *Use of allocations to non-NO_x Budget units.* EPA believes that using allowances that were allocated mistakenly under the January 2000 final rule to units that were not actually NO_x Budget units is the least disruptive method of providing allowances for the revised allocations.⁶ Appendices A and B of the January 2000 final rule list the allocations for specific units thought to be NO_x Budget units. Under § 97.42(g)(1)(i), if EPA subsequently determines that any unit in Appendix A

or B is not actually a NO_x Budget unit, the Administrator will not record the listed allocations in an account for the unit. Instead, the Administrator will record the allocations in the allocation set-aside for new units in the State in which the unit is located, in addition to the 5 percent of the EGU and non-EGU budgets already comprising the set-aside. 40 CFR 97.42(g)(2).

In establishing this mechanism for correcting allocations to non-NO_x Budget units, EPA stated that it expected that such allocations would occur “rarely, if ever.” 65 FR 2707. Obviously, EPA’s intent was not to make errors resulting in allocations to non-NO_x Budget units. Since the mechanism for correcting such errors was expected to be rarely needed, owners and operators of new units had no reasonable expectation that the mechanism would ever be used and that any incorrectly allocated allowances would be added to the allocation set-aside. Consequently, EPA believes that revising NO_x Budget units’ allocations using allowances erroneously allocated to non-NO_x Budget units is the approach that is the least disruptive of reasonable expectations of owners and operators and, thus, of compliance planning for NO_x Budget units.

ii. *Use of compliance supplement pool allowances.* EPA believes that, to the extent the number of allowances available from non-NO_x Budget units in a State under § 97.42(g) is insufficient to cover the revised allocations for the units in the State, the compliance supplement pool for the State represents the next least disruptive source for obtaining the remaining allowances needed for revised allocations.⁷ As discussed above, the purpose of the compliance supplement pool is to make available allowances in addition to the EGU and non-EGU budget amounts so any units unable to install NO_x emission controls by 2003 can buy additional allowances in the market to help meet the requirement to hold allowances equal to emissions. 63 FR 57428 and 65 FR 2714; *see also* Response to Comment for January 2000 rule, section II.F.1 at 65.

Under the January 2000 final rule, this purpose is accomplished by distributing the compliance supplement pool allowances to owners and operators of

⁵ The third “stranded” unit is a West Virginia non-EGU, whose revised allocation is addressed above in section II.B.2.a of this preamble.

⁶ *See* n.3.

⁷ As discussed below, EPA presently anticipates that it will need to use compliance supplement pool allowances only for the Birchwood unit and that allocations for non-NO_x Budget units will be sufficient to provide the revised allocations for the other identified units. However, EPA proposes to use the compliance supplement pool whenever allocations to non-NO_x Budget units are insufficient to provide the full amount of the revised allocations determine to be appropriate for a unit.

units that make NO_x emission reductions before the 2003 compliance date for the Federal NO_x Budget Trading Program. See 40 CFR 97.43(a) and (b) (requirements for early reductions or for banked allowances in the Ozone Transport Commission NO_x Budget Program) and 97.43(c) (procedure for distributing compliance supplement pool).

EPA believes that using allowances from the compliance supplement pool for revised allocations to the “stranded”, Birchwood, Blue Ridge, and Michigan State units is consistent with the purpose of the compliance supplement pool. Whether the recipients of compliance supplement pool allowances are units that made early reductions or are units receiving revised allocations, these allowances still represent an increase in the total supply of allowances beyond the State EGU and non-EGU budgets. While the “stranded”, Birchwood, Blue Ridge, and Michigan State units are NO_x Budget units and so will need to use some allowances to cover emissions, this would be true whether or not the units receive revised allocations from the compliance supplement pool. Thus, the use of compliance supplement pool allowances to provide revised allocations represents a real increase in the total supply of allowances. Any units that need allowances for compliance will have greater access to allowances for purchase due to the increased supply in the market, regardless of who initially receives allowances from the compliance supplement pool.

EPA notes that compliance supplement pool allowances are only available for two years (2003 and 2004), after which unused compliance supplement pool allowances expire. The revised allocations for the “stranded”, Birchwood, Blue Ridge, and Michigan State units are for five years (2003–2007). Some of the compliance supplement pool allowances used to provide revised allocations may expire before the year for which the units may need them for compliance. However, this should not pose a problem since the owners and operators of those units will, to the extent necessary for compliance, be able to sell their compliance supplement pool allowances in the allowance market and buy other allowances that will not expire.⁸

EPA recognizes that using some of the compliance supplement pool allowances for revised allocations reduces the amount of allowances potentially available for early reductions. However, the purpose of the compliance supplement pool is not to reward early reductions but rather is to increase the total supply of allowances to ensure units meet the 2003 compliance deadline. EPA provided credit for early reductions “merely as a mechanism for managing the [compliance supplement pool], not as an independent program with a purpose separate from that of the [compliance supplement pool]”. *State of Michigan v. EPA*, 213 F.3d 663, 694 (D.C. Cir. 2000). Further, EPA believes that the potential for reduced availability (as a result of today’s proposal) of compliance supplement pool allowances for early reductions should be balanced against the fact that, as discussed below, using other sources of allowances for revised allocations would be more disruptive to the Federal NO_x Budget Trading Program and other units.

In particular, using allowances from the new-unit allocation set-aside or reallocating to all units in the respective budget sectors of the “stranded”, Birchwood, Blue Ridge, and Michigan State units would be significantly more disruptive to the Federal NO_x Budget Trading Program and other units than using compliance supplement pool allowances. The allocation set-aside plays the important role of integrating new units into the Federal NO_x Budget Trading Program. 65 FR 2705 The set-aside is the sole source of allowances for allocating to new units until such units are treated as existing units in future allocation updating. EPA set the size of the allocation set-aside at 5 percent of the EGU and non-EGU budgets so that the pool would be large enough to accommodate all new sources. *Id.* EPA also decided to distribute the set-aside each year to all new units whose owners and operators request allocations by January 1 of that year, rather than distributing the set-aside on a first-come, first-served basis because the former approach is likely to ensure that each new unit receives at least some allowances. 65 FR 2706. EPA is concerned that using the allocation set-aside for revised allocations for existing units would likely reduce the allocation made to each new unit.

Further, EPA believes that the most disruptive approach for obtaining allowances for revised allocations would be to reallocate to all units in the

respective State EGU or non-EGU budget sector for the “stranded”, Birchwood, Blue Ridge, or Michigan State units. As discussed above, reallocation would likely change the allocation for every unit in the State budget sector. This would result in disruption of the Federal NO_x Budget Trading Program and for other units far out of proportion to the need to obtain allowances for five units.

In summary, EPA must balance several considerations in deciding whether to use compliance supplement pool allowances for revised allocations. On one hand, using such allowances will make fewer allowances potentially available for early reductions. On the other hand, this use of compliance supplement pool allowances is consistent with the pool’s purpose of increasing the supply of allowances to ensure that units will be able to meet the 2003 compliance deadline. Further, the impact of using compliance supplement pool allowances for revised allocations will be limited because these allowances will be used only to the extent that the allocations to non-NO_x Budget units are insufficient to implement revised allocations. Finally, the alternative approaches to obtaining allowances would be more disruptive to the Federal NO_x Budget Trading Program and other units. On balance, EPA believes that the use of compliance supplement pool allowances is the best approach (after using the non-NO_x Budget unit allocations) for obtaining allowances in the limited cases where revised allocations are warranted.

EPA therefore proposes this approach. However, EPA requests comment on alternative approaches discussed above.

C. Proposed Amounts of Allowances for Units’ Revised Allocations

EPA proposes to use, as revised allocations for the West Virginia non-EGUs (including one “stranded” unit), the allocations requested by the owners of those units in the request for administrative stay and petition for reconsideration submitted to EPA on May 1, 2000. (EPA intends to respond directly to the request for administrative stay, apart from today’s action.) All of the owners for West Virginia non-EGUs—including the owner of the unit that received a significantly overstated allocation in the January 2000 final rule—agree on the amounts of the allocations and the total of those allocations equals the West Virginia non-EGU budget. Under these circumstances, EPA believes that the requested allocations should be used as the revised allocations in today’s proposal.

⁸ EPA notes that part 97 integrates the allowance markets under the Federal NO_x Budget Trading Program and under any approved State NO_x Budget Trading Program by allowing units in the two programs to trade allowances. See 40 CFR 97.2

(defining “NO_x allowance” to include allowances issued under approved State programs).

Further, EPA proposes to calculate the revised allocations for two “stranded” units and the Birchwood, Blue Ridge, and Michigan State units by using the average emission rate underlying the allocations for the respective unit’s State budget sector (EGUs or non-EGUs) in Appendix A or B in the January 2000 final rule. As discussed above, the allocations to each EGU in Appendix A are calculated by multiplying the unit’s historical heat input by an initial average emission rate (0.15 lb/mmBtu) and then adjusting the results so that the total of the allocations to all EGUs in the unit’s State equals 95 percent of the State EGU budget. As a result of the latter adjustment, all EGU allocations for the State have the same underlying average emission rate that, when multiplied by each unit’s respective historical heat input, equals the unit’s allocation. The same is true for non-EGUs except that the initial average emission rate is 0.17 lb/mmBtu, total non-EGU allocations for a State equal 95 percent of the State’s non-EGU budget, and the underlying average emission rate for all non-EGUs’ allocations in the State may differ from that for EGUs’ allocations in that State.

In calculating allocations for the “stranded”, Birchwood, Blue Ridge, and Michigan State units, EPA proposes to use the underlying average emission rate for units in the State budget sector in the same State as the respective unit. EPA proposes to multiply each unit’s historical heat input by the appropriate underlying average emission rate. Each unit’s historical heat input is the heat input for the period set forth in § 97.42(a) and is supported by documentation submitted to EPA. The supporting documentation is generally heat input data routinely submitted to the State or routinely recorded by the owners and operators. *See* 40 CFR 97.42(a) (establishing 1995–1998 as the historical period for 2003–2007 allocations). This approach ensures that the “stranded”, Birchwood, Blue Ridge, and Michigan State units are allocated allowances on the same basis as units in the each respective State budget sector. *See* Memorandum on Calculation of Revised Allocations (showing how the revised allocations are calculated and attaching the supporting documentation of the heat input data).

D. Proposed Changes to Regulatory Text

This section discusses the proposed revisions to the language of specific sections of part 97. EPA is not considering, and is not requesting comment on, any other changes to these sections or to part 97 in general.

1. Appendices A and B Revisions

EPA is proposing several rule revisions to implement the above-described revised allocations and approach for obtaining allowances for those allocations. First, EPA is proposing to revise Appendices A and B to part 97 in order to include revised allocation amounts for the identified units and remove allocations for some other units that EPA has previously determined not to be NO_x Budget units. In addition, when Appendix A or B incorrectly references an identified unit or fails to list the unit at all, EPA is proposing correction of these errors.

Specifically, EPA proposes to revise Appendix A to increase the allocation listed in Appendix A for the Birchwood unit, as discussed above. Because Appendix A erroneously shows 2 units at Birchwood, rather than only 1 unit, the revision also corrects that error.

In addition, EPA proposes to remove from Appendix A each of the 4 units that EPA has previously determined not to be a NO_x Budget unit. Under § 97.42(g), the Administrator may determine that a unit allocated allowances in Appendix A or B does not meet the applicability requirements in § 97.4 and so is not actually a NO_x Budget unit. In response to requests for such determinations, EPA has issued letters finding that 4 units listed in Appendix A are not NO_x Budget units and will not have allocations recorded in their accounts. Each letter provided a 30-day period, after the letter’s issuance date, for submission of any objections. Since no objections were submitted, the determinations in the letters are final. EPA proposes to reflect these final determinations in revisions of Appendix A removing the 4 units and their allocations.

With regard to Appendix B, EPA specifically proposes to increase the allocations for all but one of the West Virginia non-EGUs (while reducing the allocation for one West Virginia non-EGU) and for the Blue Ridge and Michigan State units as discussed above. Errors in the reference in Appendix B to the Blue Ridge unit will also be corrected. Further, EPA proposes to add the “stranded” units, and allocations for them, to Appendix B. Moreover, EPA proposes to remove, from Appendix B, 27 units previously determined not to be NO_x Budget units and their allocations. As with the Appendix A units determined to be non-NO_x Budget units, EPA determined by letter that the units’ allocations should not be recorded. Since no objections to the letters were submitted, the determinations in the letters are

final. The proposal merely reflects, in regulatory text, these determinations.

2. Section 97.42(g) Revisions

EPA is also proposing revisions to § 97.42 (allocation procedures) that will authorize the Administrator to issue orders correcting other units’ allocations, where correction is warranted, using allowances allocated to units determined not to be NO_x Budget units. Under the proposed revisions, the Administrator may determine that the number of allowances actually allocated to an existing NO_x Budget unit for 2003–2007 in Appendix A or B is less than the number of allowances provided under §§ 97.42(a) through (d) and that equitable considerations warrant correction of such unit’s allocation. The Administrator may also determine that the number of allowances actually allocated to a new NO_x Budget unit for 2003–2007 or to any NO_x Budget unit for 2008 or thereafter, using procedures in §§ 97.42(a) through (d), is less than the number of allowances provided under §§ 97.42(a) through (d) and that equitable considerations warrant correction of such unit’s allocation. Moreover, in the order, the Administrator may determine that allowances mistakenly allocated to non-NO_x Budget units located in the same State as the unit will be used to supplement, and thereby correct, the unit’s actual allocation. EPA proposes that, in issuing such order, the Administrator will explain the reasons why the allocation should be corrected, will provide an opportunity for submission of objections, and may modify the order based on submitted objections. EPA intends to provide notice of each order in the **Federal Register**, and any person may submit objections to the order. The use of orders—rather than rule revisions—to make unit-specific allocations from allocations to non-NO_x Budget units (or, as discussed below, from the compliance supplement pool) will allow for much more expeditious correction of a unit’s allocations where correction is warranted and still provide opportunity for interested parties to submit objections.

3. Section 97.43 Revisions

For all but one of the units proposed in today’s action to receive revised allocations, EPA believes that the above-discussed revisions to Appendices A and B will provide the full amount of the proposed additional allowances. However, for the Birchwood unit (located in Virginia), there are insufficient allowances available from

allocations in Appendix A or B to non-NO_x Budget units in Virginia to provide to the Birchwood unit the full amount of allowances in the proposed revised allocation. EPA is therefore proposing to revise § 97.43 to add a new paragraph (c)(9) that will specifically allocate to the Birchwood unit in Virginia 725 allowances from the Virginia compliance supplement pool. The new provisions also address the interaction of this unit-specific allocation with other provisions of the rule concerning compliance supplement pool allowances. For example, the new provision addresses the recording of such allowances and the ability to use the allowances for compliance, and the effect of the unit-specific allocation on the number of allowances available in the Virginia compliance supplement pool for allocation to other units.

In addition, EPA proposes to revise § 97.43 to add a new paragraph (d) that will authorize the Administrator to issue orders determining that the number of allowances allocated in Appendix A or B (or using §§ 97.42(a) through (d) procedures) for a unit is less than the number of allowances provided under §§ 97.42(a) through (d) and that equitable considerations warrant correction of such allocation. The Administrator may further determine in the order that allowances in the compliance supplement pool of the State where the unit is located will be used to supplement, and thereby correct, the unit's allocation. EPA also proposes that, in issuing such order, the Administrator will explain the reasons why the allocation should be corrected and provide an opportunity for submission of objections and may modify the order based on submitted objections. EPA intends to provide notice of each order in the **Federal Register**, and any person may submit objections to the order. In addition, EPA proposes to provide notice in the **Federal Register** of any resulting reduction in the amount of allowances in the State compliance supplement pool that remain available for allocation for early reductions or for banked allowances from the Ozone Transport Commission NO_x Trading Program.

While the above-described proposed revisions adding a new § 97.43(d) are aimed at providing general authority to issue orders using the compliance supplement pool to correct a unit's allocations, EPA requests comment on using this general provision to issue such an order to the Birchwood unit, instead of using the proposed, unit-specific revisions in new § 97.43(c)(9) (discussed above) that add to the rule itself the allocation from the Virginia

compliance supplement pool to the Birchwood unit. It may be preferable to avoid adding a permanent rule provision dealing only with the Birchwood unit and instead to accomplish the allocation by order under the proposed general authority proposed to be added in § 97.43(d).

In order to provide for this alternative approach to allocating Virginia compliance supplement pool allowances to the Birchwood unit, EPA is including, in a separate portion of the docket of today's proceeding, a draft order proposing to allocate 725 allowances from the Virginia compliance supplement pool to the Birchwood unit. EPA requests comment on the draft order and will provide upon request an opportunity for a conference on the draft order. If, after considering public comment on the proposed general authority provision in § 97.43(d) and on the draft order for the Birchwood unit, EPA decides to issue a final rule establishing such general authority, the Agency may also issue a final order allocating allowances from the Virginia compliance supplement pool to the Birchwood unit, instead of adopting the unit-specific revisions of § 97.43(c)(9). In light of the opportunity for comment on the draft letter in today's proceeding, EPA may issue the final order without further opportunity to submit objections. EPA also requests comment on this alternative approach to implementing the additional allocation for the Birchwood unit.

III. Administrative Requirements

A. Executive Order 12866: Regulatory Impacts Analysis

Under Executive Order 12866 (58 FR 51735 (October 4, 1993)), the Agency must determine whether a regulatory action is "significant" and therefore subject to Office of Management and Budget (OMB) review and the requirements of the Executive Order. The Order defines "significant regulatory action" as one that is likely to result in a rule that may:

- (1) Have an annual effect on the economy of \$100 million or more or adversely affect in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, or tribal governments or communities;
- (2) Create a serious inconsistency or otherwise interfere with an action taken or planned by another agency;
- (3) Materially alter the budgetary impact of entitlements, grants, user fees, or loan programs or the rights and obligations of recipients thereof; or

(4) Raise novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in the Executive Order.

It has been determined that today's proposed rule is not a "significant regulatory action" under the terms of Executive Order 12866 and, therefore, is not subject to OMB review.

B. Regulatory Flexibility Act: Small Entity Impacts

The Regulatory Flexibility Act (RFA), 5 U.S.C. 601, *et seq.*, as amended by the Small Business Regulatory Enforcement Fairness Act (SBREFA), Pub. L. No. 104-121, generally requires the Agency to prepare a regulatory flexibility analysis of any rule subject to notice and comment rulemaking requirements under the Administrative Procedure Act or any other statute unless the Agency certifies that the rule will not have a significant, economic impact on a substantial number of small entities. Such entities include small businesses, small organizations, and small governmental jurisdictions.

In determining whether a rule has a significant, economic impact on a substantial number of small entities, the impact of concern is any significant, adverse, economic impact on small entities since the primary purpose of the regulatory flexibility analysis is to identify and address regulatory alternatives "which minimize any significant, economic impact of the proposed rule on small entities." 5 U.S.C. 603 and 604.

Today's proposed rule revision is not significant enough to change the regulatory burden or economic impact of the existing Federal NO_x Budget Trading Program rule. Moreover, for virtually all NO_x Budget units addressed in the proposal, the proposed rule either will increase the number of allowances allocated and thus will reduce the burden of the program or will not change the number of allowances allocated and thus will not change the program burden. To the extent the proposed rule will remove certain units from the allocation tables, EPA has already issued final orders removing the allocations for these units, and the proposed rule has no effect other than to update the allocation tables to make them consistent with those orders. Only one unit's allocation is reduced by the proposed rule, and the owners of that unit, agreeing that the unit's original allocation was erroneously overstated, requested EPA to make the reduction. With regard to the reduction in the number of allowances in the compliance supplement pool available for early

reductions, the identity of the entities that may qualify in the future for early reduction credits is speculative, and there is no reason to believe that such entities will include a substantial number of small entities.

For these reasons, I certify that today's proposed rule would not have a significant, economic impact on a substantial number of small entities.

C. Unfunded Mandates Reform Act

Title II of the Unfunded Mandates Reform Act of 1995 (UMRA), P.L. 104-4, establishes requirements for Federal agencies to assess the effects of their regulatory actions on State, local, and tribal governments and the private sector. Under section 202 of the UMRA, 2 U.S.C. 1532, the Agency generally must prepare a written statement, including a cost-benefit analysis, for any proposed or final rule with "Federal mandates" that may result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of \$100 million or more in any one year. Section 205 of the UMRA generally requires that, before promulgating a rule for which a written statement is needed, EPA must identify and consider a reasonable number of regulatory alternatives and adopt the least costly, most cost-effective, or least burdensome alternative that achieves the objectives of the rule. The provisions of section 205 do not apply when they are inconsistent with applicable law. Moreover, section 205 allows EPA to adopt an alternative other than the least costly, most cost effective, or least burdensome alternative if the Administrator publishes with the final rule an explanation why that alternative was not adopted. Before EPA establishes any regulatory requirements that may significantly or uniquely affect small governments, including tribal governments, it must have developed under section 203 of the UMRA a small government agency plan. The plan must provide for notifying potentially affected small governments, enabling officials of affected small governments to have meaningful and timely input in the development of EPA regulatory proposals with significant Federal intergovernmental mandates, and informing, educating, and advising small governments on compliance with regulatory requirements.

EPA has determined that today's proposed rule does not include a Federal mandate that may result in estimated costs of \$100 million or more to either State, local, or tribal governments in the aggregate, or to the private sector in any one year. For the reasons discussed above, today's

proposed rule revision is not significant enough to change the overall regulatory burden or economic impact of the Federal NO_x Budget Trading Program rule on any parties, including State, local or tribal governments.

Accordingly, little or no additional costs to State, local, or tribal governments in aggregate, or to the private sector, will result from the rule as proposed. Similarly, EPA has determined that today's rule contains no regulatory requirements that might significantly or uniquely affect small governments. Thus, today's proposed rule is not subject to the requirements of sections 202, 203, or 205 of the UMRA.

D. Paperwork Reduction Act

Today's proposed revisions to part 97 will not impose any new information collection burden subject to the Paperwork Reduction Act (44 U.S.C. 3501, *et seq.*). Today's proposed rule does not change either the scope of the units covered by, or the information requirements for units under, the Federal NO_x Budget Trading Program.

Burden means the total time, effort, or financial resources expended by persons to generate, maintain, retain, or disclose or provide information to or for a Federal agency. This includes the time needed to review instructions; develop, acquire, install, and utilize technology and systems for the purposes of collecting, validating, and verifying information, processing and maintaining information, and disclosing and providing information; adjust the existing ways to comply with any previously applicable instructions and requirements; train personnel to be able to respond to a collection of information; search data sources; complete and review the collection of information; and transmit or otherwise disclose the information.

Copies of the previously submitted Information Collection Request concerning the Federal NO_x Budget Trading Program may be obtained from the Director, Regulatory Information Division; EPA; 401 M St. SW (mail code 2137); Washington, DC 20460 or by calling (202) 564-2740.

E. Executive Order 13045: Protection of Children From Environmental Health Risks and Safety Risks

The Executive Order 13045 (62 FR 19885 (April 23, 1997)) applies to any rule that the Agency determines: (1) Is "economically significant" as defined under Executive Order 12866; and (2) concerns an environmental health or safety risk that EPA has reason to believe may have a disproportionate effect on children. If the regulatory

action meets both criteria, EPA must evaluate the environmental health or safety effects of the planned rule on children and explain why the planned regulation is preferable to other potentially effective and reasonably feasible alternatives considered by EPA.

Today's proposed rule is not subject to Executive Order 13045 because it is not "economically significant" as defined under Executive Order 12866. Further, EPA does not have reason to believe that the environmental health risks or safety risks addressed by this action present a disproportionate risk to children.

F. Executive Order 12898: Environmental Justice

Executive Order 12898 requires that each Federal agency make achieving environmental justice part of its mission by identifying and addressing, as appropriate, disproportionately high and adverse human health or environmental effects of its programs, policies, and activities on minorities and low-income populations.

The proposed rule does not have a disproportionately high and adverse human health or environmental effects on minorities and low-income populations.

G. Executive Order 13132: Federalism

Executive Order 13132, entitled "Federalism" (64 FR 43255 (August 10, 1999)), requires the Agency to develop an accountable process to ensure "meaningful and timely input by State and local officials in the development of regulatory policies that have federalism implications." "Policies that have federalism implications" is defined in the Executive Order to include regulations that have "substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government."

This proposed rule does not have federalism implications. It 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, as specified in Executive Order 13132. Thus, Executive Order 13132 does not apply to this rule.

In the spirit of Executive Order 13132, and consistent with EPA policy to promote communications between EPA and State and local governments, EPA specifically solicits comment on this proposed rule from State and local officials.

H. Executive Order 13084: Consultation and Coordination With Indian Tribal Governments

Under Executive Order 13084, the Agency may not issue a regulation that is not required by statute, that significantly or uniquely affects the communities of Indian tribal governments, and that imposes substantial direct compliance costs on those communities, unless the Federal government provides the funds necessary to pay the direct compliance costs incurred by the tribal governments, or EPA consults with those governments. If EPA complies by consulting, Executive Order 13084 requires EPA to provide to OMB, in a separately identified section of the preamble to the rule, a description of the extent of EPA's prior consultation with representatives of affected tribal governments, a summary of the nature of their concerns, and a statement supporting the need to issue the regulation. In addition, Executive Order 13084 requires EPA to develop an effective process permitting elected officials and other representatives of Indian tribal governments "to provide meaningful and timely input in the development of regulatory policies on matters that significantly or uniquely affect their communities."

Today's proposed rule will not significantly or uniquely affect the communities of Indian tribal governments or impose any direct compliance costs on those communities. Accordingly, the requirements of section 3(b) of Executive Order 13084 do not apply to this action.

I. National Technology Transfer and Advancement Act

Section 12(d) of the National Technology Transfer and Advancement Act of 1995 (NTTAA), Pub. L. No. 104-113, section 12(d), 15 U.S.C. 272 note, directs the Agency to use voluntary consensus standards in its regulatory activities unless to do so would be inconsistent with applicable law or otherwise impractical. Voluntary consensus standards are technical standards (e.g., materials specifications, test methods, sampling procedures, and business practices) that are developed or adopted by voluntary consensus standards bodies. The NTTAA directs EPA to provide Congress, through OMB, explanations when the Agency decides not to use available and applicable voluntary consensus standards.

Today's proposed rule does not involve any technical standards. Therefore, EPA is not considering the

use of any voluntary consensus standards.

List of Subjects in 40 CFR Part 97

Environmental protection, Administrative practice and procedure, Air pollution control, Emissions trading, Intergovernmental relations, Nitrogen oxides, Ozone, Ozone transport, Reporting and recordkeeping requirements.

Dated: December 14, 2000.

Carol M. Browner,
Administrator.

For the reasons set out in the preamble, title 40, chapter I of the Code of Federal Regulations is proposed to be amended as follows:

PART 97—FEDERAL NO_x BUDGET TRAINING PROGRAM

1. The authority citation for part 97 continues to read as follows:

Authority: 42 U.S.C. 7401, 7403, 7426, and 7601.

2. Section 97.42 is amended by adding two sentences to the end of paragraph (g)(2) to read as follows:

§ 97.42 NO_x allowance allocations.

* * * * *

(g) * * *

(2) * * * Notwithstanding the prior sentence, the Administrator may instead issue an order allocating such NO_x allowances to a NO_x Budget unit to the extent that he or she determines that the number of allowances actually allocated in appendix A or B of this part, or under paragraph (b), (c), or (d) of this section, to such unit is less than the number of allowances provided under paragraphs (a) through (d) of this section and that equitable considerations warrant correction of such allocation. In issuing such order, the Administrator will explain the reasons why the allocation should be corrected, will provide notice and opportunity for submission of objections to the order, and may modify the order based on submitted objections.

3. Section 97.43 is amended by adding paragraphs (c)(9) and (d) to read as follows:

§ 97.43 Compliance supplement pool.

* * * * *

(c) * * *

(9) Notwithstanding paragraphs (c)(3) through (8) of this section

(i) SEI Birchwood, plant 12, unit 1 in Virginia is allocated 725 allowances from the Virginia compliance supplement pool;

(ii) The Administrator will record the allocation under paragraph (c)(9)(i) of this section when allocations are recorded under § 97.53(a); and

(iii) The deduction of allowances allocated under paragraph (c)(9)(i) of this section and the treatment of such allowances as banked allowances shall be governed by paragraphs (d)(4) and (5) of this section.

(d)(1) The Administrator may issue an order allocating NO_x allowances in the compliance supplement pool that are otherwise available for allocations under paragraph (c)(3) or (4) of this section to a NO_x Budget unit under the following circumstances. The Administrator may issue such an order if he or she determines that the number of allowances actually allocated in appendix A or B of this part, or under § 97.42(b), (c), or (d), to such unit is less than the number of allowances provided under §§ 97.42(a) through (d) and that equitable considerations warrant correction of such allocation. In issuing such order, the Administrator will explain the reasons why the allocation should be corrected, will provide notice and opportunity for submission of objections to the order, and may modify the order based on submitted objections.

(2) Notwithstanding paragraph (c)(3) or (4) of this section, the number of allowances in the compliance supplement pool for a State shall be treated under paragraph (c)(3) or (4) of this section as equaling the amount set forth in appendix D of this part for the State less the number of allowances allocated from the compliance supplement pool for the State to a unit in the State under paragraph (c)(9)(i) of this section or in an order under paragraph (d)(1) of this section. After issuance of an order under paragraph (d)(1) of this section, the Administrator will provide notice in the **Federal Register** of the reduction in the number of NO_x allowances in the compliance supplement pool for the State that are available for allocation under paragraph (c)(3) or (4) of this section.

(3) The Administrator will record an allocation in an order under paragraph (d)(1) of this section as soon as practicable after the issuance of the order, taking into account the period for submission of objections to the order and any subsequent modifications of the order.

(4) NO_x allowances allocated under paragraph (c)(9)(i) of this section or in an order under paragraph (d)(1) of this section may be deducted for compliance under § 97.54 for the control period in 2003 or 2004. Notwithstanding § 97.55(a), the Administrator will deduct as retired any NO_x allowance allocated under paragraph (c)(9)(i) of this section or in an order under paragraph (d)(1) of this section that is not deducted for compliance under

§ 97.54 for the control period in 2003 or 2004.

(5) NO_x allowances allocated under paragraph (c)(9)(i) of this section or in an order under paragraph (d)(1) of this section are treated as banked allowances

in 2004 for purposes of §§ 97.54(f) and 97.55(b).

Appendix A to Part 97 [Amended]

4. Appendix A to part 97 is amended by:

- a. Removing all entries for “MI, 491 E. 48TH STREET”, “MI, JB SIMS”, “NC,

CRAVEN COUNTY WOOD ENERGY”, and “VA, STONE CONTAINER”; and

b. Removing two entries for “VA, SEI BIRCHWOOD” and adding in their place one entry for “VA, SEI BIRCHWOOD”.

The revisions read as follows:

APPENDIX A TO PART 97—FINAL SECTION 126 RULE: EGU ALLOCATIONS, 2003–2007

State	Plant	Plant ____ id	Point ____ id	NO _x allocation for EGUs
VA	SEI BIRCHWOOD	12	1	160

Appendix B to Part 97 [Amended]

5. Appendix B to part 97 is amended by:

a. Removing all entries for “IN, Allen, MICHELIN NORTH AMERICA, INC”, “IN, Elkhart, SUPERIOR LAMINATING, INC”, “IN, Kosciusko, THE DALTON FOUNDRIES INC”, “KY, Carroll, DOW CORNING CORP”, “KY, Shelby, ICHIKOH MANUFACTURING”, “KY, Scott, TOYOTA MOTOR MFG USA INC”, and “KY, Hardin, USAARMC & FORT KNOX”; removing the first entry for “MI, Midland, DOW CHEMICAL USA”; removing all entries for “MI, Wayne, NATIONAL STEEL CORP”, “MI, Wayne, ROUGE STEEL CO”, “NC, Gaston, FMC CORP-LITHIUM DIV. HWY 161”, “NJ, Middlesex, FORD MOTOR COMPANY”, “NJ, Bergen, GARDEN STATE PAPER CO”, “NJ, Passiac, HOFFMAN LAROCHE INC. C/O ENVIR”; “WV, Grant, NORTH BRANCH POWER STATION”, and

“WV, Brooke, WHEELING-PITTSBURGH STEEL”;

b. Removing the fourth entry for “MI, Ingham, MICHIGAN STATE UNIVERSITY” and adding in its place an entry for “MI, Ingham, MICHIGAN STATE UNIVERSITY”;

c. Removing the second entry for “NC, Martin, WEYERHAEUSER PAPER CO. PLYMOUTH” and adding in its place an entry for “NC, Martin, WEYERHAEUSER PAPER CO. PLYMOUTH”;

d. Removing the entry for “WV, Kanawha, DUPONT-BELLE” and adding in its place an entry for “WV, Kanawha, DUPONT-BELLE”; removing the entry for “WV, Fayette, ELKEM METALS COMPANY L.P.-ALLOY PLANT” and adding in its place an entry for “WV, Fayette, ELKEM METALS COMPANY L.P.-ALLOY PLANT”; removing two entries for “WV, Marshall, PPG INDUSTRIES, INC” and adding in their place two entries for “WV, Marshall,

PPG INDUSTRIES, INC”; removing six entries for “WV, Kanawha, RHONE-POLUENC” and adding in their place three entries for “WV, Kanawha, AVENTIS CROPSCIENCE”; removing the entry for “WV, Kanawha, UNION CARBIDE-SOUTH CHARLESTON PLANT” and adding in its place two entries for “WV, Kanawha, UNION CARBIDE-SOUTH CHARLESTON PLANT”, removing seven entries for “WV, Hancock, WEIRTON STEEL CORPORATION” and adding in their place seven entries “WV, Hancock, WEIRTON STEEL CORPORATION”; and

e. Adding in alphabetical order by State by plant and numerical order by point entries for “NC, Haywood, BLUE RIDGE PAPER PRODUCTS”, and “NC, Craven, WEYERHAEUSER COMPANY NEW BERN MILL”.

The revisions and additions read as follows:

APPENDIX B TO PART 97—FINAL SECTION 126 RULE: NON-EGU ALLOCATIONS, ALLOCATIONS, 2003–2007

State	County	Plant	Plant ID	Point ID	NO _x allocation for non-EGUs
MI	Ingham	MICHIGAN STATE UNIVERSITY	K3249	0056	73
NC	Haywood	BLUE RIDGE PAPER PRODUCTS INC.	0159	005	87
NC	Martin	WEYERHAEUSER PAPER CO. PLYMOUTH.	0069	XXX	25
NC	Craven	WEYERHAEUSER COMPANY NEW BERN MILL.	0104	XXX	72
WV	Kanawha	DUPONT-BELLE	00001	612	54
WV	Fayette	ELKEM METALS COMPANY L.P.—ALLOY PLANT.	00001	006	116
WV	Marshall	PPG INDUSTRIES, INC	00002	001	195
WV	Marshall	PPG INDUSTRIES, INC	00002	003	419

APPENDIX B TO PART 97—FINAL SECTION 126 RULE: NON-EGU ALLOCATIONS, ALLOCATIONS, 2003–2007—Continued

State	County	Plant	Plant ID	Point ID	NO _x allocation for non-EGUs
WV	Kanawha	AVENTIS CROPS SCIENCE	00007	010	113
WV	Kanawha	AVENTIS CROPS SCIENCE	00007	011	102
WV	Kanawha	AVENTIS CROPS SCIENCE	00007	012	105
WV	Kanawha	UNION CARBIDE-SOUTH CHARLESTON PLANT.	00003	0B6	92
WV	Kanawha	UNION CARBIDE-SOUTH CHARLESTON PLANT.	00003	0B7	45
WV	Hancock	WEIRTON STEEL CORPORATION	00001	030	31
WV	Hancock	WEIRTON STEEL CORPORATION	00001	088	30
WV	Hancock	WEIRTON STEEL CORPORATION	00001	089	2
WV	Hancock	WEIRTON STEEL CORPORATION	00001	090	110
WV	Hancock	WEIRTON STEEL CORPORATION	00001	091	253
WV	Hancock	WEIRTON STEEL CORPORATION	00001	092	208
WV	Hancock	WEIRTON STEEL CORPORATION	00001	093	200

[FR Doc. 00–32396 Filed 12–20–00; 8:45 am]

BILLING CODE 6560–50–P

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

50 CFR Part 17

RIN 1018–AG32

Endangered and Threatened Wildlife and Plants; Re-opening of Comment Period and Notice of Availability of the Draft Economic Analysis for Proposed Critical Habitat for the California Red-Legged Frog

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Proposed rule; re-opening of comment period and notice of availability of draft economic analysis.

SUMMARY: We, the U.S. Fish and Wildlife Service (Service), announce the availability of the draft economic analysis for the proposed designation of critical habitat for the California red-legged frog (*Rana aurora draytonii*). We are also providing notice of the re-opening of the comment period for the proposal to designate critical habitat for the California red-legged frog in order to allow all interested parties to comment simultaneously on the proposed rule and the associated draft economic analysis. Comments previously submitted need not be resubmitted as they will be incorporated into the public record as part of this re-opened comment period, and will be fully considered in the final rule.

DATES: We will accept public comments until January 22, 2001. In addition, we are planning on holding two public information meetings during this time. Refer to the Public Information Meeting

section for dates, times, and locations of these meetings.

ADDRESSES: *Comment Submission:* If you wish to comment, you may submit your comments and materials concerning this proposal by any one of several methods:

1. You may submit written comments and information to the Field Supervisor, Sacramento Fish and Wildlife Office, U.S. Fish and Wildlife Service, 2800 Cottage Way, Suite W–2605, Sacramento, California 95825.

2. You may send comments by electronic mail (e-mail) to: fw1crfch@fws.gov. See the Public Comments Solicited section below for file format and other information about electronic filing.

3. You may hand-deliver comments to our Sacramento Fish and Wildlife Office at the address given above.

Comments and materials received, as well as supporting documentation used in preparation of the proposal to designate critical habitat, will be available for inspection, by appointment, during normal business hours at the address under (1) above. Copies of the draft economic analysis are available on the Internet at “www.r1.fws.gov” or by writing to the Field Supervisor at the address under (1) above.

FOR FURTHER INFORMATION CONTACT: For general information, and for information about Alameda, Butte, Calaveras, Contra Costa, El Dorado, Fresno, Kern, Marin, Mariposa, Merced, Napa, Plumas, San Joaquin, San Mateo, Santa Clara, Sierra, Solano, Sonoma, Stanislaus, Tehama, Tuolumne, and Yuba counties, contact Curt McCasland, Stephanie Brady or Patricia Foulk, at the above address (telephone 916/414–6600; facsimile 916/414–6710).

For information about Monterey, Los Angeles, San Benito, San Luis Obispo, Santa Barbara, Santa Cruz, and Ventura

counties, contact Diane Noda, Ventura Fish and Wildlife Office, U.S. Fish and Wildlife Service, 2394 Portola Road, Suite B, Ventura, California 93003 (telephone 805/644–1766; facsimile 805/644–3958).

For information about areas in the San Gabriel Mountains of Los Angeles County or Riverside and San Diego counties, contact Ken Berg, Carlsbad Fish and Wildlife Office, U.S. Fish and Wildlife Service, 2730 Loker Avenue West, Carlsbad, California 92008 (telephone 760/431–9440; facsimile 760/431–9624).

SUPPLEMENTARY INFORMATION:

Background

The California red-legged frog (*Rana aurora draytonii*) is the largest native frog in the western United States. It is endemic to California and Baja California, Mexico. It is typically found from sea level to elevations of approximately 1,500 meters (5,000 feet). The California red-legged frog is one of two subspecies of the red-legged frog (*R. aurora*). For a detailed description of these two subspecies, see the Draft Recovery Plan for the California Red-Legged Frog (Service 2000) and references within that plan.

Pursuant to the Endangered Species Act of 1973, as amended (Act), the California red-legged frog was listed as a threatened species on May 31, 1996 (61 FR 25813). Habitat loss and alteration, over-exploitation, and introduction of exotic predators were significant factors in the species' decline in the early- to mid-1900s. Habitat fragmentation, and continued colonization of existing habitat by nonnative species, may represent the most significant current threats to California red-legged frogs. We did not propose critical habitat at the time of the final rule to list the species because we

believed that critical habitat designation was not prudent.

On March 24, 1999, The Earthjustice Legal Defense Fund, on behalf of the Jumping Frog Research Institute, the Southwest Center for Biological Diversity, and the Center for Sierra Nevada Conservation, filed a lawsuit in the Northern District of California against the U.S. Fish and Wildlife Service and Bruce Babbitt, Secretary of the Department of the Interior (Secretary), for failure to designate critical habitat for the California red-legged frog (*Jumping Frog Research Institute et al. v. Babbitt*).

On December 15, 1999, U.S. District Judge William Alsup ordered us to make a prudency determination by August 31, 2000, and issue a final rule by December 29, 2001. On January 18, 2000, Judge Alsup clarified an error in the December 15, 1999, order stating that the Service shall issue a final rule by March 1, 2001.

On September 11, 2000, we published a proposed rule to designate critical habitat for the California red-legged frog in the **Federal Register** (65 FR 54892). The original comment period closed on October 11, 2000. The comment period for this proposed rule was re-opened and closed on November 20, 2000.

Approximately 2,175,000 hectares (5,373,650 acres) of land fall within the boundaries of the proposed critical habitat designation. Specifically, the aquatic and upland areas where suitable breeding and nonbreeding habitat is interspersed throughout the landscape, and is interconnected by unfragmented dispersal habitat, are the areas proposed as critical habitat. Proposed critical habitat is located in Alameda, Butte, Calaveras, Contra Costa, El Dorado, Fresno, Kern, Los Angeles, Marin, Mariposa, Merced, Monterey, Napa, Plumas, Riverside, San Benito, San Diego, San Joaquin, San Luis Obispo, San Mateo, Santa Barbara, Santa Clara, Santa Cruz, Sierra, Solano, Sonoma, Stanislaus, Tehama, Tuolumne, Ventura, and Yuba counties, California.

Critical habitat receives protection from destruction or adverse modification through required consultation under section 7 of the Endangered Species Act of 1973, as amended (Act) (16 U.S.C. 1531 *et seq.*) with regard to actions carried out, funded, or authorized by a Federal agency. Section 4(b)(2) of the Act requires that the Secretary shall designate or revise critical habitat based upon the best scientific and commercial data available, and after taking into consideration the economic impact of specifying any particular area as critical habitat. Based upon the previously published proposal to designate critical

habitat for the California red-legged frog, and comments received during the previous comment periods, we have prepared a draft economic analysis of the proposed critical habitat designation. The draft economic analysis is available at the above Internet and mailing address (see **ADDRESSES** section).

Public Comments Solicited

We will accept written comments during this re-opened comment period, and comments should be submitted to the Sacramento Fish and Wildlife Office in the **ADDRESSES** section.

If you submit comments by e-mail, please submit them as an ASCII file and avoid the use of special characters and any form of encryption. Please also include "Attn: [RIN number]" and your name and return address in your e-mail message. If you do not receive a confirmation from the system that we have received your e-mail message, contact us directly by calling our Sacramento Fish and Wildlife Office at telephone number 919/414-6600.

Public Information Meetings

Two public information meetings have been scheduled. The first meeting will be held on January 3, 2001, from 1:00 p.m. to 4:00 p.m. at the San Luis Obispo Embassy Suites, 333 Madonna Road, San Luis Obispo, California. The second meeting will be held on January 5, 2001, from 1:00 p.m. to 4:00 p.m. at the Best Western Monarch Hotel, 6680 Regional Street, Dublin, California.

Author(s)

The primary authors of this notice is Stephanie Brady (see **ADDRESSES** section), and Barbara Behan, U.S. Fish and Wildlife Service, Regional Office, 911 N.E. 11th Avenue, Portland, Oregon 97232.

Authority

The authority for this action is the Endangered Species Act of 1973 (16 U.S.C. 1531 *et seq.*).

Dated: December 13, 2000.

Rowan W. Gould,

Acting Regional Director, Region 1, Fish and Wildlife Service.

[FR Doc. 00-32372 Filed 12-20-00; 8:45 am]

BILLING CODE 4310-55-P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 635

[I.D. 110200D]

Atlantic Highly Migratory Species Fisheries; Atlantic Bluefin Tuna Incidental Catch

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Reopening of comment period.

SUMMARY: NMFS published, on November 17, 2000, an Advance Notice of Public Rulemaking (ANPR) and request for comments. NMFS intends to undertake rulemaking to reduce the level of Atlantic bluefin tuna (BFT) that is discarded dead by vessels in the pelagic longline fishery and requested comments on potential changes to the Atlantic tuna regulations that could reduce the level of dead discards of BFT including the adjustment of target catch requirements for landing incidental catch. The level of allowed discards needs to be reduced in order to decrease the waste of valuable bycatch. The comment period on the ANPR closed on December 14, 2000. NMFS is reopening the comment period to provide additional opportunity for comment.

DATES: Written comments on the ANPR must be received on or before January 16, 2001.

ADDRESSES: Written comments should be addressed to Christopher Rogers, Acting Chief, Highly Migratory Species Management Division (F/SF1), National Marine Fisheries Service, 1315 East-West Highway, Silver Spring, MD 20910.

FOR FURTHER INFORMATION CONTACT: Brad McHale or Pat Scida, 978-281-9260.

SUPPLEMENTARY INFORMATION: A complete description of the measures and the purpose and need for the proposed action is contained in the ANPR, published November 17, 2000 (65 FR 69492) and is not repeated here. Copies of the ANPR may be obtained by calling (see **FOR FURTHER INFORMATION CONTACT**).

NMFS requests comments on possible changes to the BFT landings allowances as outlined above or on alternative means of reducing dead discards of BFT in the pelagic longline fisheries. Comments received by the due date will be considered in drafting any proposed changes to the Atlantic tuna regulations.

Authority: 16 U.S.C. 971 *et seq.*, and 16 U.S.C. 1801 *et seq.*

Dated: December 15, 2000.

William T. Hogarth,

*Deputy Assistant Administrator for Fisheries,
National Marine Fisheries Service.*

[FR Doc. 00-32435 Filed 12-15-00; 4:55 pm]

BILLING CODE: 3510-22-S

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 660

[I.D. 120600B]

RIN 0648-AO64

Fisheries Off West Coast States and in the Western Pacific; Coastal Pelagic Species Fishery; Amendment 9

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Notice of availability of an amendment to a fishery management plan; request for comments.

SUMMARY: NMFS announces that the Pacific Fishery Management Council (Council) has submitted Amendment 9 to the Coastal Pelagic Species Fishery Management Plan (FMP) for Secretarial review. The amendment was prepared to document bycatch in the coastal pelagic species fishery (CPS), ensure that a standardized reporting methodology to assess the amount and type of bycatch exists, and propose any necessary conservation and management measures to minimize bycatch. Amendment 9 also ensures that Indian fishing rights will be met according to treaties between the U.S. and specific tribes.

DATES: Comments on Amendment 9 must be received on or before February 20, 2001.

ADDRESSES: Comments on Amendment 9 should be sent to Dr. Rebecca Lent, Administrator, Southwest Region, NMFS, 501 West Ocean Boulevard, Suite 4200, Long Beach, CA 90802.

Copies of Amendment 9, which includes an Environmental Assessment/Regulatory Impact Review, are available from Donald O. McIssac, Executive Director, Pacific Fishery Management Council, 2130 SW Fifth Avenue, Suite 224, Portland, OR, 97201.

FOR FURTHER INFORMATION CONTACT: James Morgan, Sustainable Fisheries Division, NMFS, at 562-980-4036 or Daniel Waldeck, Pacific Fishery Management Council, at 503-326-6352.

SUPPLEMENTARY INFORMATION: The Magnuson-Stevens Fishery Conservation and Management Act (Magnuson-Stevens Act) requires each regional fishery management council to submit any new FMP or FMP amendment to NMFS for review and approval, disapproval, or partial approval. The Magnuson-Stevens Act also requires that NMFS, upon receiving an FMP or FMP amendment, immediately publish a notification in the **Federal Register** that the FMP or amendment is available for public review and comment. At the end of the comment period, NMFS considers the public comments received during the comment period and determines whether to approve, disapprove, or partially approve the FMP or FMP amendment.

The 1996 Sustainable Fisheries Act requires FMPs prepared by any council, or the Secretary of Commerce, with respect to any fishery to establish a standardized reporting methodology to assess the amount and type of bycatch

occurring in the fishery, and include conservation and management measures, that to the extent practicable and in the following priority minimize bycatch; and minimize the mortality of bycatch that cannot be avoided. The Council sought to address the Magnuson-Stevens Act bycatch requirement in Amendment 8. However, NMFS disapproved the bycatch provisions in Amendment 8. Therefore, Amendment 9 was prepared by the Council to document bycatch in the CPS fishery, ensure that a standardized reporting methodology to assess the amount and type of bycatch exists, and propose any necessary conservation and management measures to minimize bycatch.

Amendment 9 would also establish a framework process similar to that used in the Pacific coast groundfish fishery to allocate CPS to Indian tribes according to the requirements of U.S. treaties should such allocations become necessary.

Public comments on Amendment 9 must be received by February 20, 2001, to be considered by NMFS in the decision whether to approve, disapprove, or partially approve Amendment 9. A proposed rule to implement Amendment 9 has been submitted for Secretarial review and approval. NMFS expects to publish and request public comment on the proposed regulation to implement Amendment 9 in the near future.

Authority: 16 U.S.C. 1801 *et seq.*

Dated: December 15, 2000.

Clarence Pautzke,

*Director, Office of Sustainable Fisheries,
National Marine Fisheries Service.*

[FR Doc. 00-32472 Filed 12-20-00; 8:45 am]

BILLING CODE: 3510-22-S

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.

ADVISORY COUNCIL ON HISTORIC PRESERVATION

Agreement Between the Advisory Council on Historic Preservation and the Narragansett Indian Tribe for the Assumption by the Narragansett Tribe of Certain Responsibilities Pursuant to the National Historic Preservation Act

AGENCY: Advisory Council on Historic Preservation.

ACTION: Notice of execution of agreement with the Narragansett Indian Tribe.

Authority: 16 U.S.C. 470a(d)(5).

SUMMARY: The Advisory Council on Historic Preservation is publishing the agreement executed with the Narragansett Indian Tribe through which the Tribe assumes certain responsibilities pursuant to the National Historic Preservation Act, including the review of federal undertakings under their own, tribal historic preservation regulations instead of under the regulations promulgated by the Advisory Council.

DATES: The agreement became effective on November 27, 2000.

FOR FURTHER INFORMATION CONTACT: If you have questions about the agreement, please contact Valerie Hauser, Native American Program Coordinator, Advisory Council on Historic Preservation, 1100 Pennsylvania Avenue, NW., Suite 809, Washington, DC 20004. (202) 606-8505. The agreement and tribal procedures will be posted on our web site at <http://www.achp.gov>.

SUPPLEMENTARY INFORMATION: Section 101(d)(5) of the National Historic Preservation Act of 1966, as amended, provides that the Advisory Council may enter into an agreement with an Indian tribe to permit undertakings on tribal land to be reviewed under tribal historic preservation regulations in place of review under regulations promulgated by the

Council to govern compliance with section 106, if the Council, after consultation with the tribe and appropriate State Historic Preservation Officers, determines that the tribal preservation regulations will afford historic properties consideration equivalent to those afforded by the Council's regulations.

16 U.S.C. 470a(d)(5). Section 106 requires Federal agencies to take into account the effect of their undertakings on properties included in or eligible for inclusion in the National Register of Historic Places and to afford the Council a reasonable opportunity to comment on such undertakings.

In accordance with the provisions of section 101(d)(5), the Advisory Council and the Narragansett Indian Tribe entered into the agreement titled "Agreement between the Advisory Council on Historic Preservation and the Narragansett Indian Tribe Pursuant to section 101(d)(5) of the National Historic Preservation Act" ("Agreement"). Through it, the Narragansett Indian Tribe takes charge of the section 106 historic preservation review of federal undertakings that affect historic properties located on their tribal land, and subjects such review to the provisions of the Narragansett Indian Tribe's Procedures and Rules for the Registration and Protection of Tribal Properties, January 7, 1999 ("tribal regulations").

After negotiating and developing a draft agreement, on January 27, 1999 the Advisory Council published in the **Federal Register** a notice of intent to execute the Agreement with the Narragansett Indian Tribe for the Tribe to assume certain responsibilities pursuant to the National Historic Preservation Act (64 FR 4067). The notice invited public comment on the agreement and tribal historic preservation regulations by February 26, 1999. The Council also directly mailed a copy of the notice, along with the agreement and tribal regulations, to all Federal Preservation Officers and the State Historic Preservation Officers of Rhode Island, Connecticut and Massachusetts. The Council received approximately 12 comments on the proposed agreement and tribal regulations.

Generally, commenters supported the overall objective of the agreement for the Tribe's assumption of section 106 review responsibilities on their tribal lands. However, strong objections were

raised regarding a provision for the application, by mutual consent of the Tribe, the State Historic Preservation Officer and the Federal agency, of the agreement and tribal historic preservation regulations to Federal undertakings off tribal lands but within the Tribe's ancestral homelands. It was argued that the statute limited the substitution to tribal lands. Other comments also expressed concerns regarding overlapping ancestral lands of different tribes.

Additionally, concerns were raised regarding the absence of a role for the Keeper of the National Register when there is a dispute about a property's eligibility for listing in the National Register of Historic Places. Finally, concerns were raised over the use and definition of the term "tribal lands."

In response to these concerns, the Council and the Narragansett Indian Tribe revised the agreement and deleted the provision for substitution of the tribal historic preservation regulations for the Council's regulations off tribal lands. A role for the Keeper of the National Register was added to the agreement when there is a dispute regarding eligibility of a property for listing in the National Register of Historic Places.

However, the term "tribal lands" and its statutory definition were retained in the agreement. The National Historic Preservation Act authorizes the Council to enter into such agreements for substitution of the Council's regulations on tribal lands. Tribal lands are defined in the National Historic Preservation Act as "all lands within the exterior boundaries of any Indian reservation and all dependent Indian communities." 16 U.S.C. 470w(14). The Council is bound by statute to apply this term and its definition. Further clarification of the boundaries of an Indian reservation or of the meaning of "tribal lands" may be sought from the Department of Interior, Bureau of Indian Affairs.

The Advisory Council and Narragansett Indian Tribe also added clarifications to the Agreement including statements that (1) this is an agreement between two sovereign governments; (2) the reservation has been surveyed for historic properties; (3) the provisions of Section 101(d)(2) of the National Historic Preservation Act apply; (4) the Tribe agrees to provide

equivalent consideration to historic properties that are not of importance in Tribal history; and, (5) that Federal agencies have an affirmative responsibility to involve other consulting parties in the review process. The agreement also clarifies that a consulting party that raises an objection has the option of pursuing tribal administrative and judicial remedies, but that Federal agencies must also seek the Advisory Council's comments when there is a failure to agree.

At its business meeting on November 17, 2000, the Advisory Council approved the Agreement by a unanimous vote of 18 to 0, with two abstentions. The Agreement was thereafter signed by the Tribal Historic Preservation Officer of the Narragansett Indian Tribe on November 24, 2000, and by the Executive Director of the Advisory Council on November 27, 2000.

The Advisory Council has sent copies of the Agreement and tribal regulations to all Federal Preservation Officers, and the Rhode Island State Historic Preservation Officer.

The Agreement is reproduced below. You may obtain copies of the tribal regulations by contacting Valerie Hauser, Native American Program Coordinator, Advisory Council on Historic Preservation, 1100 Pennsylvania Avenue, Suite 809, Washington, DC 20004. (202) 606-8503.

Agreement Between the Advisory Council on Historic Preservation and the Narragansett Indian Tribe Pursuant to Section 101(d)(5) of the National Historic Preservation Act (16 U.S.C. 470)

Whereas, the Narragansett Indian Tribe is a sovereign nation recognized and acknowledged under treaties and laws of the United States; and,

Whereas, this agreement is executed between two sovereign governments, the government of the Narragansett Indian Tribe, acting by and through the Narragansett Indian Tribal Historic Preservation Office, and the United States, acting by and through the Advisory Council on Historic Preservation; and,

Whereas, the Narragansett Indian Tribe is uniquely suited to insure the integrity of historic properties on their tribal lands; and,

Whereas, enhancing the role of Indian Tribes in the national historic preservation partnership will result in a stronger and better national effort to identify and protect historic and cultural resources for future generations; and,

Whereas, Section 101(d)(5) of the NHPA provides that the Advisory Council on Historic Preservation (hereinafter the Council or Council) may enter into agreement with an Indian Tribe to permit undertakings on tribal lands to be reviewed under tribal historic preservation regulations in place of review under regulations promulgated by the Council, "Protection of Historic Properties" (36 CFR Part 800); and,

Whereas, for the purposes of this Assumption of Responsibilities Agreement (hereinafter Agreement), tribal lands, as defined by section 301(14) of the NHPA, means all lands within the exterior boundaries of the Narragansett Indian Reservation and all dependent Indian communities; and,

Whereas, the Narragansett Indian Tribe has assumed those functions of the State Historic Preservation Officer (hereinafter SHPO) with respect to its tribal lands under section 101(d)(2) of the NHPA; and,

Whereas, in accordance with section 101(d)(2)(B) of the NHPA, the Narragansett Indian Tribe has designated a tribal preservation official to serve as Tribal Historic Preservation Officer (hereinafter THPO) and to administer the tribal historic preservation program; and,

Whereas, in accordance with section 101(d)(2)(C) of the NHPA, the Tribe has provided to the Secretary of the Interior the Narragansett Indian Tribe's plan that describes how the tribal preservation official's function will be carried out; and,

Whereas, Narragansett tribal lands have been surveyed and historic properties have been identified and evaluated pursuant to the Tribal and National Registers; and,

Whereas, the Council has the unique responsibility under section 101(d)(5) of the NHPA to review proposed substitute regulations and to ensure that they afford historic properties equivalent consideration to that provided under the Council's regulations; and,

Whereas, the Council has consulted with the Rhode Island SHPO in the development of this agreement as required by section 101(d)(5) of the NHPA; and,

Whereas, the Council has determined that the Narragansett Indian Tribe's Procedures and Rules for the Registration and Protection of Tribal Properties, January 7, 1999 (hereinafter Tribal Historic Preservation Regulations), along with the Stipulations of this Agreement, will afford historic properties consideration equivalent to those afforded by the Council's regulations; and

Whereas, the Council urges the Narragansett THPO, the applicable SHPOs and Federal agencies to work in partnership to identify and protect historic properties of significance to the Narragansett Indian Tribes that are not located on tribal lands, and that they do so in a manner respectful of Narragansett traditional cultural practices and their special knowledge of their history; now, therefore,

The Advisory Council on Historic Preservation and the Narragansett Indian Tribe Do Hereby Agree as Follows:

1. The Narragansett Indian Tribe assumes responsibility pursuant to section 101(d)(5) of the NHPA for reviewing undertakings on Narragansett tribal lands, as defined by section 301(14) of the NHPA, under its Tribal Historic Preservation Regulations in place of review under regulations promulgated by the Council to govern compliance with section 106 of the NHPA (36 CFR Part 800).

2. The provisions of section 101(d)(2)(D)(iii) of the NHPA apply.

3. Nothing in this agreement is meant to abridge the rights and authority afforded the Narragansett Indian Tribe under other authorities.

4. If, after exhausting the Tribal Historic Preservation Regulations, there remains a dispute among consulting parties as to the National Register eligibility of a historic property, the Federal agency shall seek a determination of eligibility from the Keeper of the National Register.

5. The Narragansett Indian Tribe agrees to afford equivalent review and consideration to historic properties on tribal lands that are eligible for the National Historic Register whether they are or are not of significance to the Tribe. The Narragansett Indian Tribe may turn to other parties, including the relevant SHPO to assist in reviewing and protecting properties of no significance to the Tribe.

6. In carrying out the requirements of the Tribal Historic Preservation Regulations, Federal Agencies shall involve consulting parties, as defined in 36 CFR Part 800, in findings and determinations and, where appropriate, provide notification to the public.

7. In the event that questions are raised by a consulting party regarding the interpretation of the Tribal Historic Preservation Regulations, the consulting party raising the objection shall exhaust all tribal administrative and judicial remedies. If, after pursuing a resolution through tribal administrative and judicial procedures the matter cannot be resolved, the matter may be brought for

de novo review before the Federal district court.

8. In the event that consultation between the Federal agency and the THPO ends in a failure to agree, the Federal agency shall, in addition to meeting any other the obligations arising from its government-to-government relationship with the Tribe, seek the comments of the Council pursuant to section 800.7 of the Council's regulations.

9. The Narragansett Indian Tribe, acting by and through the THPO, may terminate this Agreement for any reason by providing the Council sixty days written notice of such termination. The Council may terminate this Agreement upon determining that the Narragansett Indian Tribe has not carried out its responsibilities in accordance with the Agreement, the NHPA, or any other applicable federal statute or regulation. Upon termination, Federal agencies shall again follow the Council's regulations governing compliance with section 106 of the NHPA, as codified at 36 CFR Part 800, for undertakings carried out on the tribal lands of the Narragansett Indian Tribe.

10. This Agreement may be amended by the mutual consent of the Narragansett Indian Tribe, acting by and through the THPO, and the Council.

11. This Agreement shall become effective upon signature by the Executive Director of the Council or his designee, whose signature shall not occur until after the THPO of the Narragansett Indian Tribe has signed the Agreement. (Signature lines and dates of the Agreement are omitted.)

Dated: December 18, 2000.

John M. Fowler,
Executive Director.

[FR Doc. 00-32577 Filed 12-20-00; 8:45 am]

BILLING CODE 4310-10-P

DEPARTMENT OF AGRICULTURE

Forest Service

Gold/Boulder/Sullivan; Kootenai National Forest, Lincoln County, Montana

AGENCY: Forest Service, USDA.

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

SUMMARY: The USDA—Forest Service will prepare an Environmental Impact Statement (EIS) for the Gold/Boulder/Sullivan Project to disclose the effects of vegetative management using timber harvest and prescribed fire, and road management including road reconstruction, temporary construction,

and decommissioning. The Gold/Boulder/Sullivan Decision Area encompasses the Gold Creek, Boulder Creek, and Sullivan Creek drainages, approximately 12 miles southwest of Eureka, Montana.

Wildfire suppression policies over the past 80 years have resulted in vegetative conditions in low elevation stands which include higher-than-normal tree densities and fuels levels. These increase the risk of insect and disease infestations and stand replacement wildfire. Three wildfires occurred in the Decision Area during August 2000, resulting in significant tree mortality and contributing to increased fuel loads.

The proposed activities are considered together because they represent either connected or cumulative actions as defined by the Council on Environmental Quality (40 CFR 1508.23). The purpose and need for action is to achieve desirable and sustainable conditions in forest stands, reduce fuels, improve big game winter range conditions, contribute to natural recovery processes to reduce impacts to soil and water resources, maintain and enhance scenic quality, and provide goods and services.

The EIS will tier to the Kootenai National Forest Land and Resource Management Plan, as amended, and the Final Environmental Impact Statement and Record of Decision of September 1987, which provides overall guidance for forest management of the area.

DATES: Written comments and suggestions should be received on or before January 22, 2001.

ADDRESSES: The Responsible Official is Bob Castenada, the Kootenai National Forest Supervisor, 1101 U.S. Highway 2 West, Libby, MT 59923. Written comments and suggestions concerning the scope of the analysis should be sent to Glen M. McNitt, District Ranger, Rexford Ranger District, 1299 U.S. Highway 93 N, Eureka, MT 59917.

FOR FURTHER INFORMATION CONTACT: Contact Ron Komac, Acting NEPA Coordinator, Rexford Ranger District, Phone: (406) 296-2536.

SUPPLEMENTARY INFORMATION: The Decision Area contains approximately 40,100 acres, and has a favorable climate and good site conditions for forest vegetation. Proposed activities within the Decision Area include portions of the following areas: T34-36N; R28-30W.

Average annual precipitation ranges from 14 to 100 inches. At higher elevations, most precipitation falls as snow. The Decision Area contains a combination of open-grown ponderosa pine and Douglas-fir in the lower

elevations, adjacent to Lake Koocanusa. Upland areas contain multistoried western larch/Douglas-fir intermixed with lodgepole pine, as well as uniform lodgepole pine stands.

Wildfire historically played a role in interrupting forest succession and creating much of the vegetative diversity that is apparent on the landscape today. Since the early 1900's, a policy of wildfire suppression has been in place on National Forest lands, interrupting the natural vegetation cycle. Stands of tress in the lower elevations of the Decision Area have a higher stocking level than occurred naturally, and are dominated by Douglas-fir, which is susceptible to bark beetles and root disease when stressed. Lodgepole pine stands in the upper elevations have experienced a high level of mortality due to mountain pine beetles, and are not contributing toward a desired condition of forest health.

A portion of the Decision Area is highly visible from the Tobacco Valley as well as the Scenic Byways (State Highway 37 and Forest Development Road #228). A portion of the Mount Henry Inventoried Roadless Area is included within the Decision Area. There are no treatments proposed for this area.

The Kootenai National Forest Land and Resource Management Plan provides overall management objectives in individually delineated management areas (MAs). Most of the proposed timber harvest activities encompass five MAs: 11, 12, 15, 16, and 17. Briefly described, MA 11 is managed to maintain or enhance the winter range habitat effectiveness for big game species and produce a programmed yield of timber. MA 12 is managed to maintain or enhance the summer range habitat effectiveness for big game species and produce a programmed yield of timber. MA 15 focuses upon timber production using various silvicultural practices while providing for other resource values. MA 16 is managed to produce timber while providing for a pleasing view. MA 17 is managed to maintain or enhance a natural appearing landscape and produce a programmed yield of timber. Minor amounts of timber harvest and/or other proposed activities such as prescribed burning are found in other MAs including 2 (semi-primitive non-motorized recreation); 5 (viewing areas); 10 (big game winter range); 13 (old growth), and 21 (research natural area).

Purpose and Need: The purpose and need for the project is to: (1) Achieve desirable and sustainable conditions in forest stands by reducing stand densities, maintaining and enhancing

desirable species composition, structure, and size, and reducing the risk of insect and disease epidemics; (2) reduce natural fuel accumulations in lower-to-mid elevation stands, and expected fuel loads in stands impacted by the wildfires of 2000, to contribute to increased firefighter safety and help protect forest users and forest resources; (3) improve big game winter range conditions by rejuvenating forage species; (4) contribute to natural recovery processes in order to reduce impacts to soil and water resources; (5) maintain and enhance visual quality by reducing line and form and emulating naturally appearing patterns on the landscape; and (6) respond to the social and economic desires of the surrounding communities by providing a range of products while maintaining a resilient, sustainable forest environment over time.

Proposed Activities: The Forest Service proposes to harvest approximately 70,700 CCF (hundred cubic feet), equivalent to approximately 28.9 MMBF (million board feet) of timber through the application of a variety of harvest methods on approximately 4,465 acres of forestland. Silvicultural systems include regeneration harvest (approximately 2,000 acres), improvement harvest (approximately 1,760 acres), salvage harvest (approximately 215 acres), removal of small diameter material (approximately 160 acres), and roadside salvage (approximately 330 acres). Some treatments would feather or thin stands adjacent to existing units with abrupt edges to improve the visual setting for outdoor recreation and viewing.

Removal of trees would be accomplished by a variety of methods including tractor, helicopter, and line skidding operations. Approximately 1 mile of temporary roads would be needed to access some units to be harvested with ground-based systems. These roads would be obliterated after timber sale activities are accomplished.

The proposed action would result in approximately seventeen additional openings over 40 acres, ranging from 46 to 203 acres. The sizes of approximately nine other large openings would be increased, ranging from 55 to 464 acres. A 60-day public review period, and approval of the Regional Forester for exceeding the 40 acre limitation for regeneration harvest, would be required prior to the signing of the Record of Decision. This 60-day period is initiated with this Notice of Intent.

The proposal also includes approximately 4,465 acres of prescribed burning in association with commercial timber harvest, and approximately 1,930

acres of prescribed burning without commercial timber harvest. Prescribed burning without timber harvest is proposed within MA 13 (designated old growth).

The proposal includes reconstructing approximately 120 miles of road in order to meet Best Management Practices requirements, and decommissioning approximately 21 miles of closed roads to restore natural drainage patterns.

Implementation of this proposal would require opening several miles of road currently restricted to public access. It is expected that public access would be allowed on a portion of these roads while management activities are occurring. Restrictions for motorized access would be restored following the conclusion of the management activities.

The proposed action includes precommercial thinning of sapling-sized trees on approximately 600 acres within managed plantations and natural stands that have regenerated after wildfire. Precommercial thinning would not occur in lynx habitat.

Forest Plan Amendments: The proposed action includes several project-specific Forest Plan amendments and a programmatic Forest Plan amendment necessary to meet the project's objectives:

A project-specific amendment to allow timber harvest in MA 2. A Forest Plan amendment would be needed to suspend Timber Standard #2 for this area. The standard states that timber harvest will not occur. Timber harvest would be used to reduce the visual effects of the fire by blending the affected area with the surrounding vegetation to achieve a more naturally appearing landscape.

A project-specific amendment to allow harvest adjacent to existing openings in up to 6 big game movement corridors in MA 12. A Forest Plan amendment would be needed to suspend Wildlife and Fish Standard #7 and Timber Standard #2 for this area. These standards state that movement corridors and adjacent hiding cover be retained. In this situation, high levels of mountain pine beetle activity have precluded alternative treatments. These opening sizes more closely correlate to natural disturbance patterns. Snags and down woody material would be left to provide wildlife habitat and maintain soil productivity.

A project-specific amendment to allow vegetation management in MA 21. A Forest Plan amendment would be needed to suspend Timber Standard #2 for the Big Creek area. The standard states that timber harvest will not occur.

The Cliff Point fire burned through the area in August 2000. Some light salvage would be needed for fuel reduction purposes. Any management proposals would be conducted with the full involvement of Forest Service Research.

A programmatic amendment to allow long-term MA 12 open road density to be managed at 1.1 miles/square mile, which exceeds the Facilities standard of 0.75 miles/square mile. The roads currently open access high-use recreation facilities or are important access routes for forest users and have been managed as open roads for several decades. There is a social need to maintain these roads as open to motorized access.

Range of Alternatives: 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 will be implemented. Additional alternatives will be considered to achieve the project's purpose and need for action, and to respond to specific resource issues and public concerns.

Preliminary Issues: Several issues of concern have been identified. These are briefly described below:

Transportation Systems: The Proposed Action includes approximately 21 miles of roads to be decommissioned. A portion of these roads may be permanently removed from the landscape, which may affect the public's ability to use traditional routes. All of these roads are currently restricted to motorized access.

Visual Resources: Implementation of the proposed action may alter the existing scenic resource within the Decision Area. Although the proposed action is designed to maintain and enhance the visuals of past harvest activities and recent wildfires, some members of the public may feel that it will have additional scenic impacts.

Wildlife: The proposed action could potentially reduce cavity habitat in snags and suitable hiding cover for wildlife security.

Management activities in a Research Natural Area (RNA): Typically, timber harvest is not permitted within a RNA. In this particular case, salvage is necessary to reduce fuels loads to aid in moving the area towards open grown stands of large ponderosa pine and western larch.

Decisions To Be Made: The Kootenai Forest Supervisor will decide the following:

- Whether or not to harvest timber and, if so, identify the selection of, and site-specific location of, appropriate timber management practices (silvicultural prescription, logging

system, fuels treatment, and reforestation), and road construction necessary to provide access and to achieve other resource objectives, and appropriate mitigation measures.

- Whether or not soil and water resource improvement projects (including road reconstruction and decommissioning) should be implemented and, if so, to what extent.
- Whether or not wildlife enhancement projects (including prescribed burning) should be implemented and, if so, to what extent.
- Whether road access restrictions or other actions are necessary to meet big game wildlife security needs.
- Whether or not programmatic and project-specific Forest Plan amendments are necessary to meet the specific purpose and need of this project, and whether those amendments are significant under the National Forest Management Act.
- What, if any, specific-project monitoring requirements would be needed to assure mitigation measures are implemented and effective.

Public Involvement and Scoping: In November 2000, preliminary efforts were made to involve the public in looking at management opportunities within the Gold/Boulder/Sullivan Decision Area. Comments received prior to this notice will be included in the documentation for the EIS. The public is encouraged to take part in the process and 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, Indian tribes, individuals, and organizations that may be interested in, or affected by, the proposed action. This input will be used in preparation of the draft and final EIS'. The scoping process will assist in identifying potential issues, identifying major issues to be analyzed in depth, identifying alternatives to the proposed action, and identifying potential environmental effects of this project and alternatives (i.e., direct, indirect, and cumulative effects and connected actions).

Estimated Dates for Filing: While public participation in this analysis is welcome at any time, comments received within 30 days of the publication of this notice will be especially useful in the preparation of the Draft EIS. It is expected to be filed with the Environmental Protection Agency (EPA) and to be available for public review by May 2001. At that time 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 publishes the Notice Availability in the **Federal Register**. It is very important that those interested in the management of this area participate at that time.

The final EIS is scheduled to be completed by August 2001. In the final EIS, the Forest Service is required to respond to comments and responses received during the comment period that pertain to the environmental consequences discussed in the draft EIS, and applicable laws, regulations, and policies considered in making a decision regarding the proposal.

Reviewer's Obligations: 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 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 comment period so that substantive comments and objections are made available to the Forest Service at a time when it can meaningfully consider and respond to them in the final EIS.

To be most helpful, comments on the draft EIS should be as specific as possible, and may address the adequacy of the statement or the merit of the alternatives discussed. Reviewers may wish to refer to the Council on Environmental Quality regulations (40 CFR 1503.3) for implementing the procedural provisions of the National Environmental Policy Act.

Responsible Official: As the Forest Supervisor of the Kootenai National Forest, 1101 U.S. Highway 2 West, Libby, MT 59923, I am the Responsible Official. As the Responsible Official, I will decide if the proposed project will be implemented. I will document the decision and reasons for the decision in the Record of Decision. I have delegated the responsibility for preparing the draft and final EIS' to Glen M. McNitt, District Ranger, Rexford Ranger District.

Dated: December 8, 2000.

Bob Castaneda,

Forest Supervisor, Kootenai National Forest.

[FR Doc. 00-32437 Filed 12-20-00; 8:45 am]

BILLING CODE 3410-11-M

DEPARTMENT OF AGRICULTURE

Rural Utilities Service

East Kentucky Power Cooperative; Notice of Availability of an Environmental Assessment

AGENCY: Rural Utilities Service, USDA.

ACTION: Notice of availability of an environmental assessment.

SUMMARY: Notice is hereby given that the Rural Utilities Service (RUS) is issuing an Environmental Assessment with respect to the potential environmental impacts related to the construction and operation of an 80 megawatt combustion turbine by East Kentucky Power Cooperative. RUS may provide financing assistance for the project.

FOR FURTHER INFORMATION CONTACT: Bob Quigel, Environmental Protection Specialist, RUS, Engineering and Environmental Staff, Stop 1571, 1400 Independence Avenue, SW., Washington, DC 20250-1571, telephone: (202) 720-0468. Bob's e-mail address is bquigel@rus.usda.gov. Information is also available from Jeff Hohman, Manager of Natural Resources, East Kentucky Power Cooperative, P.O. Box 707, Winchester, Kentucky 40392-0707, telephone (800) 238-3443.

SUPPLEMENTARY INFORMATION: The project consists of the construction and operation of 80 megawatt, simple cycle, combustion turbine at East Kentucky Power Cooperative's J.K. Smith Combustion Turbine Site. The J.K. Smith Combustion Turbine Site is located in Clark County, Kentucky, approximately 9 miles southeast of Winchester, Kentucky, on Kentucky Highway 89. There are currently three 80 megawatt, simple cycle, combustion turbines located at the site. A fourth unit will soon be under construction. This project will be the fifth combustion turbine to be constructed and operated at the site. There are adequate natural gas transmission facilities at the site to power this additional unit. A 12-mile, 138 kV electric transmission line will need to be constructed as part of the project to feed the electric power generated by the Unit 5 to East Kentucky Power Cooperative's existing transmission grid.

East Kentucky Power Cooperative prepared an environmental report

which describes the project further and discusses the environmental impacts of the proposed project. RUS has conducted an independent evaluation of the environmental report and believes that it accurately assesses the impacts of the proposed project. No adverse impacts are expected with the construction of the project. RUS has accepted the document as its Environmental Assessment and is making it available for public review.

The Environmental Assessment can be reviewed at the Clark County Public Library, 370 South Burns Avenue, Winchester, Kentucky, telephone (606) 744-5661, the headquarters of East Kentucky Power Cooperative, 4775 Lexington Road, Winchester, Kentucky, or the headquarters of RUS, at the address provided above.

Questions and comments should be sent to RUS at the address provided. RUS will accept questions and comments on the environmental assessment for at least 30 days from the date of publication of this notice.

Any final action by RUS related to the proposed project will be subject to, and contingent upon, compliance with all relevant Federal environmental laws and regulations and completion of environmental review procedures as prescribed by the Council on Environmental Quality Regulations and RUS Environmental Policies and Procedures (7 CFR part 1794).

Dated: December 14, 2000.

Lawrence R. Wolfe,

Acting Director, Engineering and Environmental Staff.

[FR Doc. 00-32493 Filed 12-20-00; 8:45 am]

BILLING CODE 3410-15-P

COMMISSION ON CIVIL RIGHTS

Amended Notice of Public Meeting of the Arkansas Advisory Committee

Notice is hereby given, pursuant to the provisions of the rules and regulations of the U.S. Commission on Civil Rights, that a meeting of the Arkansas Advisory Committee to the Commission which was to have convened at 6 p.m. and adjourned at 8 p.m. on November 15, 2000, has been rescheduled. The meeting will convene at 6 p.m. and adjourn at 8 p.m. on January 18, 2001, at the Doubletree Hotel, 424 West Markham, Little Rock, Arkansas 72201. The purpose of the meeting is to plan future projects. The notice published in the **Federal Register** on October 26, 2000, FR Doc. 00-27458, Vol. 65, No. 208, p. 64202.

Persons desiring additional information, or planning a presentation

to the Committee, should contact Melvin L. Jenkins, Director of the Central Regional Office, 913-551-1400 (TDD 913-551-1414). Hearing-impaired persons who will attend the meeting and require the services of a sign language interpreter should contact the Regional Office at least ten (10) working days before the scheduled date of the meeting.

The meeting will be conducted pursuant to the provisions of the rules and regulations of the Commission.

Dated at Washington, DC, December 14, 2000.

Edward A. Hailes, Jr.,

Acting General Counsel.

[FR Doc. 00-32470 Filed 12-20-00; 8:45 am]

BILLING CODE 6335-01-P

DEPARTMENT OF COMMERCE

Bureau of the Census

[Docket No. 001207345-0345-01]

Service Annual Survey

AGENCY: Bureau of the Census, Commerce.

ACTION: Notice of determination

SUMMARY: In accordance with title 13, United States Code (U.S.C.), sections 182, 224, and 225, the Bureau of the Census (U.S. Census Bureau) has determined that limited financial data (revenue, expenses, and the like) for selected service industries are needed to provide a sound statistical basis for the formation of policy by various governmental agencies, and that these data also apply to a variety of public and business needs. Selected service industries include professional, scientific, and technical services; administrative and support services; healthcare and social assistance; telecommunications, publishing, broadcasting, and other information service industries; transportation services; financial services; arts, entertainment, and recreation; and so forth. These data are not publicly available from nongovernment or other governmental sources.

FOR FURTHER INFORMATION CONTACT: Ruth A. Bramblett, Chief, Current Services Branch, Service Sector Statistics Division, on (301) 457-2766.

SUPPLEMENTARY INFORMATION: The U.S. Census Bureau conducts surveys necessary to furnish current data on subjects covered by the major censuses authorized by title 13, U.S.C. The Service Annual Survey provides continuing and timely national

statistical data for a period between the economic censuses. The next economic census is for the year 2002. Data collected in this survey are within the general scope, type, and character of those inquiries covered in the economic census.

The U.S. Census Bureau needs reports only from a limited sample of service sector firms in the United States. The probability of a firm's selection is based on its revenue size (estimated from payroll). We are mailing report forms to the firms covered by this survey and require their submission within thirty days after receipt.

Notwithstanding any other provision of law, no person is required to respond to, nor shall a person be subject to a penalty for failure to comply with, a collection of information subject to the requirements of the Paperwork Reduction Act (PRA) unless that collection of information displays a current valid Office of Management and Budget (OMB) control number. In accordance with the PRA, 44 U.S.C., Chapter 35, the OMB approved the survey under OMB Control Number 0607-0422. Copies of the proposed forms are available upon written request to the Director, U.S. Census Bureau, Washington, DC 20233.

Based upon the foregoing, I have directed that the Service Annual Survey be conducted for the purpose of collecting these data.

Dated: December 12, 2000.

Kenneth Prewitt,

Director, Bureau of the Census.

[FR Doc. 00-32448 Filed 12-20-00; 8:45 am]

BILLING CODE 3510-07-P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

National Sea Grant Review Panel; Meeting

ACTION: Notice of public meeting.

SUMMARY: This notice sets forth the schedule and proposed agenda of a forthcoming meeting of the Sea Grant Review Panel. The meeting will have several purposes. Panel members will discuss and provide advice on the National Sea Grant College Program in the areas of program evaluation, education and extension, science and technology programs, and other matters as described below:

DATES: The announced meeting is schedule during two days: Thursday, January 11, 8:30 a.m. to 5:15 p.m.;

Friday, January 12, 8:30 a.m. to 12:15 noon.

ADDRESSES: National Oceanic and Atmospheric Administration, Silver Spring Metro Center III, 1315 East-West Highway, Room 4527, Silver Spring, Maryland 20910.

FOR FURTHER INFORMATION CONTACT: Dr. Ronald C. Baird, Director, National Sea Grant College Program, National Oceanic and Atmospheric Administration, 1315 East-West Highway, Room 11716, Silver Spring, Maryland 20910, (301) 713-2448.

SUPPLEMENTARY INFORMATION: The Panel, which consists of a balanced representation from academia, industry, state government and citizens groups, was established in 1976 by Section 209 of the Sea Grant Improvement Act (Pub. L. 94-461, 33 U.S.C. 1128). The Panel advises the Secretary of Commerce and the Director of the National Sea Grant College Program with respect to operations under the Act, and such other matters as the Secretary refers to them for review and advice. The agenda for the meeting is as follows:

Thursday, January 11, 2001

8:30 a.m.—Welcoming and Opening Formalities
 8:45 a.m.—Executive Committee Report
 9:00 a.m.—State of Sea Grant Presentation
 9:20 a.m.—Sea Grant Association Presentation
 10:15 a.m.—Break
 10:30 a.m.—Sea Grant Review Panel Subcommittee Reports
 —Science & Technology Task Force Report
 —Membership Committee Report
 —Minority Serving Institutions Report
 11:00 a.m.—National Extension Review Report Presentation
 12:30 p.m.—Working Lunch
 2:00 p.m.—Transition/Sea Grant Retreat
 —NSGO Transition White Paper
 —Sea Grant Retreat 2000
 3:30 p.m.—Break
 3:45 p.m.—Sea Grant Week Update
 4:00 p.m.—Review of the National Sea Grant Office
 4:30 p.m.—Pending Panel Business
 5:15 p.m.—Adjourn

Friday, January 12, 2001

8:30 a.m.—Program Evaluation Discussion
 9:00 a.m.—NOAA and OAR Update
 9:30 a.m.—Congressional Update
 10:30 a.m.—Break
 10:45 a.m.—National Sea Grant Office Update
 11:45 a.m.—Sea Grant/John A. Knauss Marine Policy Fellow Program

12:15 p.m.—Wrap-up
 12:30 p.m.—Adjourn

This meeting will be open to the public.

David L. Evans,

Assistant Administrator, Office of Oceanic and Atmospheric Research.

[FR Doc. 00-32447 Filed 12-20-00; 8:45 am]

BILLING CODE 3510-KA-M

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

[I.D. 121800A]

New England Fishery Management Council; Public Meetings

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Notice of public meetings.

SUMMARY: The New England Fishery Management Council (Council) is scheduling a public meeting of its Research Steering Committee, Groundfish Oversight Committee and Scallop Oversight Committee Meeting in January 2001 to consider actions affecting New England fisheries in the exclusive economic zone (EEZ). Recommendations from these groups will be brought to the full Council for formal consideration and action, if appropriate.

DATES: The meetings will be held between Wednesday, January 10, 2001, and Monday, January 22, 2001. See **SUPPLEMENTARY INFORMATION** for specific dates and times.

ADDRESSES: The meetings will be held in Peabody and Danvers, MA. See **SUPPLEMENTARY INFORMATION** for specific locations.

Council Address: New England Fishery Management Council 50 Water Street, Mill 2, Newburyport, MA 01950, telephone (978) 465-0492.

FOR FURTHER INFORMATION CONTACT: Paul J. Howard, Executive Director, New England Fishery Management Council, telephone (978) 465-0492.

SUPPLEMENTARY INFORMATION:

Meeting Dates, Locations and Agendas

Wednesday, January 10, 2001, at 9:30 a.m. and Thursday, January 11, 2001, at 8:30 a.m.—Research Steering Committee Meeting

Location: Holiday Inn Peabody, One Newbury Street, Route 1, Peabody, MA 01960; telephone: (978) 535-4600.

Finalize priorities for Council review and for subsequent use in soliciting

fisheries research proposals in 2001. Review draft Request for Proposals to be used for fisheries research proposal solicitation.

Wednesday, January 17, 2001, at 9:30 a.m.—Groundfish Oversight Committee Meeting

Location: Sheraton Ferncroft, 50 Ferncroft Road, Danvers, MA 01923; telephone: (978) 777-2500.

The Groundfish Oversight Committee will continue its development of recommendations for management alternatives for Amendment 13 to the Northeast Multispecies Fishery Management Plan. This will include recommendations on rebuilding programs, measures to address capacity issues, and the four broad approaches to management that are under consideration (status quo, adjustments to the status quo, area management, and sector allocation). The Committee may also discuss changes to existing closed areas and measures to minimize, to the extent practicable, impacts on habitat. The Committees' recommendations will be reviewed by the Council at a future date. After approval by the Council, the proposed alternatives will be analyzed and a draft supplemental environmental impact statement and public hearing document prepared.

The Committee will also identify management alternatives for a framework adjustment to reduce discards of Gulf of Maine cod and ensure mortality objectives are met for Gulf of Maine cod. The initial meeting for this framework adjustment will be at the January 23-25 Council meeting. The final meeting will not be scheduled until after receipt of an updated Gulf of Maine cod assessment in summer, 2001.

Monday, January 22, 2001, at 9:30 a.m.—Scallop Oversight Committee Meeting

Location: Sheraton Ferncroft, 50 Ferncroft Road, Danvers, MA 01923; telephone: (978) 777-2500.

The Committee will discuss new strategies for developing management alternatives for Amendment 10 and develop recommendations for the final action in Framework Adjustment 14. The Committee will meet in a closed session to review advisory panel applications.

Although non-emergency issues not contained in this agenda may come before this Council for discussion, in accordance with the Magnuson-Stevens Fishery Conservation and Management Act, those issues may not be the subject of formal Council action during this meeting. Action will be restricted to those issues specifically listed in this notice and any issues arising after publication of this notice that require

emergency action under section 305(c) of the Magnuson-Stevens Fishery Conservation and Management Act, provided the public has been notified of the Council's intent to take final action to address the emergency.

Special Accommodations

This meeting is physically accessible to people with disabilities. Requests for sign language interpretation or other auxiliary aids should be directed to Paul J. Howard (see **ADDRESSES**) at least 5 days prior to the meeting date.

Dated: December 18, 2000.

Richard W. Surdi,

Acting Director, Office of Sustainable Fisheries, National Marine Fisheries Service.

[FR Doc. 00-32596 Filed 12-20-00; 8:45 am]

BILLING CODE: 3510-22-S

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

[I.D. 121500B]

North Pacific Management Council; Public Meetings

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Notice of public meetings.

SUMMARY: The North Pacific Fishery Management Council (NPFMC) will conduct public meetings on protection of deep sea corals off coastal Alaska.

DATES: The meeting dates are January 10, 2001, 7 p.m., Sitka, AK, and January 12, 2001, 12 noon, Yakutat, AK.

ADDRESSES: The meeting locations are: Sitka, AK-Northern Southeast Regional Aquaculture Association Office, 1308 Sawmill Creek Road, Sitka, AK.

Yakutat, AK-Alaska Native Brotherhood Hall, 220 Max Italio, Yakutat, AK.

Council address: North Pacific Fishery Management Council, 605 W. 4th Avenue, Suite 306, Anchorage, AK 99501-2252.

FOR FURTHER INFORMATION CONTACT: Cathy Coon, NPFMC, telephone (907) 271-2809.

SUPPLEMENTARY INFORMATION: These stakeholder meetings will address Habitat Areas of Particular Concern (HAPC) for the protection of deep-sea corals off coastal Alaska. The concept is to develop a comprehensive and iterative approach for future HAPC identification and habitat protection involving researchers, stakeholders, and management agencies. These meetings

are for an informal exchange of information between the public and management agencies.

Although non-emergency issues not contained in this notice may come before this Council for discussion, these issues may not be the subject of formal Council action during this meeting. Council action will be restricted to those issues specifically listed in this notice and any issues arising after publication of this notice that require emergency action under section 305(c) of the Magnuson-Stevens Fishery Conservation and Management Act, provided the public has been notified of the Council's intent to take final action to address the emergency.

Special Accommodations

These meetings are physically accessible to people with disabilities. Requests for sign language interpretation or other auxiliary aids should be directed to Helen Allen, telephone (907) 271-2809 at least 5 days prior to the meeting date.

Dated: December 15, 2000.

Richard W. Surdi

Acting Director, Office of Sustainable Fisheries, National Marine Fisheries Service.

[FR Doc. 00-32474 Filed 12-20-00; 8:45 am]

BILLING CODE: 3510-22 -S

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

[I.D. 121500F]

Endangered Species; Permits

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Receipt of request to modify permit 1093 for scientific research.

SUMMARY: Notice is hereby given of the following action regarding permits for takes of endangered or threatened species for the purposes of scientific research: the NMFS has received an application for modification of existing permit 1093, in due form, from the U.S. Geological Survey (USGS), California Cooperative Fishery Research Unit in Arcata, CA.

DATES: Comments or requests for a public hearing on any of the new applications or modification requests must be received at the appropriate address or fax number no later than 5 p.m. eastern standard time on January 22, 2001.

ADDRESSES: Written comments on any of the new applications or modification

requests should be sent to the appropriate office as indicated below. Comments may also be sent via fax to the number indicated for the application or modification request. Comments will not be accepted if submitted via e-mail or the Internet. The applications and related documents are available for review in the indicated office, by appointment:

Protected Species Division, NMFS, 777 Sonoma Avenue, Room 325, Santa Rosa, CA 95404-6528 (707-575-6053).

Documents may also be reviewed by appointment in the Office of Protected Resources, F/PR3, NMFS, 1315 East-West Highway, Silver Spring, MD 20910-3226 (301-713-1401).

FOR FURTHER INFORMATION CONTACT: Dan Logan, Protected Resources Division, Santa Rosa, CA (ph: 707-575-6053, fax: 707-578-3435, e-mail: Dan.Logan@noaa.gov).

SUPPLEMENTARY INFORMATION:

Authority

Issuance of permits and permit modifications, as required by the Endangered Species Act of 1973 (16 U.S.C. 1531-1543) (ESA), is based on a finding that such permits/modifications: (1) are applied for in good faith; (2) would not operate to the disadvantage of the listed species which are the subject of the permits; and (3) are consistent with the purposes and policies set forth in section 2 of the ESA. Authority to take listed species is subject to conditions set forth in the permits. Permits and modifications are issued in accordance with and are subject to the ESA and NMFS regulations governing listed fish and wildlife permits (50 CFR parts 222-226).

Those individuals requesting a hearing on an application listed in this notice should set out the specific reasons why a hearing on that application would be appropriate (see **ADDRESSES**). The holding of such hearing is at the discretion of the Assistant Administrator for Fisheries, NOAA. All statements and opinions contained in the permit action summaries are those of the applicant and do not necessarily reflect the views of NMFS.

Species Covered in This Notice

The following species and evolutionarily significant units (ESUs) are covered in this notice:

Fish

Coho salmon (*Oncorhynchus kisutch*): threatened Southern Oregon/Northern California Coasts.

Modification Requests Received

The USGS requests a modification to Permit 1093 under the authority of section 10 of the Endangered Species Act of 1973 (ESA) (16 U.S.C. 1531-1543) and the NMFS regulations governing ESA-listed fish and wildlife permits (50 CFR parts 217-227). Permit 1093 authorizes takes of adult and juvenile, threatened, SONCC coho salmon (*Oncorhynchus kisutch*) associated with defined fish population studies throughout the ESU. The ongoing study consists of five assessment tasks for which ESA-listed fish are taken: (1) Presence/absence, (2) population estimates, (3) spawner surveys, (4) genetic sampling, and (5) habitat quality evaluation. ESA-listed fish are observed or captured, anesthetized, handled, allowed to recover from the anesthetic, and released. Indirect mortalities are also authorized. Modification 11 would increase the authorized annual capture/handle take of adult SONCC coho salmon for the purpose of determining ocean survival rates, rates of straying by adults within the basin, and examine relationships between juvenile size and ocean survival of coho salmon within the SONCC ESU. These data are currently lacking for California. These data are expected to allow managers to make more informed decisions when implementing protective measures for the listed species and to benefit recovery planning for coho salmon in the northern California/southern Oregon ESU, as well as in other ESUs.

Dated: December 15, 2000.

Wanda L. Cain,

Chief, Endangered Species Division, Office of Protected Resources, National Marine Fisheries Service.

[FR Doc. 00-32597 Filed 12-20-00; 8:45 am]

BILLING CODE 3510-22-S

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

[I.D. 121100C]

Marine Mammals; File No. 995-1608

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Receipt of application.

SUMMARY: Notice is hereby given that Thomas Norris, SAIC, 3990 Old Town Avenue Suite 105A, San Diego, California 92110, has applied in due form for a permit to take mysticete whales (blue whale, *Balaenoptera*

musculus; fin whale, *Balaenoptera physalus*; Bryde's whale, *Balaenoptera edeni*; minke whale, *Balaenoptera acutorostrata*; humpback whale, *Megaptera novaeangliae*; gray whale, *Eschrichtius robustus*) for purposes of scientific research.

DATES: Written or telefaxed comments must be received on or before January 22, 2001.

ADDRESSES: The application and related documents are available for review upon written request or by appointment in the following office(s):

Permits and Documentation Division, Office of Protected Resources, NMFS, 1315 East-West Highway, Room 13130, Silver Spring, MD 20910 (301/713-2289);

Northwest Region, NMFS, 7600 Sand Point Way NE, BIN C15700, Bldg. 1, Seattle, WA 98115-0700; phone (206)526-6150; fax (206)526-6426; and

Southwest Region, NMFS, 501 West Ocean Blvd., Suite 4200, Long Beach, CA 90802-4213; phone (562)980-4001; fax (562)980-4018.

FOR FURTHER INFORMATION CONTACT: Jill Lewandowski or Simona Roberts, 301/713-2289.

SUPPLEMENTARY INFORMATION: The subject permit is requested under the authority of the Marine Mammal Protection Act of 1972, as amended (MMPA; 16 U.S.C. 1361 et seq.), the Regulations Governing the Taking and Importing of Marine Mammals (50 CFR part 216), the Endangered Species Act of 1973, as amended (ESA; 16 U.S.C. 1531 et seq.), the regulations governing the taking, importing, and exporting of endangered and threatened species (50 CFR 222-226).

The applicant proposes to tag and photograph for identification purposes mysticete whales (blue whale, *Balaenoptera musculus*; fin whale, *Balaenoptera physalus*; Bryde's whale, *Balaenoptera edeni*; minke whale, *Balaenoptera acutorostrata*; humpback whale, *Megaptera novaeangliae*; gray whale, *Eschrichtius robustus*) using Satellite-Linked ARGOS Transmitters (Sat-LAT) and a new Acoustic/Radio Tracking and data-Telemetry (ARTT) system. The ARTT system logs and acoustically telemeters underwater positions and environmental data to a tracking vessel where GPS integrated updates of animal positions and track histories are displayed with a PC. The Sat-LAT system will provide large scale, long-term information on the movement patterns of tagged whales, whereas the ARTT system will provide fine scale, short-term information for examining behavioral responses of mysticete whales to natural and anthropogenic

environmental stimuli. Both methods will provide data necessary to identify critical whale habitat, its variability in space and time, and the effects of anthropogenic activities (e.g. noise) relative to these habitat requirements.

In compliance with the National Environmental Policy Act of 1969 (42 U.S.C. 4321 et seq.), an initial determination has been made that the activity proposed is categorically excluded from the requirement to prepare an environmental assessment or environmental impact statement.

Written comments or requests for a public hearing on this application should be mailed to the Chief, Permits and Documentation Division, F/PR1, Office of Protected Resources, NMFS, 1315 East-West Highway, Room 13705, Silver Spring, MD 20910. Those individuals requesting a hearing should set forth the specific reasons why a hearing on this particular request would be appropriate.

Comments may also be submitted by facsimile at (301) 713-0376, provided the facsimile is confirmed by hard copy submitted by mail and postmarked no later than the closing date of the comment period. Please note that comments will not be accepted by e-mail or by other electronic media.

Concurrent with the publication of this notice in the **Federal Register**, NMFS is forwarding copies of this application to the Marine Mammal Commission and its Committee of Scientific Advisors.

Dated: December 15, 2000.

Ann D. Terbush,

Chief, Permits and Documentation Division, Office of Protected Resources, National Marine Fisheries Service.

[FR Doc. 00-32473 Filed 12-20-00; 8:45 am]

BILLING CODE: 3510-22-S

DEPARTMENT OF COMMERCE

United States Patent and Trademark Office

Submission for OMB Review; Comment Request

The United States Patent and Trademark Office (USPTO) has submitted to the Office of Management and Budget (OMB) for clearance the following proposal for collection of information under the provisions of the Paperwork Reduction Act (44 U.S.C. Chapter 35).

Agency: United States Patent and Trademark Office (USPTO).

Title: Legal Processes.

Form Numbers: None.

Agency Approval Number: 0651-00XX.

Type of Request: New Collection.
Burden: 28.2 hours.

Number of Respondents: 187 responses.

Avg. Hours Per Response: The USPTO estimates that it takes an average of 30 minutes to gather, prepare, and submit petitions to waive rules and requests, demands, or subpoenas for employee testimony or production of documents. It is also estimated to take 30 minutes to report unauthorized testimony and possible cases for indemnification to the Office of General Counsel. Additionally, the USPTO estimates that it takes an average of five minutes to ensure that a service of process has been properly served and ten minutes to ensure that the service of process or demands for employee testimony or documentation are forwarded to the proper authorities. Furthermore, it is estimated that it takes an average of one hour to request indemnification and to gather, prepare, and submit a claim under the Federal Tort Claims Act.

Needs and Uses: This collection of information supports a proposed rulemaking entitled "Legal Processes." This information collection covers the public and current and former USPTO employees. The USPTO believes that the number of responses received from both current and former employees will be very small. The number of responses from the public is also expected to be very small except for the service of process. In the case of service of process, the principal effect of the rule is to provide an address for service. There are no forms associated with any of the information requirements contained in this collection. The public and current or former USPTO employees use this information collection as appropriate to petition the General Counsel to either waive or suspend a rule; to forward or receive summons; to seek testimony or documentation; to request employee indemnification; to report unauthorized testimony or possible indemnification cases; and to file a claim under the Federal Tort Claims Act. The USPTO uses the collected information to ensure that the proper procedures have been followed. The USPTO also uses this information to ensure that the release of testimony or documentation is authorized; to review the demands and claims filed; to determine whether the legal process rules can be suspended; to grant indemnification; and to determine whether the agency should settle or deny a claim filed under the Federal Torts Claim Act.

Affected Public: Individuals or households, businesses or other for-profit, not-for-profit institutions, farms,

Federal government, and state, local or tribal government.

Frequency: On occasion.

Respondent's Obligation: Required to obtain or retain benefits.

OMB Desk Officer: David Rostker, (202) 395-3897.

Copies of the above information collection proposal can be obtained by calling or writing Susan Brown, Records Officer, Data Administration Division, Office of Data Management, United States Patent and Trademark Office, Crystal Park 3, 3rd Floor, Suite 310, Washington, DC, 20231, by phone at (703) 308-7400, or via the Internet at susan.brown@uspto.gov.

Written comments and recommendations for the proposed information collection should be sent within 30 days of publication to David Rostker, OMB Desk Officer, Room 10236, New Executive Office Building, 725 17th Street, NW., Washington, DC 20503.

Dated: December 11, 2000.

Susan K. Brown,

Records Officer, Data Administration Division, Office of Data Management.

[FR Doc. 00-32445 Filed 12-20-00; 8:45 am]

BILLING CODE 3510-16-P

DEPARTMENT OF EDUCATION

[CFDA No.: 84.250B]

Vocational Rehabilitation Service Projects for American Indians With Disabilities; Notice Inviting Applications for New Awards for Fiscal Year (FY) 2001

Purpose of Program: To provide vocational rehabilitation services to American Indians with disabilities who reside on or near Federal or State reservations, consistent with their individual strengths, resources, priorities, concerns, abilities, capabilities, and informed choices, so that they may prepare for and engage in gainful employment, including self-employment, telecommuting, or business ownership.

Eligible Applicants: Applications may be submitted only by the governing bodies of Indian tribes (and consortia of those governing bodies) located on Federal or State reservations.

Applications Available: December 21, 2000.

Deadline for Transmittal of Applications: June 21, 2001.

Estimated Available Funds: \$1,525,135.

The Administration has requested \$23,998,000 for this program for FY 2001. The actual level of funding, if any,

depends on final congressional action. However, we are inviting applications to allow enough time to complete the grant process before the end of the fiscal year, if Congress appropriates funds for this program.

Estimated Range of Awards:

\$250,000-\$350,000.

Estimated Average Size of Awards:

\$300,000.

Reasonable Accommodations: We will consider, and may fund, requests for additional funding as an addendum to an application to reflect the costs of reasonable accommodations necessary to allow individuals with disabilities to be employed on the project as personnel on project activities.

Estimated Number of Awards: 5.

Note: The Department is not bound by any estimates in this notice.

Project Period: Up to 60 months.

Applicable Regulations: (a) The Education Department General Administrative Regulations (EDGAR) in 34 CFR parts 75, 77, 80, 81, and 82; and (b) The regulations for this program in 34 CFR part 371.

Priority: Under section 121(b)(4) of the Rehabilitation Act of 1973, as amended, we give preference to applications that meet the following competitive priority. Under 34 CFR 74.105(c)(2)(i) we award 10 points to an application that meets this competitive priority. These points are in addition to any points the application earns under the selection criteria:

Competitive Preference Priority—Continuation of Previously Funded Tribal Programs: In making new awards under this program, we give priority consideration to applications for the continuation of tribal programs that have been funded under this program.

Selection Criteria: In evaluating an application for a new grant under this competition, we use selection criteria chosen from the general selection criteria in 34 CFR 75.210 of EDGAR. The selection criteria to be used for this competition will be provided in the application package for this competition.

For Applications Contact: Education Publications Center (ED Pubs), P.O. Box 1398, Jessup, MD 20794-1398. Telephone (toll free): 1-877-433-7827. FAX (301) 470-1244. If you use a telecommunications device for the deaf (TDD), you may call (toll free): 1-877-576-7734.

You may also contact ED Pubs at its Web site: <http://www.ed.gov/pubs/edpubs.html>

Or you may contact ED Pubs at its e-mail address: edpubs@inet.ed.gov

If you request an application from ED Pubs, be sure to identify this

competition as follows: CFDA number 84.250B.

Individuals with disabilities may obtain a copy of the application package in an alternative format by contacting the Grants and Contracts Services Team, U.S. Department of Education, 400 Maryland Avenue, SW., room 3317, Switzer Building, Washington, DC 20202-2550. Telephone: (202) 205-8351. If you use a telecommunications device for the deaf (TDD), you may call the Federal Information Relay Service (FIRS) at 1-800-877-8339. However, the Department is not able to reproduce in an alternative format the standard forms included in the application package.

FOR FURTHER INFORMATION CONTACT:

Pamela Martin or Suzanne Tillman, U.S. Department of Education, 400 Maryland Avenue, SW., room 3314, Switzer Building, Washington, DC 20202-2650. Telephone (202) 205-8494 or (202) 205-8303. If you use a telecommunications device for the deaf (TDD), you may call the Federal Information Relay Service (FIRS) at 1-800-877-8339.

Individuals with disabilities may obtain this document in an alternative format (*e.g.*, Braille, large print, audiotape, or computer diskette) on request to the contact persons listed in the preceding paragraph.

Electronic Access to This Document: You may view this document, as well as all other Department of Education documents published in the **Federal Register**, in text or Adobe Portable Document Format (PDF) on the Internet at either of the following sites:

<http://ocfo.ed.gov/fedreg.htm>

<http://www.ed.gov/news.html>

To use PDF you must have Adobe Acrobat Reader, which is available free at either of the previous sites. If you have questions about using PDF, call the U.S. Government Printing Office (GPO), toll free, at 1-888-293-6498; or in the Washington, DC, area at (202) 512-1530.

Note: The official version of this document is the document published in the **Federal Register**. Free Internet access to the official edition of the **Federal Register** and the Code of Federal Regulations is available on GPO Access at: <http://www.access.gpo.gov/nara/index.html>

Program Authority: 29 U.S.C. 773(b).

Dated: December 15, 2000.

Judith E. Heumann,

Assistant Secretary for Special Education and Rehabilitative Services.

[FR Doc. 00-32494 Filed 12-20-00; 8:45 am]

BILLING CODE 4000-01-U

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. ER01-644-000]

Allegheny Energy Service Corporation, on behalf of Monongahela Power Company, The Potomac Edison Company, and West Penn Power Company (Allegheny Power); Notice of Filing

December 15, 2000.

Take notice that on December 11, 2000, Allegheny Energy Service Corporation on behalf of Monongahela Power Company, The Potomac Edison Company and West Penn Power Company (Allegheny Power), filed Service Agreement No. 333 to add Allegheny Energy Supply Company, LLC to Allegheny Power's Open Access Transmission Service Tariff.

The proposed effective date under the agreement is January 1, 2001.

Copies of the filing have been provided to the Public Utilities Commission of Ohio, the Pennsylvania Public Utility Commission, the Maryland Public Service Commission, the Virginia State Corporation Commission, and the West Virginia Public Service Commission.

Any person desiring to be heard or to protest such filing should file a motion to intervene or protest with the Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426, in accordance with Rules 211 and 214 of the Commission's Rule of Practice and Procedure (18 CFR 385.211 and 385.214). All such motions and protests should be filed on or before January 2, 2001. Protests will be considered by the Commission to determine the appropriate action to be taken, but will not serve to make protestants parties to the proceedings. 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. This filing may also be viewed on the Internet at <http://www.ferc.fed.us/online/rims.htm> (call 202-208-2222 for assistance).

Comments and protests may be filed electronically via the internet in lieu of paper. See, 18 CFR 385.2001(a)(1)(iii) and the instructions on the Commission's web site at <http://www.ferc.fed.us/efi/doorbell.htm>.

David P. Boergers,
Secretary.

[FR Doc. 00-32538 Filed 12-20-00; 8:45 am]

BILLING CODE 6717-01-M

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. ER01-645-000]

Allegheny Energy Service Corporation, on behalf of Monongahela Power Company, The Potomac Edison Company, and West Penn Power Company (Allegheny Power); Notice of Filing

December 15, 2000.

Take notice that on December 11, 2000, Allegheny Energy Service Corporation on behalf of Monongahela Power Company, The Potomac Edison Company and West Penn Power Company (Allegheny Power), filed Service Agreement No. 332 to add FirstEnergy Services Corp. to Allegheny Power's Open Access Transmission Service Tariff.

The proposed effective date under the agreement is January 1, 2001.

Copies of the filing have been provided to the Public Utilities Commission of Ohio, the Pennsylvania Public Utility Commission, the Maryland Public Service Commission, the Virginia State Corporation Commission, and the West Virginia Public Service Commission.

Any person desiring to be heard or to protest such filing should file a motion to intervene or protest with the Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426, in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211 and 385.214). All such motions and protests should be filed on or before January 2, 2001. 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 proceedings. 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. This filing may also be viewed on the Internet at <http://www.ferc.fed.us/online/rims.htm> (call 202-208-2222 for assistance).

Comments and protests may be filed electronically via the internet in lieu of paper. See, 18 CFR 385.2001(a)(1)(iii) and the instructions on the Commission's web site at <http://www.ferc.fed.us/efi/doorbell.htm>.

David P. Boergers,
Secretary.

[FR Doc. 00-32539 Filed 12-20-00; 8:45 am]

BILLING CODE 6717-01-M

DEPARTMENT OF ENERGY**Federal Energy Regulatory Commission**

[Docket No. RT01-35-000]

Avista Corporation, The Bonneville Power Administration, Idaho Power Company, The Montana Power Company, Nevada Power Company, PacifiCorp, Portland General Electric Company, Puget Sound Energy, Inc., Sierra Pacific Power Company; Notice of Filing

December 15, 2000.

Take notice that on December 1, 2000, Avista Corporation, the Bonneville Power Administration, Idaho Power Company, The Montana Power Company, PacifiCorp, and Puget Sound Energy, Inc. (collectively, the Concurring Utilities) filed an "Amended Supplemental Compliance Filing and Request for Declaratory Order Pursuant to Order 2000" at the Federal Energy Regulatory Commission (Commission) under the Commission's Order 2000. This filing amends the "Supplemental Compliance Filing and Request for Declaratory Order Pursuant to Order 2000" submitted to the Commission by the Concurring Utilities, together with Nevada Power Company, Portland General Electric Company, and Sierra Pacific Power Company, on October 23, 2000 (the October 23 Compliance Filing). The filing includes amended versions of the Form of Transmission Operating Agreement and Form of Agreement to Suspend Provisions of Pre-Existing Transmission Agreements, which were submitted with the October 23 Compliance Filing. The filing also provides brief explanations for the agreements' amendments.

Any person desiring to be heard or to protest such filing should file a motion to intervene or protest with the Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426, in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211 and 385.214). All such motions and protests should be filed on or before January 16, 2001. Protests will be considered by the Commission to determine the appropriate action to be taken, but will not serve to make protestants parties to the proceedings. 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. This filing may also be viewed on the Internet at <http://www.ferc.fed.us/online/rims.htm> (call 202-208-2222 for assistance). Comments and protests may

be filed electronically via the internet in lieu of paper. See, 18 CFR 385.2001(a)(1)(iii) and the instructions on the Commission's web site at <http://www.ferc.fed.us/efi/doorbell.htm>.

David P. Boergers,
Secretary.

[FR Doc. 00-32533 Filed 12-20-00; 8:45 am]

BILLING CODE 6717-01-M

DEPARTMENT OF ENERGY**Federal Energy Regulatory Commission**

[Docket No. ER01-641-000]

Cinergy Services, Inc.; Notice of Filing

December 15, 2000.

Take notice that on December 11, 2000, Cinergy Services, Inc. submitted an Interconnection Agreement into, by and between Cinergy Services, Inc. (Cinergy) and Cogentrix Lawrence County, LLC (Cogentrix Lawrence County), which is dated November 6, 2000.

The Interconnection Agreement between the parties provides for the interconnection of a generation station with the transmission system of PSI Energy, Inc. (PSI), a Cinergy utility operating company, and further defines the continuing responsibilities and obligations of the parties with respect thereto.

Cinergy states that it has served a copy of its filing upon the Indiana Utility Regulatory Commission and Cogentrix Lawrence County.

Any person desiring to be heard or to protest such filing should file a motion to intervene or protests with the Federal Energy Regulatory Commission, 888 First Street, NE., Washington DC 20426, in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211 and 385.214). All such motions and protests should be filed on or before January 2, 2001. Protests will be considered by the Commission to determine the appropriate action to be taken, but will not serve to make protestants parties to the proceedings. 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. This filing may also be viewed on the Internet at <http://www.ferc.fed.us/online/rims.htm> (call 202-208-2222 for assistance). Comments and protests may be filed electronically via the internet in lieu of paper. See, 18 CFR 385.2001(a)(1)(iii) and the instructions

on the Commission's web site at <http://www.ferc.fed.us/efi/doorbell.htm>.

David P. Boergers,
Secretary.

[FR Doc. 00-32537 Filed 12-20-00; 8:45 am]

BILLING CODE 6717-01-M

DEPARTMENT OF ENERGY**Federal Energy Regulatory Commission**

[Docket No. ER01-642-000]

Cottonwood Energy Company LP; Notice of Filing

December 15, 2000.

Take notice that on December 11, 2000, Cottonwood Energy Company LP (Cottonwood) tendered for filing an application for waivers and blanket approvals under various regulations of the Commission and for an order accepting Cottonwood's Electric Rate Schedule FERC No. 1 to be effective on February 9, 2001.

Cottonwood intends to engage in electric power and energy transactions as a marketer and a broker. In transactions where Cottonwood sells electric energy, it proposes to make such sales on rates, terms and conditions to be mutually agreed to with the purchasing party. Cottonwood's proposed Rate Schedule also permits it to reassign transmission capacity.

Any person desiring to be heard or to protest such filing should file a motion to intervene or protest with the Federal Energy Regulatory Commission, 88 First Street, NE., Washington, DC 20426, in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211 and 385.214). All such motions and protests should be filed on or before January 2, 2001. Protests will be considered by the Commission to determine the appropriate action to be taken, but will not serve to make protestants parties to the proceedings. 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. This filing may also be viewed on the Internet at <http://www.ferc.fed.us/online/rims.htm> (call 202-208-2222 for assistance). Comments and protests may be filed electronically via the internet in lieu of paper. See, 18 CFR 385.2001(a)(1)(ii) and the instructions

on the Commission's web site at <http://www.ferc.fed.us/efi/doorbell.htm>.

David P. Boergers,
Secretary.

[FR Doc. 00-32536 Filed 12-20-00; 8:45 am]

BILLING CODE 6717-01-M

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. ER01-202-000]

Potomac Power Resources, Inc.; Notice of Issuance of Order

December 15, 2000.

On October 23, 2000, Potomac Power Resources, Inc. (PPR) filed with the Commission a proposed tariff that covered, among other matters, the sale of wholesale power and ancillary services at market-based rates. In its filing, PPR also requested certain waivers and authorizations. In particular, PPR requested that the Commission grant blanket approval under 18 CFR Part 34 of all future issuances of securities and assumptions of liabilities by PPR. On December 13, 2000, the Commission issued an Order Accepting For Filing Proposed Market-Based Rate Tariff And Proposed Service Agreements And Granting Waiver Of The Code Of Conduct (Order), in the above-docketed proceeding.

The Commission's December 13, 2000 Order granted the request for blanket approval under Part 34, subject to the conditions found in Ordering Paragraphs (E), (F), and (H):

(E) Within 30 days of the date of issuance of this order, any person desiring to be heard or to protest the Commission's blanket approval of issuances of securities or assumptions of liabilities by PPR should file a motion to intervene or protest with the Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426, in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure, 18 CFR 385.211 and 385.214.

(F) Absent a request to be heard within the period set forth in Ordering Paragraph (E) above, PPR is hereby authorized to issue securities and assume obligations and liabilities as guarantor, indorser, surety or otherwise in respect of any security of another person; provided that such issue or assumption is for some lawful object within the corporate purposes of PPR, compatible with the public interest, and reasonably necessary or appropriate for such purposes.

(H) The Commission reserves the right to modify this order to require a further showing that neither public nor private interests will be adversely affected by continued Commission approval of PPR's issuances of securities or assumptions of liabilities * * *.

Notice is hereby given that the deadline for filing motions to intervene or protests, as set forth above, is January 16, 2001.

Copies of the full text of the Order are available from the Commission's Public Reference Branch, 888 First Street, NW., Washington, DC 20426. The Order may also be viewed on the Internet at <http://www.ferc.fed.us/online/rims.htm> (call 202-208-2222 for assistance).

David P. Boergers,
Secretary.

[FR Doc. 00-32532 Filed 12-20-00; 8:45 am]

BILLING CODE 6717-01-M

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. ER01-643-000]

PSEG Power New York Inc.; Notice of Filing

December 15, 2000.

Take notice that on December 11, 2000, PSEG Power New York Inc. (PSEG Power New York) tendered for filing pursuant to section 205 of the Federal Power Act (FPA), 16 U.S.C. 824d (1994), and Part 35 of the Federal Energy Regulatory Commission's (Commission) Regulations, 18 CFR part 35, an application for waiver of certain filing requirements associated with the production of electric capacity, energy and ancillary services generated at the Albany Steam Station by PSEG Power New York.

Any person desiring to be heard or to protest such filing should file a motion to intervene or protest with the Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426, in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211 and 385.214). All such motions and protests should be filed on or before January 2, 2001. Protests will be considered by the Commission to determine the appropriate action to be taken, but will not serve to make protestants parties to the proceedings. 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. This filing may also be viewed on the

Internet at <http://www.ferc.fed.us/online/rims.htm> (call 202-208-2222 for assistance). Comments and protests may be filed electronically via the internet in lieu of paper. See, 18 CFR 385.2001(a)(1)(iii) and the instructions on the Commission's web site at <http://www.ferc.fed.us/efi/doorbell.htm>.

David P. Boergers,
Secretary.

[FR Doc. 00-32535 Filed 12-20-00; 8:45 am]

BILLING CODE 6717-01-M

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. EG01-48-000, et al.]

Southern Energy Chalk Point, LLC, et al.; Electric Rate and Corporate Regulation Filings

December 14, 2000.

Take notice that the following filings have been made with the Commission:

1. Southern Energy Chalk Point, LLC

[Docket No. EG01-48-000]

Take notice that on December 11, 2000, Southern Energy Chalk Point, LLC, 1155 Perimeter Center West, Suite 130, Atlanta, Georgia 30338 (SECP), filed with the Federal Energy Regulatory Commission an application for determination of exempt wholesale generator status pursuant to Part 365 of the Commission's regulations.

SECP is a Delaware limited liability company that intends to acquire a direct 100 percent ownership interest in the four (4) baseload steam units at the Chalk Point Generating Station located in Prince George's County, Maryland (the "Chalk Point Station"). The Chalk Point Station has an aggregate generating capacity of approximately 1907 MW. SECP is engaged directly and exclusively in the business of owning or operating, or both owning and operating, all or part of one or more eligible facilities and selling electric energy at wholesale. SECP may also sell certain ancillary services consistent with its EWG status.

Comment date: January 8, 2001, in accordance with Standard Paragraph E at the end of this notice. The Commission will limit its consideration of comments to those that concern the adequacy or accuracy of the application.

2. Southern Energy Mid-Atlantic, LLC

[Docket No. EG01-49-000]

Take notice that on December 11, 2000, Southern Energy Mid-Atlantic, LLC, 900 Ashwood Parkway, Suite 500,

Atlanta, Georgia 30338 (SEMA), filed with the Federal Energy Regulatory Commission an application for determination of exempt wholesale generator status pursuant to Part 365 of the Commission's regulations.

SEMA is a Delaware limited liability company that intends to acquire a direct 100 percent ownership interest in Units 1 through 3 located at the Dickerson Station located in Montgomery County, Maryland (the Dickerson Station). SEMA also intend to acquire a direct 100 percent ownership interest in Units 1 through 6 at the Morgantown Station located in Charles County, Maryland (the Morgantown Station). Units 1 through 3 at the Dickerson Station have an aggregate generating capacity of approximately 291 MW, and approximately 248 MW. SEMA will be engaged directly and exclusively in the business of owning or operating, or both owning and operating, all or part of one or more eligible facilities and selling electric energy at wholesale. SEMA may also sell certain ancillary services consistent with its EWG status.

Comment date: January 8, 2001, in accordance with Standard Paragraph E at the end of this notice. The Commission will limit its consideration of comments to those that concern the adequacy or accuracy of the application.

3. Southern Energy Peaker, LLC

[Docket No. EG01-50-000]

Take notice that on December 11, 2000, Southern Energy Peaker, LLC, 1155 Perimeter Center West, Suite 130, Atlanta, Georgia 30338 (SEP), filed with the Federal Energy Regulatory Commission an application for determination of exempt wholesale generator status pursuant to Part 365 of the Commission's regulations.

SEP is a Delaware limited liability company that intends to acquire a direct 100 percent ownership interest in the six (6) oil/gas-fired combustion turbines at the Chalk Point Generating Station located in Prince George's County, Maryland (the Chalk Point CTs). The Chalk Point CTs have an aggregate generating capacity of approximately 432 MW. SEP is engaged directly and exclusively in the business of owning or operating, or both owning and operating, all or part of one or more eligible facilities and selling electric energy at wholesale. SEP may also sell certain ancillary services consistent with its EWG status.

Comment date: January 8, 2001, in accordance with Standard Paragraph E at the end of this notice. The Commission will limit its consideration of comments to those that concern the adequacy or accuracy of the application.

4. Southern Energy Potomac River, LLC

[Docket No. EG01-51-000]

Take notice that on December 11, 2000, Southern Energy Potomac River, LLC, 1155 Perimeter Center West, Suite 130, Atlanta, Georgia 30338 (SEPR), filed with the Federal Energy Regulatory Commission an application for determination of exempt wholesale generator status pursuant to Part 365 of the Commission's regulations.

SEPR is a Delaware limited liability company that intends to acquire a direct 100 percent ownership interest in the Potomac River Generating Station located in the City of Alexandria, Virginia (the "Potomac River Station"). The Potomac River Station has an aggregate generating capacity of approximately 482 MW. SEPR is engaged directly and exclusively in the business of owning or operating, or both owning and operating, all or part of one or more eligible facilities and selling electric energy at wholesale. SEPR may also sell certain ancillary services consistent with its EWG status.

Comment date: January 8, 2001, in accordance with Standard Paragraph E at the end of this notice. The Commission will limit its consideration of comments to those that concern the adequacy or accuracy of the application.

5. Cinergy Services, Inc.

[Docket No. ER001-585-000]

Take notice that on December 15, 2000, Cinergy Services, Inc. (Cinergy), tendered for filing a Service Agreement under Cinergy's Resale, Assignment or Transfer of Transmission Rights and Ancillary Service Rights Tariff (the Tariff) entered into between Cinergy and Duke Power. This Service Agreement has been executed by both parties and is to replace the existing unexecuted Service Agreement.

Comment date: December 26, 2000, in accordance with Standard Paragraph E at the end of this notice.

6. Public Service Company of New Mexico

[Docket No. ER01-632-000]

Take notice that on December 8, 2000, Public Service Company of New Mexico (PNM), tendered for filing executed service agreements with The Legacy Energy Group, LLC (Legacy) under the term of PNM's Open Access Transmission Tariff (two agreements dated July 1, 2000, one for short-term firm point-to-point transmission service and one for non-firm point-to-point transmission service). PNM's filing is available for public inspection at its offices in Albuquerque, New Mexico.

Copies of the filing have been sent to Legacy and to the New Mexico Public Regulation Commission.

Comments date: December 29, 2000, in accordance with Standard Paragraph E at the end of this notice.

7. Allegheny Energy Service Corporation, on behalf of Allegheny Energy Supply Company, LLC

[Docket No. ER01-633-000]

Take notice that on December 8, 2000, Allegheny Energy Service Corporation on behalf of Allegheny Energy Supply Company, LLC (Allegheny Energy Supply) tendered for filing Second Revised Service Agreement No. 80 under the Market Rate Tariff to incorporate a Netting Agreement with Reliant Energy Services, Inc. into the tariff provisions.

Allegheny Energy Supply requests a waiver of notice requirements to make the Netting Agreement effective as of November 21, 2000 or such other date as ordered by the Commission.

Copies of the filing have been provided to the Public Utilities Commission of Ohio, the Pennsylvania Public Utility commission, the Maryland Public Service Commission, the Virginia State Corporation Commission, the West Virginia Public Service Commission, and all parties of record.

Comments date: December 29, 2000, in accordance with Standard Paragraph E at the end of this notice.

8. Northeast Utilities Service Company

[Docket No. ER01-634-000]

Take notice that on December 8, 2000, Northeast Utilities Service Company (NUSCO), tendered for filing a Service Agreement to provide Firm Point-To-Point Transmission Service Tariff No. 9.

NUSCO states that a copy of this filing has been mailed to NRG Power Marketing Inc.

NUSCO request that the Service Agreement become effective January 2, 2001.

Comments date: December 29, 2000, in accordance with Standard Paragraph E at the end of this notice.

9. Northeast Utilities Service Company

[Docket No. ER01-635-000]

Take notice that on December 8, 2000, Northeast Utilities Service Company (NUSCO), tendered for filing, Service Agreement to provide Non-Firm Point-To-Point Transmission Service to NRG Power Marketing Inc. under the NU System Companies' Open Access Transmission Service Tariff No. 9.

NUSCO states that a copy of this filing has been mailed to NRG Power Marketing Inc.

NUSCO request that the Service Agreement become effective January 2, 2001.

Comments date: December 29, 2000, in accordance with Standard Paragraph E at the end of this notice.

10. Ameren Energy Marketing Company

[Docket No. ER01-142-001]

Take notice that on December 11, 2000, Ameren Energy Marketing Company (AEM), tendered for filing an amended Master Power Purchase and Sale Agreement in the above-referenced docket.

Comments date: January 2, 2001, in accordance with Standard Paragraph E at the end of this notice.

11. Madison Gas and Electric Company

[Docket No. ER01-636-000]

Take notice that on December 8, 2000, Madison Gas and Electric Company (MGE), tendered for filing a service agreement under MGE's Market-Based Power Sales Tariff with Morgan Stanley.

MGE requests the agreement be effective on the date it was filed with the FERC.

Comments date: December 29, 2000, in accordance with Standard Paragraph E at the end of this notice.

12. Central Maine Power Company

[Docket No. ER01-637-000]

Take notice that on December 8, 2000, Central Maine Power Company (CMP) tendered for filing a service agreement for Non-Firm Point-to-Point Transmission service entered into with Duke Energy Trading and Marketing. Service will be provided pursuant to CMP's Open Access Transmission Tariff, designated rate schedule CMP—FERC Electric Tariff, Original Volume No. 3, as supplemented.

Comments date: December 29, 2000, in accordance with Standard Paragraph E at the end of this notice.

13. Bangor Hydro-Electric Company

[Docket No. ER01-638-000]

Take notice that on December 8, 2000, Bangor Hydro-Electric Company filed an executive service agreement for firm point-to-point transmission service with Beaver Wood Joint Venture.

Comments date: December 29, 2000, in accordance with Standard Paragraph E at the end of this notice.

14. Xcel Energy Operating Companies, Northern States Power Company, Northern States Power Company (Wisconsin)

[Docket No. ER01-639-000]

Take notice that on December 8, 2000, Northern States Power Company and Northern States Power Company

(Wisconsin) (jointly NSP), wholly-owned utility operating company subsidiaries of Xcel Energy Inc., tendered for filing a Network Integration Transmission Service Agreement and a Network Operating Agreement between NSP and Rice Like Utilities, a municipal utility. NSP proposes the Agreements be included in the Xcel Energy Operating Companies FERC Joint Open Access Transmission Tariff, Original Volume No. 2, as Service Agreement Nos. 178—NSP and 179—NSP, pursuant to Order No. 614.

NSP requests that the Commission accept the agreement effective January 1 2001, and requests waiver of the Commission's notice requirements as may be necessary for the agreements to be accepted for filing on the date requested.

Comments date: December 29, 2000, in accordance with Standard Paragraph E at the end of this notice.

Standard Paragraphs

E. Any person desiring to be heard or to protest such filing should file a motion to intervene or protest with the Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426, in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211 and 385.214). All such motions or protests should be filed on or before the comment date. 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 these filings are on file with the Commission and are available for public inspection. This filing may also be viewed on the Internet at <http://www.ferc.fed.us/online/rims.htm> (call 202-208-2222 for assistance).

David P. Boergers,
Secretary.

[FR Doc. 00-32469 Filed 12-20-00; 8:45 am]

BILLING CODE 6717-01-U

DEPARTMENT OF ENERGY

[Docket No. CP01-31-000]

Kern River Gas Transmission Company; Notice of Intent To Prepare an Environmental Assessment for the Proposed Kern River Expansion Project, and Request for Comments on Environmental Issues

December 15, 2000.

The staff of the Federal Energy Regulatory Commission (FERC or Commission) will prepare an

environmental assessment (EA) they will discuss the environmental impacts of the Kern River Expansion Project, involving construction and operation of facilities by Kern River Gas Transmission Company (Kern River) in Wyoming, Utah, and California.¹ These facilities would consist of about 49,500 horsepower (hp) of compression distributed among three new and one existing compressor stations. No new mainline pipeline construction or looping is proposed. This EA will be used by the Commission in its decision-making process to determine whether the project is in the public convenience and necessity.

If you are a landowner receiving this notice, you may be contacted by a pipeline company representative about the acquisition of an easement to construct, operate, and maintain the proposed facilities. The pipeline company would seek to negotiate a mutually acceptable government. However, if the project is approved by the Commission, that approval conveys with it the right of eminent domain. Therefore, if easement negotiations fail to produce an agreement, the pipeline company could initiate condemnation proceedings in accordance with state law.

A fact sheet prepared by the FERC entitled "An Interstate Natural Gas Facility On My Land? What Do I Need To Know?" was attached to the project notice Kern River provided to landowners. This fact sheet addresses a number of typically asked questions, including the use of eminent domain and how to participate in the Commission's proceeding. It is available for viewing on the FERC Internet website (www.ferc.fed.us)

Summary of the Proposed Project

Kern River wants to expand the capacity of its existing system which extends between the southwest corner of Wyoming and the San Joaquin Valley near Bakersfield in southern California. The expansion would enable Kern River to transport an additional 124,500 million British thermal units per day of natural gas for four shippers. At least 40 percent of this gas would be directed to the electric power generation market in southern California. To support the expansion, Kern River seeks authority to construct and operate:

- A new 15,000-hp turbine-driven centrifugal compressor station in Utah

¹ Kern River's application was filed with the Commission under Section 7(c) of the Natural Gas and Subpart A of Part 157 of the Commission's regulations.

County, Utah, to be co-located with Kern River's existing pig launching/receiving facilities² on a 27.8-acre site (the Elberta Compressor Station);

- A new 15,000-hp turbine-driven centrifugal compressor station in Washington County, Utah, on a 37.9-acre site (the Veyo Compressor Station);

- A new 6,500-hp electric motor-driven compressor station in San Bernardino County, California, to be co-located at the existing Daggett Interconnect Metering Facilities on a 27.-acre site (the Daggett Compressor Station); and

- An additional 13,000-hp compressor at its existing Muddy Creek Compressor Station in Lincoln County, Wyoming.

Kern River would also restage a compressor at its existing Fillmore Compressor Station in Millard County, Utah, and upgrade metering facilities at two existing meter stations in Lincoln County, Wyoming (the Opal Receipt Meter Station), and Kern County, California (the Wheeler Ridge Delivery Meter Station). The general location of the project facilities is shown in appendix 1.³

Ancillary facilities at each new compressor station would include a compressor building, a compressor control building, and an auxiliary building; station piping and valves; and an auxiliary electric generator. Additionally, the Veyo Compressor Station would include gas coolers, filter/separate equipment, a pig launcher/receiver, a 4.3-mile-long access road, and a 2.4-mile-long single wood pole power line. The Daggett Compressor Station would include filter/separate equipment and an electrical transformer (rather than an auxiliary electric generator).

Installation of an additional compressor at the Muddy Creek Compressor Station would necessitate an extension of the existing compressor building and installation of additional gas coolers. Kern River also proposes to sandblast and re-coat about 200 feet of the existing buried 36-inch-diameter compressor discharge piping within the station yard.

² A pipeline "pig" is a device used to internally clean or inspect the pipeline. A pig launcher/receiver is a surface facility where pigs are inserted or retrieved from the pipeline.

³ The appendices referenced in this notice are not being printed in the *Federal Register*. Copies are available on the Commission's website at the "RIMS" link or from the Commission's Public Reference and Files Maintenance Branch, 888 First Street, NE., Washington, DC 20426, or call (202) 208-1371. For instructions on connecting to RIMS refer to the last page of this notice. Copies of the appendices were sent to all those receiving this notice in the mail.

Land Requirements for Construction

Construction of the proposed facilities would require disturb about 136 acres of land. Following construction, about 86 acres would be maintained as new aboveground facility sites (including upgraded access to the new Veyo Compressor Station). The remaining 50 acres of land would be restored and allowed to revert to its former use.

The EA Process

The National Environmental Policy Act (NEPA) requires the Commission to take into account the environmental impacts that could result from an action whenever it considers the issuance of a Certificate of Public Convenience and Necessity. NEPA also requires us⁴ to discover and address concerns the public may have about proposals. We call this "scoping". The main goal of the scoping process is to focus the analysis in the EA on the important environmental issues. By this Notice of Intent, the Commission requests public comments on the scope of the issues it will address in the EA. All comments received are considered during the preparation of the EA. State and local government representatives are encouraged to notify their constituents of this proposed action and encourage them to comment on their areas of concern.

- geology and soils
- cultural resources
- vegetation and wildlife
- endangered and threatened species
- land use
- air quality and noise
- public safety

We will also evaluate possible alternatives to the proposed project or portions of the project, and make recommendations on how to lessen or avoid impacts on the various resource areas.

Our independent analysis of the issues will be in the EA. Depending on the comments received during the scoping process, the EA may be published and mailed to Federal, state, and local agencies, public interest groups, interested individuals, affected landowners, newspapers, libraries, and the Commission's official service list for this proceeding. A comment period will be allotted for review if the EA is published. We will consider all comments on the EA before we make our recommendations to the Commission.

To ensure your comments are considered, please carefully follow the

⁴ "We", and "our" refer to the environment staff of the Office of Energy Projects (OEP).

instructions in the public participation section beginning on page 5.

Currently Identified Environmental Issues

We have already identified the following issue that we think deserves attention, based on a preliminary review of the proposed facilities and the environmental information provided by Kern River. This preliminary issue list may be changed based on your comments and our analysis.

- Fifteen federally listed endangered or threatened species may occur in the proposed project area.

Public Participation

You can make a difference by providing us with your specific comments or concerns about the project. By becoming a commentor, your concerns will be addressed in the EA and considered by the Commission. You should focus on the potential environmental effects of the proposal, alternatives to the proposal (including alternative compressor station locations and/or access routes), and measures to avoid or lessen environmental impact. The more specific your comments, the more useful they will be. Please carefully follow these instructions to ensure that your comments are received in time and properly recorded:

- Send an original and two copies of your letter to: David P. Boergers, Secretary, Federal Energy Regulatory Commission, 888 First Street, NE, Room 1A, Washington, DC 20426.
- Label one copy of the comments for the attention of Gas 1.
- Reference Docket No. CP01-31-000.
- Mail your comments so that they will be received in Washington, DC on or before January 15, 2001.

Comments may also be filed electronically via the Internet in lieu of paper. See 18 CFR 385.2001(a)(1)(iii) and the instructions on the Commission's web site at <http://www.ferc.fed.us/efi/doorbell.htm> under the link to the User's Guide. Before you can file comments you will need to create an account which can be created by clicking on "Login to File" and then "New User Account."

If you do not want to send comments at this time but still want to remain on our mailing list, please return the Information Request (appendix 3). If you do not return the Information Request, you will be taken off the mailing list.

Becoming an Intervenor

In addition to involvement in the EA scoping process, you may want to become an official party to the

proceeding known as an "intervenor". Intervenor play a more formal role in the process. Among other things, intervenors have the right to receive copies of case-related Commission documents and filings by other intervenors. Likewise, each intervenor must provide 14 copies of its filings to the Secretary of the Commission and must send a copy of its filings to all other parties on the Commission's service list for this proceeding. If you want to become an intervenor, you must file a motion to intervene according to Rule 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.214) (see appendix 2). Only intervenors have the right to seek rehearing of the Commission's decision.

Affected landowners and parties with environmental concerns may be granted intervenor status upon showing good cause by stating that they have a clear and direct interest in this proceeding which would not be adequately represented by any other parties. You do not need intervenor status to have your environmental comments considered.

Additional information about the proposed project is available from the Commission's Office of External Affairs at (202) 208-0004 or on the FERC website (www.ferc.fed.us) using the "RIMS" link to information in this docket number. Click on the "RIMS" link select "Docket #" from the RIMS Menu, and follow the instructions. For assistance with access to RIMS, the RIMS helpline can be reached at (202) 208-2474.

Similarly, the "CIPS" link on FERC Internet website provides access to the texts of formal documents issued by the Commission, such as orders, notices, and rulemakings. From the FERC Internet website, click on the "CIPS" link, select "Docket #" from the CIPS menu, and follow the instructions. For assistance with access to CIPS, the CIPS helpline can be reached at (202) 208-2474.

David P. Boergers,
Secretary.

[FR Doc. 00-32540 Filed 12-20-00; 8:45 am]

BILLING CODE 6717-01-M

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Notice of Intent To File an Application for a New License

December 15, 2000.

- a. *Type of Filing:* Notice of Intent to File An Application for a New License.
- b. *Project No:* 199.

c. *Date Filed:* November 20, 2000.

d. *Submitted By:* South Carolina Public Service Authority—current licensee.

e. *Name of Project:* Santee Cooper Hydroelectric Project.

f. *Location:* On the Santee and Cooper Rivers, in Berkeley, Calhoun, Clarendon, Orangeburg, and Sumter Counties, South Carolina. The project occupies U.S. lands in the Francis Marion National Forest.

g. *Filed Pursuant to:* Section 15 of the Federal Power Act.

h. *Licensee Contact:* John Dulude, South Carolina Public Service Authority, One Riverwood Drive, P.O. Box 2946101, Moncks Corner, SC 29461 (843) 761-4046.

i. *FERC Contact:* Ron McKittrick, ronald.mckittrick@ferc.fed.us, (770) 452-3778.

j. *Effective date of current license:* May 1, 1979.

k. *Expiration date of current license:* March 31, 2006.

l. *Description of the Project:* The project consists of the following two developments:

The Santee Development consists of the following existing facilities: (1) The 50-foot-high, 7.5-mile-long Santee Dam comprised of: (i) a north earthen embankment dam; (ii) a gated concrete spillway section; and (iii) a south earthen embankment dam; (2) the 97, 274-acre Lake Marion reservoir; (3) a powerhouse, integral with the dam, containing a single generating unit with an installed capacity of 2 MW, (4) a 23-mile-long, 33-kV transmission line; and (5) other appurtenances.

The Cooper Development consists of the following existing facilities: (1) The 100-foot-high, 2.1-mile-long Pinopolis Dam comprised of: (i) the east and west earthen embankment dams; and (ii) the east, west, and north dikes; (2) the 55,394-acre Lake Moultrie reservoir; (3) the Jefferies powerhouse, integral with the dam, containing five generating units with a total installed capacity of 132 MW, (4) a 4.5-mile-long tailrace canal connecting with the Cooper River; (5) a 115-kV transmission line; (6) a 7.5-mile-long diversion canal connecting Lake Marion and Lake Moultrie; (7) a 60-foot-wide, 180-foot-long navigational lock; and (8) other appurtenances.

m. Each application for a new license and any competing license applications must be filed with the Commission at least 24 months prior to the expiration of the existing license. All applications

for license for this project must be filed by March 31, 2004.

David P. Boergers,
Secretary.

[FR Doc. 00-32534 Filed 12-20-00; 8:45 am]

BILLING CODE 6717-01-M

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. RM98-1-000]

Regulations Governing Off-the-Record Communications; Public Notice

December 15, 2000.

This constitutes notice, in accordance with 18 CFR 385.2201(h), of the receipt of exempt and prohibited off-the-record communications.

Order No. 607 (64 FR 51222, September 22, 1999) requires Commission decisional employees, who make or receive an exempt or a prohibited off-the-record communication relevant to the merits of a contested on-the-record proceeding, to deliver a copy of the communication, if written, or a summary of the substance of any oral communication, to the Secretary.

Prohibited communications will be included in a public, non-decisional file associated with, but not part of, the decisional record of the proceeding. Unless the Commission determines that the prohibited communication and any responses thereto should become part of the decisional record, the prohibited off-the-record communication will not be considered by the Commission in reaching its decision. Parties to a proceeding may seek the opportunity to respond to any facts or contentions made in a prohibited off-the-record communication, and may request that the Commission place the prohibited communication and responses thereto in the decisional record. The Commission will grant such requests only when it determines that fairness so requires. Any person identified below as having made a prohibited off-the-record communication should serve the document on all parties listed on the official service list for the applicable proceeding in accordance with Rule 2010, 18 CFR 385.2010.

Exempt off-the-record communications will be included in the decisional record of the proceeding, unless the communication was with a cooperating agency as described by 40 CFR 1501.6, made under 18 CFR 385.2201(e)(1)(v).

The following is a list of exempt and prohibited off-the-record communications received in the Office of the Secretary within the preceding 14 days. The documents may be viewed on the Internet at <http://www.ferc.fed.us/online/rims.htm> (call 202-208-2222 for assistance).

Exempt

1. CP00-14-000-11-20-00—Tim Drake.
2. CP00-14-000-11-20-00—Tim Drake.
3. Project No. 2042-013-11-21-00—Timothy Welch.
4. CP00-6-000-11-27-00—Jon Schmidt.
5. CP00-6-000-11-22-00—Ken Huntington.
6. CP00-6-000-11-20-00—Jon Schmidt.
7. Project No. 2114-11-20-00—Lynn R. Miles.
8. CP98-150-002-11-7-00—Donald J. Stauber.
9. CP00-452-000-11-20-00—Ed Martinez.
10. CP98-150-000-11-13-00 & 11-14-00—Juan Polit.
11. Project Nos. 5931 and 7282-11-29-00—Donald B. Koch.
12. Project No. 8657-11-27-00—CDL Perkins.
13. CP00-14-000-11-20-00—John Wisniewski.
14. CP00-141-000-11-30-00—Ann Garrett.
15. EL00-95-000-12-11-00—Robert D. Glynn, Jr.
16. CP97-315-000, *et al.*-12-20-00—David Geisler.
17. EL00-95-000 and-12-4-00—Lynn Schenk.
18. CP00-404-000-11-20-00—Michael McCarthy.
19. CP00-14-000 and CP00-6-000-11-29-00—John J. Wisniewski.
20. CP00-452-000-11-27-00—Joanne Wachholder.
21. CP00-14-000, CP00-15-000 and CP00-16-000-11-14-00—Joe Peterson.
22. CP00-14-000, CP00-15-000 and CP00-16-000-11-22-00—Tod Mattson, Doug Lake and Jeff Thommes.
23. CP00-14-000, CP00-15-000 and CP00-16-000-11-20-00—Jeff Thommes.
24. CP00-14-000, CP00-15-000 and CP00-16-000-10-4-00—Joe Peterson.
25. CP00-14-000, CP00-15-000 and CP00-16-000-10-9-00—Joe Peterson.
26. CP00-14-000, CP00-15-000 and CP00-16-000-10-19-00—Joe Peterson.
27. CP00-14-000, CP00-15-000 and CP00-16-000-10-23-00—Joe Peterson.
28. Project No. 1494-12-08-00—Brian Romanek.
29. Project No. 2069-03-21-00—Carol Gleichman.

30. EL00-107-12-14-00—Steve Peace.

31. ER01-607-000 and EL00-95-000-12-12-00—Governor Gray Davis, Lynn Schenk, Michael Kahn and John Stevens.

32. CP99-94-000-12-04-00—W. Ralph Hough.

33. ER00-607 and EL00-95-000-12-13-00 & 12-14-00—Governor Gray Davis, Secretary Bill Richardson, Senator Feinstein, *et al.*

Prohibited

1. EL00-95, EL00-98, EL00-107-11-25-00—Steven Stoft.

2. EL00-95, EL00-98, EL00-107-11-27-00—Steven Stoft.

3. EL00-95, EL00-98, EL00-107-11-27-00—Steven Stoft.

4. EL00-95, EL00-98, EL00-107-11-28-00—Steven Stoft.

David P. Boergers,

Secretary.

[FR Doc. 00-32531 Filed 12-20-00; 8:45 am]

BILLING CODE 6717-01-M

ENVIRONMENTAL PROTECTION AGENCY

[FRL-6920-1]

Office of Research and Development Board of Scientific Counselors, Executive Committee Meeting

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice of meeting.

SUMMARY: Pursuant to the Federal Advisory Committee Act, Public Law 92-463, as amended (5 U.S.C., App. 2) notification is hereby given that the Environmental Protection Agency, Office of Research and Development (ORD), Board of Scientific Counselors (BOSC), will hold an Executive Committee Meeting.

DATES: The Meeting will be held on January 25-26, 2001. On Thursday, January 25, the meeting will begin at 9:00 a.m., and will recess at 4:30 p.m. On Friday, January 26, the meeting will reconvene at 9:00 a.m. and will adjourn at approximately 1:00 p.m. All times noted are Eastern Time.

ADDRESSES: The meeting will be held at the Ritz Carlton, Pentagon City, 1250 South Hayes Street, Arlington, Virginia 22202, (703) 415-5000.

SUPPLEMENTARY INFORMATION: Agenda items will include, but not be limited to: BOSC upcoming activities, including Sub-Committee Appointments and Charge, Review of EPA-ORD Communications, and ORD Multi-year Plans discussion.

Anyone desiring a draft agenda may fax their request to Shirley R. Hamilton (202) 565-2444. The meeting is open to the public. Any member of the public wishing to make a presentation at the meeting should contact Shirley Hamilton, Designated Federal Officer, U.S. Environmental Protection Agency, Board of Scientific Counselors, Office of Research and Development (8701R), 1200 Pennsylvania Avenue, NW., Washington, DC 20460; or by telephone at (202) 564-6853. In general each individual making an oral presentation will be limited to a total of three minutes.

FOR FURTHER INFORMATION CONTACT:

Shirley R. Hamilton, Designated Federal Officer, U.S. Environmental Protection Agency, Office of Research and Development, (8701R), 1200 Pennsylvania Avenue, NW., Washington, DC 20460, (202) 564-6853.

Dated: December 14, 2000.

Peter W. Preuss,

Director, National Center for Environmental Research.

[FR Doc. 00-32560 Filed 12-20-00; 8:45 am]

BILLING CODE 6560-50-P

ENVIRONMENTAL PROTECTION AGENCY

[FRL-6920-3]

Velsicol/Hardeman County Landfill Superfund Site; Mathis Brothers/South Marble Top Road Landfill Superfund Site; Shaver's Farm Superfund Site

AGENCY: Environmental Protection Agency.

ACTION: Notice; request for public comment.

SUMMARY: In accordance with section 122(i) of the Comprehensive Environmental Response, Compensation, and Liability Act, as amended ("CERCLA"), 42 U.S.C. 9622(i), notice is hereby given of a proposed administrative settlement pursuant to section 122(h) of CERCLA with Velsicol Chemical Corporation for recovery of past and future response costs concerning three Superfund sites: the Velsicol/Hardeman County Landfill Superfund Site, Toone, Hardeman County, Tennessee; the Mathis Brothers/South Marble Top Road Landfill Superfund Site, Kensington, Walker County, Georgia; and the Shaver's Farm Superfund Site, Lafayette, Walker County, Georgia. The Agreement requires Velsicol Chemical Corporation to pay approximately \$4 million dollars, plus interest, to resolve its outstanding and potential liabilities at the three

Sites. The Agreement provides Velsicol Chemical Corporation with a monthly payment schedule which will allow it to pay all of the outstanding amounts over three years. For thirty (30) days following the date of publication of this notice, the Agency will receive written comments relating to the settlement. The Agency will consider all comments received and may modify or withdraw its consent to the settlement if comments received disclose facts or considerations which indicate that the settlement is inappropriate, improper, or inadequate. Copies of the proposed settlement are available from: Ms. Paula V. Batchelor, U.S. Environmental Protection Agency, Region IV, Waste Management Division 61 Forsyth Street, SW., Atlanta, Georgia 30303, 404/562-8887.

Written comments may be submitted to Ms. Batchelor at the above address on or before January 22, 2001.

Dated: December 4, 2000.

Franklin E. Hill,

Chief, CERCLA Program Services Branch,
Waste Management Division.

[FR Doc. 00-32559 Filed 12-20-00; 8:45 am]

BILLING CODE 6560-50-P

FEDERAL COMMUNICATIONS COMMISSION

Public Information Collections Approved by Office of Management and Budget

December 14, 2000.

The Federal Communications Commission (FCC) has received Office of Management and Budget (OMB) approval for the following public information collections pursuant to the Paperwork Reduction Act of 1995, Public Law 104-13. An agency may not conduct or sponsor and a person is not required to respond to a collection of information unless it displays a currently valid control number. For further information contact Shoko B. Hair, Federal Communications Commission, (202) 418-1379.

Federal Communications Commission

OMB Control No.: 3060-0853.

Expiration Date: 12/31/2003.

Title: Receipt of Service Confirmation Form and Adjustment of Funding Commitment and Modification to Receipt of Service Confirmation Form—Universal Service for Schools and Libraries.

Form No.: FCC Form 486 and FCC Form 500.

Respondents: Business or other for-profit; Not-for-profit institutions.

Estimated Annual Burden: 40,000 respondents; 1.5 hours per response (avg.); 45,000 total annual burden hours.

Estimated Annual Reporting and Recordkeeping Cost Burden: \$0.

Frequency of Response: On occasion.

Description: The Commission adopted rules providing support for all telecommunications services, Internet access, and internal connections for all eligible schools and libraries. To participate in the program schools and libraries must confirm that they are actually receiving the services eligible for support via FCC Form 486. The purpose of FCC Form 486 is to ensure that services are actually being provided and that a billing relationship exists between the service provider and applicant. Failure to file a Form 486 means that no payments may be made to a service provider (or for an applicant reimbursement, which is passed through the service provider) on the particular Funding Request Number. (No. of respondents: 30,000; hours per response: 1 hour; total annual burden: 30,000). FCC Form 500 is used to adjust funding commitments and/or modify the dates for receipt of services. Only some applicants will avail themselves of the Form 500. It is available for applicants who wish to keep their information current or who wish to return funds to the Universal Service Fund. (No. of respondents: 10,000; hours per response: 1.5 hours; total annual burden: 15,000 hours). Copies of the forms are available via the Internet at www.sl.universalservice.org. Obligation to respond: Required to obtain or retain benefits.

OMB Control No.: 3060-0711.

Expiration Date: 12/31/2003.

Title: Implementation of Section 34(a)(1) of the Public Utility Holding Company Act of 1935, as amended by the Telecommunications Act of 1996 (47 CFR Sections 1.5001-1.5007).

Form No.: N/A.

Respondents: Business or other for-profit.

Estimated Annual Burden: 15 respondents; 10 hours per response (avg.); 150 total annual burden hours.

Estimated Annual Reporting and Recordkeeping Cost Burden: \$48,000.

Frequency of Response: On occasion.

Description: 47 CFR 1.5001-1.5007 implement section 34(a) of the Public Utility Holding Company Act. The rules provide filing requirements and procedures to expedite public utility holding company entry into the telecommunications industry. Persons seeking a determination of exempt telecommunications company (ETC) status must file in good faith for a determination by the Commission.

Applicants are required to file, among other things, with the Commission a brief description of their planned activities, and a sworn statement attesting to any facts presented to demonstrate eligibility for ETC status and attesting to any representation otherwise offered to demonstrate eligibility for ETC status. Applicants are required to submit sworn statements certifying that they complied with part 1, subpart P of the Commission's regulations. Finally, applicants are also required to serve copies of their application with the SEC and affected state commissions. The applicants must notify the Commission of material change in facts within 30 days of the change in fact. The information will be used by the Commission to determine whether persons satisfy the statutory criteria for exempt telecommunications company status. Obligation to respond: Required to obtain or retain benefits.

Public reporting burden for the collection of information is as noted above. Send comments regarding the burden estimate or any other aspect of the collections of information, including suggestions for reducing the burden to Performance Evaluation and Records Management, Washington, DC 20554.

Federal Communications Commission.

Magalie Roman Salas,

Secretary.

[FR Doc. 00-32468 Filed 12-20-00; 8:45 am]

BILLING CODE 6712-01-U

FEDERAL RESERVE SYSTEM

Change in Bank Control Notices; Acquisitions of Shares of Banks or Bank Holding Companies

The notificants listed below have applied under the Change in Bank Control Act (12 U.S.C. 1817(j)) and § 225.41 of the Board's Regulation Y (12 CFR 225.41) to acquire a bank or bank holding company. The factors that are considered in acting on the notices are set forth in paragraph 7 of the Act (12 U.S.C. 1817(j)(7)).

The notices are available for immediate inspection at the Federal Reserve Bank indicated. The notices also will be available for inspection at the offices of the Board of Governors. Interested persons may express their views in writing to the Reserve Bank indicated for that notice or to the offices of the Board of Governors. Comments must be received not later than January 5, 2001.

A. Federal Reserve Bank of Kansas City (D. Michael Manies, Assistant Vice

President) 925 Grand Avenue, Kansas City, Missouri 64198-0001:

1. *Michael L. Dahir*, Omaha, Nebraska, to acquire voting shares of DB Holding Company, Inc., Omaha, Nebraska, and thereby indirectly acquire voting shares of Omaha State Bank, Omaha, Nebraska.

B. Federal Reserve Bank of San Francisco (Pat Marshall, Manager of Analytical Support, Consumer Regulation Group) 101 Market Street, San Francisco, California 94105-1579:

2. *Louis Charles McMurray*, Madera, California, to acquire additional voting shares of Central Valley Community Bancorp, Clovis, California, and thereby indirectly acquire additional voting shares of Clovis Community Bank, Clovis, California.

Board of Governors of the Federal Reserve System, December 15, 2000.

Robert deV. Frierson,

Associate Secretary of the Board.

[FR Doc. 00-32506 Filed 12-20-00; 8:45 am]

BILLING CODE 6210-01-P

FEDERAL RESERVE SYSTEM

Formations of, Acquisitions by, and Mergers of Bank Holding Companies

The companies listed in this notice have applied to the Board for approval, pursuant to the Bank Holding Company Act of 1956 (12 U.S.C. 1841 *et seq.*) (BHC Act), Regulation Y (12 CFR part 225), and all other applicable statutes and regulations to become a bank holding company and/or to acquire the assets or the ownership of, control of, or the power to vote shares of a bank or bank holding company and all of the banks and nonbanking companies owned by the bank holding company, including the companies listed below.

The applications listed below, as well as other related filings required by the Board, are available for immediate inspection at the Federal Reserve Bank indicated. The application also will be available for inspection at the offices of the Board of Governors. Interested persons may express their views in writing on the standards enumerated in the BHC Act (12 U.S.C. 1842(c)). If the proposal also involves the acquisition of a nonbanking company, the review also includes whether the acquisition of the nonbanking company complies with the standards in section 4 of the BHC Act (12 U.S.C. 1843). Unless otherwise noted, nonbanking activities will be conducted throughout the United States.

Unless otherwise noted, comments regarding each of these applications must be received at the Reserve Bank indicated or the offices of the Board of

Governors not later than January 16, 2001.

A. Federal Reserve Bank of Chicago (Philip Jackson, Applications Officer) 230 South LaSalle Street, Chicago, Illinois 60690-1413:

1. *Stichting Prioriteit ABN AMRO Holding*, Amsterdam, The Netherlands; Stichting Administratiekantoor ABN AMRO Holding, Amsterdam, The Netherlands; ABN AMRO Holding N.V., Amsterdam, The Netherlands; ABN AMRO Bank N.V., Amsterdam, The Netherlands; ABN AMRO North America Holding Company, Chicago, Illinois; and ABN AMRO North America, Inc., Chicago, Illinois; to acquire 100 percent of the voting shares of Michigan National Corporation, Farmington Hills, Michigan, and thereby indirectly acquire Michigan National Bank, Farmington Hills, Michigan. Applicants also have applied to acquire Independence Life Insurance Company, Phoenix, Arizona, and thereby engage in the sale of credit related insurance, pursuant to § 225.28(b)(11) of Regulation Y and Independence One Capital Management Corporation, Farmington Hills, Michigan, and thereby engage in investment advisory services, pursuant to § 225.28(b)(6) of the Board's Regulation Y.

Board of Governors of the Federal Reserve System, December 15, 2000.

Robert deV. Frierson,

Associate Secretary of the Board.

[FR Doc. 00-32507 Filed 12-20-00; 8:45 am]

BILLING CODE 6210-01-P

FEDERAL RESERVE SYSTEM

Notice of Proposals To Engage in Permissible Nonbanking Activities or To Acquire Companies That Are Engaged in Permissible Nonbanking Activities

The companies listed in this notice have given notice under section 4 of the Bank Holding Company Act (12 U.S.C. 1843) (BHC Act) and Regulation Y, (12 CFR Part 225) to engage de novo, or to acquire or control voting securities or assets of a company, including the companies listed below, that engages either directly or through a subsidiary or other company, in a nonbanking activity that is listed in § 225.28 of Regulation Y (12 CFR 225.28) or that the Board has determined by Order to be closely related to banking and permissible for bank holding companies. Unless otherwise noted, these activities will be conducted throughout the United States.

Each notice is available for inspection at the Federal Reserve Bank indicated.

The notice also will be available for inspection at the offices of the Board of Governors. Interested persons may express their views in writing on the question whether the proposal complies with the standards of section 4 of the BHC Act. Additional information on all bank holding companies may be obtained from the National Information Center website at www.ffiec.gov/nic/.

Unless otherwise noted, comments regarding the applications must be received at the Reserve Bank indicated or the offices of the Board of Governors not later than January 5, 2001.

A. Federal Reserve Bank of Cleveland (Jeffrey Hirsch, Banking Supervisor) 1455 East Sixth Street, Cleveland, Ohio 44101-2566:

1. *United Bancshares, Inc.*, Columbus Grove, Ohio; to acquire Citizens Bank of Delphos, Federal Savings Bank, Delphos, Ohio, and engage in permissible savings association activities pursuant to § 225.28(b)(4) of Regulation Y. Comments on this application must be received by January 16, 2001.

B. Federal Reserve Bank of Chicago (Philip Jackson, Applications Officer) 230 South LaSalle Street, Chicago, Illinois 60690-1413:

1. *Michigan National Corporation*, Farmington Hills, Michigan; to acquire Standard Federal Bancorporation, Inc., Troy, Michigan, and thereby indirectly acquire Standard Federal Bank, Troy, Michigan, and thereby engage in the nonbanking activity of operating a savings association pursuant to § 225.28(b)(4) of Regulation Y. Comments on this application must be received by January 16, 2001.

C. Federal Reserve Bank of San Francisco (Pat Marshall, Manager of Analytical Support, Consumer Regulation Group) 101 Market Street, San Francisco, California 94105-1579:

1. *City National Corporation*, Beverly Hills, California; to acquire Reed, Conner & Birdwell, Inc., Los Angeles, California, and thereby engage in acting as investment and financial advisor pursuant to § 225.28(b)(6) of Regulation Y; and providing administrative services to mutual funds. Lloyds TSB Group plc, 84 Federal Reserve Bulletin 128 (1998).

Board of Governors of the Federal Reserve System, December 15, 2000.

Robert deV. Frierson,

Associate Secretary of the Board.

[FR Doc. 00-32508 Filed 12-20-00; 8:45 am]

BILLING CODE 6210-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES**Agency for Toxic Substances and Disease Registry****[ATSDR-161]****Public Health Assessments Completed**

AGENCY: Agency for Toxic Substances and Disease Registry (ATSDR), Department of Health and Human Services (HHS).

ACTION: Notice.

SUMMARY: This notice announces those sites for which ATSDR has completed public health assessments during the period from July through September 2000. This list includes sites that are on or proposed for inclusion on the National Priorities List (NPL), and includes sites for which assessments were prepared in response to requests from the public.

FOR FURTHER INFORMATION CONTACT: Robert C. Williams, P.E., DEE, Assistant Surgeon General, Director, Division of Health Assessment and Consultation, Agency for Toxic Substances and Disease Registry, 1600 Clifton Road, NE., Mailstop E-32, Atlanta, Georgia 30333, telephone (404) 639-0610.

SUPPLEMENTARY INFORMATION: The most recent list of completed public health assessments was published in the **Federal Register** on September 21, 2000 (65 FR57190). This announcement is the responsibility of ATSDR under the regulation, Public Health Assessments and Health Effects Studies of Hazardous Substances Releases and Facilities (42 CFR part 90). This rule sets forth ATSDR's procedures for the conduct of public health assessments under section 104(i) of the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA), as amended by the Superfund Amendments and Reauthorization Act (SARA) (42 U.S.C. 9604(i)).

Availability

The completed public health assessments and addenda are available for public inspection at the Division of Health Assessment and Consultation, Agency for Toxic Substances and Disease Registry, Building 33, Executive Park Drive, Atlanta, Georgia (not a mailing address), between 8 a.m. and 4:30 p.m., Monday through Friday except legal holidays. The completed public health assessments are also available by mail through the U.S. Department of Commerce, National Technical Information Service (NTIS), 5285 Port Royal Road, Springfield,

Virginia 22161, or by telephone at (703) 605-6000. NTIS charges for copies of public health assessments and addenda. The NTIS order numbers are listed in parentheses following the site names.

Public Health Assessments Completed or Issued

Between July 1 and September 30, 2000, public health assessments were issued for the sites listed below:

NPL Sites

Florida

Tyndall Air Force Base—Panama City—(PB20-108005)

Whiting Field Naval Air Station (Aliases: Naval Air Station

Whiting Field\USN Naval Air Station Whiting Field Site)—Milton—(PB20-108505)

Iowa

Electro-Coatings, Incorporated—Cedar Rapids—(PB20-108077)

Massachusetts

Fort Devens—Ayer—(PB20-106950)

New Jersey

Cornell Dubilier Electronics Incorporated—South Plainfield—(PB21-101226)

Federal Creosote—Manville—(PB21-100165)

Route 561 Dump (a/k/a Route 561) and United States

Avenue Burn (a/k/a US Avenue Burn Site)—(PB20-108506)

New York

Pelham Bay Landfill—Bronx—(PB20-107333)

Peter Cooper—Gowanda—(PB20-108091)

Sidney Landfill—Sidney—(PB20-108092)

Oklahoma

Tulsa Fuel and Manufacturing—Collinsville—(PB21-100129)

Washington

Bangor Naval Submarine Base and Bangor Ordnance Disposal (US Navy)—(PB20-107348)

Non NPL Petitioned Sites

Alaska

Alaska Pulp Corporation—Sitka—(PB21-100495)

California

Koppers Company, Incorporated (Oroville Plant) [a/k/a Koppers (Oroville)]—(PB21-100496)

Dated: December 14, 2000.

Georgi Jones,

Director, Office of Policy and External Affairs, Agency for Toxic Substances and Disease Registry.

[FR Doc. 00-32500 Filed 12-20-00; 8:45 am]

BILLING CODE 4163-70-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES**Centers for Disease Control And Prevention****[60Day-01-09]****Proposed Data Collections Submitted for Public Comment and Recommendations**

In compliance with the requirement of section 3506 (c)(2)(A) of the Paperwork reduction Act of 1995, the Center for Disease Control and Prevention is providing opportunity for public comment on proposed data collection projects. To request more information on the proposed projects or to obtain a copy of the data collection plans and instruments, call the CDC Reports Clearance Officer on (404) 639-7090.

Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques for other forms of information technology. Send comments to Anne O'Connor, CDC Assistant Reports Clearance Officer, 1600 Clifton Road, MS-D24, Atlanta, GA 30333. Written comments should be received within 60 days.

Proposed Project

A Questionnaire to Assess HIV-prevention Program Activities for Adolescent and School Health Programs—New—National Center for HIV, STD and TB (NCHSTP). The proposed project is an annual web-based questionnaire to report on and to assess HIV-prevention program activities among local and state and territorial education agencies funded by the Division of Adolescent and School Health, Centers for Disease Control and Prevention. The purpose of this request is to obtain OMB clearance to conduct

an annual questionnaire focusing on HIV prevention program activities: assistance and training on school HIV policies, assistance and training on HIV curricula and instruction, training on student standards and assessment for HIV prevention, collaboration with external partners, targeting priority populations, planning and improving projects and information about

additional activities. There is currently no standardized annual reporting process for HIV prevention activities among local and state education agencies funded by the Division of Adolescent and School Health. Data gathered from this questionnaire will (1) provide standardized information about how HIV prevention funds are used by local and state education agencies, (2)

assess the extent to which programmatic adjustments are indicated, (3) determine the collective impact of funded programs, and (4) provide accountability of information for use of public funds. The estimated cost to respondents is \$12,819.45 assuming an hourly wage of \$26.40 and \$22.96 for local and state education agency staff respectively.

Respondents	Number of respondents	Number of responses/ respondent	Burden per respondent (in hrs.)	Total burden (in hrs.)
District Officials	17	1	7.2	122.4
State & Territorial Officials	58	1	7.2	417.6
Total				540.0

Dated: December 15, 2000.

Nancy Cheal,

Acting Associate Director for Policy Planning, and Evaluation, Centers for Disease Control and Prevention (CDC).

[FR Doc. 00-32543 Filed 12-20-00; 8:45 am]

BILLING CODE 4163-18-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[60Day-01-10]

Proposed Data Collections Submitted for Public Comment and Recommendations

In compliance with the requirement of section 3506 (c)(2)(A) of the Paperwork Reduction Act of 1995, the Center for Disease Control and Prevention is providing opportunity for public comment on proposed data collection projects. To request more information on the proposed projects or to obtain a copy of the data collection plans and instruments, call the CDC Reports Clearance Officer on (404) 639-7090.

Comments are invited on: (a) Whether the proposed collection of information

is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques for other forms of information technology. Send comments to Seleda Perryman, CDC Assistant Reports Clearance Officer, 1600 Clifton Road, MS-D24, Atlanta, GA 30333. Written comments should be received within 60 days.

Proposed Project

National Childhood Blood Lead Surveillance System—Renewal—(OMB No. 0920-0337), National Center for Environmental Health (NCEH), Centers for Disease Control and Prevention (CDC). In 1992, the Centers for Disease Control and Prevention began the National Childhood Lead Surveillance Program at the National Center for Environmental Health (NCEH). The goals of the childhood lead surveillance program are to (1) establish childhood

lead surveillance systems at the state and national levels; (2) use surveillance data to estimate the extent of elevated blood-lead levels among children; (3) assess the follow-up of children with elevated blood-lead levels; (4) examine potential sources of lead exposure; and (5) help allocate resources for lead poisoning prevention activities. State surveillance systems are based on reports of blood-lead tests from laboratories. Ideally laboratories report results of all lead tests, not just elevated values, to the state health department, but each state determines the reporting level for blood lead tests. In addition to blood lead test results, state child-specific surveillance databases contain follow-up data on children with elevated blood-lead levels including data on medical treatment, environmental investigations, and potential sources of lead exposure. Surveillance data for the national database are extracted from the state child-specific databases and transferred to CDC.

OMB approval for this package will expire on 31 March 2001. This request is for a 3-year renewal with a change in the burden hours. There is no cost to respondents.

Type of respondents	No. of respondents	Frequency of responses	Avg. burden/ response in hours	Total burden hours
State Health Departments:..				
a) annual report	28	1	10.0	280
b) quarterly report	40	4	2.0	320
Total				600

Date: December 15, 2000.
Nancy Cheal,
Acting Associate Direct for Policy Planning, and Evaluation, Centers for Disease Control and Prevention (CDC).
[FR Doc. 00-32544 Filed 12-20-00; 8:45 am]
BILLING CODE 4163-18-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[60Day-01-11]

Proposed Data Collections Submitted for Public Comment and Recommendations

In compliance with the requirement of section 3506 (c)(2)(A) of the Paperwork Reduction Act of 1995, the Center for Disease Control and Prevention is providing opportunity for public comment on proposed data collection projects. To request more information on the proposed projects or to obtain a copy of the data collection plans and instruments, call the CDC Reports Clearance Officer on (404) 639-7090.

Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have

practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques for other forms of information technology. Send comments to Anne O'Connor, CDC Assistant Reports Clearance Officer, 1600 Clifton Road, MS-D24, Atlanta, GA 30333. Written comments should be received within 60 days.

Proposed Project: Vital Statistics Training Application Reinstatement—(OMB No. 0920-0217) National Center for Health Statistics (NCHS). In the United States, legal authority for the registration of vital events, *i.e.* births, deaths, marriages, divorces, fetal deaths, and induced terminations of pregnancy, resides individually with the States (as well as cities in the case of New York City and Washington, DC) and Puerto Rico, the Virgin Islands, Guam, American Samoa, and the Commonwealth of the Northern Mariana Islands. These governmental entities are the full legal proprietors of vital records and the information contained therein. As a result of this State authority, the collection of registration-based vital statistics at the national level, referred to as the U.S. National Vital Statistics

System (NVSS), depends on a cooperative relationship between the States and the Federal government. This data collection, authorized by 42 U.S.C. 242k, has been carried out by NCHS since it was created in 1960.

To help in achieving the comparability needed for combining data from all States into national statistics, NCHS carries out a training program for State and local vital statistics staff to assist in developing expertise in all aspects of vital registration and vital statistics. The training offered under this program includes courses for registration staff, statisticians, and coding specialists, all designed to bring about a high degree of uniformity and quality in the data provided by the States. This training program is authorized by 42 U.S.C. 242b, section 304(a). In order to offer the types of training that would be most useful to vital registration staff members, NCHS requests information from State and local vital registration officials about their projected needs for training. NCHS also asks individual candidates for training to submit an application form containing name, address, occupation, work experience, education, and previous training. These data enable NCHS to determine those individuals whose needs can best be met through the available training resources. There is no cost to respondents in providing these data.

Respondents	Number of respondents	Responses/ respondents	Avg. burden/ response (in hrs)	Total burden hours
State, local, and Territory Registration Officials	57	1	.33	19
Training Applicants	100	1	.25	25
Total				44

Dated: December 15, 2000.
Nancy Cheal,
Acting Associate Director for Policy, Planning, and Evaluation Centers for Disease Control and Prevention (CDC).
[FR Doc. 00-32545 Filed 12-20-00; 8:45 am]
BILLING CODE 4163-18-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[30DAY-12-01]

Agency Forms Undergoing Paperwork Reduction Act Review

The Centers for Disease Control and Prevention (CDC) publishes a list of information collection requests under review by the Office of Management and Budget (OMB) in compliance with the Paperwork Reduction Act (44 U.S.C. Chapter 35). To request a copy of these requests, call the CDC Reports Clearance Officer at (404) 639-7090. Send written comments to CDC, Desk Officer; Human

Resources and Housing Branch, New Executive Office Building, Room 10235; Washington, DC 20503. Written comments should be received within 30 days of this notice.

Proposed Project: Questionnaire Design Research Laboratory (QDRL) 2001-2003, (OMB No. 0920-0222)—Revision—National Center for Health Statistics (NCHS), Centers for Disease Control and Prevention (CDC). The QDRL conducts pretesting activities related to the development of NCHS and other Federal survey questionnaires, such as the National Health Interview Survey (NHIS). These activities mainly involve use of the cognitive interview, in which volunteer respondents ("laboratory subjects") are administered draft survey questions, and are asked to

react to those questions. The cognitive interviewer notes sources of error in these questions, based on problems that subjects have in comprehending the questions and in attempting to recall the information requested. After several cycles of testing of small numbers of respondents (generally 10–12), and development of the questions between testing “rounds,” the questionnaires are improved to the point to which they are

ready for field testing and household administration. QDRL staff are also engaged in the conduct of general questionnaire design research, in which survey questions are administered to laboratory subjects using different phrases, or under different administration modes (*e.g.*, face-to-face versus telephone), in order to determine the optimal means for presenting the questions. These investigative pretesting

activities are now routinely used by NCHS and by other survey organizations for testing and development purposes, and result in high data quality at a minimal cost, especially in terms of respondent burden. We also support field testing on occasion to assure adequate pretesting of health survey instruments. Total burden hours for this data collection are 550 hours.

Respondents	Number of respondents	Number of responses per respondent	Avg. burden response (in hours)	Response burden (hours)
2001 test volunteers	500	1	1.1	550
2002 test volunteers	500	1	1.1	550
2003 test volunteers	500	1	1.1	550

Dated: December 15, 2000.

Nancy Cheal,

Acting Director for Policy, Planning, and Evaluation Centers for Disease Control and Prevention (CDC).

[FR Doc. 00–32546 Filed 12–20–00; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[30DAY–11–01]

Agency Forms Undergoing Paperwork Reduction Act Review

The Centers for Disease Control and Prevention (CDC) publishes a list of information collection requests under review by the Office of Management and Budget (OMB) in compliance with the Paperwork Reduction Act (44 U.S.C. Chapter 35). To request a copy of these requests, call the CDC Reports Clearance Officer at (404) 639–7090. Send written comments to CDC, Desk Officer; Human Resources and Housing Branch, New Executive Office Building, Room 10235; Washington, DC 20503. Written comments should be received within 30 days of this notice.

Proposed Project

National Survey of Hospital Coagulation Laboratories—New—Public Health Practice Program Office (PHPPO), Centers for Disease Control and Prevention (CDC). As part of the

continuing effort to support public health objectives of treatment, disease prevention and surveillance programs, the Centers for Disease Control and Prevention (CDC), Public Health Practice Program Office (PHPPO), seeks to collect information on coagulation testing practices among U.S. hospital laboratories. The purpose of this project is to define the state of testing practices in a random sample of 800 U.S. hospital laboratories for selected coagulation analytes by conducting a questionnaire survey of these laboratories. The objectives of this survey are to collect data to assess the variability of selected analytical and non-analytical variables, such as normal ranges, used for selected coagulation tests. There has not been a systematic and nationally based survey of coagulation testing practices among U.S. hospital laboratories. Such a surveillance is needed due to the impact that coagulation testing practices can have on the diagnosis and management of coagulation disorders.

There is ample evidence of variability in coagulation testing practices based on published literature corresponding to experiences of individual institutions that deal with analytical (*e.g.*, impact of instrument and kit reagents on laboratory results) as well as pre-analytical (such as specimen treatment) and post-analytical (such as results presentation) issues. However, there has not been a systematic survey of national hospital laboratories that has documented the nature and extent of such variability for selected coagulation tests. Preliminary observations

document substantial inter-institutional variability in coagulation testing practices, with likely effect on patient outcome.

This study will explore current practices for one or more selected coagulation tests to document the extent and nature of variability in the testing processes. It is anticipated that information from this study will be used for several purposes. First, results from this project may be used in a future study in order to surmise the potential impact of various testing practices on patient outcomes. A second anticipated use of this study's results is to implement targeted laboratory improvement efforts. Finally, this study may form the basis for a future study to assess the extent and nature of problems in diagnosis and treatment of patients caused by inaccurate laboratory results. Because hypo- and hypercoagulability disorders are prevalent in the U.S. and they are defined to a great extent by laboratory tests, a well designed laboratory practice survey is expected to be of great public health significance for the nation.

CDC plans to sample 800 laboratories that perform selected coagulation tests. The time required to complete a survey will be approximately 0.5 hours. We anticipate that, of the respondents, approximately 80 will be Coagulation Laboratory Directors (physicians) and approximately 720 will be Coagulation Laboratory Supervisors. The total estimated annualized burden is 425 hours.

Respondent	Number of respondents	Responses per respondent	Average No. hrs/response
Laboratory Director	80	1	30/60
Laboratory Supervisor	720	1	30/60

Respondent	Number of respondents	Responses per respondent	Average No. hrs/response
Director Follow-up	300	1	5/60

Dated: December 15, 2000.

Nancy Cheal,

Acting Director for Policy, Planning, and Evaluation, Centers for Disease Control and Prevention (CDC).

[FR Doc. 00-32547 Filed 12-20-00; 8:45 am]

BILLING CODE 4163-18-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[30DAY-08-01]

Agency Forms Undergoing Paperwork Reduction Act Review

The Centers for Disease Control and Prevention (CDC) publishes a list of information collection requests under review by the Office of Management and Budget (OMB) in compliance with the Paperwork Reduction Act (44 U.S.C. Chapter 35). To request a copy of these requests, call the CDC Reports Clearance Officer at (404) 639-7090. Send written comments to CDC, Desk Officer; Human Resources and Housing Branch, New Executive Office Building, Room 10235; Washington, DC 20503. Written comments should be received within 30 days of this notice.

Proposed Project

Thyroid Disease in Persons Exposed to Radioactive Fallout From Atomic Weapons Testing at the Nevada Test Site: Phase III—NEW—National Center for Environmental Health (NCEH), Centers for Disease Control and

Prevention (CDC). In 1997, the National Cancer Institute (NCI) released a report entitled, Estimated Exposures and Thyroid Doses Received by the American People from I-131 in Fallout Following Nevada Nuclear Bomb Test. This report provided county-level estimates of the potential radiation doses to the thyroid gland of American citizens resulting from atmospheric nuclear weapons testing at the Nevada Test Site (NTS) in the 1950's and 1960's. The Institute of Medicine (IOM) conducted a formal peer review of the report at the request of the Department of Health and Human Services. In the review, IOM noted that the public might desire an assessment of the potential health impact of nuclear weapons testing on American populations. The IOM also suggested that further studies of the Utah residents who have participated in previous studies of radiation exposure and thyroid disease might provide this information.

The National Center for Environmental Health (NCEH), Centers for Disease Control and Prevention (CDC), proposes to conduct a study of the relation between exposure to radioactive fallout from atomic weapons testing and the occurrence of thyroid disease on an extension of a cohort study previously conducted by the University of Utah, Salt Lake City, Utah. This study is designed as a follow-up to a retrospective cohort study begun in 1965. This is the third examination (hence Phase III) of a cohort of individuals who were children living in Washington County, Utah, and Lincoln County, Nevada, in 1965 (Phase I) and

who were presumably exposed to fallout from above-ground nuclear weapons testing at the Nevada Test Site in the 1950s. The cohort also includes a control group who were children living in Graham County, Arizona, in 1966 and presumably unexposed to fallout.

The study headquarters will be at the University of Utah in Salt Lake City, Utah. The field teams will spend the majority of their time in the urban areas nearest the original counties if the same pattern of migration holds that was found in Phase II. These urban areas include St. George, Utah, the Wasatch Front in Utah, Las Vegas, Nevada, Phoenix/Tucson, Arizona, and Denver, Colorado. In addition, some time will be spent in California as a number of subjects had relocated there at the time of Phase II.

The purposes of Phase III are three fold: First to re-examine the participants in Phase II for occurrence of thyroid neoplasia and other diseases since 1986. Residents of the three counties who moved before they could be included in the original cohort will be located and examined. Second, disease incidence will be analyzed in addition to period prevalence as used in the Phase II analysis. Use of incidence will allow for greater power to detect increased risk of disease in the exposed population through the use of person-time. Third, disease specific mortality rates for Washington County, Utah, and a control county, Cache County, Utah, will be compared for people who lived in these two counties during the time of above-ground testing.

Respondents	Number of respondents	Responses/ respondent	Average burden response (hrs)
Telephone Location Script	4800	1	5/60
Telephone Location Script (Return Letter)	240	1	5/60
Refusal Telephone Script	48	1	5/60
New Person Location Telephone Script	2400	1	5/60
Recruitment Next of Kin Telephone Script	240	1	5/60
Questionnaire Not Returned Script #1 (New)	48	1	5/60
Questionnaire Not Returned Script #2 (New)	12	1	5/60
Recruitment & Appointment Script	4800	1	5/60
Broken Appointment Telephone Script	240	1	5/60
New Parent Recruitment & Appointment Script	120	1	5/60
New Parent Alternate Recruitment Script	60	1	5/60
Other New Parent Recruitment & Appointment	30	1	5/60
Other Parent or Relative Permissions Script	30	1	5/60
Exposure Questionnaire	2400	1	1
Questionnaire Preparation Booklet	2400	1	30/60
Group Member Information	4800	1	5/60
Consent Forms	4800	1	10/60

Respondents	Number of respondents	Responses/ respondent	Average burden response (hrs)
Interview Booklet	4800	1	30/60
Medical History Questionnaire (male)	2400	1	1
Medical Records Release Telephone Script	240	1	5/60
Medical History Questionnaire (female)	2400	1	1
Travel Form	480	1	20/60
Residence History	2400	1	5/60
Refusal Questionnaire	48	1	5/60

This comparison will determine if the risk of mortality in Washington County (the exposed group) is significantly greater than Cache County (the control group). CDC/NCEH is requesting a three-year clearance. The annual burden hours are estimated to be 13,607.

Dated: December 15, 2000.

Nancy Cheal,

Acting Associate Director for Policy, Planning, and Evaluation Centers for Disease Control and Prevention (CDC).

[FR Doc. 00-32548 Filed 12-20-00; 8:45 am]

BILLING CODE 4163-18-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[30DAY-10-01]

Agency Forms Undergoing Paperwork Reduction Act Review

The Centers for Disease Control and Prevention (CDC) publishes a list of

information collection requests under review by the Office of Management and Budget (OMB) in compliance with the Paperwork Reduction Act (44 U.S.C. Chapter 35). To request a copy of these requests, call the CDC Reports Clearance Officer at (404) 639-7090. Send written comments to CDC, Desk Officer; Human Resources and Housing Branch, New Executive Office Building, Room 10235; Washington, DC 20503. Written comments should be received within 30 days of this notice.

Proposed Project

The Incidence of Breast and Other Cancers among Female Flight Attendants—New—National Institute for Occupational Safety and Health (NIOSH), Centers for Disease Control and Prevention (CDC)—Flight attendants experience exposures which may affect breast cancer risk including exposure to elevated levels of cosmic radiation and circadian rhythm disruption. This study will evaluate the incidence of breast and other cancers among a cohort of approximately 10,000

women who were employed as flight attendants.

The occurrence of breast and other cancers will be obtained from death certificates and from telephone interviews with living women and next-of-kin of deceased women. Each interview will take approximately 60 minutes to complete. Medical records will be requested to confirm cancer diagnoses. The primary analysis will evaluate the risk of breast and other cancers associated with occupational exposure within the cohort. The secondary analysis will compare the incidence of breast and other cancers in the cohort to that in the general population, with adjustment for factors which might increase cancer risk in the cohort independent of occupational exposure to cosmic radiation and circadian rhythm disruption. The annualized total burden is 10,525 hours.

Respondents	Number of respondents	Number of responses/ respondent	Avg. burden per response (in hrs.)
Flight attendants/proxies	10,000	1	60/60
Flight attendants/proxies whose eligibility for the study is unknown	300	1	5/60
Medical providers	1,000	1	30/60

Dated: December 15, 2000.

Nancy Cheal,

Acting Associate Director for Policy, Planning, and Evaluation, Centers for Disease Control and Prevention (CDC).

[FR Doc. 00-32549 Filed 12-20-00; 8:45 am]

BILLING CODE 4163-18-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 00N-1637]

Agency Information Collection Activities; Proposed Collection; Comment Request; Transmittal of Advertising and Promotional Labeling for Drugs and Biologics for Human Use

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing an opportunity for public comment on the proposed collection of certain information by the agency. Under the Paperwork Reduction Act of 1995 (the PRA), Federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on the collection of information regarding the promotion of prescription human drugs and biologics—specifically advertising and promotional labeling.

DATES: Submit written or electronic comments on the collection of information by February 20, 2001.

ADDRESSES: Submit electronic comments on the collection of information to <http://www.accessdata.fda.gov/scripts/oc/dockets/edockethome.cfm>. Submit written comments on the collection of information to the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Karen L. Nelson, Office of Information Resources Management (HFA-250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-1482.

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501-3520), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. "Collection of information" is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques when appropriate, and other forms of information technology.

Transmittal of Advertising and Promotional Labeling for Drugs and Biologics for Human Use (OMB Control Number 0910-0376) (Form FDA 2253)

Under § 314.81(b)(3)(i) (21 CFR 314.81(b)(3)(i)), sponsors of approved applications for marketed prescription drugs and antibiotic drugs for human use are required to submit specimens of promotional labeling and advertisements at the time of initial dissemination of the labeling and at the time of initial publication of the advertisements. Each submission is required to be accompanied by a completed transmittal Form FDA 2253 (Transmittal of Advertisements and Promotional Labeling for Drugs and Biologics for Human Use). Statutory authority for the collection of this information is provided by sections 505(a), (b), (j), and (k) and 701(a) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(a), (b), (j), and (k) and 371(a)). Similarly, under 21 CFR 601.12(f)(4) (62 FR 39890, July 24, 1997; effective October 7, 1997), manufacturers of licensed biological products are required to submit specimens of advertising and promotional labeling to FDA in accordance with § 314.81(b)(3)(i). Statutory authority for the collection of this information is provided by section 351 of the Public Health Service Act (42 U.S.C. 262), which gives FDA the responsibility to prescribe standards designed to ensure the safety, purity, potency, and effectiveness of biological products. In furtherance of this responsibility, FDA regulates advertising and labeling for biological products. Currently, specimens of advertising and promotional labeling are submitted to FDA's Center for Biologics Evaluation and Research (CBER) with either Form FDA 2253 or Form FDA 2567, which is a two-part transmittal form that is also used to transmit other forms of labeling (e.g., circulars, package labels, and container labels) for CBER review when a sponsor is requesting premarket approval of a product or proposing changes to a product carton or container labeling.

The many types of promotional materials are described on Form FDA 2253 for easy reference. For example, possible submitted promotional materials could be a consumer advertisement, a professional sales aid, or a consumer broadcast advertisement. A single submission would include two copies each of the promotional materials, Form FDA 2253, and the approved product labeling. Submissions of multiple applications are handled in

a similar manner as described in the form.

In 1998, FDA revised Form FDA 2253 to enable it to be used to transmit specimens of promotional labeling and advertisements for biological products as well as for prescription drugs and antibiotics. The revised form had the following major changes:

1. The revised, harmonized form is now used by sponsors of approved applications for marketed prescription drugs and antibiotic drugs regulated by the Center for Drug Evaluation and Research (CDER) who must submit specimens of advertisements and promotional labeling to the agency, and it may be used by manufacturers of licensed biological products regulated by the Center for Biologics and Research (CBER) who submit draft and/or final copies of promotional labeling and advertisements to the agency. The revised and harmonized Form FDA 2253 eliminated the need for sponsors to use two different forms to transmit similar materials for submission to the two centers. Although manufacturers of biological products had the option to continue to use Form FDA 2567 to transmit advertisements and promotional labeling if they wished, the other uses of Form FDA 2567 remained unchanged.

2. The revised, harmonized form updated the information about the types of promotional materials and the codes that are used to clarify the type of advertisement or promotional labeling (e.g., consumers, professionals, news services); and it helped ensure that the submission is complete.

3. The revised form provides for sponsors to submit specimens of multiproduct promotional labeling and advertisements to only two files; to the approved product application of the sponsor's choice (generally the most frequently promoted product), and to a company name file. This revision in the form has saved sponsors time and money by eliminating the need for making multiple submissions of the same promotional materials. In addition, because the form was revised, sponsors no longer need to maintain dual inventories of both forms, and they now have multiple processing capabilities.

From October 1, 1999, through September 30, 2000, 386 sponsors submitted 12,235 postmarketing reports via Form FDA 2253 to CDER; this included 2,343 multiple submissions. In the same time period, 134 sponsors submitted 4,243 postmarketing reports via Forms FDA 2253 and 2567 to CBER.

FDA estimates the burden of this collection of information as follows:

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN¹

21 CFR Section	No. of Respondents	Annual Frequency per Response ²	Total Annual Responses ³	Hours per Response	Total Hours
CBER (none)	134 ⁴	32	4,243	2	8,486
CDER § 314.81(b)(3)(i)	386 ⁵	32	12,395	2	24,790
Total					33,276

¹ There are no capital costs or operating and maintenance costs associated with this collection of information.

² Average number (rounded to the nearest whole number) of submissions submitted annually per sponsor. We note that some sponsors submit only once per year, whereas one sponsor had 893 submissions in 1999.

³ Total number of Form FDA 2253 submissions to CDER and Form FDA 2253 plus Form FDA 2567 to CBER in fiscal year (FY) 1999.

⁴ Number of sponsors that submitted establishment license applications and product license applications to CBER in FY 1999.

⁵ Number of sponsors that submitted new drug applications (including applications for new antibiotics), abbreviated new drug applications, and abbreviated antibiotic applications in FY 1999.

In FY 1999, CDER received a total of 12,395 submissions and CBER received 4,353 submissions that would require the use of this form. FDA estimates that 2 hours would be required for an industry regulatory affairs specialist to fill out the form, collate the documentation, and send the submissions to CDER or CBER.

Electronic Submission of Promotional Materials Regarding Prescription Drugs and Biologics for Human Use

CDER and CBER are currently piloting with approximately 20 sponsors, different methods to submit postmarketing submissions of advertising and promotional labeling. FDA anticipates publishing in the **Federal Register** a draft guidance for industry entitled "Providing Regulatory Submissions in Electronic Format—Prescription Drug Advertising and Promotional Labeling." By using this suggested format for electronically submitting promotional materials, we anticipate that by January 2002, sponsors will submit about 20 percent of all materials electronically via Form FDA 2253. Further, we anticipate posting a fillable electronic Form FDA 2253 on FDA's Internet site. Applicants may then have the option to fill out the form on their computer, and with additional software, they can maintain records regarding submitted promotional materials.

Dated: December 14, 2000.

Margaret M. Dotzel,

Associate Commissioner for Policy.

[FR Doc. 00–32617 Filed 12–20–00 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 00N–1395]

Agency Information Collection Activities; Announcement of OMB Approval; Medicated Feed Mill License

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a collection of information entitled "Medicated Feed Mill License" has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

FOR FURTHER INFORMATION CONTACT: Denver Presley, Office of Information Resources Management (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1472.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of October 6, 2000 (65 FR 59852), the agency announced that the proposed information collection had been submitted to OMB for review and clearance under 44 U.S.C. 3507. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. OMB has now approved the information collection and has assigned OMB control number 0910–0337. The approval expires on November 30, 2003. A copy of the supporting statement for this information collection is available on the Internet at <http://www.fda.gov/ohrms/dockets>.

Dated: December 14, 2000.

Margaret M. Dotzel,

Associate Commissioner for Policy.

[FR Doc. 00–32615 Filed 12–20–00; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 00D–1316]

Agency Information Collection Activities; Announcement of OMB Approval; Guidance for Industry on How to Use E-Mail to Submit a Request for a Meeting or Teleconference to the Office of New Animal Drug Evaluation

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a collection of information entitled "Guidance for Industry on How to Use E-Mail to Submit a Request for a Meeting or Teleconference to the Office of New Animal Drug Evaluation" has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

FOR FURTHER INFORMATION CONTACT: Denver Presley, Office of Information Resources Management (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1472.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of September 21, 2000 (65 FR 57194), the agency announced that the proposed information collection had been submitted to OMB for review and clearance under 44 U.S.C. 3507. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. OMB has now approved the information collection and has assigned OMB control number 0910–0452. The approval expires on November 30, 2003. A copy of the supporting statement for this information collection is available on the Internet at <http://www.fda.gov/ohrms/dockets>.

Dated: December 14, 2000.

Margaret M. Dotzel,

Associate Commissioner for Policy.

[FR Doc. 00-32616 Filed 12-20-00 8:45 am]

BILLING CODE 4160-01-F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 00N-1449]

Agency Information Collection Activities; Submission for OMB Review; Comment Request; Guidance for Industry: Changes to an Approved NDA or ANDA

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that the proposed collection of information listed below has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Submit written comments on the collection of information by January 22, 2001.

ADDRESSES: Submit written comments on the collection of information to the Office of Information and Regulatory Affairs, OMB, New Executive Office Bldg., 725 17th St. NW., rm. 10235, Washington, DC 20503, Attn: Wendy Taylor, Desk Officer for FDA.

FOR FURTHER INFORMATION CONTACT: Karen L. Nelson, Office of Information Resources Management (HFA-250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-1482.

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Guidance for Industry: Changes to an Approved NDA or ANDA

On November 21, 1997, the President signed the Food and Drug Administration Modernization Act (the Modernization Act) (Pubic Law 105-115) into law. Section 116 of the Modernization Act amended the Federal Food, Drug, and Cosmetic Act (the act) by adding section 506A (21 U.S.C. 356a), which describes requirements and procedures for making and reporting manufacturing changes to approved new drug applications (NDA's) and abbreviated new drug

applications (ANDA's), to new and abbreviated animal drug applications, and to license applications for biological products.

The guidance is intended to assist applicants in determining how they should report changes to an approved NDA or ANDA under section 116 of the Modernization Act, which provides requirements for making and reporting manufacturing changes to an approved application and for distributing a drug product made with such changes.

The guidance provides recommendations to holders of approved NDA's and ANDA's who intend to make postapproval changes in accordance with section 506A of the act. The guidance covers recommended reporting categories for postapproval changes for drugs, other than specified biotechnology and specified synthetic biological products. Recommendations are provided for postapproval changes in: (1) Components and composition, (2) sites, (3) manufacturing process, (4) specification(s), (5) package, (6) labeling, and (7) miscellaneous changes.

Some of the basic elements of section 506A of the act are as follows:

A drug made with a manufacturing change, whether a major manufacturing change or otherwise, may be distributed only after the applicant validates the effects of the change on the identity, strength, quality, purity, and potency of the drug as these factors may relate to the safety or effectiveness of the drug (sections 506A(a)(1) and (b) of the act). This section recognizes that additional testing, beyond testing to ensure that an approved specification is met, is required to ensure unchanged identity, strength, quality, purity, or potency as these factors may relate to the safety or effectiveness of the drug.

A drug made with a major manufacturing change may be distributed only after the applicant submits a supplemental application to FDA and the supplemental application is approved by the agency. The application is required to contain information determined to be appropriate by FDA and include the information developed by the applicant when "validating the effects of the change" (section 506A(c)(1) of the act).

A major manufacturing change is a manufacturing change determined by FDA to have substantial potential to adversely affect the identity, strength, quality, purity, or potency of the drug as these factors may relate to the safety or effectiveness of the drug. Such changes include: (1) A change made in the qualitative or quantitative formulation of the drug involved or in the specifications in the approved

application or license unless exempted by FDA by regulation or guidance; (2) a change determined by FDA by regulation or guidance to require completion of an appropriate clinical study demonstrating equivalence of the drug to the drug manufactured without the change; and (3) other changes determined by FDA by regulation or guidance to have a substantial potential to adversely affect the safety or effectiveness of the drug (section 506A(c)(2) of the act).

FDA may require submission of a supplemental application for drugs made with manufacturing changes that are not major (section 506A(d)(1)(B) of the act) and establish categories of manufacturing changes for which a supplemental application is required (section 506A(d)(1)(C) of the act). In such a case the applicant may begin distribution of the drug 30 days after FDA receives a supplemental application unless the agency notifies the applicant within the 30-day period that prior approval of the application is required (section 506A(d)(3)(B)(i) of the act). FDA may also designate a category of manufacturing changes that permit the applicant to begin distributing a drug made with such changes upon receipt by the agency of a supplemental application for the change (section 506A(d)(3)(B)(ii) of the act). If FDA disapproves a supplemental application, the agency may order the manufacturer to cease the distribution of drugs that have been made with the disapproved change (section 506A(d)(3)(B)(iii) of the act).

FDA may authorize applicants to distribute drugs without submitting a supplemental application (section 506A(d)(1)(A) of the act) and may establish categories of manufacturing changes that may be made without submitting a supplemental application (section 506A(d)(1)(C) of the act). The applicant is required to submit a report to FDA on such a change and the report is required to contain information the agency deems to be appropriate and information developed by the applicant when validating the effects of the change. FDA may also specify the date on which the report is to be submitted (section 506A(d)(2)(A) of the act). If during a single year an applicant makes more than one manufacturing change subject to an annual reporting requirement, FDA may authorize the applicant to submit a single report containing the required information for all the changes made during the year (annual report) (section 506A(d)(2)(B) of the act).

Section 506A of the act provides FDA with considerable flexibility to

determine the information and filing mechanism required for the agency to assess the effect of manufacturing changes in the safety and effectiveness of the product. There is a corresponding need to retain such flexibility in the guidance on section 506A of the act to ensure that the least burdensome means for reporting changes are available. FDA believes that such flexibility will allow it to be responsive to increasing knowledge of and experience with certain types of changes and help ensure the efficacy and safety of the products involved. For example, a change that may currently be considered to have a substantial potential to have an adverse

effect on the safety or effectiveness of the product may, at a later date, based on new information or advances in technology, be determined to have a lesser potential to have such an adverse effect. Conversely, a change originally considered to have a minimal or moderate potential to have an adverse effect on the safety or effectiveness of the product may later, as a result of new information, be found to have an increased, substantial potential to adversely affect the product. The guidance enables the agency to respond more readily to knowledge gained from manufacturing experience, further research and data collection, and

advances in technology. The guidance describes the agency's current interpretation of specific changes falling into the four filing categories. Section 506A of the act explicitly provides FDA the authority to use guidance documents to determine the type of changes that do or do not have a substantial potential to adversely affect the safety or effectiveness of the drug product. The use of guidance documents allows FDA to more easily and quickly modify and update important information.

FDA estimates the burden of this collection of information as follows:

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN ¹

Federal Food, Drug, and Cosmetic Act Section	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
506A(c)(1) and (c)(2) Prior approval supplement	594	3	1,782	150	267,300
506A(d)(1)(B), (d)(1)(C), and (d)(3)(B)(i) Changes being made (CBE) in 30-day supplement	594	5	2,970	95	282,150
506A(d)(1)(B), (d)(1)(C), and (d)(3)(B)(ii) CBE supplement	486	1	486	95	46,170
506A(d)(1)(A), (d)(1)(C), (d)(2)(A), and (d)(2)(B) Annual report	704	10	7,040	35	246,400
Total					842,020

¹There are no capital costs or operating and maintenance costs associated with this collection of information.

Section 506A(a)(1) and (b) of the act require the holder of an approved application to validate the effects of a manufacturing change on the identity, strength, quality, purity, or potency of the drug as these factors may relate to the safety or effectiveness of the drug before distributing a drug made with the change. Under section 506A(d)(3)(A) of the act, information developed by the applicant to validate the effects of the change regarding identity, strength, quality, purity, and potency is required to be submitted to FDA as part of the supplement or annual report. Thus, no separate estimates are provided for these sections in table 1 of this document; estimates for validation requirements are included in the estimates for supplements and annual reports. The guidance does not provide recommendations on the specific information that should be developed by the applicant to validate the effect of the change on the identity, strength (e.g., assay, content uniformity); quality (e.g., physical, chemical, and biological properties); purity (e.g., impurities and degradation products); or potency (e.g., biological activity, bioavailability, and bioequivalence) of a product as they may relate to the safety or effectiveness of the product.

Section 506A(c)(1) and (c)(2) of the act set forth requirements for changes requiring supplement submission and approval prior to distribution of the product made using the change (major changes). Under these sections of the act, a supplement must be submitted for any change in the product, production process, quality controls, equipment, or facilities that has a substantial potential to have an adverse effect on the identity, strength, quality, purity, or potency of the product as these factors may relate to the safety or effectiveness of the product. The applicant must obtain approval of a supplement from FDA prior to distribution of a product made using the change.

Based on data concerning the number of supplements received by the agency, FDA estimates that approximately 1,782 supplements will be submitted annually under section 506A(c)(1) and (c)(2) of the act. FDA estimates that approximately 594 applicants will submit such supplements, and that it will take approximately 150 hours to prepare and submit to FDA each supplement.

Section 506A(d)(1)(B), (d)(1)(C), and (d)(3)(B)(i) of the act set forth requirements for changes requiring supplement submission at least 30 days prior to distribution of the product

made using the change (moderate changes). Under these sections, a supplement must be submitted for any change in the product, production process, quality controls, equipment, or facilities that has a moderate potential to have an adverse effect on the identity, strength, quality, purity, or potency of the product as these factors may relate to the safety or effectiveness of the product. Distribution of the product made using the change may begin not less than 30 days after receipt of the supplement by FDA.

Based on data concerning the number of supplements received by the agency, FDA estimates that approximately 2,970 supplements will be submitted annually under section 506A(d)(1)(B), (d)(1)(C), and (d)(3)(B)(i) of the act. FDA estimates that approximately 594 applicants will submit such supplements, and that it will take approximately 95 hours to prepare and submit to FDA each supplement.

Under section 506A(d)(3)(B)(ii) of the act, FDA may designate a category of changes for the purpose of providing that, in the case of a change in such category, the holder of an approved application may commence distribution of the drug upon receipt by the agency of a supplement for the change. Based on data concerning the number of

supplements received by the agency, FDA estimates that approximately 486 supplements will be submitted annually under section 506A(d)(3)(B)(ii) of the act. FDA estimates that approximately 486 applicants will submit such supplements, and that it will take approximately 95 hours to prepare and submit to FDA each supplement.

Section 506A(d)(1)(A), (d)(1)(C), (d)(2)(A), and (d)(2)(B) of the act set forth requirements for changes to be described in an annual report (minor changes). Under these sections, changes in the product, production process, quality controls, equipment, or facilities that have a minimal potential to have an adverse effect on the identity, strength, quality, purity, or potency of the product as these factors may relate to the safety or effectiveness of the product must be documented by the applicant in the next annual report.

Based on data concerning the number of supplements and annual reports received by the agency, FDA estimates that approximately 7,040 annual reports will include documentation of certain manufacturing changes as required under section 506A(d)(1)(A), (d)(1)(C), (d)(2)(A), and (d)(2)(B) of the act. FDA estimates that approximately 704 applicants will submit such information and that it will take approximately 35 hours to prepare and submit to FDA the information for each annual report.

In the **Federal Register** of September 7, 2000 (65 FR 54279), the agency requested comments on the proposed collections of information. FDA received one comment which, disagreed with the "hours per response" burden. The comment estimated that it would take approximately 182 hours to prepare and submit prior approval supplements; 130 hours for changes-being effected supplements; and 50 hours for changes to be described in an annual report.

FDA has considered the comment as well as other information it has received, and it has revised the burden estimates. The estimate for preparing and submitting prior approval supplements has been increased to 150 hours, from the previous estimate of 120 hours; the estimate for changes-being-effected supplements has been increased to 95 hours, from previous estimate of 80 hours; and the estimate for changes to be described in an annual report has been increased to 35 hours, from the previous estimate of 25 hours.

The comment also recommended that FDA summarize reporting requirements in a tabular format in addition to the discussion provided in the guidance, and that flow charts should be developed to aid sponsors through the process of determining the proper

reporting mechanism. The comment also stated that it would be helpful to have easy access to "such things as inks used in CDER-approved products and GMP status."

FDA declines to discuss these suggestions in this notice. The purpose of this notice and the September 7, 2000, notice is to obtain comments on the agency's estimates of the information collection burden that would result from the Guidance "Changes to an Approved NDA or ANDA." The above comments pertain to the guidance document itself and should be directed to Docket Number 99D-0529 (see the notice announcing the availability of the guidance document that published in the **Federal Register** of November 23, 1999 (64 FR 65716)).

Dated: December 14, 2000.

Margaret M. Dotzel,

Associate Commissioner for Policy.

[FR Doc. 00-32614 Filed 12-20-00; 8:45 am]

BILLING CODE 4160-01-F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

[HCFA-2092-N]

Medicare Program; Deductible Amount for Medigap High Deductible Policy Options for Calendar Year 2001

AGENCY: Health Care Financing Administration (HCFA), HHS.

ACTION: Notice.

SUMMARY: This notice announces the annual deductible amount of \$1,580 for the Medicare supplemental health insurance (Medigap) high deductible policy options for 2001. High deductible policy options are those with benefit packages classified as "F" or "J" that have a high deductible feature. The deductible amount represents the annual out-of-pocket expenses (excluding premiums) that a beneficiary who chooses one of these options must pay before the policy begins paying benefits.

EFFECTIVE DATE: January 1, 2001.

FOR FURTHER INFORMATION CONTACT: Kathryn McCann, (410) 786-7623.

SUPPLEMENTARY INFORMATION:

I. Background

A. Medicare Supplemental Insurance

A Medicare supplemental, or Medigap, policy is the principal type of private health insurance that a beneficiary may purchase to cover

certain costs that Medicare does not cover. The beneficiary is responsible for deductibles and coinsurance amounts for both Part A (hospital insurance) and Part B (supplementary medical insurance) of the Medicare program. In addition, Medicare generally does not cover custodial nursing home care, eyeglasses, dental care, and most outpatient prescription drugs. A beneficiary must either pay the full cost of these services, or he or she may purchase additional private health insurance to help pay these costs. Medigap policies offer coverage for some or all of the deductibles and coinsurance amounts required by Medicare. Additionally, Medigap policies may provide coverage for some services that are not covered under the Medicare program.

Section 1882 of the Social Security Act (the Act) establishes, among other things, minimum standards for Medigap policies. No Medigap policy may be issued in a State unless the policy meets one of the following criteria: (a) the Secretary has certified it as meeting Federal standards and requirements, or (b) it complies with State laws established in accordance with section 1882(b)(1) of the Act.

The Omnibus Budget Reconciliation Act of 1990 (OBRA 90) amended the Act by standardizing Medigap benefits and requiring that no more than 10 Medigap benefit packages, Plans "A" through "J," be offered nationwide. Three States (Wisconsin, Minnesota, and Massachusetts) experimented with standardizing benefits before the enactment of Federal standards. These States were permitted to keep their alternative forms of Medigap standardization, and we refer to them as the "waivered States."

Plan "A" is the basic benefit package. It covers Medicare Part A hospital coinsurance plus coverage for 365 additional days after Medicare benefits end, over the beneficiary's lifetime, Medicare Part B coinsurance (generally 20 percent of the Medicare-approved amount) or, in the case of hospital outpatient department services under a prospective payment system, the applicable copayment, and coverage for the first 3 pints of blood per year. Medigap Plans "B" through "J" contain this basic benefit package, as well as different combinations of coverage for some or all of the following benefits:

- Medicare Part A inpatient hospital deductibles.
- Skilled-nursing facility coinsurance.
- Foreign travel health emergencies, at home recovery.
- Preventive care.

- Some prescription drug coverage.
- Medicare Part B excess charges protection.

B. High Deductible Medigap Standard Policies

Section 4032 of the Balanced Budget Act of 1997 (BBA) added high deductible versions of two of the standard Medigap policies or their counterparts in the waived States. In the three waived States, high deductible versions of the plans that most closely approximate the benefits contained in Plans "F" and "J" are authorized by the Balanced Budget Act. Unlike the regular versions of Plans "F" and "J," the high deductible versions of these policies do not begin paying benefits until the deductible amount is met. Amounts included in this deductible are the expenses that would ordinarily be paid by the regular version of the policy, including Medicare deductibles for Parts A and B. The Plan "F" deductible does not include the separate foreign travel emergency deductible of \$250. The Plan "J" deductible does not include the plan's separate \$250 prescription drug deductible or the plan's separate \$250 deductible for foreign travel emergencies.

II. Provisions of This Notice

In 1998 and 1999, the high deductible amount was statutorily-defined as \$1,500 in section 1882(p)(11)(C)(i) of the Act. For 2000, the high deductible amount was increased to \$1,530, based on the percent increase in the Consumer Price Index (CPI) for all urban consumers for the 12-month period ending August 1999. For 2001, the high deductible amount is increased by the percent increase in the Consumer Price Index (CPI) for all urban consumers (all items, U.S. city average) for the 12-month period ending August 2000. The percent increase in the CPI for all urban consumers (all items, U.S. city average) for the 12-month period ending in August 2000 was 3.35 percent, according to the Division of Labor Statistics, Department of Labor. A 3.35 percent increase in \$1,530 is \$1,581.26. (This figure can also be found by dividing the August 2000 CPI (172.7) by the August 1999 CPI (167.1), which equals 1.0335129. Multiplying this number by the 2000 deductible (\$1,530) equals 1581.27 which, rounded to the nearest \$10 multiple, is \$1,580. Section 1882(p)(11)(C)(ii) of the Act stipulates that this amount (\$1,581.26) be rounded to the nearest multiple of \$10 to find the high deductible amount for the subsequent year. After rounding \$1,581.26 to the nearest \$10 multiple,

the 2001 deductible for the Medigap high deductible options is \$1,580. 2

Authority: Section 1882 of the Social Security Act.
(Catalog of Federal Domestic Assistance Program No. 93.773, Medicare—Hospital Insurance, and Program No. 93.774, Medicare—Supplementary Medical Insurance Program)

November 6, 2000.

Michael M. Hash

Acting Administrator, Health Care Financing Administration

[FR Doc. 00-32441 Filed 12-20-00; 8:45 am]

BILLING CODE 4120-01-U

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

[HCFA-1172-N]

Medicare Program; January 10, 2001, Meeting of the Advisory Panel on Medicare Education

AGENCY: Health Care Financing Administration (HCFA), HHS.

ACTION: Notice of meeting.

SUMMARY: In accordance with section 10(a) of the Federal Advisory Committee Act, this notice announces a meeting on January 10, 2001 of the Advisory Panel on Medicare Education (the Panel). This Panel advises and makes recommendations to the Secretary of the Department of Health and Human Services (HHS) and the Administrator of the Health Care Financing Administration (HCFA) on opportunities for HCFA to optimize the effectiveness of the National Medicare Education Program and other HCFA programs that help Medicare beneficiaries understand Medicare and the range of Medicare options available with the passage of the Medicare+Choice Program. The Panel meeting is open to the public.

DATES: The meeting is scheduled for Wednesday, January 10, 2001, from 8 a.m. e.s.t until 5:15 p.m. e.s.t.

ADDRESSES: The meeting will be held at the Madison Hotel, at 1177 15th Street, NW., Washington, DC 20005, Telephone: (202) 862-1600.

FOR FURTHER INFORMATION CONTACT: Ms. Nancy Caliman, Public Affairs Specialist, Partnership Development Group, Center for Beneficiary Services, Health Care Financing Administration, 7500 Security Boulevard, S2-23-05, Baltimore, MD, 21244-1850, (410) 786-5052. Please refer to the HCFA Advisory Committees Information Line (1-877-449-5659 toll free)/(410-786-9379

local) or the Internet (<http://www.hcfa.gov/events/apme/homepage.htm>) for additional information and updates on committee activities, or by contacting Ms. Caliman via E-mail at APME@hcfa.gov. Press inquiries are handled through the HCFA Press Office at (202) 690-6145.

SUPPLEMENTARY INFORMATION: The Federal Advisory Committee Act (5 U.S.C. App. 2, Sec. 9(a)), Public Law 92-463, grants to the Secretary the authority to establish an advisory panel if the Secretary finds the panel necessary and in the public interest. The Secretary signed the charter establishing this Panel on January 21, 1999 (64 FR 7899, February 17, 1999). The Advisory Panel on Medicare Education advises us on opportunities to enhance the effectiveness of consumer education materials serving the Medicare program.

The goals of the Panel are as follows:

- Developing and implementing a national Medicare education program that describes the options for selecting a health plan under Medicare.

- Enhancing the Federal Government's effectiveness in informing the Medicare consumer, including the appropriate use of public-private partnerships.

- Expanding outreach to vulnerable and underserved communities, including racial and ethnic minorities, in the context of a national Medicare education program.

- Assembling an information base of best practices for helping consumers evaluate health plan options, and for building a community infrastructure for information, counseling, and assistance.

The current members of the Panel are: Diane Archer, J.D., President, Medicare Rights Center; David Baldrige, Executive Director, National Indian Council on Aging; Bruce Bradley, M.B.A., Director, Managed Care Plans, General Motors Corporation; Carol Cronin, Chairperson, Advisory Panel on Medicare Education; Joyce Dubow, M.U.P., Senior Policy Advisor, Public Policy Institute, AARP; Jennie Chin Hansen, Executive Director, On Lok Senior Services; Elmer Huerta, M.D., M.P.H., Director, Cancer Risk and Assessment Center, Washington Hospital Center; Bonita Kallestad, J.D., M.S., Western Minnesota Legal Services, Mid Minnesota Legal Assistance; Steven Larsen, J.D., M.A., Maryland Insurance Commissioner, Maryland Insurance Administration; Brian Lindberg, M.M.H.S., Executive Director, Consumer Coalition for Quality Health Care; Heidi Margulis, B.A., Vice President, Government Affairs, Humana, Inc.; Patricia Neuman, Sc.D., Director,

Medicare Policy Project, Henry J. Kaiser Family Foundation; Elena Rios, M.D., M.S.P.H., President, National Hispanic Medical Association; Samuel Simmons, B.A., President and CEO, The National Caucus and Center on Black Aged, Inc.; Nina Weinberg, M.A., President, National Health Council; and Edward Zesk, B.A., Executive Director, Aging 2000.

The agenda for the January 10, 2001, meeting will include the following:

- Recap of the previous (September 21, 2000) meeting.
- Legislative and agency update.
- Presentation on the Federal agency budget process.
- Medicare education budget and priorities for the 2000/2001 and 2001/2002 budget periods.
- Panel discussion and examination of model programs that provide culturally and linguistically appropriate education and information services to the Medicare population.
- Public comment.

Individuals or organizations that wish to make 5-minute oral presentations on the agenda issues should contact Nancy Caliman by 12 noon, Wednesday, January 3, 2001, to be scheduled. The number of oral presentations may be limited by the time available. A written copy of the oral remarks should be submitted to Ms. Caliman no later than 12 noon, Wednesday, January 3, 2001. Anyone who is not scheduled to speak may submit written comments to Ms. Caliman by 12 noon, Wednesday, January 3, 2001. The meeting is open to the public, but attendance is limited to the space available. Individuals requiring sign language interpretation for the hearing impaired or other special accommodations should contact Ms. Caliman at least 15 days before the meeting.

(Section 222 of the Public Health Service Act (42 U.S.C. 217(a)) and section 10(a) of Public Law 92-463 (5 U.S.C. App. 2, section 10(a)); 41 CFR 101-6.1015)

(Catalog of Federal Domestic Assistance Program No. 93.773, Medicare—Hospital Insurance; and Program No. 93.774, Medicare—Supplementary Medical Insurance Program)
Dated: December 12, 2000.

Michael M. Hash,
Acting Administrator, Health Care Financing Administration.
[FR Doc. 00-32440 Filed 12-20-00; 8:45 am]
BILLING CODE 4120-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Proposed Data Collection; Comment Request; Health Information National Trends Survey (HINTS)

SUMMARY: In compliance with the requirement of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 for opportunity for public comment on proposed data collection projects, the National Institutes of Health (NIH), National Cancer Institute (NCI) will publish periodic summaries of proposed projects to be submitted to the Office of Management and Budget (OMB) for review and approval.

Proposed Collection

Title: Health Information National Trends Survey (HINTS). *Type of Information Collection Request:* New. *Need and Use of Information Collection:* As a result of the ongoing and rapidly expanding communication revolution (e.g., the development of the Internet), there is an unprecedented opportunity to rapidly communicate information about cancer and other health topics to the general public. Developing appropriate messages for the public about cancer prevention, detection, diagnosis, treatment, and survivorship requires an understanding of individuals' sources and access to cancer-related information, their knowledge about cancer and other

health information, or the factors that enhance or may hinder access, use, or knowledge of health information.

The HINTS is a new telephone survey designed to provide nationally representative, population-based standardized data on health knowledge and health information for the United States. The survey will establish important baseline data about cancer communication practices, preferences for information, and cancer knowledge across the country. This survey will provide data on the public's perceived needs for cancer information, sources and access to health information (e.g., health care providers, Internet, mass media), current knowledge and understanding about cancer prevention and detection, and the barriers to more effectively understanding and utilizing cancer-related information. The HINTS is intended to be conducted every 2 years to measure progress in improving cancer knowledge and communication among the general public. The survey will be administered to one sample adult in 12,000 households, and is intended to have an adequate sample size to produce stable estimates for racial and ethnic minority populations.

Data from this survey are essential for NCI to develop improved cancer-related messages and materials and to tailor these messages for different audiences, especially for cancer prevention and detection. Data will be used to help selecting the best means of communicating cancer-related messages to different audiences (communication channels) to reach the diverse audiences in the United States. Finally, information obtained in this survey data will be used to identify research gaps and to guide the direction and decisions about NCI's research efforts in health promotion and health communication.

Frequency of response: One-time. *Affected public:* Individuals. *Type of Respondents:* U.S. adults. The annual reporting burden is as follows:

TABLE X.—ANNUALIZED BURDEN ESTIMATES FOR HINTS DATA COLLECTION

Data collection	Estimated number of respondents	Frequency of response	Average time per response	Annual burden hours
Pilot Survey	150	1	0.333	50
HINTS	12,000	1	0.333	4,000
Totals	12,150			4,050

There are no Capital Costs to report. There are no Operating or Maintenance Costs to report.

Request for Comments: Written comments and/or suggestions from the

public and affected agencies are invited on one or more of the following points: (1) Whether the proposed collection of information is necessary for the proposed performance of the functions

of the agency, including whether the information shall have practical utility; (2) The accuracy of the estimate of the burden of the proposed collection of information including the validity of the

methodology and assumptions used; (3) Ways to enhance the quality, utility, and clarity of the information to be collected; and (4) Ways to minimize the burden of the collection of information on those who are to respond, including the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

FOR FURTHER INFORMATION CONTACT: To request more information on the proposed project or to obtain a copy of the data collection plans and instruments, contact David E. Nelson, M.D., M.P.H., Project Officer, National Cancer Institute, EPN 4068, 6130 Executive Boulevard MSC 7365, Bethesda, Maryland 20852-7365, or call non-toll-free number (301) 594-9904, or FAX your request to (301) 480-2087, or E-mail your request, including your address, to dn83r@nih.gov.

Comments Due Date: Comments regarding this information collection are best assured of having their full effect if received within 30 days of this notice.

Dated: December 15, 2000.

Reesa L. Nichols,

OMB Clearance Liaison.

[FR Doc. 00-32595 Filed 12-20-00; 8:45 am]

BILLING CODE 4140-01-M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Notice of Meeting: Chronic Fatigue Syndrome Coordinating Committee

In accordance with section 10(a) of the Federal Advisory Committee Act, as amended (5 U.S.C., Appendix 2), notice is hereby given of a meeting of the Chronic Fatigue Syndrome Coordinating Committee.

Name: Chronic Fatigue Syndrome Coordinating Committee (CFSCC).

Time and Date: Tuesday, January 30, 2001, from 9 a.m. to 5 p.m.

Place: WestCoast Grant Hotel Seattle, 1415 Fifth Avenue, Seattle, WA 98101.

Status: Open to the public, limited only by the space available. The meeting room will accommodate approximately 100 people. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should notify the Contact Person listed below in advance of the meeting.

Purpose: The Committee is charged with providing advice to the Secretary, the Assistant Secretary for Health, and the Commissioner, Social Security Administration (SSA), to assure interagency coordination and communication regarding chronic fatigue syndrome (CFS) research and other related issues; facilitating increased

DHHS and agency awareness of CFS research and educational needs; developing complementary research programs that minimize overlap; identifying opportunities for collaborative and/or coordinated efforts in research and education; and developing informed responses to constituency groups regarding DHHS and SSA efforts and progress.

Matters to be Discussed: The meeting will include disability issues and CFS as a primary focus, with a presentation by representatives from the Northwest Disability and Business Technical Assistance Center at the Washington State Governor's Committee on Disability Issues and Employment. Other matters to be discussed will include; progress reports from the Name Change Working Group and other working groups of the CFSCC; update on current Federal activities; and identification of areas for future focus for the CFSCC. Public comments will be received at the meeting from no more than 6 individuals on the designated topic of disability and CFS, specifically, obstacles in the process of applying for disability benefits; obstacles faced in the workplace by those disabled with CFS; and employment issues and reasonable accommodation in the workplace. Priority will be given to members of the public from the region (Western United States) who have never had the opportunity to provide formal public comments at meetings of the CFSCC since its inception in May 1997. Persons wishing to make oral comments on the topic above should notify the contact person listed below no later than COB on January 12, 2001. Five minutes will be allotted for each statement; both printed and electronic copies are requested for the record. Individuals designated to present comments will be notified no later than January 16, 2001.

Contact Person for More Information: Janice C. Ramsden, Executive Secretary, CFSCC, Office of the Principal Deputy Director, NIH, Building 1, Room 333, 1 Center Drive MSC 0159, Bethesda, Maryland 20892-0159, e-mail jr52h@nih.gov or telephone 301-496-0959.

Dated: December 14, 2000.

LaVerne Stringfield,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 00-32594 Filed 12-20-00; 8:45 am]

BILLING CODE 4140-01-M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute on Drug Abuse; 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 meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections

552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The contract proposals and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the contract proposals, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute on Drug Abuse Special Emphasis Panel, "Develop Drug Abuse Screening/Assessment and Intervention for Youth for Primary Care/Managed Care Providers."

Date: December 18, 2000.

Time: 9:30 am to 12:00 pm.

Agenda: To review and evaluate contract proposals.

Place: Neuroscience Center, National Institutes of Health, 6001 Executive Blvd., Bethesda, MD 20892 (Telephone Conference Call).

Contact Person: Lyle Furr, Contract Review Specialist, Office of Extramural Affairs, National Institute on Drug Abuse, National Institutes of Health, DHHS, 6001 Executive Boulevard, Room 3158, MSC 9547, Bethesda, MD 20892-9547, (301) 435-1439.

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

(Catalogue of Federal Domestic Assistance Program Nos. 93.277, Drug Abuse Scientist Development Award for Clinicians, Scientist Development Awards, and Research Scientist Awards; 93.278, Drug Abuse National Research Service Awards for Research Training; 93.279, Drug Abuse Research Programs, National Institutes of Health, HHS)

Dated: December 15, 2000.

LaVerne Y. Stringfield,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 00-32590 Filed 12-20-00; 8:45 am]

BILLING CODE 4140-01-M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute on Aging; Notice of 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 a meeting of the National Advisory Council on Aging.

The meeting will be open to the public as indicated below, with attendance limited to space available. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should notify the Contact Person listed below in advance of the meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(9c)(6), Title 5 U.S.C., as amended. The grant applications and/or contract proposals and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant application and/or contract proposals, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Advisory Council on Aging.

Date: February 6–7, 2001.

Closed: February 6, 2001, 4 PM to 6 PM.

Agenda: To review and evaluate grant applications and/or proposals.

Place: 9000 Rockville Pike, Building 31C, Conference Room 6, Bethesda, MD 20892.

Open: February 7, 2001, 8 AM to 2 PM.

Agenda: Call to Order; Program Highlights; Report on the Working Group on Program; Statement of Understanding; and Review of Intramural Research Program—Laboratory of Clinical Investigation.

Place: 9000 Rockville Pike, Building 31C, Conference Room 6, Bethesda, MD 20892.

Closed: February 7, 2001, 2:00 PM to 2:30 PM.

Agenda: To review and evaluate program documents.

Place: 9000 Rockville Pike, Building 31C, Conference Room 6, Bethesda, MD 20892.

Contact Person: Miriam F. Kelty, PhD, Director, Office of Extramural Affairs, National Institute on Aging, National Institutes of Health, 7201 Wisconsin Avenue, Suite 2C218, Bethesda, MD 20892, 301-496-9322.

(Catalogue of Federal Domestic Assistance Program Nos. 93.866, Aging Research, National Institutes of Health, HHS)

Dated: December 15, 2000.

LaVerne Y. Stringfield,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 00-32591 Filed 12-20-00; 8:45 am]

BILLING CODE 4140-01-M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute on Aging; 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 meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The contract proposals and

the discussion could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the contract proposals, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute on Aging Special Emphasis Panel, Contract Review for Aged Rodent Tissue Bank.

Date: January 12, 2001.

Time: 1 pm to 5 pm.

Agenda: To review and evaluate contract proposals.

Place: 7201 Wisconsin Avenue, Bethesda, MD 20892, (Telephone Conference Call).

Contact Person: Arthur D. Schaerdel, DVM, Scientific Review Administrator, The Bethesda Gateway Building, 7201 Wisconsin Avenue/Suite 2C212, Bethesda, MD 20892 (301) 496-9666.

(Catalogue of Federal Domestic Assistance Program Nos. 93.866, Aging Research, National Institutes of Health, HHS)

Dated: December 15, 2000.

LaVerne Y. Stringfield,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 00-32592 Filed 12-20-00; 8:45 am]

BILLING CODE 4140-01-M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institutes of Child Health and Human Development; Notice of 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 a meeting of the National Advisory Child Health and Human Development Council.

The meeting will be open to the public as indicated below, with attendance limited to space available. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should notify the Contact Person listed below in advance of the meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Advisory Child Health and Human Development Council.

Date: January 25–26, 2001.

Open: January 25, 2001, 8:30 a.m. to 5 p.m.

Agenda: The agenda includes: Report of the Director, NICHD; a presentation by the Mental Retardation and Developmental Disabilities Branch; an update on the Strategic Planning process; and other business of the Council.

Place: 9000 Rockville Pike, Building 31C, Conference Room 6, Bethesda, MD 20892.

Closed: January 26, 2001, 8:30 a.m. to adjournment.

Agenda: To review and evaluate grant applications.

Place: 9000 Rockville Pike, Building 31C, Conference Room 6, Bethesda, MD 20892.

Contact Person: Mary Plummer, Committee Management Officer, Division of Scientific Review, National Institute of Child Health and Human Development, National Institutes of Health, 6100 Executive Blvd., Room 5E03, Bethesda, MD 20892, (301) 496-1485.

(Catalogue of Federal Domestic Assistance Program Nos. 93.209, Contraception and Infertility Loan Repayment Program; 93.864, Population Research; 93.865, Research for Mothers and Children; 93.929, Center for Medical Rehabilitation Research, National Institutes of Health, HHS)

Dated: December 14, 2000.

LaVerne Y. Stringfield,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 00-32593 Filed 12-20-00; 8:45 am]

BILLING CODE 4140-01-M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; 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 meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committees: Center for Scientific Review Special Emphasis Panel.

Date: December 19, 2000.

Time: 2 PM to 3 PM.

Agenda: To review and evaluate grant applications.

Place: NIH, Rockledge 2, Bethesda, MD 20892, (Telephone Conference Call).

Contact Person: Lee Rosen, Phd, Scientific Review Administrator, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5116, MSC 7854, Bethesda, MD 20892, (301) 435-1171.

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine, 93.306; 93.333, Clinical Research, 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: December 15, 2000.

LaVerne Y. Stringfield,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 00-32589 Filed 12-20-00; 8:45 am]

BILLING CODE 4140-01-M

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR-4301-N-03]

HUD Programs Subject to the Requirements of Title IX of the Education Amendments of 1972

AGENCY: Office of the Secretary, HUD.

ACTION: Notice.

SUMMARY: On August 30, 2000, twenty Federal agencies, including the Department of Housing and Urban Development, published a final common rule providing for the enforcement of Title IX of the Education Amendments of 1972 (referred to as "Title IX"). The August 30, 2000 final rule provides that, by November 30, 2000, each agency shall publish a notice in the **Federal Register** that identifies its respective programs covered by the Title IX regulations. This notice implements this requirement by publishing the list of HUD programs subject to the requirements of the common rule. HUD will periodically update this notice to reflect changes in the covered programs.

FOR FURTHER INFORMATION CONTACT: David Enzel, Deputy Assistant Secretary for Enforcement and Programs, Office of Fair Housing and Equal Opportunity, Department of Housing and Urban Development, 451 Seventh Street, SW., Washington, DC 20410-0500; telephone (202) 708-0836 (this is not a toll-free telephone number). Hearing or speech-impaired persons may access this number via TTY by calling the toll-free Federal Information Relay Service at 1-800-877-8339.

SUPPLEMENTARY INFORMATION:

I. Background—The August 30, 2000 Common Rule

On August 30, 2000 (65 FR 52858), twenty Federal agencies, including the Department of Housing and Urban Development, published a final common rule providing for the enforcement of Title IX of the Education Amendments of 1972 (20 U.S.C. 1681 *et seq.*) (referred to as "Title IX"). Title IX prohibits recipients of Federal financial assistance from discriminating on the basis of sex in educational programs or activities. The Title IX regulations were presented as a common rule because the standards established for the enforcement of Title IX are the same for all participating agencies. The procedures for how an agency will enforce Title IX, including the conduct of investigations and compliance reviews, also follows the same structure. HUD's Title IX regulations are located at 24 CFR part 3.

The August 30, 2000 common rule also provides that, by November 30, 2000, each agency shall publish a notice in the **Federal Register** that identifies its respective programs covered by the Title IX regulations. This notice implements this requirement by publishing the list of HUD programs subject to the requirements of the common rule. HUD will periodically update this notice to reflect changes in the covered programs.

II. HUD Federal Financial Assistance Covered By Title IX

The following list is organized by HUD program office. Where applicable, the program's Catalog of Federal Domestic Assistance (CFDA) number and/or the citation to HUD's implementing regulations in title 24 of the Code of Federal Regulations is also provided.

A. Programs Administered by the Office of Community Planning and Development

1. HOME Investment Partnerships Program (14.239) (24 CFR part 92).
2. Section 312 Rehabilitation Loan Program (24 CFR part 510).
3. Rental Rehabilitation Grant Program (24 CFR part 511).
4. Community Development Block Grants/Entitlement Grants (14.218) (24 CFR part 570, subpart D).
5. Community Development Block Grants/Special Purpose Grants/Insular Areas (14.225) (24 CFR part 570, subpart E).
6. Community Development Block Grants/Special Purpose Grants/Technical Assistance Program (14.227) (24 CFR part 570, subpart E).
7. Historically Black Colleges and Universities Program (14.237) (24 CFR

570.400 and 570.404; 24 CFR part 570 subparts A, C, J, K, and O).

8. Community Development Block Grants/Small Cities Programs (14.219) (24 CFR part 570, subpart F).

9. Community Development Block Grants/Economic Development Initiative (14.246) (24 CFR part 570, subpart M).

10. Community Development Block Grants/Section 108 Loan Guarantees (14.248) (24 CFR part 570, subpart M).

11. State Community Development Block Grants Program (14.228) (24 CFR part 570, subpart I).

12. HOPE for Homeownership of Single Family Homes Program (HOPE 3) (24 CFR 572).

13. Housing Opportunities for Persons With AIDS (HOPWA) Program (14.241) (24 CFR part 574).

14. Emergency Shelter Grants Program (14.231) (24 CFR part 576).

15. Use of Federal Real Property to Assist the Homeless (24 CFR 581).

16. Shelter Plus Care (14.238) (24 CFR part 582).

17. Supportive Housing Program (14.235) (24 CFR part 583).

18. Youthbuild Program (14.243) (24 CFR part 585).

19. Revitalizing Base Closure Communities and Community Assistance—Community Redevelopment and Homeless Assistance (24 CFR part 586).

20. Urban Homesteading (24 CFR part 590).

21. John Heinz Neighborhood Development Program (24 CFR part 594).

22. Urban Empowerment Zones (14.244) (24 CFR parts 597 and 598).

23. Section 8 Moderate Rehabilitation Single Room Occupancy (14.249) (24 CFR part 882).

24. Rural Housing and Economic Development (14.250).

B. Programs Administered by the Office of Fair Housing and Equal Opportunity

1. Fair Housing Assistance Program (14.401) (24 CFR part 115).

2. Fair Housing Initiatives Program—Administrative Enforcement Initiative (14.408) (24 CFR part 125).

3. Fair Housing Initiatives Program—Education and Outreach Initiative (14.409) (24 CFR part 125).

4. Fair Housing Initiatives Program—Private Enforcement Initiative (14.410) (24 CFR part 125).

5. Fair Housing Initiatives Program—Fair Housing Organizations Initiative (14.413) (24 CFR part 125).

C. Programs Administered by the Office of Housing

1. Rent Supplements—Rental Housing for Lower Income Families (14.149) (24 CFR part 215).
2. Operating Assistance for Troubled Multifamily Housing Projects (14.164) (24 CFR part 219).
3. Low Cost and Moderate Income Mortgage Insurance (14.120) (24 CFR part 221).
4. Interest Reduction Payments—Rental and Cooperative Housing for Lower Income Families (14.103) (24 CFR part 236).
5. Nehemiah Housing Opportunity Grants Program (24 CFR part 280).
6. Officer Next Door Sales Program (14.198) (24 CFR part 291).
7. Teacher Next Door Initiative (14.310).
8. Housing Counseling Assistance Program (14.169) (see the Housing Counseling Handbook 7610.01 REV 4).
9. Multifamily Housing Service Coordinators (14.191) (see Housing's Management Agent Handbook 4381.5 REV 2).
10. Congregate Housing Services Program (24 CFR part 700).
11. Federally Assisted Low-Income Housing Drug Elimination Grants Program (14.193) (24 CFR part 761).
12. Housing Development Grants (24 CFR part 850).
13. Section 8 Housing Assistance Payments Program for New Construction (24 CFR 880).
14. Section 8 Housing Assistance Payments Program for Substantial Rehabilitation (24 CFR part 881).
15. Section 8 Housing Assistance Payments Program—State Housing Agencies (24 CFR part 883).
16. Section 8 Housing Assistance Payment Program, New Construction Set-Aside for Section 515 Rural Rental Housing Projects (24 CFR part 884).
17. Section 8 Housing Assistance Payments Program—Special Allocations (14.195) (24 CFR part 886).
18. Supportive Housing for the Elderly (14.157) (24 CFR part 891).
19. Supportive Housing for Persons with Disabilities (14.181) (24 CFR part 891).

D. Programs Administered by the Office of Public and Indian Housing

1. Public and Indian Housing Drug Elimination Program (14.854) (24 CFR 24 part 761).
2. Public Housing Agency Section 8 Fraud Recoveries (24 CFR part 792).
3. New Approaches Anti-Drug Grants (14.312).
4. Lower Income Housing Assistance Program—Section 8 Moderate

Rehabilitation (14.856) (24 CFR part 882).

5. Low Rent Housing Homeownership Opportunities (24 CFR part 904).
6. Public Housing Capital Fund (14.872) (24 CFR part 905).
7. Section 5(h) Homeownership Program (24 CFR part 906).
8. Public Housing Development (14.850) (24 CFR part 941).
9. Designated Housing—Public Housing Designated for Occupancy by Disabled, Elderly, or Disabled and Elderly families (24 CFR part 945).
10. Indian HOME Program (24 CFR part 954).
11. Admission to, and Occupancy of, Public Housing (24 CFR part 960).
12. Public Housing—Contracting with Resident-Owned Businesses (24 CFR part 963).
13. Public and Indian Housing—Tenant Opportunities Program (14.853) (24 CFR part 964).
14. PHA-Owned or Leased Projects—General Provisions (24 CFR part 965).
15. Public Housing Modernization (24 CFR part 968).
16. Public Housing Program—Demolition or Disposition of Public Housing Projects (24 CFR part 970).
17. Section 8 Housing Choice Voucher Program (14.871) (24 CFR part 982).
18. Section 8 Project-Based Certificate Program (24 CFR part 983).
19. Section 8 and Public Housing Family Self-Sufficiency Program (24 CFR part 984).
20. Annual Contributions for Operating Subsidy (24 CFR part 990).
21. Economic Development and Support Services Program (14.864).
22. Demolition and Revitalization of Severely Distressed Public Housing (HOPE VI) (14.866).
23. Resident Opportunity and Support Services (14.870).
24. Indian Housing Block Grant Program (14.867) (24 CFR part 1000).
25. Indian Community Development Block Grant Program (14.862) (24 CFR part 1003).
26. Title VI Federal Guarantees for Financing Tribal Housing Activities (14.869) (24 CFR part 1000, subpart E).

E. Programs Administered by the Office of Policy Development and Research

1. Community Outreach Partnership Center Program (14.511).
2. Community Development Work-Study Program (14.512) (24 CFR 570.415).
3. Hispanic-Serving Institutions Work-Study Program (14.513).
4. Alaska Native/Native Hawaiian Institutions Assisting Communities (14.515).

F. Programs Administered by the Office of Multifamily Housing Assistance Restructuring (OMHAR)

1. Multifamily Housing Mortgage and Housing Assistance Restructuring Program (Market-to-Market) (14.197) (24 CFR part 401).
2. Project-Based Section 8 Contract Renewal without Restructuring (under Section 524(a) of MAHRA) (24 CFR part 402).

G. Programs Administered by the Office of Healthy Homes and Lead Hazard Control

1. Lead-Based Paint Hazard Control in Privately Owned Housing (14.900) (24 CFR part 35).
2. Healthy Homes Initiative Grants (14.901).

Dated: December 4, 2000.

Andrew Cuomo,
Secretary.

[FR Doc. 00-32489 Filed 12-20-00; 8:45 am]

BILLING CODE 4210-32-P

DEPARTMENT OF THE INTERIOR

Office of the Secretary

California Desert District Advisory Council—Notice of Renewal

AGENCY: Bureau of Land Management (BLM), Interior.

ACTION: California Desert District Advisory Council—Notice of renewal.

SUMMARY: This notice is published in accordance with section 9(a)(2) of the Federal Advisory Committee Act of 1972 (Public Law 92-463). Notice is hereby given that the Secretary of the Interior has renewed the Bureau of Land Management's California Desert District Advisory Council.

The purpose of the Council is to provide counsel and advice to the BLM District Manager concerning planning and management of the public land resources within the BLM California Desert District and implementation of the comprehensive, long-range plan for the management, use, development, and protection of the public lands within the California Desert Conservation Area.

Certification Statement

I hereby certify that the renewal of the California Desert District Advisory Council is necessary and in the public interest in connection with the Secretary of the Interior's responsibilities to manage the lands, resources, and facilities administered by the Bureau of Land Management.

FOR FURTHER INFORMATION CONTACT: Melanie Wilson, Intergovernmental

Affairs (640), Bureau of Land Management, 1620 L Street, NW., Room 406 LS, Washington, DC 20240, telephone (202) 452-0377.

Dated: December 11, 2000.

Bruce Babbitt,

Secretary of the Interior.

[FR Doc. 00-32488 Filed 12-20-00; 8:45 am]

BILLING CODE 4310-84-P

DEPARTMENT OF THE INTERIOR

Office of the Secretary

Delaware & Lehigh National Heritage Corridor Commission Meeting

AGENCY: Office of the Secretary; Department of Interior.

ACTION: Notice of meeting.

SUMMARY: This notice announces an upcoming meeting of the Delaware & Lehigh National Heritage Corridor Commission. Notice of this meeting is required under the Federal Advisory Committee Act (Public Law 92-463).

Meeting Date and Time: Friday, January 12, 2001, Time 1:30 p.m. to 4 p.m.

Address: Lehigh Valley Planning Commission Office, 961 Marcon Boulevard, Suite 310, Allentown, PA 18103.

The agenda for the meeting will focus on implementation of the Management Action Plan for the Delaware and Lehigh National Heritage Corridor and State Heritage Park. The Commission was established to assist the Commonwealth of Pennsylvania and its political subdivisions in planning and implementing an integrated strategy for protecting and promoting cultural, historic and natural resources. The Commission reports to the Secretary of the Interior and to Congress.

SUPPLEMENTARY INFORMATION: The Delaware & Lehigh National Heritage Corridor Commission was established by Public Law 100-692, November 18, 1988 and extended through Public Law 105-355, November 13, 1998.

FOR FURTHER INFORMATION CONTACT: C. Allen Sachse, Executive Director, Delaware & Lehigh National Heritage Corridor Commission, 10 E. Church Street, Room A-208, Bethlehem, PA 18018, (610) 861-9345.

Dated: December 14, 2000.

C. Allen Sachse,

Executive Director, Delaware & Lehigh National Heritage Corridor Commission.

[FR Doc. 00-32501 Filed 12-20-00; 8:45 am]

BILLING CODE 6820-PE-M

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

Information Collection To Be Submitted to the Office of Management and Budget (OMB) for Approval Under the Paperwork Reduction Act

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Notice; request for comments.

SUMMARY: The U.S. Fish and Wildlife Service will submit a request for approval of a collection of information to OMB under the provisions of the Paperwork Reduction Act. A copy of the information collection requirement is included in this notice. If you wish to obtain copies of the proposed information collection requirement, related forms, and explanatory material, contact the Service Information Collection Clearance Officer at the address listed below.

DATES: You must submit comments on or before February 20, 2001.

ADDRESSES: Send your comments on the requirement to the Information Collection Clearance Officer, U.S. Fish and Wildlife Service, 4401 North Fairfax Drive, Mail Stop 222-ARLSQ, Arlington, Virginia 22203.

FOR FURTHER INFORMATION CONTACT: To request a copy of the information collection approval request, explanatory information and related forms, contact Rebecca A. Mullin at (703) 358-2287, or electronically at rmullin@fws.gov.

SUPPLEMENTARY INFORMATION: The Office of Management and Budget (OMB) regulations at 5 CFR part 1320, which implement provisions of the Paperwork Reduction Act of 1995 (Pub. L. 104-13), require that interested members of the public and affected agencies have an opportunity to comment on information collection and recordkeeping activities (see 5 CFR 1320.8(d)). The U.S. Fish and Wildlife Service (We) plans to submit a request to OMB to renew its existing approval of the collection of information for Threatened and Endangered Species Permit Applications, which expires on February 28, 2001. We are requesting a 3-year term of approval for this information collection activity.

Federal agencies may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. The OMB control number for this collection of information is 1018-0094.

The information collection requirements in this submission implement the regulatory requirements of the Endangered Species Act (16

U.S.C. 1539), the Migratory Bird Treaty Act (16 U.S.C. 704), the Lacey Act (18 U.S.C. 42-44), the Bald Eagle Protection Act (16 U.S.C. 668), and the Marine Mammal Protection Act (16 U.S.C. 1374) contained in Service regulations in Chapter I, Subchapter B of Title 50 of the Code of Federal Regulations (CFR).

Previously, common permit application and recordkeeping requirements were consolidated in 50 CFR part 13, and unique requirements of the various statutes in separate parts as identified below. The Service redesigned the standard license/permit application form 3-200 to assist persons in applying for Service permits issued under Subchapter B. Under the present clearance, the Service consolidated all requirements in one submission, and they were assigned OMB Approval Number 1018-0022, the Federal Fish and Wildlife License/Permit and Related Reports. In an attempt to make the application process more "user friendly," and to aid the public in commenting on specific license/permit requirements without having to comment on the entire package, similar types of permits were previously grouped together and numbered. The application to apply for Service permits issued under Subchapter B of 50 CFR, still requires the completion of the Service form 3-200, which has been revised and renumbered and is now Service form 3-200-1. In addition to the permit application (Service form 3-200-1), attachments are often necessary to provide additional information required for each specific type of permit, and these attachments have been assigned numbers, (e.g., 3-200-54). The information to be supplied on the application form and the attachments will be used to review the application and allow the Service to make decisions, according to criteria established in various Federal wildlife conservation statutes and regulations on the issuance, suspension, revocation, or denial of permits. The obligation to respond is, "required to obtain a benefit." An agency may not conduct or sponsor a collection of information unless the collection of information displays a currently valid OMB control number. We have revised the following requirements, and they are included in this submission:

1. *Title:* Native Endangered and Threatened Species—Enhancement of Survival Permits associated with Safe Harbor Agreements, and Candidate Conservation Agreements with Assurances.

Approval Number: 1018-0094.

Service Form Number: 3-200-54.

Frequency of Collection: Annually.

Description of Respondents:

Individuals, households, businesses, State agencies, private organizations.

Total Annual Burden Hours: The reporting burden is estimated to average 2.5 hours per respondent for the application and 5 hours per respondent for the annual report of permitted activities. The Total Annual Burden hours is 125 hours for the application and 750 hours for the annual report on the permitted activities.

Total Annual Responses: The number of respondents is estimated to average 50 respondents for the application and 150 for the annual report of the permitted activities.

The Endangered Species Act (ESA) provides a number of exceptions to its prohibitions against "take" of listed species. Regulations have been promulgated at 50 CFR 17.22 (endangered species) and 17.32 (threatened species) to guide implementation of these exceptions to the "take" prohibitions through permitting programs. Service form number 3-200-54 addresses application requirements for permits for Enhancement of Survival permits associated with Safe Harbor Agreements and Candidate Conservation Agreements with assurances. The permittee is required to notify the Service of any transfer of lands subject to the Safe Harbor Agreement so that any landowners may be offered the opportunity to continue the actions which the original landowner agreed to and thus he or she may be offered the same regulatory assurances. A major incentive for landowner participation in the Safe Harbor program is the long-term certainty the program provides, including the certainty that the take authorization will stay with the land when it changes hands. The Service also requires the permittee/landowner to notify the Service as far in advance as possible when he or she expects to take any species covered under the permit and provide the Service with an opportunity to translocate affected individual specimens if possible and appropriate.

2. Title: Native Endangered and Threatened Species—Permits for Scientific Purposes, Enhancement of Propagation or Survival (i.e., Recovery Permits) and Interstate Commerce.

Approval Number: 1018-0094.

Service Form Number: 3-200-55.

Frequency of Collection: Annually.

Description of Respondents:

Individuals, scientific and research institutions.

Total Annual Burden Hours: The reporting burden is estimated to average 2 hours per respondent for the

application and 2 hours per respondent for the annual report on the permitted activities. The Total Annual Burden hours is 1,050 hours for the application and 200 hours for the annual report on the permitted activities.

Total Annual Responses: The number of respondents is estimated to average 525 respondents for the application and 100 respondents for the annual report of the permitted activities.

Form number 3-200-55 addresses application and reporting information requirements for Recovery and Interstate Commerce permits under Section 10(a)(1)(A) of the ESA. Recovery permits allow "take" of listed species as part of scientific research and management actions, enhancement of propagation or survival, zoological exhibition, educational purposes, or special purposes consistent with the ESA designed to benefit the species involved. Interstate Commerce permits allow transport and sale of listed species across State lines as part of breeding programs enhancing the survival of the species. Detailed descriptions of the proposed taking, its necessities for success of the proposed action, and benefits to the species resulting from the proposed action are required under the implementing regulations cited above. Take authorized under this permit program would otherwise be prohibited by the ESA.

3. Title: Native Endangered and Threatened Species—Incidental Take Permits Associated With a Habitat Conservation Plan.

Approval Number: 1018-0094.

Service Form Number: 3-200-56.

Frequency of Collection: Annually.

Description of Respondents:

Individuals, households, businesses, local and State agencies.

Total Annual Burden Hours: The reporting burden is estimated to average 2.5 hours per respondent for the application and 5 hours per respondent for the annual report on the permitted activities. The Total Annual Burden hours is 250 hours for the application and 1,750 hours for the annual report on the permitted activities.

Total Annual Responses: The number of respondents is estimated to be 100 respondents for the application and 350 respondents for the annual report of the permitted activities.

Form number 3-200-56 addresses applications and reporting requirements for Incidental Take Permits under section 10(a)(1)(B) of the ESA. These permits allow "take" of listed species that is incidental to otherwise lawful non-federal actions. Take authorized under this permit program would otherwise be prohibited by the ESA.

We invite comments concerning this renewal on: (1) Whether the collection of information is necessary for the proper performance of our endangered and threatened species management functions, including whether the information will have practical utility; (2) the accuracy of our estimate of the burden of the collection of information; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and, (4) ways to minimize the burden of the collection of information on respondents. The information collections in this program are part of a system of records covered by the Privacy Act (5 U.S.C. 552(a)).

Dated: December 15, 2000.

Gary D. Frazer,

Assistant Director for Endangered Species.

[FR Doc. 00-32542 Filed 12-20-00; 8:45 am]

BILLING CODE 4310-55-P

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

Notice of Receipt of Applications for Permit

Endangered Species

The following applicants have applied for a permit to conduct certain activities with endangered species. This notice is provided pursuant to Section 10(c) of the Endangered Species Act of 1973, *as amended* (16 U.S.C. 1531, *et seq.*). Written data or comments should be submitted to the Director, U.S. Fish and Wildlife Service, Division of Management Authority, 4401 North Fairfax Drive, Room 700, Arlington, Virginia 22203 and must be received by the Director within 30 days of the date of this publication.

Applicant: Los Angeles Zoo, Los Angeles, CA, PRT-306429

The applicant request a permit to import two (1.1) red uakari (*Cacajao calvus*) from the Centro de Primatologia do Rio de Janeiro, San Cristovao, Brazil for the purpose of enhancement of the survival of the species through captive propagation.

Applicant: Douglass M. Eberhardt, Stockton, CA, PRT-037012.

The applicant request a permit to import the sport-hunted trophy of one male bontebok (*Damaliscus pygargus dorcas*) culled from a captive herd maintained under the management program of the Republic of South Africa, for the purpose of enhancement of the survival of the species.

Applicant: Reed Lewis, Plymouth, MN, PRT-037030

The applicant requests a permit to import the sport-hunted trophy of one

male bontebok (*Damaliscus pygargus dorcax*) culled from a captive herd maintained under the management program of the Republic of South Africa, for the purpose of enhancement of the survival of the species.

Marine Mammals

The public is invited to comment on the following application(s) for a permit to conduct certain activities with marine mammals. The application(s) was submitted to satisfy requirements of the Marine Mammal Protection Act of 1972, *as amended* (16 U.S.C. 1361 *et seq.*) and the regulations governing marine mammals (50 CFR 18).

Written data, comments, or requests for copies of these complete applications or requests for a public hearing on these applications should be sent to the U.S. Fish and Wildlife Service, Division of Management Authority, 4401 N. Fairfax Drive, Room 700, Arlington, Virginia 22203, telephone 703/358-2104 or fax 703/358-2281. These requests must be received within 30 days of the date of publication of this notice. Anyone requesting a hearing should give specific reasons why a hearing would be appropriate. The holding of such a hearing is at the discretion of the Director.

Applicant: Gene Perry, Malta, MT, PRT-037029

The applicant requests a permit to import a polar bear (*Ursus maritimus*) sport-hunted from the Western Hudson Bay polar bear population in Canada for personal use.

Applicant: John Dow, Horseheads, NY PRT-037143.

The applicant requests a permit to import a polar bear (*Ursus maritimus*) sport-hunted from the Northern Beaufort polar bear population in Canada for personal use.

Applicant: Stephen Fullmer, Salt Lake City, UT, PRT-036997

The applicant requests a permit to import a polar bear (*Ursus maritimus*) sport-hunted from the Western Hudson Bay polar bear population in Canada for personal use.

The U.S. Fish and Wildlife has information collection approval from OMB through February 28, 2001. OMB Control Number 1018-0093. Federal Agencies may not conduct or sponsor and a person is not required to respond to a collection of information unless it displays a current valid OMB control number.

Documents and other information submitted with these applications are available for review, subject to the requirements of the Privacy Act and Freedom of Information Act, by any

party who submits a written request for a copy of such documents to the following office within 30 days of the date of publication of this notice: U.S. Fish and Wildlife Service, Division of Management Authority, 4401 North Fairfax Drive, Room 700, Arlington, Virginia 22203. Phone: (703/358-2104); Fax: (703/358-2281).

Dated: December 15, 2000.

Anna Barry,

Branch of Permits, Division of Management Authority.

[FR Doc. 00-32494 Filed 12-20-00; 8:45 am]

BILLING CODE 4310-55-P

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

Notice of Extension for Public Review of a revised Environmental Assessment/Habitat Conservation Plan and Implementing Agreement Related to Application for an Incidental Take Permit for the Magic Carpet Woods Association Project, Leelanau Township, Leelanau County, Michigan

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Notice of availability; extension of comment period.

SUMMARY: This document announces an extension of the comment period for an additional 30 days to allow review of the Implementing Agreement which was inadvertently omitted from the package for public review. Comments on the revised draft Environmental Assessment/Habitat Conservation Plan (EA/HCP) will also be accepted during this period. For additional information, the original announcement regarding the notice of availability of a revised draft EA/HCP for an Incidental Take Permit for the Magic Carpet Woods Association Project, Leelanau Township, Leelanau County, Michigan was in the **Federal Register** on November 13, 2000, beginning on page 67753. Copies of the documents can be obtained by contacting the Service personnel listed in the original announcement. The EA/HCP and Implementing Agreement can also be reviewed via the internet at "http://midwest.fws.gov/nepa"

DATES: Written comments must be received on or before COB January 22, 2001.

FOR FURTHER INFORMATION CONTACT: Mr. Peter Fasbender, Regional HCP Coordinator, U.S. Fish and Wildlife Service, Fort Snelling, Minnesota, 55111, telephone (612)713-5343 or e-mail peter_fasbender@fws.gov.

Dated: December 15, 2000.

Charlie Wooley,

Assistant Regional Director, Ecological Services, Region 3, Fort Snelling, Minnesota.
[FR Doc. 00-32523 Filed 12-20-00; 8:45 am]

BILLING CODE 4310-55-P

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

Notice of Issuance of Permit for Marine Mammals

On June 8, 2000, a notice was published in the **Federal Register**, Vol. 65, No. 111, Page 36455, that an application had been filed with the Fish and Wildlife Service by William McClure for a permit (PRT-027989) to import one polar bear (*Ursus maritimus*) trophy taken from the Lancaster Sound population, Canada for personal use.

Notice is hereby given that on August 4, 2000, as authorized by the provisions of the Marine Mammal Protection Act of 1972, *as amended* (16 U.S.C. 1361 *et seq.*), the Fish and Wildlife Service authorized the requested permit subject to certain conditions set forth therein.

On September 4, 2000, a notice was published in the **Federal Register**, Vol. 65, No. 193, Page 59197, that an application had been filed with the Fish and Wildlife Service by Robert Miller for a permit (PRT-034022) to import one polar bear (*Ursus maritimus*) trophy taken from the M'Clintock Channel population, Canada for personal use.

Notice is hereby given that on December 7, 2000, as authorized by the provisions of the Marine Mammal Protection Act of 1972, *as amended* (16 U.S.C. 1361 *et seq.*), the Fish and Wildlife Service authorized the requested permit subject to certain conditions set forth therein.

On August 4, 2000, a notice was published in the **Federal Register**, Vol. 65, No. 151, Page 48010, that an application had been filed with the Fish and Wildlife Service by Cererino Machado for a permit (PRT-024024) to import one polar bear (*Ursus maritimus*) trophy taken from the Southern Beaufort Sea population, Canada for personal use.

Notice is hereby given that on October 11, 2000, as authorized by the provisions of the Marine Mammal Protection Act of 1972, *as amended* (16 U.S.C. 1361 *et seq.*), the Fish and Wildlife Service authorized the requested permit subject to certain conditions set forth therein.

On September 19, 2000, a notice was published in the **Federal Register**, Vol. 65, No. 182, Page 56589, that an

application had been filed with the Fish and Wildlife Service by Noah J. Horn for a permit (PRT-032748) to import one polar bear (*Ursus maritimus*) trophy taken from the Southern Beaufort Sea population, Canada for personal use.

Notice is hereby given that on October 26, 2000, as authorized by the provisions of the Marine Mammal Protection Act of 1972, *as amended* (16 U.S.C. 1361 *et seq.*), the Fish and Wildlife Service authorized the requested permit subject to certain conditions set forth therein.

On August 31, 2000, a notice was published in the **Federal Register**, Vol. 65, No. 170, Page 53027, that an application had been filed with the Fish and Wildlife Service by Lawrence Franks for a permit (PRT-032240) to import one polar bear (*Ursus maritimus*) trophy taken from the Southern Beaufort Sea population, Canada for personal use.

Notice is hereby given that on October 24, 2000, as authorized by the provisions of the Marine Mammal Protection Act of 1972, *as amended* (16 U.S.C. 1361 *et seq.*), the Fish and Wildlife Service authorized the requested permit subject to certain conditions set forth therein.

On August 10, 2000, a notice was published in the **Federal Register**, Vol. 65, No. 155, Page 49005, that an application had been filed with the Fish and Wildlife Service by Larry Masserant for a permit (PRT-031377) to import one polar bear (*Ursus maritimus*) trophy taken from the Lancaster Sound population, Canada for personal use.

Notice is hereby given that on October 27, 2000, as authorized by the provisions of the Marine Mammal Protection Act of 1972, *as amended* (16 U.S.C. 1361 *et seq.*), the Fish and Wildlife Service authorized the requested permit subject to certain conditions set forth therein.

On July 20, 2000, a notice was published in the **Federal Register**, Vol. 65, No. 140, Page 45099, that an application had been filed with the Fish and Wildlife Service by William Niederer for a permit (PRT-030197) to import one polar bear (*Ursus maritimus*) trophy taken from the Northern Beaufort Sea population, Canada for personal use.

Notice is hereby given that on August 29, 2000, as authorized by the provisions of the Marine Mammal Protection Act of 1972, *as amended* (16 U.S.C. 1361 *et seq.*), the Fish and Wildlife Service authorized the requested permit subject to certain conditions set forth therein.

On October 19, 2000, a notice was published in the **Federal Register**, Vol.

65, No. 203, Page 62747, that an application had been filed with the Fish and Wildlife Service by Branko Terkovich for a permit (PRT-034570) to import one polar bear (*Ursus maritimus*) trophy taken from the Lancaster Sound population, Canada for personal use.

Notice is hereby given that on December 7, 2000, as authorized by the provisions of the Marine Mammal Protection Act of 1972, *as amended* (16 U.S.C. 1361 *et seq.*), the Fish and Wildlife Service authorized the requested permit subject to certain conditions set forth therein.

On July 27, 2000, a notice was published in the **Federal Register**, Vol. 65, No. 145, Page 46170, that an application had been filed with the Fish and Wildlife Service by Jerry W. Peterman for a permit (PRT-030691) to import one polar bear (*Ursus maritimus*) trophy taken from the Northern Beaufort Sea population, Canada for personal use.

Notice is hereby given that on December 14, 2000, as authorized by the provisions of the Marine Mammal Protection Act of 1972, *as amended* (16 U.S.C. 1361 *et seq.*), the Fish and Wildlife Service authorized the requested permit subject to certain conditions set forth therein.

Documents and other information submitted for these applications are available for review by any party who submits a written request to the U.S. Fish and Wildlife Service, Division of Management Authority, 4401 North Fairfax Drive, Room 700, Arlington, Virginia 22203. Phone (703) 358-2104 or Fax (703) 358-2281.

Dated: December 15, 2000.

Anna Barry,

Branch of Permits, Division of Management Authority.

[FR Doc. 00-32496 Filed 12-20-00; 8:45 am]

BILLING CODE 4310-55-P

DEPARTMENT OF THE INTERIOR

[WY-030-2001-1060-JJ]

Bureau of Land Management

AGENCY: Bureau of Land Management, Interior.

ACTION: Notice of intent to conduct a hearing on the use of helicopters and other motorized vehicles in the management and removal of wild horses on the public lands in Wyoming.

SUMMARY: The Wild, Free Roaming Horse and Burro Act, as amended (PL 92-195) provides, among other things, for the use of aircraft and motor vehicles in all phases of the administration of the

Act. The Code of Federal Regulations provides, at 43 CFR 4740.1(a), that the authorized officer conduct a public hearing in the area where such use is to be made.

The Bureau of Land Management (BLM) has and plans to continue use of helicopters in the removal of wild, free roaming horses from the public lands within the Rawlins, Lander, Rock Springs, Cody, and Big Horn Basin Field Office jurisdictions.

Pursuant to the requirements noted above, the BLM will conduct a public hearing on the use of helicopters in gathering operations during the calendar year of 2001 on January 30, 2001, at 3 p.m. MDT, in the large conference room of the Rawlins Field Office of the Bureau of Land Management located at 1300 North Third Street in Rawlins, Wyoming.

FOR FURTHER INFORMATION CONTACT: For further information, please contact Chuck Reed, Resource Advisor, Bureau of Land Management, Rawlins Field Office, 1300 North Third Street, P.O. Box 2407, Rawlins, Wyoming 82301, (307) 328-4200; electronic mail at Chuck_Reed@blm.gov.

Kurt J. Kotter,

Field Manager.

[FR Doc. 00-32446 Filed 12-20-00; 8:45 am]

BILLING CODE 4310-22-P

DEPARTMENT OF THE INTERIOR

National Park Service

General Management Plan, Draft Environmental Impact Statement, Fort Davis National Historic Site, Texas

AGENCY: National Park Service, Department of the Interior.

ACTION: Availability of draft environmental impact statement and general management plan for Fort Davis national historic site.

SUMMARY: Pursuant to section 102(2)(C) of the National Environmental Policy Act of 1969, the National Park Service announces the availability of a Draft Environmental Impact Statement and General Management Plan (DEIS/GMP) for Fort Davis National Historic Site, Texas.

DATES: The DEIS/GMP will remain available for public review through March 15, 2001. If any public meetings are held concerning the DEIS/GMP, they will be announced at a later date.

COMMENTS: If you wish to comment, you may submit your comments by any one of several methods. You may mail comments to Superintendent, Fort Davis

National Historic Site, P.O. Box 1456, Fort Davis, Texas 79734. You may also comment via the Internet to <http://www.nps.gov/planning/foda/>. Please submit Internet comments as an ASCII file avoiding the use of special characters and any form of encryption. Please also include "Attn: (any identifying names or codes)" and your name and return address in your Internet message. If you do not receive a confirmation from the system that we have received your Internet message, contact us directly at Fort Davis National Historic Site, 915-426-3225. Finally, you may hand-deliver comments to Fort Davis National Historic Site, P.O. Box 1456, Fort Davis, Texas 79734. Our practice is to make comments, including names and home addresses of respondents, available for public review during regular business hours. Individual respondents may request that we withhold their home address from the record, which we will honor to the extent allowable by law. There also may be circumstances in which we would withhold from the record a respondent's identity, as allowable by law. If you wish us to withhold your name and/or address, you must state this prominently at the beginning of your comment. We will make all submissions from organizations or businesses, and from individuals identifying themselves as representatives or officials of organizations or businesses, available for public inspection in their entirety.

ADDRESSES: Copies of the DEIS/GMP are available from the Superintendent, Fort Davis National Historic Site, P.O. Box 1456, Fort Davis, Texas 79734. Public reading copies of the DEIS/GMP will be available for review at the following locations: Office of the Superintendent, Fort Davis National Historic Site, P.O. Box 1456, Fort Davis, Texas 79734, Telephone: 915-426-3225; Planning and Environmental Quality, Intermountain Support Office—Denver, National Park Service, 12795 W. Alameda Parkway, Lakewood, CO 80228, Telephone: (303) 969-2851; Office of Public Affairs, National Park Service, Department of Interior 18th and C Streets NW, Washington, DC 20240, Telephone: (202) 208-6843.

SUPPLEMENTARY INFORMATION: The DEIS/GMP analyzes four (4) alternatives a no-action and three action alternatives including the National Park Service proposal. Alternative C, the proposed General Management Plan would retain most existing visitor experiences and would improve outreach programs, visitor orientation, collaborative research partnership opportunities, and

administrative staff services. It also provides for enhanced protection for facilities and resources from flooding. Alternative B would protect and preserve the fort's historic setting and historic viewscape and would minimize modern intrusions in the historic core area. Alternative D would broaden the interpretive themes to highlight the more complex role of Fort Davis in the history of the American West. Under the no-action alternative, existing administrative, maintenance, land use, and resource management activities would continue with current use serving as the basis for mapping management prescriptions.

The DEIS/GMP in particular evaluates the environmental consequences of the proposed action and the other alternatives on visitor experience, archeological resources, cultural landscapes and historic resources, long-term health of natural ecosystems, economic contribution to local communities, adjacent landowners, and facility/operational efficiency. The plan also identifies cumulative effects on wetlands and floodplains for the National Park Service proposal.

FOR FURTHER INFORMATION CONTACT: Contact Superintendent, Fort Davis National Historic Site, at the above address and telephone number.

Dated: December 8, 2000.

Michael D. Snyder,

Director, Intermountain Region, National Park Service.

[FR Doc. 00-32439 Filed 12-20-00; 8:45 am]

BILLING CODE 4310-10-P

DEPARTMENT OF THE INTERIOR

National Park Service

Star Spangled Banner National Historic Trail Study

AGENCY: National Park Service.

ACTION: Notice of Intent to prepare an Environmental Impact Statement and to Hold Public Scoping Meetings for the Star Spangled Banner National Historic Trail Study.

SUMMARY: This notice announces the intent to prepare an environmental impact statement and hold public scoping meetings for the Star Spangled Banner National Historic Trail Study.

Public Law 106-135 authorizes the Star-Spangled Banner National Historic Trail Study to determine the suitability and desirability of designating as a national historic trail the route of the 1812 British invasion of Maryland and Washington, DC, and of the American defense. The proposed trail traces: the

arrival of the British fleet in the Patuxent River; the landing of British forces at Benedict; the sinking of the Chesapeake Flotilla at Pig Point in Prince George's County and Anne Arundel County, Maryland; the American defeat at the Battle of Bladensburg; the siege of the Nation's Capital; the British naval diversions in the upper Chesapeake Bay leading to the Battle of Caulk's Field in Kent County, Maryland; and, the route of the American troops from Washington through Georgetown, the Maryland Counties of Montgomery, Howard, and Baltimore, Americans at Fort McHenry on September 14, 1814.

Three public meetings will be held in January 2001 to discuss the Star Spangled Banner National Historic Trail Study being undertaken by the National Park Service and to conduct scoping for an associated Environmental Impact Statement. Public Law 106-135 authorizes the study of a proposed trail following the route of the 1814 British invasion up the Patuxent River to Washington, DC, and their defeat at Baltimore, MD. The first meeting will be held on Wednesday, January 10, 2001, 6-8 pm, Ft. Henry Visitor Center, Auditorium, Baltimore, MD. The second meeting will be held on Wednesday, January 17, 2001, 5-7 pm. HNTB Offices, 421 7th St., NW., Washington, DC. The third meeting will be held from 6:30-8:30 pm, Calvert County Public Library, Prince Frederick, MD.

For more information look at www.nps.gov/chal/sp/ or contact William Sharp, Planner, National Park Service, 200 Chestnut St., Philadelphia, PA 19106, 215-597-1655, william_sharp@nps.gov.

Dated: December 7, 2000.

Dale Ditmanson,

Acting Northeast Region Director.

[FR Doc. 00-32471 Filed 12-20-00; 8:45 am]

BILLING CODE 4310-70-M

DEPARTMENT OF THE INTERIOR

National Park Service

Kaloko-Honokohau National Historical Park Advisory Commission; Notice of Meeting

Notice is hereby given in accordance with the Federal Advisory Committee Act that a meeting of the Na Hoapili O Kaloko Honokohau, Kaloko-Honokohau National Historical Park Advisory Commission, will be held at 9:00 a.m. on January 26, 2001, at the King Kamehameha's Kona Beach Hotel, Kulana Huli Honua Room, Kailua-Kona, Hawaii. The agenda will include the following: Committee Assignments and

Workplans for 2001, Update on General Management Plan, Visitor Facilities, Park Interpretive and Resource Management Programs.

This meeting is open to the public. It will be recorded for documentation and transcribed for dissemination. Minutes of the meeting will be available to the public after approval of the full Advisory Commission. A transcript will be available after February 31, 2001. For copies of the minutes, contact Kaloko-Honokohau National Historical Park at (808) 329-6881.

Dated: December 7, 2000.

Geraldine K. Bell,

Superintendent, Kaloko-Honokohau National Historical Park.

[FR Doc. 00-32438 Filed 12-20-00; 8:45 am]

BILLING CODE 4310-70-M

INTERNATIONAL TRADE COMMISSION

[Inv. No. 337-TA-442]

In the Matter of Certain Closet Flange Rings; Notice of Investigation

AGENCY: U.S. International Trade Commission.

ACTION: Institution of investigation pursuant to 19 U.S.C. 1337.

SUMMARY: Notice is hereby given that a complaint was filed with the U.S. International Trade Commission on November 20, 2000, under section 337 of the Tariff Act of 1930, as amended, 19 U.S.C. 1337, on behalf of Pasco Specialty and Manufacturing Co. of Lynwood, California. Supplements to the complaint were filed on November 28 and December 6, 2000. The complaint, as supplemented, alleges violations of section 337 in the importation into the United States, the sale for importation, and the sale within the United States after importation of certain closet flange rings by reason of infringement of claims 1-5, 7-9, and 11-14 of U.S. Letters Patent 5,890,239. The complaint further alleges that an industry in the United States exists as required by subsection (a)(2) of section 337.

The complainant requests that the Commission institute an investigation and, after the investigation, issue a permanent exclusion order and a permanent cease and desist order.

ADDRESSES: The complaint and supplements, except for any confidential information contained therein, are available for inspection during official business hours (8:45 a.m. to 5:15 p.m.) in the Office of the Secretary, U.S. International Trade

Commission, 500 E Street, SW., Room 112, Washington, DC 20436, telephone 202-205-2000. Hearing-impaired individuals are advised that information on this matter can be obtained by contacting the Commission's TDD terminal on 202-205-1810. 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. General information concerning the Commission may be obtained by accessing its internet server (<http://www.usitc.gov>).

FOR FURTHER INFORMATION CONTACT:

Steven A. Glazer, Esq., Office of Unfair Import Investigations, U.S. International Trade Commission, telephone 202-205-2577.

Authority: The authority for institution of this investigation is contained in section 337 of the Tariff Act of 1930, as amended, and in section 210.10 of the Commission's Rules of Practice and Procedure, 19 CFR 210.10 (2000).

Scope of investigation: Having considered the complaint, the U.S. International Trade Commission, on December 13, 2000, ORDERED THAT—

(1) Pursuant to subsection (b) of section 337 of the Tariff Act of 1930, as amended, an investigation be instituted to determine:

(a) Whether there is a violation of subsection (a)(1)(B) of section 337 in the importation into the United States, the sale for importation, or the sale within the United States after importation of certain closet flange rings by reason of infringement of claims 1-5, 7-9, or 11-14 of U.S. Letters Patent 5,890,239, and whether there exists an industry in the United States as required by subsection (a)(2) of section 337.

(2) For the purpose of the investigation so instituted, the following are hereby named as parties upon which this notice of investigation shall be served:

(a) The complainant is—Pasco Specialty and Manufacturing Co., 11156 Wright Road, Lynwood, California 90262-1247.

(b) The respondent is the following company alleged to be in violation of section 337, and is the party upon which the complaint is to be served: Jones Stephens Corporation 3249 Moody Parkway Moody, Alabama 35004.

(c) Steven A. Glazer, Esq., Office of Unfair Import Investigations, U.S. International Trade Commission, 500 E Street, SW., Room 401-K, Washington, DC 20436, who shall be the Commission investigative attorney, party to this investigation; and

(3) For the investigation so instituted, the Honorable Debra Morris is designated as the presiding administrative law judge.

A response to the complaint and the notice of investigation must be submitted by the named respondent in accordance with section 210.13 of the Commission's Rules of Practice and Procedure, 19 CFR 210.13. Pursuant to 19 CFR 201.16(d) and 210.13(a) of the Commission's Rules, such response will be considered by the Commission if received not later than 20 days after the date of service by the Commission of the complaint and the notice of investigation. Extensions of time for submitting a response to the complaint will not be granted unless good cause therefor is shown.

Failure of the respondent to file a timely response to each allegation in the complaint and in this notice may be deemed to constitute a waiver of the right to appear and contest the allegations of the complaint and this notice, and to authorize the administrative law judge and the Commission, without further notice to the respondent, to find the facts to be as alleged in the complaint and this notice and to enter both an initial determination and a final determination containing such findings, and may result in the issuance of a limited exclusion order or a cease and desist order or both directed against such respondent.

By order of the Commission.

Issued: December 14, 2000.

Donna R. Koehnke,

Secretary.

[FR Doc. 00-32443 Filed 12-20-00; 8:45 am]

BILLING CODE 7020-02-P

INTERNATIONAL TRADE COMMISSION

[Inv. No. 337-TA-441]

In the Matter of Certain Field Programmable Gate Arrays and Products Containing Same; Notice of Investigation

AGENCY: U.S. International Trade Commission.

ACTION: Institution of investigation pursuant to 19 U.S.C. 1337.

SUMMARY: Notice is hereby given that a complaint was filed with the U.S. International Trade Commission on November 16, 2000, under section 337 of the Tariff Act of 1930, as amended, 19 U.S.C. 1337, on behalf of Xilinx, Inc., of California. A supplemental letter was filed on December 1, 2000. The

complaint, as supplemented, alleges violations of section 337 in the importation into the United States, the sale for importation, and the sale within the United States after importation of certain field programmable gate arrays and products containing same by reason of infringement of claims 1, 2, 3 and 5 of U.S. Letters Patent 5,343,406, claims 1 and 3 of U.S. Letters Patent 5,432,719, and claim 16 of U.S. Letters Patent 5,861,761. The complaint further alleges that there exists an industry in the United States as required by subsection (a)(2) of section 337.

The complainant requests that the Commission institute an investigation and, after the investigation, issue a permanent exclusion order and a permanent cease and desist order.

ADDRESSES: The complaint and supplement, except for any confidential information contained therein, are available for inspection during official business hours (8:45 a.m. to 5:15 p.m.) in the Office of the Secretary, U.S. International Trade Commission, 500 E Street, SW., Room 112, Washington, DC 20436, telephone 202-205-2000. Hearing impaired individuals are advised that information on this matter can be obtained by contacting the Commission's TDD terminal on 202-205-1810. 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. General information concerning the Commission may be obtained by accessing its Internet server (<http://www.usitc.gov>).

FOR FURTHER INFORMATION CONTACT: Karin J. Norton, Esq., Office of Unfair Import Investigations, U.S. International Trade Commission, telephone 202-205-2606.

Authority: The authority for institution of this investigation is contained in section 337 of the Tariff Act of 1930, as amended, and in section 210.10 of the Commission's Rules of Practice and Procedure, 19 CFR 210.10 (2000).

Scope of Investigation: Having considered the complaint, the U.S. International Trade Commission, on December 13, 2000, ORDERED THAT—

(1) Pursuant to subsection (b) of section 337 of the Tariff Act of 1930, as amended, an investigation be instituted to determine whether there is a violation of subsection (a)(1)(B) of section 337 in the importation into the United States, the sale for importation, or the sale within the United States after importation of certain field programmable gate arrays or products containing same by reason of

infringement of claims 1, 2, 3 or 5 of U.S. Letters Patent 5,343,406, claims 1 or 3 of U.S. Letters Patent 5,432,719, or claim 16 of U.S. Letters Patent 5,861,761, and whether there exists an industry in the United States as required by subsection (a)(2) of section 337.

(2) For the purpose of the investigation so instituted, the following are hereby named as parties upon which this notice of investigation shall be served:

(a) The complainant is—Xilinx, Inc., 2100 Logic Drive, San Jose, CA 95124.

(b) The respondent is the following company alleged to be in violation of section 337, and is the party upon which the complaint is to be served: Altera Corporation, 101 Innovation Drive, San Jose, CA 95134.

(c) Karin J. Norton, Esq., Office of Unfair Import Investigations, U.S. International Trade Commission, 500 E Street, SW., Room 401-A, Washington, DC 20436, who shall be the Commission investigative attorney, party to this investigation; and

(3) For the investigation so instituted, the Honorable Sidney Harris is designated as the presiding administrative law judge.

A response to the complaint and the notice of investigation must be submitted by the named respondent in accordance with section 210.13 of the Commission's Rules of Practice and Procedure, 19 CFR 210.13. Pursuant to 19 CFR 201.16(d) and 210.13(a), such response will be considered by the Commission if received no later than 20 days after the date of service by the Commission of the complaint and the notice of investigation. Extensions of time for submitting a response to the complaint will not be granted unless good cause therefor is shown.

Failure of the respondent to file a timely response to each allegation in the complaint and in this notice may be deemed to constitute a waiver of the right to appear and contest the allegations of the complaint and to authorize the administrative law judge and the Commission, without further notice to the respondent, to find the facts to be as alleged in the complaint and this notice and to enter both an initial determination and a final determination containing such findings, and may result in the issuance of a limited exclusion order or a cease and desist order or both directed against the respondent.

By order of the Commission.

Dated: December 14, 2000.

Donna R. Koehnke,
Secretary.

[FR Doc. 00-32442 Filed 12-20-00; 8:45 am]

BILLING CODE 7020-02-P

INTERNATIONAL TRADE COMMISSION

[Investigation No. TA-204-4]

Wheat Gluten; Extension of Action

AGENCY: United States International Trade Commission.

ACTION: Institution and scheduling of an investigation under section 204(c) of the Trade Act of 1974 (19 U.S.C. 2254(c)) (the Act).

SUMMARY: Following receipt of a petition on November 30, 2000, requesting extension of the relief action currently in place on imports of wheat gluten, the Commission instituted investigation No. TA-204-4 under section 204(c) of the Act to determine whether the action taken by the President under section 203 of the Act with respect to wheat gluten, provided for in subheadings 1109.00.10 and 1109.00.90 of the Harmonized Tariff Schedule of the United States (HTS), continues to be necessary to prevent or remedy serious injury and whether the domestic industry is making a positive adjustment to import competition. The petition was filed on behalf of the Wheat Gluten Industry Council, Washington, DC.

For further information concerning the conduct of this investigation, hearing procedures, and rules of general application, consult the Commission's Rules of Practice and Procedure, part 201, subparts A through E (19 CFR part 201, subparts A-E), and part 206, subparts A and F (19 CFR part 206, subparts A and F).

Background

Following receipt of a report from the Commission in March 1998 under section 202 of the Trade Act of 1974 (19 U.S.C. 2252) containing an affirmative determination and remedy recommendation, the President, on May 30, 1998, pursuant to section 203 of the Trade Act of 1974 (19 U.S.C. 2253), issued Proclamation 7103 (as amended by Proclamation 7202 of May 28, 1999), imposing import relief in the form of quantitative limitations on imports of wheat gluten for a period of 3 years and 1 day.

EFFECTIVE DATE: November 30, 2000.

FOR FURTHER INFORMATION CONTACT: Jim McClure (202-205-3191), Office of

Investigations, U.S. International Trade Commission, 500 E Street SW., Washington, DC 20436. Hearing-impaired persons can obtain information on this matter by contacting the Commission's TDD terminal on 202-205-1810. 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. General information concerning the Commission may also be obtained by accessing its internet server (<http://www.usitc.gov>).

SUPPLEMENTARY INFORMATION:

Participation in the investigation and service list.—Persons wishing to participate in the investigation as parties must file an entry of appearance with the Secretary to the Commission, as provided in section 201.11 of the Commission's rules, not later than 21 days after publication of this notice in the **Federal Register**. The Secretary will prepare a service list containing the names and addresses of all persons, or their representatives, who are parties to this investigation upon the expiration of the period for filing entries of appearance.

Limited disclosure of confidential business information (CBI) under an administrative protective order (APO) and CBI service list.—Pursuant to section 206.54(e) of the Commission's rules, the Secretary will make CBI gathered in this investigation available to authorized applicants under the APO issued in the investigation in accordance with the procedures set forth in section 206.17 of the rules, provided that the application is made not later than 21 days after the publication of this notice in the **Federal Register**. A separate service list will be maintained by the Secretary for those parties authorized to receive CBI under the APO.

Hearing.—The Commission has scheduled a hearing in connection with this investigation, to be held beginning at 9:30 a.m. on February 27, 2001, at the U.S. International Trade Commission Building. Requests to appear at the hearing should be filed in writing with the Secretary to the Commission on or before February 20, 2001. All persons desiring to appear at the hearing and make oral presentations should attend a prehearing conference to be held at 9:30 a.m. on February 22, 2001, at the U.S. International Trade Commission Building. Oral testimony and written materials to be submitted at the hearing are governed by sections 201.6(b)(2) and 201.13(f) of the Commission's rules. Parties must submit any request to

present a portion of their hearing testimony in *camera* no later than 7 days prior to the date of the hearing.

Written submissions.—Each party is encouraged to submit a prehearing brief to the Commission. The deadline for filing prehearing briefs is February 20, 2001. Parties may also file posthearing briefs. The deadline for filing posthearing briefs is March 6, 2001. In addition, any person who has not entered an appearance as a party to the investigation may submit a written statement of information on or before March 6, 2001. All written submissions must conform with the provisions of section 201.8 of the Commission's rules; any submissions that contain confidential business information must also conform with the requirements of section 201.6 of the Commission's rules. The Commission's rules do not authorize filing of submissions with the Secretary by facsimile or electronic means.

In accordance with section 201.16(c) of the Commission's rules, each document filed by a party to the investigation must be served on all other parties to the investigation (as identified by the service list), and a certificate of service must be timely filed. The Secretary will not accept a document for filing without a certificate of service.

Authority: This investigation is being conducted under the authority of section 204(c) of the Trade Act of 1974; this notice is published pursuant to section 206.3 of the Commission's rules.

By order of the Commission.

Issued: December 15, 2000.

Donna R. Koehnke,
Secretary.

[FR Doc. 00-32444 Filed 12-20-00; 8:45 am]

BILLING CODE 7020-02-P

INTERNATIONAL TRADE COMMISSION

[USITC SE-00-054]

Sunshine Act Meeting

AGENCY HOLDING THE MEETING:

International Trade Commission.

TIME AND DATE: December 28, 2000 at 11 a.m.

PLACE: Room 101, 500 E Street SW., Washington, DC 20436, Telephone: (202) 205-2000.

STATUS: Open to the public.

MATTERS TO BE CONSIDERED:

1. Agenda for future meeting: none
2. Minutes
3. Ratification List
4. Inv. Nos. 701-TA-404-408 and 731-TA-898-908 (Preliminary)(Certain Hot-

Rolled Steel Products from Argentina, China, India, Indonesia, Kazakhstan, the Netherlands, Romania, South Africa, Taiwan, Thailand, and Ukraine)—briefing and vote. (The Commission is currently scheduled to transmit its determination to the Secretary of Commerce on December 28, 2000; Commissioners' opinions are currently scheduled to be transmitted to the Secretary of Commerce on January 5, 2001.)

5. Outstanding action jackets: none.

In accordance with Commission policy, subject matter listed above, not disposed of at the scheduled meeting, may be carried over to the agenda of the following meeting.

By order of the Commission.

Issued: December 18, 2000.

Donna R. Koehnke,
Secretary.

[FR Doc. 00-32658 Filed 12-19-00; 10:55 am]

BILLING CODE 7020-02-U

DEPARTMENT OF LABOR

Employment and Training Administration

Notice of Determinations Regarding Eligibility To Apply for Worker Adjustment Assistance and NAFTA Transitional Adjustment Assistance

In accordance with section 223 of the Trade Act of 1974, as amended, the Department of Labor herein presents summaries of determinations regarding the eligibility to apply for trade adjustment assistance for workers (TA-W) issued during the period of December, 2000.

In order for an affirmative determination to be made and a certification of eligibility to apply for worker adjustment assistance to be issued, each of the group eligibility requirements of section 222 of the Act must be met.

(1) That a significant number or proportion of the workers in the workers' firm, or an appropriate subdivision thereof, have become totally or partially separated,

(2) that sales or production, or both, of the firm or subdivision have decreased absolutely, and

(3) that increases of imports of articles like or directly competitive with articles produced by the firm or appropriate subdivision have contributed importantly to the separations, or threat thereof, and to the absolute decline in sales or production.

Negative Determinations for Worker Adjustment Assistance

In each of the following cases the investigation revealed that criterion (3)

has not been met. A survey of customers indicated that increased imports did not contribute importantly to worker separations at the firm.

TA-W-38,111; *Standard Forged Products, Inc., Johnstown, PA*
 TA-W-38,209; *Chieftain Products, Marine City, MI*
 TA-W-38,185; *GP Timber, Central Point, OR*
 TA-W-38,146; *Rosboro Lumber, Dimension Lumber Div., Springfield, OR*
 TA-W-38,147; *Potlatch Corp., Wood Products Div.: Jaype Mill, Pierce, ID*
 TA-W-38,059; *Crown Vantage, Parchment, MI*
 TA-W-38,080; *Ilissa Bridals, Ltd, New York, NY*

In the following cases, the investigation revealed that the criteria for eligibility have not been met for the reasons specified.

TA-W-38,264; *The Chase Manhattan Bank NA, Oil and Gas Asset Management Group, Midland, TX*
 TA-W-38,215; *Entertainment Partners, EPSG Pixpay Service, Burbank, CA*
 TA-W-38,355; *LSC Kentucky, LLC, Morganfield, KY*
 TA-W-38,183; *Seagate Technology, CSO Div., Oklahoma City, OK*
 TA-W-38,229; *Dana Engine Controls, Branford, CT*

The workers firm does not produce an article as required for certification under Section 222 of the Trade Act of 1974.

TA-W-38,329; *Fashion Technologies, Inc., Hackensack, NJ*
 TA-W-38,112; *The Mead Corp., School and Office Products Div., Kalamazoo, MI*
 TA-W-38,266; *Jones and Vining, Lewiston, ME*
 TA-W-38,192; *Metal Powder Products Co., Logan, OH*
 TA-W-38,216; *Samsonite Corp., Tucson, AZ*
 TA-W-38,191; *Windfall Products, St. Mary's, PA*
 TA-W-38,067 & A; *Paccar/Kenworth, Seattle, WA and Renton, WA*
 TA-W-38,310; *ABC-NACO, Ashland, WI*
 TA-W-38,113; *Eramet Marietta, Inc., North Plant, Marietta, OH*
 TA-W-38,314; *International Security Printers, Ogdensburg, NY*
 TA-W-38,317; *Vanalco, Inc., Vancouver, WA*
 TA-W-38,242; *Homestake Mining Co., Lead, SD*
 TA-W-38,043; *Freightliner, LLC, Portland Truck Manufacturing Plant, Portland, OR*
 TA-W-38,024; *Alabama Structural Beams, (A Div. of Gulf States Steel), Gadsden, AL*

TA-W-38,053; *Pillowtex Corp., Fieldale, VA*
 TA-W-38,150; *Key Circuit Co., Fountain Valley, CA*
 TA-W-38,069; *Asarco, Inc., East Helena, MT*
 TA-W-38,174; *Paper, Calmenson & Co., Blade Div., Bucyrus, OH*
 TA-W-38,217; *Union Pacific Fuel, Inc., Union Resources Co. and Union Pacific Resources Group, Inc., Headquartered in Fort Worth, TX and Operating in the Following States: A; CO, B; WY, C; OK, D; KS, E; LA, F; UT, G; TX*

Increased imports did not contribute importantly to worker separations at the firm.

TA-W-38,098; *Burlington Resources, Oil and Gas, Mid Continent—Rockies, Sidney, MT*

In July through June 1999 and 2000, aggregate U.S. imports of both natural gas and crude oil declined absolutely and relative to domestic shipments.

TA-W-38,287; *Poland Springs Bottling Co., Poland Springs, ME*
 TA-W-38,274; *Tingley Rubber Co., South Plainfield, NJ*
 TA-W-38,928; *Danecraft, Providence, RI*

The investigation revealed that criteria (2) has not been met. Sales or production did not decline during the relevant period as required for certification.

TA-W-37,859; *Hurwitz Co., Inc., Buffalo, NY*

The investigation revealed that criteria (2) and criteria (3) have not been met. Sales or production did not decline during the relevant period as required for certification. Increases of imports of articles like or directly competitive with articles produced by the firm or an appropriate subdivision have not contributed importantly to the separations or threat thereof, and the absolute decline in sales or production.

Affirmative Determinations for Worker Adjustment Assistance

The following certifications have been issued; the date following the company name and location of each determination references the impact date for all workers of such determination.

TA-W-38,207; *Bynum Concepts, Inc., Lubbock, TX: September 28, 1999.*
 TA-W-38,268; *Ride Snowboard Mfg., Corona CA: October 18, 1999.*
 TA-W-38,032; *JBL, Inc./Harmon Mfg., Wood Mill, Northridge, CA: August 9, 1999.*
 TA-W-38,221; *Auto Pocket Operators, Outer Banks, Div. of Sara Lee Co., Lumberton, NC: October 3, 1999.*

TA-W-38,074; *Contour Medical Technology, Laverne, TN: August 25, 1999.*
 TA-W-38,089; *Federal Bag Co., Inc., St. Louis, MO: September 5, 1999.*
 TA-W-38,212; *Echo Bay Minerals Co., Kettle River Operation, Republic, WA: September 22, 1999.*
 TA-W-38,166; *Garan Manufacturing Corp., Rainsville, AL: September 14, 1999.*
 TA-W-38,144; *Avoca Manufacturing, Avoca, PA: September 15, 1999.*
 TA-W-38,046; *Paramount Headwear, Inc., Dexter Straw Manufacturing Div., Dexter, MO: August 25, 1999.*
 TA-W-38,247; *North Power Lumber Co., A Subsidiary of Tree Source, North Power, OR: October 2, 1999.*
 TA-W-38,320; *American Baseball Cap, Inc., Freidens, PA: October 6, 1999.*
 TA-W-38,021; *Cardinal Shoe Corp., Lawrence, MA: August 8, 1999.*
 TA-W-38,054; *Merrimac Industries, Inc., West Caldwell, NJ: August 11, 1999.*
 TA-W-38,352; *Mulox, Inc., Macon, GA: November 13, 1999.*
 TA-W-38,307; *Progress Lighting, Cowpens, SC: October 28, 1999.*
 TA-W-38,131; *Imperial Coat Front, New York, NY: September 10, 1999.*
 TA-W-38,127; *Ansell Health Care, Dothan, AL: September 25, 1999.*
 TA-W-38,161; *Liberty Precision Tool Co., Bessemer City, NC: September 21, 1999.*
 TA-W-38,117; *California Direct Service, San Diego, CA: September 13, 1999.*
 TA-W-37,978; *Permair Leathers, Salem, MA: August 4, 1999.*
 TA-W-38,040; *Reynolds Metals Co., Troutdale, OR: August 18, 1999.*
 TA-W-38,201; *Tyco Electronics, Clinton Township, MI: September 28, 1999.*
 TA-W-38,163; *Omron Manufacturing of America, Inc., St. Charles, IL: September 19, 1999.*
 TA-W-38,252; *A.O. Smith Electrical Products Co., Paoli Plant, Paoli, IN: October 19, 1999.*
 TA-W-38,263; *Columbia Footwear Corp., Hazleton, PA: October 21, 1999.*
 TA-W-38,285; *Fairfield Manufacturing Co., Inc., Lafayette, IN: October 16, 1999.*
 TA-W-38,262; *Paramount Headwear, Inc., Mountain Grove, MO: September 28, 1999.*
 TA-W-38,110; *Authentic Fitness Corp., Bell, CA: September 6, 1999.*
 TA-W-38,091; *American Metal Products, The Retail Div., Union, MO: August 31, 1999.*
 TA-W-38,254; *Craftwood Designs, Caldwell Chair Co., Haleyville, CA: October 19, 1999.*
 TA-W-38,286; *American Bag Corp., Stearns, KY: October 18, 1999.*

TA-W-37,881; *Hart Mountain Millworks, Inc., Conact Lujber Co., Inc., Lakeview, OR: June 29, 1999.*

TA-W-38,306; *Alstom Power, Heat Recovery Steam Generators Div., Kings Mountain, NC: November 6, 1999.*

TA-W-38,339; *Maytag, Jefferson City Component Parts Plant, Jefferson City, MO: November 8, 1999.*

TA-W-38,319; *Hit Apparel, Inc., Athens, TN: April 29, 2000.*

TA-W-38,123 & A; *Thaw Corp., Seattle, WA, Excluding the Cutting Dept., Kent, WA: September 6, 1999.*

TA-W-38,276; *Coach, Medley, FL: October 24, 1999.*

TA-W-38,275; *American Garment Finishers Corp., El Paso, TX: May 13, 2000.*

TA-W-38,289; *Grant Western Lumber Co., John Day, OR: October 25, 1999.*

Also, pursuant to Title V of the North American Free Trade Agreement Implementation Act (Pub. L. 103-182) concerning transitional adjustment assistance hereinafter called (NAFTA-TAA) and in accordance with Section 250(a), Subchapter D, Chapter 2, Title II, of the Trade Act as amended, the Department of Labor presents summaries of determinations regarding eligibility to apply for NAFTA-TAA issued during the month of December, 2000.

In order for an affirmative determination to be made and a certification of eligibility to apply for NAFTA-TAA the following group eligibility requirements of Section 250 of the Trade Act must be met:

(1) That a significant number of proportion of the workers in the workers' firm, or an appropriate subdivision thereof, (including workers in any agricultural firm or appropriate subdivision thereof) have become totally or partially separated from employment and either—

(2) That sales or production, or both, of such firm or subdivision have decreased absolutely,

(3) That imports from Mexico or Canada of articles like or directly competitive with articles produced by such firm or subdivision have increased, and that the increases import contributed importantly to such workers' separations or threat of separation and to the decline in sales or production of such firm or subdivision; or

(4) That there has been a shift in production by such workers' firm or subdivision to Mexico or Canada of articles like or directly competitive with articles which are produced by the firm or subdivision.

Negative Determinations NAFTA-TAA

In each of the following cases the investigation revealed that criteria (3) and (4) were not met. Imports from Canada or Mexico did not contribute importantly to workers' separations. There was no shift in production from the subject firm to Canada or Mexico during the relevant period.

NAFTA-TAA-04254; *Jakel, Inc., East Prairie, MO*

NAFTA-TAA-04262; *ABC-NACO, Ashland, WI*

NAFTA-TAA-04274; *Vanalco, Inc., Vancouver, WA*

NAFTA-TAA-04192; *ADM Milling Co., Milwaukee, WI*

NAFTA-TAA-04256; *Fairfield Manufacturing Co., Inc., Lafayette, IN*

NAFTA-TAA-04265; *Tingley Rubber Co., South Plainfield, NJ*

NAFTA-TAA-04187; *Metal Powder Products Co., Logan, OH*

NAFTA-TAA-04185; *Liberty Precision Tool Co., Inc., Bessemer City, NC*

NAFTA-TAA-04148; *The Mead Corp., School and Office Products Div., Kalamazoo, MI*

NAFTA-TAA-04202; *Samsonite Corp., Tucson, AZ*

NAFTA-TAA-04253; *Homestake Mining Co., Homestake Gold Mine, Lead, SD*

NAFTA-TAA-04102; *Freightliner LLC, Portland Truck Manufacturing Plant, Portland, OR*

NAFTA-TAA-04147 & A; *Paccar/Kenworth, Seattle, WA and Renton, WA*

NAFTA-TAA-04009; *Hart Mountain Millworks, Inc., Contact Lumber Co., Inc., Lakeview, OR*

NAFTA-TAA-04122; *Asarco, Inc., East Helena, MT*

NAFTA-TAA-04221; *Key Circuit Co., Fountain Valley, CA*

NAFTA-TAA-04248; *Union Pacific Fuels, Inc., Union Resources Co., and Union Pacific Resources Group, Inc., Headquartered in Fort Worth, TX and Operating in the following states: A; CO, B; WY, C; OK, D; KS, E; LA, F; Ut, G; TX*

The investigation revealed that the criteria for eligibility have not been met for the reasons specified.

NAFTA-TAA-04203; *Entertainment Partners, EPSG Pixpay Services, Burbank, CA*

NAFTA-TAA-04252; *Tri-Co Blueprint and Supply, Inc., Ventura, CA*

NAFTA-TAA-04244; *Robert Helmick, Inc., Kingston, ID*

The investigation revealed that workers of the subject firm did not product an article within the meaning of

Section 250(a) of the Trade Act, as amended.

NAFTA-TAA-04024; *Portac, Inc., Tacoma, WA*

The investigation revealed that criteria (1) has not been met. A significant number or proportion of the workers in such workers' firm or an appropriate subdivision (including workers in any agricultural firm or appropriate subdivision thereof) have become totally or partially separated from employment.

NAFTA-TAA-0450; *Poland Springs Bottling Co., Poland Springs, MD*

NAFTA-TAA-0408; *Spreckels Sugar, Woodland, CA*

The investigation revealed that criteria (2) has not been met. Sales or production did not decline during the relevant period as required for certification.

AFFIRMATIVE DETERMINATIONS NAFTA-TAA

NAFTA-TAA-04189; *Talon, Inc., Commerce, CA: September 25, 1999.*

NAFTA-TAA-04235; *Precision Interconnect, Medical Cable Div., Waupin, WI: October 28, 1999.*

NAFTA-TAA-04273; *Hit Apparel, Inc., Athens, TN: April 29, 2000.*

NAFTA-TAA-04205; *North Powder Lumber Co., A Subsidiary of Tree Source, North Powder, OR: October 2, 1999.*

NAFTA-TAA-04255; *Exide Technologies, Automotive Battery Div., a/k/a GNB Batteries, Inc., a/k/a Exide Corp., Farmers Branch, TX: October 10, 1999.*

NAFTA-TAA-04271; *American Baseball Cap, Inc., Freidens, PA: October 6, 1999.*

NAFTA-TAA-04285; *Asten Johnson, Walterboro, SC: November 3, 1999.*

NAFTA-TAA-04142; *Fawn Industries, Maryville, TN: September 1, 1999.*

NAFTA-TAA-04249; *Autoliv ASP, Inc., Autoliv American Components, Including Leased Workers of Adecco Staffing Service Ogden, UT: October 23, 1999.*

NAFTA-TAA-04212; *Bay Club Sportswear, Inc., Copiague, NY: October 10, 1999.*

NAFTA-TAA-04232; *California Direct Service, San Diego, CA: September 13, 1999.*

NAFTA-TAA-04144; *Milliken and Company, Gaffney, SC: September 7, 1999.*

NAFTA-TAA-04127; *Paramount Headwear, Inc., Dexter Straw Manufacturing Div., Dexter, MO: August 28, 1999.*

NAFTA-TAA-04315; *Consolidated Metco, Inc., Rivergate Mfg. Plant, Portland, OR: November 13, 1999.*

NAFTA-TAA-04215; Stanley Door Systems, The Stanley Works, San Dimas, CA: October 11, 1999.

NAFTA-TAA-04228; Contour Medical Technology, Laverne, TN: September 27, 1999.

NAFTA-TAA-04110; JBL, Inc./Harmon Mfg., Wood Mill, Northridge, CA: August 9, 1999.

NAFTA-TAA-0487; Seattle Wash, Inc., Astro Design Div., Seattle, WA: August 9, 1999.

NAFTA-TAA-04325; Maytag, Jefferson City Component Parts Plant, Jefferson City, MO: November 22, 1999.

NAFTA-TAA-0458; and A; Thaw Corp., Seattle, WA and Excluding The Cutting Department, Kent, WA: September 6, 1999.

NAFTA-TAA-04261; Grant Western Lumber Co., John Day, OR: October 25, 1999.

NAFTA-TAA-04291; American Garment Finishers Corp., El Paso, TX: May 13, 2000.

NAFTA-TAA-04293; Artex International, St. George, UT: October 26, 1999.

NAFTA-TAA-04279; Alstom Power, Heat Recovery Steam Generators Div., Kings Mountain, NC: November 7, 1999.

I hereby certify that the aforementioned determinations were issued during the month of December, 2000. Copies of these determinations are available for inspection in Room C-5311, U.S. Department of Labor, 200 Constitution Avenue, NW., Washington, DC 20210 during normal business hours or will be mailed to persons who write to the above address.

Dated: December 13, 2000.

Edward A. Tomchick,

Director, Division of Trade Adjustment Assistance.

[FR Doc. 00-32585 Filed 12-20-00; 8:45 am]

BILLING CODE 4510-30-M

DEPARTMENT OF LABOR

Employment and Training Administration

[TA-W-32,216]

Samsonite Corporation, Tucson, AZ; Notice of Negative Determination Regarding Application for Reconsideration

By application of December 5, 2000, the petitioner requested administrative reconsideration of the Department's negative determination regarding

worker eligibility to apply for trade adjustment assistance, applicable to workers of the subject firm. The denial notice was signed on November 29, 2000 and will soon be published in the **Federal Register**.

Pursuant to 29 CFR 90.18(c) reconsideration may be granted under the following circumstances:

(1) If it appears on the basis of facts not previously considered that the determination complained of was erroneous;

(2) If it appears that the determination complained of was based on a mistake in the determination of facts not previously considered; or

(3) If in the opinion of the Certifying Officer, a misinterpretation of facts or of the law justified reconsideration of the decision.

The request for reconsideration claims that subject plant production of cut fabric used for further production of soft-sided luggage is being transferred to Mexico and the cut fabric is then incorporated into soft-sided luggage at the Mexican facility. The finished suitcase is then shipped back to the United States.

The denial of TAA for the workers of Samsonite in Tucson, Arizona, was based on the finding that criterion (3) of the worker group's eligibility requirements of Section 222 of the Trade Act was not met. Layoffs at the subject firm were the direct result of a shift in subject plant production of cut fabric to Mexico. The cut fabric is not imported back to the United States, but incorporated into the further production of soft-sided luggage. The luggage is then imported back to the United States.

As depicted in the negative determination, the preponderance in the declines in employment at the subject plant may be related to the subject firm's increasing imports of finished luggage made of cut fabric pieces. Increased imports of finished articles cannot be used as the basis for certification of workers producing a component for the finished article. Imports of cut fabric for soft-sided luggage and not of finished soft-sided luggage must be considered as the basis for possible certification of this case.

Conclusion

After review of the application and investigative findings, I conclude that there has been no error or misinterpretation of the law or of the facts which would justify reconsideration of the Department of Labor's prior decision. Accordingly, the application is denied.

Signed at Washington, DC, this 11th day of December 2000.

Linda G. Poole,

Certifying Officer, Division of Trade Adjustment Assistance.

[FR Doc. 00-32588 Filed 12-20-00; 8:45 am]

BILLING CODE 4510-30-M

DEPARTMENT OF LABOR

Employment and Training Administration

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 Division 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, Division of Trade Adjustment Assistance, at the address shown below, not later than January 2, 2001.

Interested persons are invited to submit written comments regarding the subject matter of the investigations to the Director, Division of Trade Adjustment Assistance, at the address shown below, not later than January 2, 2001.

The petitions filed in this case are available for inspection at the Office of the Director, Division of Trade Adjustment Assistance, Employment and Training Administration, U.S. Department of Labor, Room C-5311, 200 Constitution Avenue, NW., Washington, DC 20210.

Signed at Washington, D.C. this 4th day of December, 2000.

Edward A. Tomchick,

Director, Division of Trade Adjustment Assistance.

APPENDIX

[Petitions instituted on 12/04/2000]

TA-W	Subject firm (petitioners)	Location	Date of petition	Product(s)
38,371	Sasib (USWA)	DePere, WI	11/14/2000	Packaging Machines.
38,372	Alcoa Lebanon Works (Wkrs)	Lebanon, PA	01/15/2000	Rolled Aluminum.
38,373	Kirkwood, Inc. (Wkrs)	Cleveland, OH	01/07/2000	Carbon and Copper Brushes.
38,374	Owens Brockway (GMP)	Lakeland, FL	11/16/2000	Glass Containers.
38,375	CHF Industrial, Inc. (Wkrs)	Kaufman, TX	11/16/2000	Curtains.
38,376	Galey and Lord (Co.)	Shannon, GA	11/17/2000	Yarn Spinning.
38,377	Dearborn Brass (GMPPA)	Tyler, PA	11/16/2000	Bathroom and Kitchen Plumbing Fixtures.
38,378	Honeywell (Wkrs)	Rocky Mount, NC	11/02/2000	Fuel Controls for Aircraft.
38,379	Trumark Industries (Co.)	Spokane, WA	11/08/2000	Fingerjoint Studs.
38,380	Rexam (Wkrs)	Mt. Holly, NJ	11/16/2000	Medical Pouches.
38,381	Karmazin Products (Co.)	Wyandotte, MI	11/17/2000	Hat Exchangers.
38,382	Cherokee Finishing Co. (Co.)	Gaffney, SC	11/08/2000	Printing Fabric for Home Furnishings.
38,383	Burruss Company (Wkrs)	Galax, VA	11/02/2000	Hardwood Flooring.
38,384	Thompson Steel Co. (Co.)	Baltimore, MD	11/22/2000	Steel Products.
38,385	Findlay Industries (UNITE)	Morrison, TN	11/22/2000	Automobile Seat Covers.
38,386	Unocal (Co.)	Sugar Land, TX	11/16/2000	Crude Oil, Natural Gas.
38,387	Indigio Concepts (Wkrs)	Vernon, CA	01/21/2000	Pants—Jeans.
38,388	Corbin Russwin, Inc. (IAMAW)	Berlin, CT	11/16/2000	Electronic Hotel Door Locks.
38,389	Best Manufacturing (Wkrs)	Woodbury, GA	11/20/2000	Cloth Table Linens.
38,390	Eaton Corporation (Co.)	Carol Stream, IL	11/20/2000	Hydraulic Valves.
38,391	Foxboro Company (Co.)	Foxboro, MA	11/17/2000	Printed Circuit Board.
38,392	Hagale Industries (Wkrs)	Ava, MO	10/27/2000	Sportswear.
38,393	Tyco Electronics (Co.)	Chesterfield, MI	11/22/2000	Electronic Connectors.
38,394	Velvac, Inc. (Co.)	New Berlin, WI	11/24/2000	Heavy Duty Truck Parts.

[FR Doc. 00-32584 Filed 12-20-00; 8:45 am]

BILLING CODE 4510-30-M

DEPARTMENT OF LABOR

Employment and Training
Administration

[TA-W-38, 061]

TRW, Valve Division, Danville, PA;
Notice of Revised Determination on
Reconsideration

On November 30, 2000, the Department issued an Affirmative Determination Regarding Application on Reconsideration applicable to workers and former workers of the subject firm. The notice will soon be published in the **Federal Register**.

On October 10, 2000 the Department initially denied TAA to workers of TRW, Valve Division, Danville, Pennsylvania producing internal combustion engine valves because the "contributed importantly" group eligibility requirement of Section 222 of the Trade Act of 1974, as amended, was not met.

On reconsideration, the subject firm reported that it recently began importing combustion engine valves to their United States customers.

Conclusion

After careful review of the additional facts obtained on reconsideration, I conclude that increased imports of

articles like or directly competitive with combustion engine valves, contributed importantly to the declines in sales or production and to the total or partial separation of workers of TRW, Valve Division, Danville, Pennsylvania. In accordance with the provisions of the Act, I make the following certification:

"All workers of TRW, Valve Division, Danville, Pennsylvania who became totally or partially separated from employment on or after August 23, 1999 through two years of this certification, are eligible to apply for adjustment assistance under section 223 of the Trade Act of 1974."

Signed in Washington, DC this 11th day of December 2000.

Linda G. Poole,

*Certifying Officer, Division of Trade
Adjustment Assistance.*

[FR Doc. 00-32587 Filed 12-20-00; 8:45 am]

BILLING CODE 4510-30-M

DEPARTMENT OF LABOR

Employment and Training
Administration

[Docket No. NAFTA-04202]

Samsonite Corporation Tucson, AZ;
Notice of Revised Determination On
Reconsideration

On November 29, 2000, the Department issued a Negative Determination Regarding Eligibility to Apply for NAFTA-Transitional Adjustment Assistance (NAFTA-TAA)

applicable to all workers of Samsonite Corporation located in Tucson, Arizona. The notice will soon be published in the **Federal Register**.

By letter of December 5, 2000, the petitioner requested administrative reconsideration of the Department's findings.

The employees of the Samsonite Corporation located in Tucson, Arizona were engaged in the cutting of fabric used in soft-sided luggage.

New findings on reconsideration show that the production of all cut fabric produced by Samsonite Corporation, Tucson, Arizona is currently being shifted to Mexico. The transfer will be completed on December 15, 2000 impacting all workers at the subject plant.

Conclusion

After careful review of the additional facts obtained on reconsideration, I conclude that increased imports of articles from Mexico like or directly competitive with cut fabrics contributed importantly to the decline in sales or production and to the total or partial separation of workers of Samsonite Corporation, Tucson, Arizona. In accordance with the provisions of the Act, I make the following certification:

"All workers of Samsonite Corporation, Tucson, Arizona who became totally or partially separated from employment on or after September 29, 1999 through two years from the date of the certification are eligible

to apply for NAFTA-TAA under Section 250 of the Trade Act of 1974.”

Signed at Washington, DC this 8th day of December 2000.

Linda G. Poole,

Certifying Officer, Division of Trade Adjustment Assistance.

[FR Doc. 00-32586 Filed 12-20-00; 8:45 am]

BILLING CODE 4510-30-M

DEPARTMENT OF LABOR

Pension and Welfare Benefits Administration

[Prohibited Transaction Exemption 2000-66; Exemption Application No. D-10706, et al.]

Grant of Individual Exemptions; Allfirst Bank

AGENCY: Pension and Welfare Benefits Administration, Labor.

ACTION: Grant of individual exemptions.

SUMMARY: This document contains exemptions issued by the Department of Labor (the Department) from certain of the prohibited transaction restrictions of the Employee Retirement Income Security Act of 1974 (the Act) and/or the Internal Revenue Code of 1986 (the Code).

Notices were published in the **Federal Register** of the pendency before the Department of proposals to grant such exemptions. The notices set forth a summary of facts and representations contained in each application for exemption and referred interested persons to the respective applications for a complete statement of the facts and representations. The applications have been available for public inspection at the Department in Washington, D.C. The notices also invited interested persons to submit comments on the requested exemptions to the Department. In addition the notices stated that any interested person might submit a written request that a public hearing be held (where appropriate). The applicants have represented that they have complied with the requirements of the notification to interested persons. No public comments and no requests for a hearing, unless otherwise stated, were received by the Department.

The notices of proposed exemption were issued and the exemptions are being granted solely by the Department because, effective December 31, 1978, section 102 of Reorganization Plan No. 4 of 1978, 5 U.S.C. App. 1 (1996), transferred the authority of the Secretary of the Treasury to issue exemptions of the type proposed to the Secretary of Labor.

Statutory Findings

In accordance with section 408(a) of the Act and/or section 4975(c)(2) of the Code and the procedures set forth in 29 CFR part 2570, Subpart B (55 FR 32836, 32847, August 10, 1990) and based upon the entire record, the Department makes the following findings:

(a) The exemptions are administratively feasible;

(b) They are in the interests of the plans and their participants and beneficiaries; and

(c) They are protective of the rights of the participants and beneficiaries of the plans.

Allfirst Bank, Located in Baltimore, Maryland

[Prohibited Transaction Exemption 2000-66; Exemption Application No. D-10706]

Exemption

Section I—Exemption for Receipt of Fees

The restrictions of section 406(a) and 406(b) of the Act and the sanctions resulting from the application of section 4975 of the Code, by reason of section 4975(c)(1)(A) through (F) of the Code, shall not apply, as of November 13, 1998, to the receipt of fees by Allfirst from the ARK Funds, open-end investment companies registered under the Investment Company Act of 1940 (the 1940 Act), for acting as an investment adviser for such Funds, as well as for providing other services to the ARK Funds which are “Secondary Services,” as defined in Section III(i), in connection with the investment by plans for which Allfirst serves as a fiduciary (the Client Plans) in shares of the ARK Funds, provided that the following conditions and the general conditions of Section II are met:

(a) Each Client Plan satisfies either (but not both) of the following:

(1) The Client Plan receives a cash credit of such Plan’s proportionate share of all fees charged to the Funds by Allfirst for investment advisory services, including any investment advisory fees paid by Allfirst to third party sub-advisers, no later than the same day as the receipt of such fees by Allfirst. The crediting of all such fees to the Client Plans by Allfirst is audited by an independent accounting firm on at least an annual basis to verify the proper crediting of the fees to each Plan.

(2) The Client Plan does not pay any Plan-level investment management fees, investment advisory fees, or similar fees to Allfirst with respect to any of the assets of such Plan that are invested in shares of any of the ARK Funds. This condition does not preclude the

payment of investment advisory or similar fees by the ARK Funds to Allfirst under the terms of an investment management agreement adopted in accordance with section 15 of the 1940 Act, nor does it preclude the payment of fees for Secondary Services to Allfirst pursuant to a duly adopted agreement between Allfirst and the ARK Funds.

(b) The price paid or received by a Client Plan for shares in a Fund is the net asset value per share, as defined in Section III(f), at the time of the transaction and is the same price that would have been paid or received for the shares by any other investor at that time.

(c) Allfirst, including any officer or director of Allfirst, does not purchase or sell shares of the ARK Funds from or to any Client Plan.

(d) No sales commissions are paid by the Client Plans in connection with the purchase or sale of shares of the ARK Funds, and no redemption fees are paid in connection with the sale of shares by the Client Plans to the ARK Funds.

(e) For each Client Plan, the combined total of all fees received by Allfirst for the provision of services to a Client Plan, and in connection with the provision of services to the ARK Funds in which the Client Plan may invest, are not in excess of “reasonable compensation” within the meaning of section 408(b)(2) of the Act.

(f) Allfirst does not receive any fees payable pursuant to Rule 12b-1 under the 1940 Act in connection with the transactions.

(g) The Client Plans are not employee benefit plans sponsored or maintained by Allfirst.

(h) The Second Fiduciary receives, in advance of any initial investment by the Client Plan in a Fund, full and detailed written disclosure of information concerning the ARK Funds, including but not limited to:

(1) A current prospectus for each Fund in which a Client Plan is considering investing;

(2) A statement describing the fees for investment advisory or similar services, any secondary services as defined in Section III(i), and all other fees to be charged to or paid by the Client Plan and by the ARK Funds, including the nature and extent of any differential between the rates of such fees;

(3) The reasons why Allfirst may consider such investment to be appropriate for the Client Plan;

(4) A statement describing whether there are any limitations applicable to Allfirst with respect to which assets of a Client Plan may be invested in the ARK Funds, and if so, the nature of such

limitations; and (5) Upon request of the Second Fiduciary, a copy of the notice of proposed exemption and/or a copy of the final exemption, as published in the **Federal Register**.

(i) After consideration of the information described in paragraph (h) above, the Second Fiduciary authorizes in writing the investment of assets of the Client Plan in each particular Fund and the fees to be paid by such ARK Funds to Allfirst.

(j) All authorizations made by a Second Fiduciary regarding investments in a Fund and the fees paid to Allfirst are subject to an annual reauthorization, wherein any such prior authorization referred to in paragraph (i) above shall be terminable at will by the Client Plan, without penalty to the Client Plan, upon receipt by Allfirst of written notice of termination. A form expressly providing an election to terminate the authorization described in paragraph (i) above (the Termination Form) with instructions on the use of the form must be supplied to the Second Fiduciary no less than annually—provided that the Termination Form need not be supplied to the Second Fiduciary pursuant to this paragraph sooner than six months after such Termination Form is supplied pursuant to paragraph (l) below, except to the extent required by such paragraph in order to disclose an additional service or fee increase. The instructions for the Termination Form must include the following information:

(1) The authorization is terminable at will by the Client Plan, without penalty to the Client Plan, upon receipt by Allfirst of written notice from the Second Fiduciary; and

(2) Failure to return the Termination Form will result in continued authorization of Allfirst to engage in the transactions described in paragraph (i) above on behalf of the Client Plan.

(k) For each Client Plan using the fee structure described in paragraph (a)(1) above with respect to investments in a particular Fund, the Second Fiduciary of the Client Plan receives full written disclosure in a Fund prospectus or otherwise of any increases in the rates of fees charged by Allfirst to the ARK Funds for investment advisory services.

(l) (1) For each Client Plan using the fee structure described in paragraph (a)(2) above with respect to investments in a particular Fund, an increase in the rate of fees paid by the Fund to Allfirst regarding any investment management services, investment advisory services, or similar services that Allfirst provides to the Fund over an existing rate for such services that had been authorized by a Second Fiduciary in accordance with paragraph (i) above; or

(2) For any Client Plan under this exemption, an addition of a Secondary Service (as defined in Section III(i) below) provided by Allfirst to the Fund for which a fee is charged, or an increase in the rate of any fee paid by the ARK Funds to Allfirst for any Secondary Service that results either from an increase in the rate of such fee or from a decrease in the number or kind of services performed by Allfirst for such fee over an existing rate for such Secondary Service that had been authorized by the Second Fiduciary of a Client Plan in accordance with paragraph (j) above;

Allfirst will, at least 30 days in advance of the implementation of such additional service for which a fee is charged or fee increase, provide a written notice (which may take the form of a proxy statement, letter, or similar communication that is separate from the prospectus of the Fund and that explains the nature and amount of the additional service for which a fee is charged or of the increase in fees) to the Second Fiduciary of the Client Plan. Such notice shall be accompanied by a Termination Form with instructions as described in paragraph (i) above.

(m) On an annual basis, Allfirst provides the Second Fiduciary of a Client Plan investing in the ARK Funds with:

(1) A copy of the current prospectus for the ARK Funds in which the Client Plan invests and, upon such Fiduciary's request, a copy of the Statement of Additional Information for such ARK Funds that contains a description of all fees paid by the ARK Funds to Allfirst;

(2) A copy of the annual financial disclosure report prepared by Allfirst that includes information about the Fund portfolios, as well as audit findings of an independent auditor, within 60 days of the preparation of the report; and

(3) Oral or written responses to inquiries of the Second Fiduciary as they arise.

(n) With respect to each of the ARK Funds in which a Client Plan invests, in the event such Fund places brokerage transactions with Allfirst, Allfirst will provide the Second Fiduciary of such Plan at least annually with a statement specifying:

(1) The total, expressed in dollars, of brokerage commissions of each Fund that are paid to Allfirst by such Fund;

(2) The total, expressed in dollars, of brokerage commissions of each Fund that are paid by such Fund to brokerage firms unrelated to Allfirst;

(3) The average brokerage commissions per share, expressed as

cents per share, paid to Allfirst by each Fund; and

(4) The average brokerage commissions per share, expressed as cents per share, paid by each Fund to brokerage firms unrelated to Allfirst.

(o) All dealings between the Client Plans and the ARK Funds are on a basis no less favorable to the Plans than dealings with other shareholders of the ARK Funds.

Section II—General Conditions

(a) Allfirst maintains for a period of six years the records necessary to enable the persons described in paragraph (b) below to determine whether the conditions of this exemption have been met, except that—

(1) a prohibited transaction will not be considered to have occurred if, due to circumstances beyond the control of Allfirst, the records are lost or destroyed prior to the end of the six-year period; and

(2) no party in interest other than Allfirst shall be subject to the civil penalty that may be assessed under section 502(i) of the Act, or to the taxes imposed by section 4975(a) and (b) of the Code, if the records are not maintained or are not available for examination as required by paragraph (b) below.

(b) (1) Except as provided in paragraph (b)(2) below and notwithstanding any provisions of section 504(a)(2) of the Act, the records referred to in paragraph (a) above are unconditionally available at their customary location for examination during normal business hours by—

(i) Any duly authorized employee or representative of the Department or the Internal Revenue Service,

(ii) Any fiduciary of the Client Plans who has authority to acquire or dispose of shares of the ARK Funds owned by the Client Plans, or any duly authorized employee or representative of such fiduciary, and

(iii) Any participant or beneficiary of the Client Plans or duly authorized employee or representative of such participant or beneficiary;

(2) None of the persons described in paragraph (b)(1)(ii) and (iii) above shall be authorized to examine trade secrets of Allfirst, or commercial or financial information that is privileged or confidential.

Section III—Definitions

For purposes of this exemption:

(a) The term "Allfirst" means (i) from June 28, 1999 and onward, Allfirst Bank, and any affiliate thereof (as "affiliate" is defined below in paragraph (c)(1) of this section), and (ii) from

November 13, 1998 to June 28, 1999, First National Bank of Maryland (First Maryland), and any affiliate thereof (as "affiliate" is defined below in paragraph (c)(1) of this section), the period prior to the date that First Maryland changed its name to Allfirst Bank.

(b) The term "First Maryland" refers to First National Bank of Maryland, and any affiliate thereof (as "affiliate" is defined below in paragraph (c)(1) of this section), prior to June 28, 1999.

(c) An "affiliate" of a person includes:

(1) Any person directly or indirectly through one or more intermediaries, controlling, controlled by, or under common control with the person;

(2) Any officer, director, employee, relative, or partner in any such person; and

(3) Any corporation or partnership of which such person is an officer, director, partner, or employee.

(d) The term "control" means the power to exercise a controlling influence over the management or policies of a person other than an individual.

(e) The term "Fund" or "ARK Funds" shall include the ARK Funds or any other diversified open-end investment company or companies registered under the 1940 Act for which Allfirst serves as an investment adviser and may also serve as a custodian, dividend disbursing agent, shareholder servicing agent, transfer agent, Fund accountant, or provide some other "Secondary Service" (as defined below in paragraph (i) of this Section), which has been approved by such ARK Funds.

(f) The term "net asset value" means the amount for purposes of pricing all purchases and sales, calculated by dividing the value of all securities (determined by a method as set forth in the Fund's prospectus and Statement of Additional Information) and other assets belonging to the Fund or portfolio of the Fund, less the liabilities charged to each such portfolio or Fund, by the number of outstanding shares.

(g) The term "relative" means a "relative" as that term is defined in section 3(15) of the Act (or a "member of the family" as that term is defined in section 4975(e)(6) of the Code), or a brother, a sister, or a spouse of a brother or a sister.

(h) The term "Second Fiduciary" means a fiduciary of a Client Plan who is independent of and unrelated to Allfirst. For purposes of this exemption, the Second Fiduciary will not be deemed to be independent of and unrelated to Allfirst if:

(1) Such fiduciary directly or indirectly controls, is controlled by, or is under common control with Allfirst;

(2) Such fiduciary, or any officer, director, partner, employee, or relative of the fiduciary is an officer, director, partner or employee of Allfirst (or is a relative of such persons);

(3) Such fiduciary directly or indirectly receives any compensation or other consideration for his or her own personal account in connection with any transaction described in this exemption.

If an officer, director, partner or employee of Allfirst (or relative of such persons), is a director of such Second Fiduciary, and if he or she abstains from participation in (i) the choice of the Client Plan's investment adviser, (ii) the approval of any such purchase or sale between the Client Plan and the ARK Funds, and (iii) the approval of any change in fees charged to or paid by the Client Plan in connection with any of the transactions described in Section I above, then paragraph (h)(2) of this section shall not apply.

(i) The term "Secondary Service" means a service other than an investment management, investment advisory, or similar service, which is provided by Allfirst to the ARK Funds, including but not limited to custodial, accounting, brokerage, administrative, or any other service.

(j) The term "Termination Form" means the form supplied to the Second Fiduciary that expressly provides an election to the Second Fiduciary to terminate on behalf of a Client Plan the authorization described in paragraph (i) of Section I. Such Termination Form may be used at will by the Second Fiduciary to terminate an authorization without penalty to the Client Plan and to notify Allfirst in writing to effect a termination by selling the shares of the ARK Funds held by the Client Plan requesting such termination within one business day following receipt by Allfirst of the form—provided that if, due to circumstances beyond the control of Allfirst, the sale cannot be executed within one business day, Allfirst shall have one additional business day to complete such sale.

EFFECTIVE DATE: The exemption is effective as of November 13, 1998, the date that Dauphin Deposit Bank and Trust Company ceased to exist as a separate bank as a result of its acquisition by First Maryland.

For a more complete statement of the facts and representations supporting the Department's decision to grant this exemption, refer to the notice of proposed exemption (the Notice) published on October 22, 1999 at 64 FR 57129.

Notice to Interested Persons: The applicant was unable to notify

interested persons within the time period specified in the Notice. However, the applicant stated that all interested persons, including the Second Fiduciaries of Client Plans invested in the ARK Funds, were notified in the manner and time agreed to by the Department, no later than June 1, 2000. Interested persons were informed that they had 30 days to submit any written comments or requests for a hearing regarding the Notice to the Department.

Written Comments

The Department received one written comment with respect to the Notice. The comment was submitted by the applicant. The applicant requested certain corrections and clarifications to the proposed operative language for the exemption, and to the Summary of Facts and Representations (the Summary) relating thereto (see 64 FR 57129).

1. First, the applicant requested that the tenth line in Section I(l)(2) of the Notice (64 FR at 57130, third column) be revised to read as follows: "* * * the decrease in the number or [rather than "of"] kind of services * * *"

2. Second, the applicant noted that the cross-reference to paragraph (i) in the last line of Section I(l)(2) of the Notice (64 FR at 57130, third column) should have been a cross-reference to paragraph (j).

3. Third, as stated in Item 1 of the Summary (64 FR at 57131), the top of page 57132, "First National Bank of Maryland" changed its name to "Allfirst Bank," effective June 28, 1999. The applicant noted that the exemption, which has a retroactive effective date of November 13, 1998, was intended to apply to First Maryland from November 13, 1998 through June 28, 1999, and to Allfirst from June 28, 1999, onward. However, Section I of the Notice (64 FR at 57129) refers only to Allfirst, which is later defined in Section III(a) of the Notice (64 FR at 57131) as follows:

(a) The term "Allfirst" means Allfirst Bank, and any affiliate thereof as defined below in paragraph (c)(1) of this section, effective as of June 28, 1999 [emphasis added], the date the First National Bank of Maryland (First Maryland) changed its name to Allfirst Bank.

Thus, the applicant expressed concern that the exemption, as proposed, has an effective date of November 13, 1998, but appears to apply, by its terms, only beginning on June 28, 1999, the date in the Allfirst definition.

To clarify this matter, the applicant suggested revising the definition of "Allfirst" in Section III(a) to include First Maryland for the period prior to June 28, 1999. The Department concurs in the applicant's suggestion and, accordingly, has revised the definition

of "Allfirst" in Section III(a) of the final exemption to read as follows:

(a) The term "Allfirst" means (i) from June 28, 1999 and onward, Allfirst Bank, and any affiliate thereof (as "affiliate" is defined below in paragraph (c)(1) of this section) and (ii) from November 13, 1998 to June 28, 1999, First National Bank of Maryland (First Maryland), and any affiliate thereof (as "affiliate" is defined below in paragraph (c)(1) of this section), the period prior to the date that First Maryland changed its name to Allfirst Bank.

4. Fourth, with respect to Section III(e) of the Notice (64 FR at 57131), the definition of "Fund," the applicant requested that "Inc." be deleted from the reference to "ARK Funds, Inc." The applicant explained that this deletion is appropriate because the ARK Funds are organized as a business trust rather than as a corporation.

5. Fifth, the applicant wanted to correct Item 1 of the Summary (64 FR 57131, third column), which states at the top of page 57132 that, when "First National Bank of Maryland" became "Allfirst Bank," effective June 28, 1999, no further name changes had occurred, as of September 21, 1999. The applicant stated that the following additional name changes have also occurred.

a. First Maryland Bancorp, the parent company, became Allfirst Financial Inc., effective September 15, 1999;

b. FMB Trust Company, N.A. became Allfirst Trust Company, N.A., effective June 28, 1999;

c. First Maryland Brokerage Corp. became Allfirst Brokerage Corporation, effective June 28, 1999; and

d. First Omni Bank, N.A. became Allfirst Financial Center, N.A., effective June 28, 1999.

6. Finally, the applicant noted that some language in the Summary appeared to incorrectly refer to a conversion of collective investment funds to mutual funds. Thus, the applicant requested the following clarifications.

a. In Item 7 of the Summary (64 FR at 57133, third column), the last full paragraph on page 57133 makes a reference to the "change" to the ARK Funds, as if the investments were occurring as part of a conversion transaction, which should be deleted.

b. In Item 14(a) of the Summary (64 FR at 57135, third column), the reference to "collective investment ARK Funds" should be deleted.

The Department acknowledges and concurs in the applicant's requested modifications to the language of the Notice. The Department received no other written comments, nor requests for a hearing, from interested persons regarding the proposed exemption.

Accordingly, based upon the information contained in the entire record, the Department has determined to grant the proposed exemption as modified herein.

FOR FURTHER INFORMATION CONTACT: Ms. Karin Weng of the Department, telephone (202) 219-8881. (This is not a toll-free number.)

Butler-Johnson Corporation, Profit Sharing Plan (the Plan), Located in San Jose, California

[Prohibited Transaction Exemption No. 2000-67; Application No. D-10780]

Exemption

The restrictions of sections 406(a), 406(b)(1) and (b)(2) of the Act and the sanctions resulting from the application of section 4975 of the Code, by reason of section 4975(c)(1)(A) through (E) of the Code, shall not apply, effective as of October 25, 1996, to:

(1) the past sale on October 25, 1996, by the Plan of four residential mortgage notes (the Purchased Notes) to the Greater Bay Trust Company (the Trustee), the trustee of the Plan and, as such, a party in interest with respect to the Plan;

(2) the past sale on October 25, 1996, by the Plan of a seventy-one percent (71%) interest (the Interest) in a certain parcel of real property located in Oakland, California (the Oakland Property) to the Trustee;

(3) the "makewhole" payment made by the Trustee to the Plan on October 25, 1996 in connection with the Plan's investment losses with respect to certain other real property previously owned by the Plan which was sold to an unrelated party on June 28, 1996; and

(4) the proposed payment to the Plan of the accrued but unpaid interest (the Accrued Interest Payment) that was due on the Purchased Notes at the time of the past sale to the Trustee, as well as two other mortgage notes that were in default while held by the Plan (collectively, the Notes) which resulted in foreclosures on the underlying properties, and the proposed payment to the Plan of an additional interest payment for the period from October 25, 1996, until the date that the Accrued Interest Payment is made to the Plan (the Additional Interest Payment), based on the total amount of the Accrued Interest Payment; provided the following conditions are met:

(A) The sale of the Purchased Notes and the Interest by the Plan to the Trustee were one-time transactions for cash;

(B) The Plan was not required to pay any fees or commissions in connection therewith;

(C) The Plan received prices for the Purchased Notes constituting no less than the greater of either:

(i) the outstanding principal balances for each Purchased Note, or

(ii) the fair market value of each Purchased Note, as of the date of the sale transactions;

(D) The Plan received a price for the Interest which was equal to the outstanding principal balance that was due on the mortgage note which had been secured by the Oakland Property, and this price represented an amount which exceeded the fair market value of the Interest at the time of the transaction;

(E) The Accrued Interest Payment to be paid by the Trustee to the Plan represents an amount equal to the total accrued but unpaid interest that was due on the Notes on October 25, 1996;

(F) The Additional Interest Payment to be paid by the Trustee to the Plan represents a reasonable rate of interest on the amount of accrued but unpaid interest on the Notes that was due to the Plan on October 25, 1996 (i.e., the Accrued Interest Payment referred to in (E) above), as determined by an appropriate third party source (i.e., the U.S. Treasury rate for 3-month Treasury Bills);

(G) The Trustee provides the Department with documentation, within thirty (30) days of the Accrued Interest Payment and Additional Interest Payment, which verifies that the total amount of such payments have been made to the Plan;

(H) The Trustee, as the responsible fiduciary for the Plans, took appropriate actions necessary to safeguard the interests of the Plan and its participants and beneficiaries in connection with the past transactions, and will take whatever actions are necessary to continue to protect the Plan's interest with respect to the Accrued Interest Payment and the Additional Interest Payment;

(I) The Plan received a reasonable rate of return on the Purchased Notes and the Interest during the period of time that it held these assets; and

(J) Upon any sale or other disposition of any of the Purchased Notes or the Interest by the Trustee, in the event the Trustee receives proceeds in excess of the amount which the Trustee paid the Plan for such assets, the additional proceeds shall be promptly forwarded to the Plan by the Trustee.

EFFECTIVE DATE: This exemption is effective as of October 25, 1996.

For a more complete statement of the facts and representations supporting the Department's decision to grant this

exemption, refer to the Notice of Proposed Exemption (the Proposal) published on October 19, 2000 at 65 FR 62763.

Clarification: Condition (D) of the Proposal required that the Plan must have received a purchase price for the Interest constituting no less than seventy-one percent (71%) of the fair market value of the Oakland Property, as of the date of the sale transaction. The Department, on its own motion, has revised the language of condition (D) in the final exemption, with the applicant's concurrence, to read as follows:

"* * * (D) The Plan received a price for the Interest which was equal to the outstanding principal balance that was due on the mortgage note which had been secured by the Oakland Property, and this price represented an amount which exceeded the fair market value of the Interest at the time of the transaction."

The Department modified the language in condition (D) in the final exemption to make the requirements of that condition more consistent with the discussion of the transaction involving the Interest that was included in the Summary of Facts and Representations contained in the Proposal.

After consideration of the entire record, the Department has determined to grant the proposed exemption as modified herein.

FOR FURTHER INFORMATION CONTACT:

Khalif Ford of the Department, telephone (202) 219-8883 (this is not a toll-free number).

The Masters, Mates and Pilots Pension Plan (the Pension Plan) and Individual Retirement Account Plan (the IRAP; together, the Plans) Located in Linthicum Heights, Maryland

[Prohibited Transaction Exemption 2000-68; Exemption Application Nos. D-10800 and D-10801]

Exemption

The restrictions of sections 406(a), 406(b)(1) and (b)(2) and 407(a) of the Act and the sanctions resulting from the application of section 4975 of the Code, by reason of section 4975(c)(1)(A) through (E) of the Code, shall not apply to: (1) The transfer and sale by the Plans of their shares of stock (the AHL Stock or the Stock) in American Heavy Lift Shipping Company (AHL) to AHL Holdings, Inc. (AHL Holdings), in exchange for a note (the Note) from AHL Holdings to the Plans; (2) the holding of the Note by the Plans; (3) the guarantee (the Guarantee) of the Note to the Plans by AHL; (4) the continued holding of the AHL Stock by the Plans for the period from January 1, 1999 until the

date of the sale of the Stock by the Plans to AHL Holdings; and (5) the holding by the Plans for a period of two years of any collateral, including the Stock, received by the Plans as a result of the exercise of their rights in the event of a default under the Note or under the Guarantee, provided that: (a) The Plans' independent fiduciary, Independent Fiduciary Services, Inc. (IFS), has determined that the transactions are appropriate for the Plans and in the best interests of the Plans' participants and beneficiaries; (b) the Plans' independent investment manager with respect to the Stock, Hellmold Associates, Inc. (HAI), negotiated the terms of the subject transactions with AHL Holdings and has made the decision for the Plans' to enter the subject transactions with AHL Holdings; (c) HAI continues to monitor the Plans' holding of the Note, determines at all times that such transaction remains in the best interests of the Plans and takes whatever actions are necessary to enforce the Plans' rights under the Note; (d) HAI has determined that the current fair market value of the Note is not less than the current fair market value of the Stock; and (e) HAI has determined that the proposed transactions have terms and conditions which are at least as favorable to the Plans as the terms and conditions which would exist in similar transactions with unrelated parties.

EFFECTIVE DATE: With respect to the Plans' holding of the AHL Stock, this exemption is effective from January 1, 1999 until the date of the sale of the Stock by the Plans to AHL Holdings; with respect to the sale of the AHL Stock by the Plans to AHL Holdings, this exemption is effective December 21, 2000.

For a more complete statement of the facts and representations supporting the Department's decision to grant this exemption, refer to the notice of proposed exemption (the Notice) published on September 22, 2000 at 65 FR 57390.

Written Comments

The Department received 11 written comments and one request for a hearing from interested persons in response to the Notice. Three of the commentators stated that they approved of the proposed exemption and that they desired to see the exemption granted as it was proposed.

The remaining seven comments raised the following concerns: (1) AHL is a poor company in which to invest the assets of the Plans on either a debt or equity basis, and (2) the proposed transaction will represent a new and riskier commitment of capital by the

Plans in AHL. In this regard, the commentators stated that there is a real possibility that AHL will become bankrupt, its shares will have no value, and that not even the wage and work rule concessions (the Concessions) described in the Notice will make it profitable. Based on these assessments, the commentators concluded that the Plans should not invest in AHL and not assume any AHL debt. One commentator specifically stated that none of the monies in his IRAP account currently invested in the Vanguard Funds should be invested in AHL.

The applicant responded to the comments as follows. The proposed exemption would convert the Plans' current equity ownership in AHL to a more secure debt investment, and would not permit any new investment by the Plans in AHL. No part of any IRAP participant's investment in the Vanguard Funds or any other investment option under the IRAP would be liquidated to invest in AHL. None of the commentators suggests any alternative to the proposed transaction which would enhance the position of the Plans with respect to the Plans' existing investment in AHL Stock.

As has been repeatedly made clear by HAI, the Plans' independent investment manager, there are significant issues relating to the viability of AHL. The proposed transaction improves the Plans' position by giving each Plan a priority claim on AHL's cash flow and, through the Concessions, increasing the likelihood that the Plans will realize a return on their investment. The transaction is designed to reduce the Plans' investment risk and permit them to exit their current equity position in AHL.

HAI has reviewed and updated its determinations, as of November 28, 2000, that the transaction is in the interests of the Plans. Among the reasons given for this conclusion by HAI are:

(1) The transaction creates for the Plans a structurally senior position to the Plans' current equity interest in AHL, thereby reducing the risk of the investment for the Plans. The Note from AHL Holdings will be secured by a pledge of all the AHL Stock (none of which will be released until the Note is paid in full), the Guarantee, and a pledge of the cash in the escrow account established for wage increases, none of which will be released until the Note is paid in full;

(2) The transaction provides an automatic mechanism for the Plans to begin to realize a cash return on their investment after three years and a mechanism creating an incentive for

early cash prepayments due to the discounted prepayment formula under the Note;

(3) It provides a mechanism which should motivate AHL's employees, as 100% shareholders of AHL, to insure that AHL has a cost structure which is viable in the long run, including providing for the payment of interest and principal on the Note (because a default on the Note could result in AHL's bankruptcy and a total loss of the economic benefits created by the Concessions);

(4) AHL Holdings will not be permitted to incur any debt, file for bankruptcy or amend its Articles of Incorporation without the unanimous consent of its Board of Directors (the Board), and HAI will maintain a seat on the Board until the Note is fully repaid;

(5) The net present value of the Note is fair under the current circumstances;

(6) The transaction should result in lower annual administrative costs to the Plans; and

(7) The transaction satisfies the regulatory mandate that the Plans dispose of their equity interest in AHL.

In conclusion, HAI has stated that absent the transaction, the Plans' equity interest in AHL is likely worth nothing¹. With the closing of the transaction, the Plans will have a superior position in AHL since the company will have a much more attractive cost structure and better financial prospects.

In addition, the Department has received an updated letter from a representative of the AHL ESOP Committee (the Committee) confirming that as of November 23, 2000, the Committee continues to believe that the

transaction would be in the best interests of participants in the employee stock ownership plan (the ESOP) which is being established by AHL, and which will hold all the shares of stock of AHL Holdings.

With respect to the request for a hearing made by one commentator, the Department has determined that a public hearing is not necessary in this case. Accordingly, based on all of the information contained in the record, including the comments submitted and the applicant's response thereto, the Department has determined to grant the exemption as proposed.

Interested persons are invited to review the complete exemption file, which is available for public inspection in the Public Disclosure Room of the Pension and Welfare Benefits Administration, Room N-1513, U.S. Department of Labor, 200 Constitution Avenue, NW., Washington, DC 20210.

FOR FURTHER INFORMATION CONTACT: Gary H. Lefkowitz of the Department, telephone (202) 219-8881. (This is not a toll-free number.)

Gillespie Real Estate Professional Corporation Defined Benefit Plan (the Plan) Located in Phoenix, Arizona

[Prohibited Transaction Exemption No. 2000-69; Applicant No. D-10880]

Exemption

The sanctions resulting from the application of section 4975 of the Code, by reason of section 4975(c)(1)(A) through (E) of the Code, shall not apply to the proposed cash sale (the Sale) of a certain residential lot (the Property) by the Plan² to Bruce and Ann Gillespie, disqualified persons with respect to the Plan, provided that the following conditions are met:

(a) The Sale is a one-time transaction for cash;

(b) The terms and conditions of the Sale are at least as favorable to the Plan as those obtainable in an arm's length transaction with an unrelated party;

(c) The Plan receives the greater of \$450,000 or the fair market value of the Property at the time of the Sale; and

(d) The Plan is not required to pay any commissions, costs or other expenses in connection with the Sale.

For a more complete statement of the facts and representations supporting the Department's decision to grant this exemption, refer to the notice of

proposed exemption published on October 31, 2000 at 65 FR 65015.

FOR FURTHER INFORMATION CONTACT: Mr. Khalif Ford of the Department, telephone (202) 219-8881. (This is not a toll-free number.)

HSBC Holdings plc, Located in London, England

[Prohibited Transaction No. 2000-70 Exemption Application No.: D-10910]

Exemption

HSBC Asset Management Americas, Inc., HSBC Asset Management Hong Kong, Ltd., HSBC Bank USA, any current affiliate of HSBC Holdings plc (HSBC) that in the future becomes eligible to serve as a qualified professional asset manager, as defined in Prohibited Transaction Class Exemption 84-14 (PTCE 84-14)(QPAM),³ HSBC, itself, if in the future it becomes a QPAM, and any newly acquired or newly established affiliate of HSBC that is a QPAM or in the future becomes a QPAM, other than the Bangkok Metropolitan Bank PLC (BMB), shall not be precluded from functioning as a QPAM, pursuant to the terms and conditions of PTCE 84-14, for the period beginning on June 16, 2000, and ending ten (10) years from the date this exemption is published in the **Federal Register**, solely because of a failure to satisfy Section I(g) of PTCE 84-14, as a result of an affiliation with BMB; provided that:

(a) BMB has not in the past acted, nor does it now act, nor will it act as a fiduciary with respect to any employee benefit plans subject to the Act;

(b) This exemption is not applicable if HSBC and/or any successor or affiliate becomes affiliated with any person or entity convicted of any of the crimes described in Section I(g) of PTCE 84-14, other than BMB; and

(c) This exemption is not applicable if HSBC and/or any successor or affiliate is convicted of any of the crimes described in Section I(g) of PTCE 84-14, including any such crimes subsequently committed by BMB.

EFFECTIVE DATE: This exemption is effective for the period beginning on June 16, 2000, the date the application for exemption was filed with the Department, and ending ten (10) years from the date of publication of this exemption in the **Federal Register**.

Written Comments

In the Notice of Proposed Exemption (the Notice), the Department of Labor (the Department) invited all interested

¹ The Department wishes to note that ERISA's general standards of fiduciary conduct would apply to the acquisition and holding of the Note by the Plans and the acquisition and holding of the Stock by the ESOP, and that satisfaction of the conditions of this exemption should not be viewed as an endorsement of the investments by the Department. Section 404(a) of the Act requires, among other things, that a plan fiduciary discharge his duties with respect to a plan solely in the interest of the plan's participants and beneficiaries and in a prudent fashion. Accordingly, the plan fiduciary must act prudently with respect to the decision to enter into an investment transaction. The Department further emphasizes that it expects the plan fiduciary to fully understand the benefits and risks associated with engaging in a specific type of investment, following disclosure to such fiduciary of all relevant information. In addition, such plan fiduciary must be capable, either directly or indirectly through the use of hired professional experts, of monitoring the investment, including any changes in the value of the investment. Thus, in considering an investment, a fiduciary should take into account its ability to provide adequate oversight of the particular investment.

The Department also wishes to note that it reserves the right to investigate and take any other action with respect to the transaction which is the subject of the exemption.

² Because Bruce Gillespie is the sole shareholder of the Employer and he and his wife, Ann Gillespie, are the only participants in the Plan, there is no jurisdiction under Title I of the Act pursuant to 29 CFR 2510.3-3(b). However, there is jurisdiction under Title II of the Act under section 4975 of the Code.

³ 49 FR 9494 (March 13, 1984), as amended, 50 FR 41430 (October 10, 1985).

persons to submit written comments and requests for a hearing on the proposed exemption. As set forth in the Notice, interested persons consisted of the trustee or other fiduciary of each of the ERISA Plan Clients for which one or more of the applicants have discretionary investment authority. The deadline for submission of comments and requests for a hearing was within forty-five (45) days of the date of the publication of the Notice in the **Federal Register** on October 11, 2000. Accordingly, all comments and requests for a hearing were due on November 27, 2000.

The applicants informed the Department in writing that, as of October 26, 2000, all interested persons, with the exception of two (2) individuals, were mailed a copy of the Notice along with the supplemental statement (the Supplemental Statement), described at 29 CFR § 2570.43(b)(2) of the Department's regulations. The Supplemental Statement mailed on October 26, 2000, provided that such interested persons had a right to comment on the proposed exemption or request a hearing by November 27, 2000.

In a letter dated November 13, 2000, the applicants notified the Department that, as of November 9, 2000, a copy of the Notice and a copy of the Supplemental Statement was sent to the two individuals who had not received the initial mailing. In light of the fact that notification to these two interested persons was delayed until November 9, 2000, and in order to allow such interested persons the benefit of the full thirty (30) day comment period, the Department required, and the applicants agreed to, an extension of the deadline within which to comment and request a hearing on the proposed exemption. In this regard, the applicants confirmed that the Supplemental Statement mailed to these two interested persons provided that all comments and requests for a hearing on the proposed exemption were due on December 11, 2000.

During the comment period, the Department received no comments and no requests for a hearing from interested persons. Accordingly, after giving full consideration to the entire record, the Department has decided to grant the exemption. The complete application file, including all submissions received by the Department, is available for public inspection in the Public Documents Room of the Pension Welfare Benefits Administration, Room N-5638, U.S. Department of Labor, 200 Constitution Avenue, NW., Washington, DC 20210.

For a more complete statement of the facts and representations supporting the Department's decision to grant this exemption refer to the Notice published on October 11, 2000, at 65 FR 60466.

FOR FURTHER INFORMATION CONTACT: Ms. Angelena C. Le Blanc of the Department, telephone (202) 219-8883 (this is not a toll-free number).

General Information

The attention of interested persons is directed to the following:

(1) The fact that a transaction is the subject of an exemption under section 408(a) of the Act and/or section 4975(c)(2) of the Code does not relieve a fiduciary or other party in interest or disqualified person from certain other provisions to which the exemptions does not apply and the general fiduciary responsibility provisions of section 404 of the Act, which among other things require a fiduciary to discharge his duties respecting the plan solely in the interest of the participants and beneficiaries of the plan and in a prudent fashion in accordance with section 404(a)(1)(B) of the Act; nor does it affect the requirement of section 401(a) of the Code that the plan must operate for the exclusive benefit of the employees of the employer maintaining the plan and their beneficiaries;

(2) These exemptions are supplemental to and not in derogation of, any other provisions of the Act and/or the Code, including statutory or administrative exemptions and transactional rules. Furthermore, the fact that a transaction is subject to an administrative or statutory exemption is not dispositive of whether the transaction is in fact a prohibited transaction; and

(3) The availability of these exemptions is subject to the express condition that the material facts and representations contained in each application accurately describes all material terms of the transaction which is the subject of the exemption.

Signed at Washington, DC, this 18th day of December, 2000.

Ivan Strasfeld,

*Director of Exemption Determinations,
Pension and Welfare Benefits Administration,
U.S. Department of Labor.*

[FR Doc. 00-32583 Filed 12-20-00; 8:45 am]

BILLING CODE 4510-29-P

NATIONAL CREDIT UNION ADMINISTRATION

Community Development Revolving Loan Program for Credit Unions

AGENCY: National Credit Union Administration.

ACTION: Notice of application period.

SUMMARY: The National Credit Union Administration (NCUA) will accept applications for participation in the Community Development Revolving Loan Program for Credit Unions throughout calendar year 2001, subject to availability of funds. Application procedures for qualified low-income credit unions are set forth in Part 705, NCUA Rules and Regulations.

ADDRESSES: Applications for participation may be obtained from and should be submitted to: NCUA, Office of Community Development Credit Unions, 1775 Duke Street, Alexandria, VA 22314-3428.

DATES: Applications may be submitted throughout calendar year 2001.

FOR FURTHER INFORMATION CONTACT: The Office of Community Development Credit Unions at the above address or telephone (703) 518-6610.

SUPPLEMENTARY INFORMATION: Part 705 of the NCUA Rules and Regulations implements the Community Development Revolving Loan Program for Credit Unions. The purpose of the Program is to assist officially designated "low-income" credit unions in providing basic financial services to residents in their communities that result in increased income, ownership and employment. The Program makes available low interest loans and deposits in amounts up to \$300,000 in the aggregate to qualified participating "low-income" credit unions. Program participation is limited to existing credit unions with an official "low-income" designation. Student credit unions are not eligible to participate in this program.

This notice is published pursuant to Part 705.9 of the NCUA Rules and Regulations which states that NCUA will provide notice in the **Federal Register** when funds in the program are available.

By the National Credit Union Administration Board on December 14, 2000.

Sheila Albin,

Acting Secretary, NCUA Board.

[FR Doc. 00-32475 Filed 12-20-00; 8:45 am]

BILLING CODE 7535-01-P

NATIONAL FOUNDATION ON THE ARTS AND THE HUMANITIES

National Endowment for the Arts, Leadership Initiatives Advisory Panel

Pursuant to section 10(a)(2) of the Federal Advisory Committee Act (Public Law 92-463), as amended, notice is hereby given that two meetings of the Leadership Initiatives Advisory Panel to the National Council on the Arts will be held at the Nancy Hanks Center, 1100 Pennsylvania Avenue, NW., Washington, DC 20506 as follows:

Media Arts (Arts on Radio and Television category): January 9-11, 2001, Room 716. A portion of this meeting, from 2:00 p.m. to 3:00 p.m. on January 11th, will be open to the public for policy discussion. The remaining portions of this meeting, from 9:00 a.m. to 6:00 p.m. on January 9th, from 9:00 a.m. to 6:30 p.m. on January 10th, and from 9:00 a.m. to 3:00 p.m. and 4:00 p.m. to 5:00 p.m. on January 11th, will be closed.

Folk & Traditional Arts (Infrastructure Initiative category): January 10-11, 2001, Room 708. A portion of this meeting, from 9:00 a.m. to 10:30 a.m. on January 11th, will be open to the public for policy discussion. The remaining portions of this meeting, from 9:00 a.m. to 6:30 p.m. on January 10th, and from 10:30 a.m. to 1:30 p.m. on January 11th, will be closed.

The closed portions of these meetings are for the purpose of Panel review, discussion, evaluation, and recommendation on applications for financial assistance under the National Foundation on the Arts and the Humanities Act of 1965, as amended, including information given in confidence to the agency by grant applicants. In accordance with the determination of the Chairman of May 12, 2000, these sessions will be closed to the public pursuant to (c)(4)(6) and (9)(B) of section 552b of Title 5, United States Code.

Any person may observe meetings, or portions thereof, of advisory panels that are open to the public, and, if time allows, may be permitted to participate in the panel's discussions at the discretion of the panel chairman and with the approval of the full-time Federal employee in attendance.

If you need special accommodations due to a disability, please contact the Office of AccessAbility, National Endowment for the Arts, 1100 Pennsylvania Avenue, NW., Washington, DC 20506, 202/682-5532, TDY-TDD 202/682-5496, at least seven (7) days prior to the meeting.

Further information with reference to this meeting can be obtained from Ms. Kathy Plowitz-Worden, Office of Guidelines & Panel Operations, National Endowment for the Arts, Washington, DC 20506, or call 202/682-5691.

Dated: December 13, 2000.

Kathy Plowitz-Worden,

Panel Coordinator, Panel Operations, National Endowment for the Arts.

[FR Doc. 00-32499 Filed 12-20-00; 8:45 am]

BILLING CODE 7537-01-U

NATIONAL SCIENCE FOUNDATION

Special Emphasis Panel in Advanced Networking and Infrastructure Research; Notice of Meeting

In accordance with the Federal Advisory Committee Act (Pub. L. 92-463, as amended), the National Science Foundation announces the following meeting.

Name: Special Emphasis Panel in Advanced Networking and Infrastructure Research (#1207).

Date/Time: January 8, 2001; 8 am-5 pm (This meeting was previously scheduled for December 6, 2000.).

Place: Room 1150, National Science Foundation, 4201 Wilson Blvd., Arlington, VA 22230.

Type of Meeting: Closed.

Contact Persons: Taieb Znati, Division of Advanced Networking and Infrastructure Research, Room 1175, National Science Foundation, 4201 Wilson Blvd., Arlington, VA 22230. Phone: (703) 292-8949.

Purpose of Meeting: To provide advice and recommendations concerning proposals submitted to NSF for financial support.

Agenda: to review and evaluate proposals submitted to the Networking Research and Special Projects Programs as part of the selection process for awards.

Reason for Closing: The proposals being reviewed include information of a proprietary or confidential nature, including technical information; financial data, such as salaries; and personal information concerning individuals associated with the proposals. These matters are exempt under 5 U.S.C. 552b(c), (4) and (6) of the Government in the Sunshine Act.

Dated: December 13, 2000.

Karen J. York,

Committee Management Officer.

[FR Doc. 00-32457 Filed 12-20-00; 8:45 am]

BILLING CODE 7555-01-M

NATIONAL SCIENCE FOUNDATION

Special Emphasis Panel in Biological Sciences: Notice of Meeting

In accordance with the Federal Advisory Committee Act (Pub. L. 92-463, as amended), the National Science

Foundation announces the following meeting:

Name: Special Emphasis Panel in Biological Sciences (1754)

Date and Time: February 22-23, 2001; 8:00 a.m.-5:00 p.m.

Place: National Science Foundation, 4201 Wilson Boulevard, Arlington, VA 22230

Type of Meeting: Closed.

Contact Person: Dr. Penelope Firth, Room 635, National Science Foundation, 4201 Wilson Boulevard, Arlington, Virginia 22230. Telephone: (703) 292-8480.

Minutes: May be obtained from the contact person listed above.

Purpose of Meeting: To provide advice and recommendations concerning proposals to the National Science Foundation for financial support.

Agenda: Review and evaluate proposals as part of the selection process for awards.

Reason for Closing: The proposals being reviewed include information of a proprietary or confidential nature, including technical information; financial data, such as salaries; and personal information concerning individuals associated with the proposals. These matters are exempt under 5 U.S.C. 552b(c), (4) and (6) of the Government in the Sunshine Act.

Dated: December 13, 2000.

Karen J. York,

Committee Management Officer.

[FR Doc. 00-32452 Filed 12-20-00; 8:45 am]

BILLING CODE 7555-01-M

NATIONAL SCIENCE FOUNDATION

Special Emphasis Panel in Chemical and Transport Systems; Notice of Meeting

In accordance with the Federal Advisory Committee Act (Pub. L. 92-463, as amended), the National Science Foundation announces the following meeting:

Name: Special Emphasis Panel in Chemical and Transport Systems (1190).

Date and Time: January 22-23, 2001; 8:30 a.m. to 5:00 p.m.

Place: National Science Foundation, 4201 Wilson Boulevard, Arlington, VA.

Type of Meeting: Closed.

Contact Person: Dr. M. C. Roco, Division of Chemical and Transport Systems, 4201 Wilson Boulevard, Room 525, Arlington, VA 22230. Telephone: (703) 292-8370.

Purpose of Meeting: To provide advice and recommendations concerning proposals submitted to NSF for financial support.

Agenda: To review and evaluate proposals as part of the selection process for awards.

Reason for Closing: The proposals being reviewed include information of a proprietary or confidential nature, including technical information; financial data, such as salaries and personal information concerning individuals associated with the proposals. These matters are exempt under 5 U.S.C. 552b(c), (4) and (6) of the Government in the Sunshine Act.

Dated: December 13, 2000.

Karen J. York,

Committee Management Officer.

[FR Doc. 00-32460 Filed 12-20-00; 8:45 am]

BILLING CODE 7555-01-M

NATIONAL SCIENCE FOUNDATION

Special Emphasis Panel in Chemistry; Notice of Meeting

In accordance with the Federal Advisory Committee Act (Pub. L. 92-463, as amended), the National Science Foundation announces the following meeting:

Name: Special Emphasis Panel in Chemistry (#1191).

Date and Time: January 23, 2001; 8:30 a.m.-5 p.m. and January 24, 2001; 8 a.m.-12 noon.

Place: Department of Chemistry, University of New Mexico, Albuquerque, NM.

Type of Meeting: Closed.

Contact Person: Dr. John Stevens, Program Officer, Division of Chemistry, Room 1055, National Science Foundation, 4201 Wilson Boulevard, Arlington, VA 22230. Telephone: (703) 292-4958.

Purpose of Meeting: To provide advice and recommendations concerning the University of New Mexico Research Site for Educators in Chemistry, submitted to NSF for financial support.

Agenda: To review and evaluate the progress to date on all aspects of the Research Site.

Reason for Closing: The project being reviewed includes information of a proprietary or confidential nature, including technical information, financial data such as salaries, and personal information concerning individuals associated with the proposals. These matters are exempt under 5 U.S.C. 552b(c), (4) and (6) of the Government in the Sunshine Act.

Dated: December 13, 2000.

Karen J. York,

Committee Management Officer.

[FR Doc. 00-32458 Filed 12-20-00; 8:45 am]

BILLING CODE 7550-01-M

NATIONAL SCIENCE FOUNDATION

Special Emphasis Panel in Civil and Mechanical Systems; Notice of Meeting

In accordance with the Federal Advisory Committee Act (Pub. L. 92-463, as amended), the National Science Foundation announces the following meeting:

Name: Special Emphasis Career Panel in Civil and Mechanical Systems (1205).

Date and Time: February 5, 2001; 8:00 a.m. to 5:00 p.m.

Place: NSF, 4201 Wilson Boulevard, Room 530, Arlington, Virginia 22230.

Type of Meeting: Closed.

Contact Persons: Dr. Jorn Larsen-Basse, Program Director, Division of Civil and Mechanical Systems, 4201 Wilson Boulevard, Room 545, Arlington, VA 22230. Phone: (703) 292-8360.

Purpose of Meeting: To provide advice and recommendations concerning proposals submitted to NSF for financial support.

Agenda: To review and evaluate nominations for the FY'00 Mechanics and Structures of Materials and Surface Engineering and Material design proposals as part of the selection process for awards.

Reason for Closing: The proposals being reviewed include information of a proprietary or confidential nature, including technical information; financial data, such as salaries and personal information concerning individuals associated with the proposals. These matters are exempt under 5 U.S.C. 552b(c), (4) and (6) of the Government in the Sunshine Act.

Dated: December 13, 2000.

Karen J. York,

Committee Management Officer.

[FR Doc. 00-32449 Filed 12-20-00; 8:45 am]

BILLING CODE 7555-01-M

NATIONAL SCIENCE FOUNDATION

Special Emphasis Panel in Civil and Mechanical Systems; Notice of Meeting

In accordance with the Federal Advisory Committee Act (Pub. L. 92-463, as amended), the National Science Foundation announces the following meeting:

Name: Special Emphasis Panel in Civil and Mechanical Systems (1205).

Date and Time: Thursday, February 1, 2001, 8:30 a.m. to 5:00 p.m., Friday, February 2, 2001, 8:30 a.m. to 5:00 p.m.

Place: NSF, 4201 Wilson Boulevard, Room 530, Arlington, Virginia 22230.

Type of Meeting: Closed.

Contact Person: Dr. Ken P. Chong, Program Director, Mechanics and Structures of Materials, Division of Civil and Mechanical Systems, Room 545, (703) 292-8360.

Purpose of Meeting: To provide advice and recommendations concerning proposals submitted to NSF for financial support.

Agenda: To review and evaluate nominations for the FY'01 Surface Engineering and Material Design Review Panel as part of the selection process for awards.

Reason for Closing: The proposals being reviewed include information of a proprietary or confidential nature, including technical information; financial data, such as salaries and personal information concerning individuals associated with the proposals.

These matters are exempt under 5 U.S.C. 552b(c) (4) and (6) of the Government in the Sunshine Act.

Dated: December 12, 2000.

Karen J. York,

Committee Management Officer.

[FR Doc. 00-32463 Filed 12-20-00; 8:45 am]

BILLING CODE 7555-01-M

NATIONAL SCIENCE FOUNDATION

Advisory Panel Meeting for Ecological Studies; Notice of Meeting

In accordance with the Federal Advisory Committee Act (Pub. L. 92-463, as amended), the National Science Foundation announces the following meeting:

Name and Committee Code: Advisory Panel for Ecological Studies (1751)

Date and Time: April 4-6, 2001; 8 a.m.-5 p.m.

Place: National Science Foundation, 4201 Wilson Boulevard, Arlington, VA 22230.

Type of Meeting: Closed.

Contact Person: Dr. Michael Willig, Room 635, National Science Foundation, 4201 Wilson Boulevard, Arlington, Virginia 22230. Telephone: (703) 292-8481.

Minutes: May be obtained from the contact person listed above.

Purpose of Meeting: To provide advice and recommendations concerning proposals to the National Science Foundation for financial support.

Agenda: Review and evaluate proposals as part of the selection process for awards.

Reason for Closing: The proposals being reviewed include information of a proprietary or confidential nature, including technical information; financial data, such as salaries; and personal information concerning individuals associated with the proposals. These matters are exempt under 5 U.S.C. 552b(c), (4) and (6) of the Government in the Sunshine Act.

Dated: December 13, 2000.

Karen J. York,

Committee Management Officer.

[FR Doc. 00-32454 Filed 12-20-00; 8:45 am]

BILLING CODE 7555-01-M

NATIONAL SCIENCE FOUNDATION

Advisory Panel Meeting for Ecological Studies; Notice of Meeting

In accordance with the Federal Advisory Committee Act (Pub. L. 92-463, as amended), the National Science Foundation announces the following meeting:

Name and Committee Code: Advisory Panel for Ecological Studies (1751).

Date and Time: April 5-6, 2001; 8 a.m.-5 p.m.

Place: National Science Foundation, 4201 Wilson Boulevard, Arlington, VA 22230.

Type of Meeting: Closed.

Contact Person: Dr. Penelope Firth, Room 635, National Science Foundation, 4201

Wilson Boulevard, Arlington, VA 22230.
Telephone: (703) 292-8481.

Minutes: May be obtained from the contact person listed above.

Purpose of Meeting: To provide advice and recommendations concerning proposals to the National Science Foundation for financial support.

Agenda: Review and evaluate proposals as part of the selection process for awards.

Reason for Closing: The proposals being reviewed include information of a proprietary or confidential nature, including technical information; financial data, such as salaries; and personal information concerning individuals associated with the proposals. These matters are exempt under 5 U.S.C. 552b(c), (4) and (6) of the Government in the Sunshine Act.

Dated: December 13, 2000.

Karen J. York,

Committee Management Officer.

[FR Doc. 00-32455 Filed 12-20-00; 8:45 am]

BILLING CODE 7555-01-M

NATIONAL SCIENCE FOUNDATION

Special Emphasis Panel in Electrical and Communications Systems; Notice of Meeting

In accordance with the Federal Advisory Committee Act (Pub. L. 92-463, as amended), the National Science Foundation announces the following meeting:

Name: Special Emphasis Panel in Electrical and Communications Systems (1196).

Date & Time: January 11-12, 2001; 8:30 am-5 pm.

Place: Room 330, National Science Foundation, 4201 Wilson Boulevard, Arlington, VA.

Type of Meeting: Closed.

Contact Persons: Dr. James Mink, Program Director, Electronics, Photonics, and Device Technologies (EPDT), Division of Electrical and Communications Systems, National Science Foundation, 4201 Wilson Blvd., Room 675, Arlington, VA 22230. Telephone: (703) 292-8339.

Purpose of Meeting: To provide advice and recommendations concerning proposals submitted to NSF for financial support.

Agenda: To review and evaluate **Regular Research** proposals as part of the selection process for awards.

Reason for Closing: The proposals being reviewed include information of a proprietary or confidential nature, including technical information; financial data, such as salaries; and personal information concerning individuals associated with the proposals. These matters are exempt under 5 U.S.C. 552b(c), (4) and (6) of the Government in the Sunshine Act.

Dated: December 12, 2000.

Karen J. York,

Committee Management Officer.

[FR Doc. 00-32464 Filed 12-20-00; 8:45 am]

BILLING CODE 7555-01-M

NATIONAL SCIENCE FOUNDATION

Special Emphasis Panel in Geosciences; Notice of Meeting

In accordance with the Federal Advisory Committee Act (Pub. L. 92-463, as amended), the National Science Foundation announces the following meeting:

Name: Special Emphasis Panel in Geosciences (1756).

Date and Time: January 8, 2001; 8 a.m.-5 p.m.

Place: National Science Foundation, 4201 Wilson Boulevard, Arlington, VA 22230.

Type of Meeting: Closed.

Contact Person: Dr. Michael Mayhew, Room 785, National Science Foundation, 4201 Wilson Boulevard, Arlington, Virginia 22230. Telephone: (703) 292-8557.

Minutes: May be obtained from the contact person listed above.

Purpose of Meeting: To provide advice and recommendations concerning proposals to the National Science Foundation for financial support.

Agenda: Review and evaluate proposals as part of the selection process for awards.

Reason for Closing: The proposals being reviewed include information of a proprietary or confidential nature, including technical information; financial data, such as salaries; and personal information concerning individuals associated with the proposals. These matters are exempt under 5 U.S.C. 552b(c), (4) and (6) of the Government in the Sunshine Act.

Dated: December 13, 2000.

Karen J. York,

Committee Management Officer.

[FR Doc. 00-32451 Filed 12-20-00; 8:45 am]

BILLING CODE 7555-01-M

NATIONAL SCIENCE FOUNDATION

Special Emphasis Panel for Geosciences; Notice of Meeting

In accordance with the Federal Advisory Committee Act (Pub. L. 92-463, as amended), the National Science Foundation announces the following meeting:

Name: Special Emphasis Panel for Geosciences (1756).

Date and Time: January 18, 2001; 8 am-5 pm.

Place: National Science Foundation, 4201 Wilson Blvd., Arlington, VA 22230.

Type of Meeting: Closed.

Contact Person: Michael Reeve, Section Head, Division of Ocean Sciences, National Science Foundation, 4201 Wilson Blvd., Arlington, VA 22230. Telephone: (703) 292-8580.

Purpose of Meeting: To provide advice and recommendations concerning proposals submitted to NSF for financial support.

Agenda: Review and evaluate proposals as part of the selection process for awards.

Reason for Closing: The proposals being reviewed include information of a

proprietary or confidential nature, including technical information; financial data, such as salaries; and personal information concerning individuals associated with the proposals. These matters are exempt under 5 U.S.C. 552b(c), (4) and (6) of the Government in the Sunshine Act.

Dated: December 13, 2000.

Karen J. York,

Committee Management Officer.

[FR Doc. 00-32453 Filed 12-20-00; 8:45 am]

BILLING CODE 7555-01-M

NATIONAL SCIENCE FOUNDATION

Special Emphasis Panel in Geosciences; Notice of Meeting

In accordance with the Federal Advisory Committee Act (Pub. L. 92-463, as amended), the National Science Foundation announces the following meeting:

Name: Special Emphasis Panel in Geosciences (1756).

Date and Time: January 9, 2001; 8 a.m.-5 p.m.

Place: National Science Foundation, 4201 Wilson Boulevard, Arlington, VA 22230.

Type of Meeting: Closed.

Contact Person: Michael Reeve, Room 785, National Science Foundation, 4201 Wilson Boulevard, Arlington, Virginia 22230. Telephone: (703) 292-8580.

Minutes: May be obtained from the contact person listed above.

Purpose of Meeting: To provide advice and recommendations concerning proposals to the National Science Foundation for financial support.

Agenda: Review and evaluate proposals as part of the selection process for awards.

Reason for Closing: The proposals being reviewed include information of a proprietary or confidential nature, including technical information; financial data, such as salaries; and personal information concerning individuals associated with the proposals. These matters are exempt under 5 U.S.C. 552b(c), (4) and (6) of the Government in the Sunshine Act.

Dated: December 13, 2000.

Karen J. York,

Committee Management Officer.

[FR Doc. 00-32461 Filed 12-20-00; 8:45 am]

BILLING CODE 7555-01-M

NATIONAL SCIENCE FOUNDATION

Special Emphasis Panel in Materials Research; Notice of Meeting

In accordance with the Federal Advisory Committee Act (Pub. L. 92-463 as amended), the National Science Foundation announces the following meetings:

Name: Special Emphasis Panel in Materials Research (1203).

Dates and Times: January 17, 2001; 8 a.m.–6 p.m.

Place: National Science Foundation, 4201 Wilson Blvd., Room 220, Arlington, VA 22230.

Type of Meeting: Closed.

Contact Person: Dr. Lynnete D. Madsen, Program Director, Ceramics Program, Division of Materials Research, Room 1065, National Science Foundation, 4201 Wilson Boulevard, Arlington, VA 22230, Telephone (703) 292–4936.

Purpose of Meeting: To provide advice and recommendations concerning proposals submitted to NSF for financial support.

Agenda: Review and evaluate proposals as part of the selection process for awards.

Reason for Closing: The proposals being evaluated include information of a proprietary or confidential nature, including technical information; financial data, such as salaries and personal information concerning individuals associated with the proposals. These matters are exempt under 5 U.S.C. 552b(c), (4) and (6) of the Government in the Sunshine Act.

Dated: December 13, 2000.

Karen J. York,

Committee Management Officer.

[FR Doc. 00–32459 Filed 12–20–00; 8:45 am]

BILLING CODE 7555–01–M

NATIONAL SCIENCE FOUNDATION

Special Emphasis Panel in Physics; Notice Of Meeting

In accordance with the Federal Advisory Committee Act (Pub. L. 92–463, as amended), the National Science Foundation announces the following meetings of the Special Emphasis Panel in Physics (1208):

Date/Time: January 10–12, 2001; 8 a.m.–6 p.m.

Contact Person: C. Denise Caldwell, National Science Foundation, 4201 Wilson Boulevard, Room 1015, Arlington, VA 22230. Telephone: (703) 292–7371.

Date/Time: February 7–9, 2001; 8 a.m.–6 p.m.

Contact Person: Dr. Sidney A. Coon, Program Director for Nuclear Theory, Division of Physics, National Science Foundation, 4201 Wilson Boulevard, Room 1015, Arlington, VA 22230 (Telephone (703) 292–7382).

Date/Time: February 26–28, 2001; 8 a.m.–5 p.m.

Contact Person: Dr. Richard H. Pratt, National Science Foundation, 4201 Wilson Boulevard, Room 1015, Arlington, VA 22230. Telephone: (703) 292–8890.

Type of Meeting: Closed.

Place: National Science Foundation, 4201 Wilson Boulevard, Arlington, VA.

Purpose of Meeting: To provide advice and recommendations concerning proposals submitted to NSF for financial support.

Agenda: To review and evaluate proposals as part of the selection process for awards.

Reason for Closings: The proposals being reviewed include information of a

proprietary or confidential nature, including technical information, financial data, such as salaries; and personal information concerning individuals associated with the proposals. These matters are exempt under 5 U.S.C. 552b(c), (4) and (6) of the Government in the Sunshine Act.

Dated: December 13, 2000.

Karen J. York,

Committee Management Officer.

[FR Doc. 00–32450 Filed 12–20–00; 8:45 am]

BILLING CODE 7555–01–M

NATIONAL SCIENCE FOUNDATION

Special Emphasis Panel in Research Evaluation and Communication; Notice of Meeting

In accordance with Federal Advisory Committee Act (Pub. L. 92–463, as amended), the National Science Foundation announces the following meetings of the Special Emphasis Panel in Research Evaluation and Communication (1210):

Date/Time: January 25–26, 2001; 8:00 a.m.–5:00 p.m.

Date/Time: January 29–30, 2001; 8:00 a.m.–5:00 p.m.

Place: National Science Foundation, 4201 Wilson Boulevard, Arlington, VA.

Type of Meeting: Closed.

Contact Person: Elizabeth VanderPutten, National Science Foundation, Room 855, 4201 Wilson Boulevard, Arlington, VA 22230. (703) 292–8650.

Purpose of Meeting: To provide advice and recommendations concerning proposals submitted to NSF for financial support.

Agenda: Review and evaluate proposals as part of the selection process for awards.

Reason for Closing: The proposals being reviewed include information of a proprietary or confidential nature, including technical information; financial data, such as salaries; and personal information concerning individuals associated with the proposals. These matters are exempt under 5 U.S.C. 552b(c), (4) and (6) of the Government in the Sunshine Act.

Dated: December 13, 2000.

Karen J. York,

Committee Management Officer.

[FR Doc. 00–32462 Filed 12–20–00; 8:45 am]

BILLING CODE 7555–01–M

NATIONAL SCIENCE FOUNDATION

Advisory Panel for Systematic and Population Biology; Notice of Meeting

In accordance with the Federal Advisory Committee Act (Pub. L. 92–463, as amended), the National Science Foundation announces the following meeting:

Name: Advisory Panel for Systematic and Population Biology (1753).

Date and Time: February 15–16, 2001; 8 a.m.–5 p.m.

Place: National Science Foundation, 4201 Wilson Boulevard, Arlington, VA 22230.

Type of Meeting: Closed.

Contact Person: Dr. Quentin Wheeler, Room 635, National Science Foundation, 4201 Wilson Boulevard, Arlington, Virginia 22230. Telephone: (703) 292–8480.

Minutes: May be obtained from the contact person listed above.

Purpose of Meeting: To provide advice and recommendations concerning proposals to the National Science Foundation for financial support.

Agenda: Review and evaluate proposals as part of the selection process for awards.

Reason for Closing: The proposals being reviewed include information of a proprietary or confidential nature, including technical information; financial data, such as salaries; and personal information concerning individuals associated with the proposals. These matters are exempt under 5 U.S.C. 552b(c), (4) and (6) of the Government in the Sunshine Act.

Dated: December 13, 2000.

Karen J. York,

Committee Management Officer.

[FR Doc. 00–32456 Filed 12–20–00; 8:45 am]

BILLING CODE 7555–01–M

NUCLEAR REGULATORY COMMISSION

[Docket No. 50–305]

Nuclear Management Company, LLC, Kewaunee Nuclear Power Plant; 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. DPR–43, issued to the Nuclear Management Company, LLC (the licensee), for operation of Kewaunee Nuclear Power Plant, located in Kewaunee County, Wisconsin.

The proposed amendment would revise the Technical Specifications by changing the number of fuel assemblies that can be stored in the Kewaunee spent fuel pools (SFPs) from 990 fuel assemblies to 1,205 fuel assemblies, an increase of 215 fuel assemblies, by installing 215 new spent fuel storage racks in the new north canal pool. In addition, the new spent fuel storage racks will use Boral as the neutron absorber material.

On November 1, 2000, the Commission issued a Biweekly Notice of Applications and Amendments to Operating Licenses Involving No

Significant Hazards Considerations (65 FR 65337) which included notice concerning the proposed amendment of the Kewaunee license (65 FR 65347). The Notice contained the Commission's proposed determination that the requested amendment involved no significant hazards considerations, offered an opportunity for comments on the Commission's proposed determination and offered an opportunity for the applicant to request a hearing on the amendment and for persons whose interest might be affected to petition for leave to intervene.

Due to an oversight, the November 1, 2000, Notice did not provide notice that this application involves a proceeding on an application for a license amendment falling within the scope of section 134 of the Nuclear Waste Policy Act (NWPA) of 1982. Such notice is required by Commission regulations at 10 CFR 2.1107.

The Commission hereby provides notice that this is a proceeding on an application for a license amendment falling within the scope of section 134 of the NWPA, 42 U.S.C. 10154. Under section 134 of the NWPA, the Commission, at the request of any party to the proceeding, must use hybrid hearing procedures with respect to "any matter which the Commission determines to be in controversy among the parties."

The hybrid procedures in section 134 provide for oral argument on matters in controversy, preceded by discovery under the Commission's rules and the designation, following argument of only those factual issues that involve a genuine and substantial dispute, together with any remaining questions of law, to be resolved in an adjudicatory hearing. Actual adjudicatory hearings are to be held on only those issues found to meet the criteria of Section 134 and set for hearing after oral argument.

The Commission's rules implementing section 134 of the NWPA are found in 10 CFR part 2, subpart K, "Hybrid Hearing Procedures for Expansion of Spent Fuel Storage Capacity at Civilian Nuclear Power Reactors" (published at 50 FR 41662 dated October 15, 1985). Under those rules, any party to the proceeding may invoke the hybrid hearing procedures by filing with the presiding officer a written request for oral argument under 10 CFR 2.1109. To be timely, the request must be filed within ten (10) days of an order granting a request for hearing or petition to intervene. The presiding officer must grant a timely request for oral argument. The presiding officer may grant an untimely request for oral argument only upon a showing of good

cause by the requesting party for the failure to file on time and after providing the other parties an opportunity to respond to the untimely request. If the presiding officer grants a request for oral argument, any hearing held on the application must be conducted in accordance with the hybrid hearing procedures. In essence, those procedures limit the time available for discovery and require that an oral argument be held to determine whether any contentions must be resolved in an adjudicatory hearing. If no party to the proceeding timely requests oral argument, and if all untimely requests for oral argument are denied, then the usual procedures in 10 CFR part 2, subpart G, apply.

By [insert date 30 days from date of publication], 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 and who wishes to invoke the hybrid hearing procedures of 10 CFR part 2, subpart K discussed above 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, One White Flint North, 11555 Rockville Pike (first floor), Rockville, Maryland, and accessible electronically through the ADAMS Public Electronic Reading Room link at the NRC Web site (<http://www.nrc.gov>). 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, designated 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 or 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 prehearing conference scheduled in the proceeding, but such an amended petition must satisfy the specificity requirements described above.

Not later than 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 on 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.

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 20555-0001, Attention: Rulemakings and Adjudications Staff, or may be delivered to the Commission's Public Document Room, One White Flint North, 11555 Rockville Pike (first floor), Rockville, Maryland, by the above date. A copy of the petition should also be sent to the Office of the General Counsel, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, and to Bradley D. Jackson, Esq., Foley and Lardner, P.O. Box 1497, Madison, WI 53701-1497, 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).

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 final 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 Chief, Rules and Directives Branch, Division of Administrative Services, Office of Administration, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, and should cite the publication date and page number of this **Federal Register** notice. Written comments may also be delivered to Room 6D59, 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, One White Flint North, 11555 Rockville Pike (first floor), Rockville, Maryland.

For further details with respect to this action, see the application for amendment dated November 18, 1999, as supplemented by letter dated August 7, 2000, which are available for public inspection at the Commission's Public Document Room located at One White Flint North, 11555 Rockville Pike (first floor), Rockville, Maryland, and accessible electronically through the ADAMS Public Electronic Reading Room link at the NRC Web site (<http://www.nrc.gov>).

Dated at Rockville, Maryland, this 18th day of December 2000.

For the Nuclear Regulatory Commission.

John G. Lamb,

Project Manager, Section 1, Project Directorate III, Division of Licensing Project Management, Office of Nuclear Reactor Regulation.

[FR Doc. 00-32556 Filed 12-20-00; 8:45 am]

BILLING CODE 7590-01-P

NUCLEAR REGULATORY COMMISSION

Risk-Informed Regulation Implementation Plan

AGENCY: Nuclear Regulatory Commission.

ACTION: Notice of availability of plan and request for public comment.

SUMMARY: The Nuclear Regulatory Commission's 1995 policy statement on the use of probabilistic risk assessment provided the Commission's expectation on the use of risk information in its regulatory activities. The Risk-Informed Regulation Implementation Plan (RIRIP) provides guidance and describes the staff's plans for applying criteria to select regulatory requirements and practices to risk-inform, risk-informing those requirements and practices, and developing the necessary data, methods, guidance, and training. The RIRIP is also intended to explain the agency's activities, philosophy, and approach to risk-informed regulatory policy to internal and external stakeholders. The public is invited to provide feedback on the agency's plans and progress toward implementing risk-informed regulatory initiatives.

SUPPLEMENTARY INFORMATION: This notice serves as a request for public comment on the Nuclear Regulatory Commission's Risk-Informed Regulatory

Implementation Plan (SECY-00-0213) that is dated October 26, 2000 (web address: <http://www.nrc.gov/RES/nrc.html>). Written comments are requested by February 28, 2001. A workshop will be scheduled in early 2001 to discuss comments received and to provide for the exchange of information will all stakeholders regarding the staff's efforts to risk-inform its regulatory requirements and practices. The workshop agenda and other details will be provided in a forthcoming **Federal Register** notice prior to the workshop. Feedback is especially requested on the following specific questions—

1. Does the RIRIP include information activities that *should not* be undertaken? If so, why not?

2. Does the RIRIP omit implementation activities that *should* be undertaken? Describe such activities and why they should be undertaken.

3. How should the NRC measure its success in implementing risk-informed regulation?

4. Is the pace for implementing risk-informed regulation about right, or is too fast or too slow?

5. Are there concerns about the agency's ability to maintain safety while implementing risk-informed regulation? If so, describe the concerns and, if possible, their basis.

6. How can risk-informed regulation increase public confidence?

7. Are the screening criteria clear and sufficient? If applied properly, would they result in identifying those activities amenable for transition to risk-informed regulation?

8. Will the implementation activities described in the RIRIP appropriately improve regulatory efficiency, effectiveness, and realism?

9. Other than requests such as this for written comment and a public workshop, how can stakeholder participation in risk-informed regulation be enhanced?

10. What communication activities would be desired to describe risk-informed regulation? What other interactions would be useful to provide input to, and understanding of, risk-informed regulation?

FOR FURTHER INFORMATION CONTACT:

Written comments may be sent to Thomas L. King, Director of the Division of Risk Analysis and Applications, Office of Nuclear Regulatory Research, MS: T10-E50, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, email: tlk@nrc.gov.

Dated this 13th day of December 2000.
Thomas L. King,
Director, Division of Risk Analysis and Applications, Office of Nuclear Regulatory Research.
 [FR Doc. 00-32555 Filed 12-20-00; 8:45 am]
 BILLING CODE 7590-01-M

PRESIDIO TRUST

The Presidio of San Francisco, California; Extension of the Public Comment Period for the Presidio Trust Implementation Plan Supplemental Environmental Impact Statement; Correction

AGENCY: The Presidio Trust.

ACTION: Correction to date of public comment period.

SUMMARY AND CORRECTION: On November 13, 2000, the Presidio Trust published a notice announcing the extension of the scoping period to comment on proposed conceptual alternatives to be evaluated in the Presidio Trust Implementation Plan Environmental Impact Statement (65 FR 67783). The notice contained an error in the date for the close of the comment period. The extension of the scoping period is from December 8, 2000 to January 15, 2001, not from December 8, 2000 to January 15, 2000, as previously published.

FOR FURTHER INFORMATION CONTACT: John Pelka, NEPA Compliance Coordinator, the Presidio Trust, 34 Graham Street, PO Box 29052, San Francisco, CA 94129-0052. Telephone: 415-561-5300.

Dated: December 15, 2000.

Karen A. Cook,
General Counsel.

[FR Doc. 00-32502 Filed 12-20-00; 8:45 am]
 BILLING CODE 4310-4R-U

UNITED STATES SENTENCING COMMISSION

Sentencing Guidelines for United States Courts

AGENCY: United States Sentencing Commission.

ACTION: Notice of promulgation of temporary, "emergency" guideline amendment increasing penalties for any offense relating to the manufacture, attempt to manufacture, or conspiracy to manufacture methamphetamine or amphetamine that involves a substantial risk of harm to human life or the environment.

SUMMARY: Pursuant to section 102 of the Methamphetamine and Club Drug Anti-

Proliferation Act of 2000, Pub. L. 106-310, the Commission is promulgating a temporary, emergency amendment to §§ 2D1.1 and 2D1.10 and accompanying commentary. This notice sets forth the emergency amendment and a synopsis of the issues addressed by the amendment.

DATES: The Commission has specified an effective date of December 16, 2000, for the emergency amendment.

FOR FURTHER INFORMATION CONTACT: Michael Courlander, Public Affairs Officer, Telephone: (202) 502-4590.

SUPPLEMENTARY INFORMATION: (1) The Methamphetamine and Anti-Proliferation Act of 2000 (The "Act").—Section 102 of the Act directs the Commission to amend the federal sentencing guidelines with respect to any offense relating to the manufacture, attempt to manufacture, or conspiracy to manufacture amphetamine or methamphetamine in (A) the Controlled Substances Act (21 U.S.C. 801 *et seq.*); (B) the Controlled Substances Import and Export Act (21 U.S.C. 951 *et seq.*); or (C) the Maritime Drug Law Enforcement Act (46 U.S.C. App. 1901 *et seq.*).

In carrying out this directive, the Act requires the Commission to provide a 3-level enhancement or a minimum offense level of level 27 if the offense created a substantial risk of harm to human life or the environment. If the offense created a substantial risk of harm to the life of a minor or incompetent, the Act requires a 6-level enhancement and a minimum offense level of level 30.

(2) Effective Date.—The Act requires the Commission to promulgate amendments under emergency amendment authority. Although the Act generally provides that the Commission shall promulgate various amendments "as soon as practicable," the directive in section 102 of the Act specifically requires that the amendment implementing this specific directive shall apply "to any offense occurring on or after the date that is 60 days after the date of the enactment" of the Act (*i.e.*, December 16, 2000). Accordingly, the effective date of this amendment is December 16, 2000.

(3) Website.—The temporary, emergency amendment set forth in this notice may also be accessed through the Commission's website at www.ussc.gov.

Authority: 28 U.S.C. 994(a), (o), (p).

Diana E. Murphy,
Chair.

Amendment: Substantial Risks Associated With Production of Methamphetamine and Amphetamine

1. Synopsis of Amendment: This amendment addresses the directive in section 102 (the "substantial risk directive") of the Methamphetamine Anti-Proliferation Act of 2000 (the "Act"), Pub. L. 106-310.

The Act requires the Commission to promulgate amendments under emergency amendment authority. Although the Act generally provides that the Commission shall promulgate various amendments "as soon as practicable," the substantial risk directive specifically requires that the amendment implementing the directive shall apply "to any offense occurring on or after the date that is 60 days after the date of the enactment" of the Act.

The directive instructs the Commission to amend the federal sentencing guidelines with respect to any offense relating to the manufacture, attempt to manufacture, or conspiracy to manufacture amphetamine or methamphetamine in (1) the Controlled Substances Act (21 U.S.C. 801 *et seq.*); (2) the Controlled Substances Import and Export Act (21 U.S.C. 951 *et seq.*); or (3) the Maritime Drug Law Enforcement Act (46 U.S.C. App. 1901 *et seq.*).

The Act requires the Commission, in carrying out the substantial risk directive, to provide the following enhancements—

(A) if the offense created a substantial risk of harm to human life (other than a life described in subparagraph (B)) or the environment, increase the base offense level for the offense—

(i) by not less than 3 offense levels above the applicable level in effect on the date of the enactment of this Act; or
 (ii) if the resulting base offense level after an increase under clause (i) would be less than level 27, to not less than level 27; or

(B) if the offense created a substantial risk of harm to the life of a minor or incompetent, increase the base offense level for the offense—

(i) by not less than 6 offense levels above the applicable level in effect on the date of the enactment of this Act; or
 (ii) if the resulting base offense level after an increase under clause (i) would be less than level 30, to not less than level 30.

The pertinent aspects of this amendment are as follows:

(1) Guidelines Amended.—The amendment provides new

enhancements in §§ 2D1.1 (Unlawful Manufacturing, Importing, Exporting, or Trafficking) and 2D1.10 (Endangering Human Life While Illegally Manufacturing a Controlled Substance) that also apply in the case of an attempt or a conspiracy to manufacture amphetamine or methamphetamine. The amendment does not amend § 2D1.11 (Unlawfully Distributing, Importing, Exporting or Possessing a Listed Chemical) or § 2D1.12 (Unlawful Possession, Manufacture, Distribution, or Importation or Prohibited Flask or Equipment). Although offenses that involve the manufacture of amphetamine or methamphetamine also are referenced in Appendix A (Statutory Index) to §§ 2D1.11 and 2D1.12, the cross reference in these guidelines, which applies if the offense involved the manufacture of a controlled substance, will result in application of § 2D1.1 and accordingly, the new enhancements.

(2) Structure.—The basic structure of the amendment to §§ 2D1.1 and 2D1.10 tracks the structure of the directive. Accordingly, in § 2D1.1, the amendment provides a three-level increase and a minimum offense level of level 27 if the offense (A) involved the manufacture of amphetamine or methamphetamine; and (B) created a substantial risk of either harm to human life or the environment. For offenses that created a substantial risk of harm to the life of a minor or an incompetent, the amendment provides a six-level increase and a minimum offense level of 30.

However, the structure of the amendment in § 2D1.10 differs from that in § 2D1.1 with respect to the first prong of the enhancement (regarding substantial risk of harm to human life or to the environment). Specifically, the amendment provides a three-level increase and a minimum offense level of level 27 if the offense involved the manufacture of amphetamine or methamphetamine without making application of the enhancement dependent upon whether the offense also involved a substantial risk of either harm to human life or the environment. Consideration of whether the offense involved a substantial risk of harm to human life is unnecessary because § 2D1.10 applies only to convictions under 21 U.S.C. 858, and the creation of a substantial risk of harm to human life is an element of a § 858 offense. Therefore, the base offense level already takes into account the substantial risk of harm to human life. Consideration of whether the offense involved a substantial risk of harm to the environment is unnecessary because the directive predicated application of the

enhancement on substantial risk of harm either to human life or to the environment, and the creation of a substantial risk of harm to human life is necessarily present because it is an element of the offense.

(3) Determining “Substantial Risk of Harm”.—Neither the directive nor any statutory provision defines “substantial risk of harm”. Based on an analysis of relevant case law that interpreted “substantial risk of harm”, the amendment provides commentary setting forth factors that may be relevant in determining whether a particular offense created a substantial risk of harm.

(4) Definitions.—The definition of “incompetent” is modeled after several state statutes, which proved useful for purposes of this amendment.

The definition of “minor” has the meaning given that term in Application Note 1 of the Commentary to § 2A3.1 (Criminal Sexual Abuse).

Amendment

Section 2D1.1(b)(5) is amended by striking the comma after “substance” and inserting a semicolon.

Section 2D1.1(b) is amended by redesignating subdivision (6) as subdivision (7); and by inserting after subdivision (5) the following:

“(6) (Apply the greater):

(A) If the offense (i) involved the manufacture of amphetamine or methamphetamine; and (ii) created a substantial risk of harm to (I) human life other than a life described in subsection (b)(6)(B); or (II) the environment, increase by 3 levels. If the resulting offense level is less than level 27, increase to level 27.

(B) If the offense (i) involved the manufacture of amphetamine or methamphetamine; and (ii) created a substantial risk of harm to the life of a minor or an incompetent, increase by 6 levels. If the resulting offense level is less than level 30, increase to level 30.”.

The Commentary to § 2D1.1 captioned “Application Notes” is amended in Note 20 by inserting “Hazardous or Toxic Substances.” before “Subsection (b)(5)”.

The Commentary to § 2D1.1 captioned “Application Notes” is amended by adding at the end the following:

“21. Substantial Risk of Harm Associated with the Manufacture of Amphetamine and Methamphetamine.”

(A) Factors to Consider.—In determining, for purposes of subsection (b)(6), whether the offense created a substantial risk of harm to human life or the environment, the court may consider factors such as the following:

(i) The quantity of any chemicals or hazardous or toxic substances found at the laboratory, or the manner in which the chemicals or substances were stored.

(ii) The manner in which hazardous or toxic substances were disposed, or the likelihood of release into the environment of hazardous or toxic substances.

(iii) The duration of the offense, or the extent of the manufacturing operation.

(iv) The location of the amphetamine or methamphetamine laboratory (e.g., in a residential neighborhood or a remote area) and the number of human lives placed at substantial risk of harm.

(B) Definitions.—For purposes of subsection (b)(6)(B): ‘Incompetent’ means an individual who is incapable of taking care of the individual’s self or property because of a mental or physical illness or disability, mental retardation, or senility.

‘Minor’ has the meaning given that term in Application Note 1 of the Commentary to § 2A3.1 (Criminal Sexual Abuse).”

The Commentary to § 2D1.1 captioned “Background” is amended by adding at the end the following:

“Subsection (b)(5) implements the instruction to the Commission in section 303 of Public Law 103–237.

Subsection (b)(6) implements the instruction to the Commission in section 102 of Public Law 106–878.”.

Section 2D1.10 is amended by inserting after subsection (a) the following:

“(b) Specific Offense Characteristic (1) (Apply the greater):

(A) If the offense involved the manufacture of amphetamine or methamphetamine, increase by 3 levels. If the resulting offense level is less than level 27, increase to level 27.

(B) If the offense (i) involved the manufacture of amphetamine or methamphetamine; and (ii) created a substantial risk of harm to the life of a minor or an incompetent, increase by 6 levels. If the resulting offense level is less than level 30, increase to level 30.”.

The Commentary to § 2D1.10 is amended by adding at the end the following:

“Application Note:

1. Substantial Risk of Harm Associated with the Manufacture of Amphetamine and Methamphetamine.—

(A) Factors to Consider.—In determining, for purposes of subsection (b)(1)(B), whether the offense created a substantial risk of harm to the life of a minor or an incompetent, the court may consider factors such as the following:

(i) The quantity of any chemicals or hazardous or toxic substances found at

the laboratory, or the manner in which the chemicals or substances were stored.

(ii) The manner in which hazardous or toxic substances were disposed, or the likelihood of release into the environment of hazardous or toxic substances.

(iii) The duration of the offense, or the extent of the manufacturing operation.

(iv) The location of the amphetamine or methamphetamine laboratory (e.g., in a residential neighborhood or a remote area) and the number of human lives placed at substantial risk of harm.

(B) Definitions.—For purposes of subsection (b)(1)(B):

'Incompetent' means an individual who is incapable of taking care of the individual's self or property because of a mental or physical illness or disability, mental retardation, or senility.

'Minor' has the meaning given that term in Application Note 1 of the Commentary to § 2A3.1 (Criminal Sexual Abuse).

Background: Subsection (b)(1) implements the instruction to the Commission in section 102 of Public Law 106–878.”

[FR Doc. 00–32578 Filed 12–20–00; 8:45 am]

BILLING CODE 2210–01–P

DEPARTMENT OF TRANSPORTATION

Coast Guard

[USCG–2000–8538]

Chemical Transportation Advisory Committee

AGENCY: Coast Guard, DOT.

ACTION: Notice of meeting.

SUMMARY: The Subcommittee of the Chemical Transportation Advisory Committee (CTAC) on Hazardous Substances Response Standards will meet to discuss the progress of its three (3) working groups on Training Issues, Response Organization, and Response Resource Identification and Verification. This meeting will be open to the public.

DATES: The Subcommittee will meet on Tuesday, January 16, 2001, from 8:30 a.m. to 4 p.m. and on Wednesday, January 17, 2001, from 8:30 a.m. to 12 p.m. The meeting may close early if all business is finished. Written material and requests to make oral presentations should reach the Coast Guard on or before January 5, 2001. Requests to have a copy of your material distributed to each member of the subcommittee should reach the Coast Guard on or before January 3, 2001.

ADDRESSES: The Subcommittee will meet in Conference room 1021/1022,

Marathon Oil Company Headquarters Offices, 5555 San Felipe St., Houston, Texas. Send written material and requests to make oral presentations to Lieutenant Susan Klein, Coast Guard Technical Representative for the Subcommittee, Commandant (G–MOR–2), U.S. Coast Guard Headquarters, 2100 Second Street SW., Washington, DC 20593–0001.

FOR FURTHER INFORMATION CONTACT:

Lieutenant Gregory F. Herold, Deputy Assistant to the Executive Director of CTAC, telephone 202–267–1217, fax 202–267–4570.

SUPPLEMENTARY INFORMATION: Notice of this meeting is given under the Federal Advisory Committee Act, 5 U.S.C. App. 2.

Agenda of Meeting

The agenda of the Subcommittee of the Chemical Transportation Advisory Committee (CTAC) on Hazardous Substances Response Standards includes the following:

(1) Introduction of Subcommittee members.

(2) Brief overview of Subcommittee tasking and desired outcome.

(3) Review and discussion on the progress and activities of the three (3) working groups; Training Issues, Response Organization, and Response Resources Identification and Verification.

(4) Development of future Subcommittee activities.

Procedural

The meeting is open to the public. Please note that the meeting may close early if all business is finished. All attendees at the meeting are encouraged to fully review the Subcommittee's task statement prior to the meeting. Copies of the Subcommittee's task statement can be obtained from Lieutenant Susan Klein, telephone 202–267–0417, or Lieutenant Gregaroy F. Herold, telephone 202–267–1217, fax 202–267–4570. It is also available from the CTAC Internet Website at: www.uscg.mil/hq/g-m/advisory/ctac. At the discretion of the Subcommittee Chair, members of the public may make oral presentations during the meeting. If you would like to make an oral presentation at the meeting, please notify the Coast Guard Technical Representative to the Subcommittee and submit written material on or before January 5, 2001. If you would like a copy of your material distributed to each member of the Subcommittee in advance of a meeting, please submit 25 copies to the Coast Guard Technical Representative to the Subcommittee no later than January 3, 2001.

Information on Services for Individuals With Disabilities

For information on facilities or services for individuals with disabilities, or to request special assistance at the meeting, contact the Deputy Assistant to the Executive Director of CTAC as soon as possible.

Dated: December 14, 2000.

Howard L. Hime,

Director of Standards, Acting Marine Safety and Environmental Protection.

[FR Doc. 00–32579 Filed 12–20–00; 8:45 am]

BILLING CODE 4910–15–M

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

Approval of Noise Compatibility Program; Burbank-Glendale-Pasadena Airport, Burbank, California

AGENCY: Federal Aviation Administration, DOT.

ACTION: Notice.

SUMMARY: The Federal Aviation Administration (FAA) announces its findings on the Noise Compatibility Program submitted by the Burbank-Glendale-Pasadena Airport Authority, Burbank, California, under the provisions of Title I of the Aviation Safety and Noise Abatement Act of 1979 (Public Law 96–193) and Title 14, Code of Federal Regulations, Part 150 (FAR Part 150). These findings are made in recognition of the description of Federal and nonfederal responsibilities in Senate Report No. 96–52 (1980). On January 31, 2000, the FAA determined that the noise exposure maps submitted by the Burbank-Glendale-Pasadena Airport Authority under FAR Part 150 were in compliance with applicable requirements. On November 27, 2000, the Acting Associate Administrator for Airports approved the Burbank-Glendale-Pasadena Airport Noise Compatibility Program. Twenty-five of the twenty-eight program measures have been approved. Four measures were approved as voluntary measures, one measure was approved in part, twenty measures were approved outright, two measures were disapproved pending the submission of additional information and compliance with Part 161, and no action was taken on one measure relating to flight procedures.

EFFECTIVE DATE: The effective date of the FAA's approval of the Burbank-Glendale-Pasadena Airport Noise Compatibility Program is November 27, 2000.

FOR FURTHER INFORMATION CONTACT:

Brian Armstrong, Airport Planner, Airports Division, AWP-611.1, Federal Aviation Administration, Western-Pacific Region. Mailing address: P.O. Box 92007, Worldway Postal Center, Los Angeles, California 90009-2007.

Telephone: (310) 725-3614. Street address: 15000 Aviation Boulevard, Hawthorne, California 90261.

Documents reflecting this FAA action may be reviewed at this location.

SUPPLEMENTARY INFORMATION: This notice announces that the FAA has given its overall approval to the Noise Compatibility Program for the Burbank-Glendale-Pasadena Airport, effective November 27, 2000.

Under Section 104(a) of the Aviation Safety and Noise Abatement Act of 1979 (hereinafter referred to as "the Act"), an airport operator who has previously submitted a Noise Exposure Map, may submit to the FAA, a Noise Compatibility Program which sets forth the measures taken or proposed by the airport operator for the reduction of existing noncompatible land uses and prevention of additional noncompatible land uses within the area covered by the Noise Exposure Maps. The Act requires such programs to be developed in consultation with interested and affected parties including local communities, government agencies, airport users, and FAA personnel.

Each airport Noise Compatibility Program developed in accordance with FAR Part 150 is a local program, not a federal program. The FAA does not substitute its judgment for that of the airport proprietor with respect to which measures would be recommended for action. The FAA's approval or disapproval of FAR Part 150 program recommendations is measured according to the standards expressed in FAR Part 150 and is limited to the following determinations:

a. The Noise Compatibility Program was developed in accordance with the provisions and procedures of FAR Part 150;

b. Program measures are reasonably consistent with achieving the goals of reducing existing noncompatible land uses around the airport and preventing the introduction of additional noncompatible land uses;

c. Program measures would not create an undue burden on interstate or foreign commerce, unjustly discriminate against types or classes of aeronautical uses, violate the terms of airport grant agreements, or intrude into areas preempted by the Federal Government; and

d. Program measures relating to the use of flight procedures can be

implemented within the period covered by the program without derogating safety, adversely affecting the efficient use and management of the navigable airspace and air traffic control systems, or adversely affecting other powers and responsibilities of the Administrator prescribed by law.

Specific limitations with respect to FAA's approval of an airport Noise Compatibility Program are delineated in FAR Part 150, section 150.5. Approval is not a determination concerning the acceptability of land uses under Federal, State, or local law. Approval does not by itself constitute a FAA implementing action. A request for Federal action or approval to implement specific noise compatibility measures may be required, and a FAA decision on the request may require an environmental assessment of the proposed action. Approval does not constitute a commitment by the FAA to financially assist in the implementation of the program nor a determination that all measures covered by the program are eligible for grant-in-aid funding from the FAA. Where Federal funding is sought, requests for project grants must be submitted to the FAA Airports Division office in Hawthorne, California.

The Burbank-Glendale-Pasadena Airport Authority submitted the Noise Exposure Maps, descriptions, and other documentation produced during the noise compatibility planning study conducted from February 1997 through November 1999 to the FAA on December 23, 1998, and September 20, 1999. The Burbank-Glendale-Pasadena Airport Noise Exposure Maps were determined by FAA to be in compliance with applicable requirements on January 31, 2000. Notice of this determination was published in the Federal Register on February 14, 2000.

The Burbank-Glendale-Pasadena Airport study contains a proposed Noise Compatibility Program comprised of actions designed for implementation by airport management and adjacent jurisdictions. It was requested that the FAA evaluate and approve this material as a Noise Compatibility Program as described in Section 104(b) of the Act. The FAA began its review of the program on May 31, 2000 and was required by a provision of the Act to approve or disapprove the program within 180 days (other than the use of new flight procedures for noise control). Failure to approve or disapprove such program within the 180-day period shall be deemed to be an approval of such program.

The submitted program contained twenty-eight proposed actions for noise mitigation on and off the airport. The

FAA completed its review and determined that the procedural and substantive requirements of the Act and FAR Part 150 have been satisfied. The Acting Associate Administrator for Airports approved the overall program effective November 27, 2000.

Twenty-five of the twenty-eight program measures have been approved. The following four measures were approved as voluntary measures: Continue promoting use of AC 91-53A noise abatement departures procedures by air carrier jets; continue promoting use of NBAA noise abatement procedures, or equivalent manufacturers procedures, by general aviation jet aircraft; continue working with the FAA Airport Traffic Control Tower to maintain the typical traffic pattern altitude of 1,800 feet MSL; and, designate Runway 26 as nighttime preferential departure runway. The following measure was approved in part: Offer purchase assurance as an option for homeowners in the acoustical treatment eligibility area. The following twenty measures were approved outright: Continue requiring all transport category and turbojet aircraft to comply with Federal aircraft noise regulations; continue requiring compliance with the Airport's Engine Test Run Up Policy; continue the placement of new buildings on the airport north of Runway 8-26 to shield nearby neighborhood from noise on runway; build extension of Taxiway D to promote nighttime general aviation departures on Runway 26; build engine maintenance run-up enclosure; continue existing acoustical treatment program for single-family homes; expand residential acoustical treatment program to include homes within 65 CNEL contour based on 2003 NEM; establish acoustical treatment program for schools and preschools not previously treated within the 65 CNEL contour based on 2003 NEM; used Baseline 2010 noise contours as basis for noise compatibility planning; establish noise compatibility guidelines for the review of development projects within the 65 CNEL contour; amend Sun Valley-La Tuna Canyon Community Plan to establish infill development standards for noise compatibility; Amend North Hollywood-Valley Village Community Plan to establish land use policies promoting airport noise compatibility; establish airport noise overlay zoning to implement infill development policies of local General Plans; amend building codes to establish sound insulation construction standards to implement requirements of State law and infill development policies; continue noise

abatement information program; monitor implementation of updated Noise Compatibility Program; update Noise Exposure Maps and Noise Compatibility Program; expand noise monitoring system; enhance Airport Authority's geographic information system; and, maintain log of nighttime runway use and operations by aircraft type. The following two measures were disapproved pending the submission of additional information and compliance with Part 161: Phase-out operations by all State 2 jets; and, establish a mandatory curfew on departures by all Stage 2 aircraft between 10 p.m. and 7 a.m., departures by all aircraft over 75,000 pounds between 10:30 p.m. and 6:30 a.m., and arrivals by all aircraft over 75,000 pounds between 11 p.m. and 6 a.m. No action was taken on the following measure related to flight procedures: Establish noise abatement departure turn for jet takeoffs on Runway 26.

These determinations are set forth in detail in a Record of Approval endorsed by the Acting Associate Administrator for Airports on November 27, 2000. The Record of Approval, as well as other evaluation materials and the documents comprising the submittal are available for review at the FAA office listed above and at the administrative offices of the Burbank-Glendale-Pasadena Airport Authority, Burbank, California.

Issued in Hawthorne, California on December 5, 2000.

Herman C. Bliss,

*Manager, Airports Division, AWP-600,
Western-Pacific Region.*

[FR Doc. 00-32525 Filed 12-20-00; 8:45 am]

BILLING CODE 4910-13-M

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

Approval of Noise Compatibility Program, Lanai Airport, Lanai, HI

AGENCY: Federal Aviation Administration, DOT.

ACTION: Notice.

SUMMARY: The Federal Aviation Administration (FAA) announces its findings on the Noise Compatibility Program submitted by the state of Hawaii, Honolulu, Hawaii, under the provisions of Title I of the Aviation Safety and Noise Abatement act of 1979 (Pub. L. 96-193) and Title 14, Code of Federal Regulations, Part 150 (FAR Part 150). These findings are made in recognition of the description of Federal and nonfederal responsibilities in Senate Report No. 96-52 (1980). On

December 23, 1999, the FAA determined that the noise exposure maps submitted by the state of Hawaii under FAR Part 150 were in compliance with applicable requirements. On November 27, 2000, the Acting Associate Administrator for Airports approved the Lanai Airport Noise Compatibility Program. All three of the recommended program measures have been approved. One measure was approved as a voluntary measure and two measures were approved outright.

EFFECTIVE DATE: The effective date of the FAA's approval of the Lanai Airport Noise Compatibility Program is November 27, 2000.

FOR FURTHER INFORMATION CONTACT:

David Welhouse, Airport Planner, Federal Aviation Administration, Honolulu Airports District Office, HNL-621. Telephone: (808) 541-1243. Mailing address: P.O. Box 50244, Honolulu, Hawaii 96850-0001. Street address: 300 Ala Moana Blvd., Room 7-128, Honolulu, HI 96813. Documents reflecting this FAA action may be reviewed at this location.

SUPPLEMENTARY INFORMATION: This notice announces that the FAA has given its overall approval to the Noise Compatibility Program for the Lanai Airport, effective November 27, 2000. Under section 104(a) of the Aviation Safety and Noise Abatement Act of 1979 (hereinafter referred to as "the Act"), an airport operator who has previously submitted a Noise Exposure Map, may submit to the FAA, a Noise Compatibility Program which sets forth the measures taken or proposed by the airport operator for the reduction of existing noncompatible land uses and prevention of additional noncompatible land uses within the area covered by the Noise Exposure Maps. The Act requires such programs to be developed in consultation with interested and affected parties including local communities, government agencies, airport users, and FAA personnel.

Each airport Noise Compatibility Program developed in accordance with FAR Part 150 is a local program, not a federal program. The FAA does not substitute its judgment for that of the airport proprietor with respect to which measures should be recommended for action. The FAA's approval or disapproval of FAR Part 150 program recommendations is measured according to the standards expressed in FAR Part 150 and is limited to the following determinations:

a. The Noise Compatibility Program was developed in accordance with the provisions and procedures of FAR Part 150;

b. Program measures are reasonably consistent with achieving the goals of reducing existing noncompatible land uses around the airport and preventing the introduction of additional noncompatible land uses;

c. Program measures would not create an undue burden on interstate or foreign commerce, unjustly discriminate against types or classes of aeronautical uses, violate the terms of airport grant agreements, or intrude into areas preempted by the Federal Government; and

d. Program measures relating to the use of flight procedures can be implemented within the period covered by the program without derogating safety, adversely affecting the efficient use and management of the navigable airspace and air traffic control systems, or adversely affecting other powers and responsibilities of the Administrator prescribed by law.

Specific limitations with respect to FAA's approval of an airport Noise Compatibility Program are delineated in FAR Part 150, Section 150.5. Approval is not a determination concerning the acceptability of land uses under Federal, State, or local law. Approval does not by itself constitute a FAA implementing action. A request for Federal action or approval to implement specific noise compatibility measures may be required, and a FAA decision on the request may require an environmental assessment of the proposed action. Approval does not constitute a commitment by the FAA to financially assist in the implementation of the program nor a determination that all measures covered by the program are eligible for grant-in-aid funding from the FAA. Where Federal funding is sought, requests for project grants must be submitted to the FAA Airports District Office in Honolulu, Hawaii.

The state of Hawaii submitted the Noise Exposure Maps, descriptions, and other documentation produced during the noise compatibility planning study conducted from March 1998 through December 1999 to the FAA on August 27, 1999. The Lanai Airport Noise Exposure Maps were determined by FAA to be in compliance with applicable requirements on December 23, 1999. Notice of this determination was published in the **Federal Register** on January 6, 2000.

The Lanai Airport study contains a proposed Noise Compatibility Program comprised of actions designed for implementation by airport management and adjacent jurisdictions. It was requested that the FAA evaluate and approve this material as a Noise Compatibility Program as described in

Section 104(b) of the Act. The FAA began its review of the program on May 31, 2000, and was required by a provision of the Act to approve or disapprove the program within 180 days (other than the use of new flight procedures for noise control). Failure to approve or disapprove such program within the 180-day period shall be deemed to be an approval of such program.

The submitted program contained three proposed actions for noise mitigation on and off the airport. The FAA completed its review and determined that the procedural and substantive requirements of the Act and FAR Part 150 have been satisfied. The Acting Associate Administrator for Airports approved the overall program effective November 27, 2000.

All three of the program measures have been approved. The following measure was approved as a voluntary measure: Publication and implementation of an informal runway use program. The following two measures were approved outright: Continue monitoring of development proposals in Lanai Airport environs, disclosing airport Noise Exposure Maps to the community; annually monitor aircraft noise levels and operations at Lanai Airport and conduct public informational meetings on the progress of the Part 150 Program.

These determinations are set forth in detail in a Record of Approval endorsed by the Acting Associate Administrator for Airports on November 27, 2000. The Record of Approval, as well as other evaluation materials and the documents comprising the submittal are available for review at the FAA office listed above and at the administrative offices of the state of Hawaii, Honolulu, Hawaii.

Issued in Hawthorne, California, on December 5, 2000.

Herman C. Bliss,

Manager, Airports Division, AWP-600, Western-Pacific Region.

[FR Doc. 00-32524 Filed 12-20-00; 8:45 am]

BILLING CODE 4910-13-M

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

Noise Exposure Map Notice, Tampa International Airport, Tampa, Florida

AGENCY: Federal Aviation Administration, DOT.

ACTION: Notice.

SUMMARY: The Federal Aviation Administration (FAA) announces its determination that the existing

conditions noise exposure map submitted by Hillsborough County Aviation Authority for Tampa International Airport under the provisions of Title I of the Aviation Safety and Noise Abatement Act of 1979 (Pub. L. 96-193) and 14 CFR Part 150 is in compliance with applicable requirements.

EFFECTIVE DATE: The effective date of the FAA's determination on the existing conditions noise exposure map is December 5, 2000.

FOR FURTHER INFORMATION CONTACT: Mr. Tommy J. Pickering, P.E., Federal Aviation Administration, Orlando Airports District Office, 9677 Tradeport Drive, Suite 130, Orlando, Florida 32827-5397, (407) 648-6583, Extension 29.

SUPPLEMENTARY INFORMATION: This notice announces that the FAA finds that the existing conditions noise exposure map submitted for Tampa International Airport is in compliance with applicable requirements of Part 150, effective December 5, 2000. The 5-year noise exposure map was not revised.

Under Section 103 of the Aviation Safety and Noise Abatement Act of 1979 (hereinafter referred to as "the Act"), an airport operator may submit to the FAA noise exposure maps which meet applicable regulations and which depict noncompatible land uses as of the date of submission of such maps, a description of projected aircraft operations, and the ways in which such operations will affect such maps. The Act requires such maps to be developed in consultation with interested and affected parties in the local community, government agencies, and persons using the airport.

An airport operator who has submitted noise exposure maps that are found by FAA to be in compliance with the requirements of Federal Aviation Regulations (FAR) Part 150, promulgated pursuant to Title I of the Act, may submit a noise compatibility program for FAA approval which sets forth the measures the operator has taken or proposes for the reduction of existing noncompatible uses and for the prevention of the introduction of additional noncompatible uses.

The FAA has completed its review of the noise exposure map and related descriptions submitted by Hillsborough County Aviation Authority. The specific map under consideration is "2000 Existing Conditions Noise Exposure Map with Revised Noise Compatibility Program" shown as Figure 6-3R in the submission. The FAA has determined that this map for Tampa International

Airport is in compliance with applicable requirements. This determination is effective on December 5, 2000. FAA's determination on an airport operator's noise exposure map is limited to a finding that the map was developed in accordance with the procedures contained in Appendix A of FAR Part 150. Such determination does not constitute approval of the applicant's data, information or plans, or a commitment to approve a noise compatibility program or to fund the implementation of that program.

If questions arise concerning the precise relationship of specific properties to noise exposure contours depicted on a noise exposure map submitted under Section 103 of the Act, it should be noted that the FAA is not involved in any way in determining the relative locations of specific properties with regard to the depicted noise contours, or in interpreting the noise exposure maps to resolve questions concerning, for example, which properties should be covered by the provisions of Section 107 of the Act. These functions are inseparable from the ultimate land use control and planning responsibilities of local government. These local responsibilities are not changed in any way under Part 150 or through FAA's review of noise exposure maps. Therefore, the responsibility for the detailed overlaying of noise exposure contours onto the map depicting properties on the surface rests exclusively with the airport operator which submitted those maps, or with those public agencies and planning agencies with which consultation is required under Section 103 of the Act. The FAA has relied on the certification by the airport operator, under section 150.21 of FAR part 150, that the statutorily required consultation has been accomplished.

Copies of the noise exposure map and of the FAA's evaluation of the map is available for examination at the following locations:

Federal Aviation Administration,
Orlando Airports District Office, 9677
Tradeport Drive, Suite 130, Orlando,
Florida 32827-5397

Hillsborough County Aviation
Authority, Tampa International
Airport, 3rd Floor, Blue Side,
Landside Terminal Building, Tampa,
FL 33607

Questions may be directed to the individual named above under the heading, **FOR FURTHER INFORMATION CONTACT.**

Issued in Orlando, Florida, December 5, 2000.

W. Dean Stringer,

Manager, Orlando Airports District Office.

[FR Doc. 00-32520 Filed 12-20-00; 8:45 am]

BILLING CODE 4910-13-M

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

Acceptance of Noise Exposure Maps for Hilo International Airport, Hilo, Hawaii

AGENCY: Federal Aviation Administration, Department of Transportation.

ACTION: Notice.

SUMMARY: The Federal Aviation Administration (FAA) announces its determination that the Noise Exposure Maps submitted by the State of Hawaii, Department of Transportation for the Hilo International Airport, Hilo, Hawaii, under the provisions of Title I of the Aviation Safety and Noise Abatement Act of 1979 (Pub. L. 96-193) and Title 14, Code of Federal Regulations, part 150, are in compliance with applicable requirements.

EFFECTIVE DATE: The effective date of the FAA's acceptance of the Noise Exposure Maps for Hilo International Airport is November 28, 2000.

FOR FURTHER INFORMATION CONTACT: David J. Welhouse, Airport Planner, Honolulu Airports District Office, Federal Aviation Administration. Mailing Address: Box 50244, Honolulu, Hawaii 96850. Street Address: 300 Ala Moana Blvd, Room 7-128, Honolulu, Hawaii 96813. Telephone (808) 541-1243.

SUPPLEMENTARY INFORMATION: This notice announces that the FAA finds that the Noise Exposure Maps submitted for Hilo International Airport are in compliance with the applicable requirements of Title 14, Code of Federal Regulations, part 150 (hereafter referred to as "FAR part 150"), effective November 28, 2000.

Under section 103 of Title I of the Aviation Safety and Noise Abatement Act of 1979 (hereafter referred to as "the Act"), an airport operator may submit to the FAA Noise Exposure Maps which meet applicable regulations and which depict noncompatible land uses as of the date of submission of such maps, a description projected aircraft operations, and the ways in which such operations will affect such maps. The Act requires such maps to be developed in consultation with interested and affected parties in the local community,

government agencies, and persons using the airport.

An airport operator who has submitted Noise Exposure Maps that are found by FAA to be in compliance with the requirements of FAR part 150, promulgated pursuant to Title I of the Act, may submit a Noise Compatibility Program for FAA approval which sets forth the measures the operator has taken or proposes for the reduction of existing noncompatible uses and for the prevention of the introduction of additional noncompatible uses.

The FAA has completed its review of the Noise Exposure Maps and supporting documentation submitted by the State of Hawaii, Department of Transportation. The specific maps under consideration are Figure 4-1, Base Year (2000) Noise Exposure Map, and Figure 5-1, Five Year (2005) Noise Exposure Map (No Mitigation Scenario), in the submission. The FAA has determined that these maps for Hilo International Airport are in compliance with applicable requirements. This determination is effective on November 28, 2000. FAA's acceptance of an airport operator's Noise Exposure Maps is limited to a finding that the maps were developed in accordance with the procedures contained in Appendix A of FAR part 150. Such acceptance does not constitute approval of the applicant's data, information or plans, or a commitment to approve a Noise Compatibility Program or to fund the implementation of that program.

If questions arise concerning the precise relationship of specific properties to noise exposure contours depicted on a Noise Exposure Map submitted under section 103 of the Act, it should be noted that the FAA is not involved in any way in determining the relative locations of specific properties with regard to the depicted noise contours, or in interpreting the Noise Exposure Maps to resolve questions concerning, for example, which properties should be covered by the provisions of section 107 of the Act. These functions are inseparable from the ultimate land use control and planning responsibilities of local government. These local responsibilities are not changed in any way under part 150 or through FAA's review of Noise Exposure Maps. Therefore, the responsibility for the detained overlaying of noise exposure on tours onto the map depicting properties on the surface rests exclusively with the airport operator which submitted those maps, or with those public agencies and planning agencies with which consultation is required under section 103 of the Act. The FAA has relied on

the certification by the airport operator, under § 150.21 of FAR part 150, that the statutorily required consultation has been accomplished.

Copies of the Noise Exposure Maps and of the FAA's evaluation of the maps are available for examination at the following locations:

Federal Aviation Administration, 800 Independence Avenue, SW., Room 617, Washington, DC 20591

Federal Aviation Administration, Western-Pacific Region, Airports Division, AWP-600, 15999 Aviation Blvd., Room 3012, Hawthorne, California 90261

Federal Aviation Administration, Honolulu Airports District Office, 300 Ala Moana Boulevard, Room 7-128, Honolulu, Hawaii 96813

State of Hawaii, Department of Transportation, Airports Division, Honolulu International Airport Division, Honolulu International Airport, 400 Rodgers Boulevard, Suite 700, Honolulu, Hawaii 96819

State of Hawaii, Department of Transportation, Airports Division, Assistant District Office Manager, Hilo International Airport, Hilo, Hawaii 96720

Questions may be directed to the individual named above under the heading, **FOR FURTHER INFORMATION CONTACT**.

Issued in Hawthorne, California on November 28, 2000.

Herman C. Bliss,

Manager, Airports Division, AWP-600, Western-Pacific Region.

[FR Doc. 00-32517 Filed 12-20-00; 8:45 am]

BILLING CODE 4910-13-M

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

Air Traffic Procedures Advisory Committee

AGENCY: Federal Aviation Administration (FAA), DOT.

SUMMARY: The FAA is issuing this notice to advise the public that a meeting of the Federal Aviation Administration Air Traffic Procedures Advisory Committee (ATPAC) will be held to review present air traffic control procedures and practices for standardization, clarification, and upgrading of terminology and procedures.

DATES: The meeting will be held from January 22-25, 2001, from 9 a.m. to 5 p.m. each day.

ADDRESSES: The meeting will be held at the Southwest Airlines Training Center, 2750 Seelco Street, Dallas, Texas 75235.

FOR FURTHER INFORMATION CONTACT: Mr. Eric Harrell, Executive Director, ATPAC, Terminal and En Route Procedures Division, 800 Independence Avenue, SW., Washington, DC 20591, telephone (202) 267-3725.

SUPPLEMENTARY INFORMATION: Pursuant to Section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92-463; 5 U.S.C. App. 2), notice is hereby given of a meeting of the ATPAC to be held January 22 through January 25, 2001, at the Southwest Airlines Training Center, 2750 Seelco Street, Dallas, Texas 75235.

The agenda for this meeting will cover: a continuation of the Committee's review of present air traffic control procedures and practices for standardization, clarification, and upgrading of terminology and procedures. It will also include:

1. Approval of Minutes.
2. Submission and Discussion of Areas of Concern.
3. Discussion of Potential Safety Items.
4. Report from Executive Director.
5. Items of Interest.
6. Discussion and agreement of location and dates for subsequent meetings.

Attendance is open to the interested public but limited to the space available. With the approval of the Chairperson, members of the public may present oral statements at the meeting. Persons desiring to attend and persons desiring to present oral statements should notify the person listed above not later than January 19, 2001. The next quarterly meeting of the FAA ATPAC is planned to be held from April 2-5, 2001, in Washington, DC.

Any member of the public may present a written statement to the Committee at any time at the address given above.

Issued in Washington, DC, on December 11, 2000.

Eric Harrell,

Executive Director, Air Traffic Procedures Advisory Committee.

[FR Doc. 00-32518 Filed 12-20-00; 8:45 am]

BILLING CODE 4910-13-M

ACTION: Notice of intent to rule on application.

SUMMARY: The FAA proposes to rule and invites public comment on the application to impose and use the revenue from a PFC at Brainerd-Crow Wing County Regional Airport under the provisions of the Aviation Safety and Capacity Expansion Act of 1990 (Title IX of the Omnibus Budget Reconciliation Act of 1990) (Pub. L. 101-508) and part 158 of the Federal Aviation Regulations (14 CFR part 158).

DATES: Comments must be received on or before January 22, 2001.

ADDRESSES: Comments on this application may be mailed or delivered in triplicate to the FAA at the following address: Federal Aviation Administration, Minneapolis Airports District Office, 6020 28th Avenue South, Room 102, Minneapolis, Minnesota 55450-2706.

In addition, one copy of any comments submitted to the FAA must be mailed or delivered to Mr. Steve Sievek, Airport Manager, Brainerd-Crow Wing County Regional Airport, at the following address: Brainerd-Crow Wing County Regional Airport Commission, 2375 Airport Road NE, Brainerd, MN 56401.

Air carriers and foreign air carriers may submit copies of written comments previously provided to the Brainerd-Crow Wing County Regional Airport Commission under section 158.23 of part 158.

FOR FURTHER INFORMATION CONTACT: Mr. Gordon Nelson, Program Manager, Federal Aviation Administration, Airports District Office, 6020 28th Avenue South, Room 102, Minneapolis, Minnesota 55450-2706, telephone (612) 713-4358. The application may be reviewed in person at this same location.

SUPPLEMENTARY INFORMATION: The FAA proposes to rule and invites public comment on the application to impose and use the revenue from a PFC at Brainerd-Crow Wing County Regional Airport under the provisions of the Aviation Safety and Capacity Expansion Act of 1990 (Title IX of the Omnibus Budget Reconciliation Act of 1990) (Pub. L. 101-508) and Part 158 of the Federal Aviation Regulations (14 CFR part 158).

On November 29, 2000, the FAA determined that the application to impose and use the revenue from a PFC submitted by the Brainerd-Crow Wing County Regional Airport Commission was substantially complete within the requirements of §§ 158.25 of part 158. The FAA will approve or disapprove the

application, in whole or in part, no later than March 2, 2001.

The following is a brief overview of the application.

PFC application number: 01-03-C-00-BRD.

Level of the proposed PFC: \$4.50.

Proposed charge effective date: April 1, 2001.

Proposed charge expiration date: April 1, 2006.

Total estimated PFC revenue: \$488,231.00.

Brief description of proposed projects at the \$4.50 level: Airport Layout Plan update; Phase II archaeological study; acquire snowblower; design and install Runway 5 Medium-Intensity Approach Lighting System (MALs); clearing/grubbing and obstruction removal; terminal road repair and reconstruction; install deer fencing; Master Plan update/benefit cost analysis; acquire ARFF replacement vehicle; Runway 5/23 friction improvements; construct Southwest Development area; acquire one-ton utility truck with snowplow; acquire end loader with ramp snowplow; and PFC application preparation.

Brief description of proposed project at the \$3.00 level: Sealcoat general aviation apron.

Class or classes of air carriers which the public agency has requested not be required to collect PFCs: Air Taxi/Commercial Operators (ATCO) filing Form 1800-31. Any person may inspect the application in person at the FAA office listed above under **FOR FURTHER INFORMATION CONTACT**.

In addition, any person may, upon request, inspect the application, notice and other documents germane to the application in person at the Brainerd-Crow Wing County Regional Airport Commission Office.

Issued in Des Plaines, Illinois, on December 8, 2000.

Benito De Leon,

Manager, Planning/Programming Branch Airports Division, Great Lakes Region.

[FR Doc. 00-32519 Filed 12-20-00; 8:45 am]

BILLING CODE 4910-13-M

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

Notice of Intent To Rule on Application To Impose and Use the Revenue From a Passenger Facility Charge (PFC) at Brainerd-Crow Wing County Regional Airport, Brainerd, Minnesota

AGENCY: Federal Aviation Administration (FAA), DOT.

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

Notice of Intent To Rule on Application 00-02-C-00-GRI To Impose and Use the Revenue From a Passenger Facility Charge (PFC) at Central Nebraska Regional Airport, Grand Island, NE

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

ACTION: Notice of Intent to Rule on Application; correction.

SUMMARY: This action corrects information in the notice of intent to rule on application published in 65 FR 67789 dated November 13, 2000, FR Document 00-28994. Under

SUPPLEMENTARY INFORMATION: In the first column, in the 25th line, the date the FAA will approve or disapprove the application, in whole or in part, should read, "no later than February 3, 2001".

FOR FURTHER INFORMATION CONTACT:

Lorna Sandridge, PFC Program Manager, FAA, Central Region, 901 Locust, Kansas City, MO 64106, (816)329-2641.

Issued in Kansas City, Missouri on November 20, 2000.

George A. Hendon,

Manager, Airports Division, Central Region.

[FR Doc. 00-32516 Filed 12-20-00; 8:45 am]

BILLING CODE 4910-13-M

DEPARTMENT OF TRANSPORTATION

National Highway Traffic Safety Administration

RIN 2127-A123

Reports, Forms and Record Keeping Requirements; Agency Information Collection Activity Under OMB Review

AGENCY: National Highway Traffic Safety Administration, DOT.

ACTION: Emergency Federal Register Notice.

SUMMARY: The Department of Transportation has submitted the following emergency processing public information collection request to the Office of Management and Budget for review and clearance under the Paperwork Reduction Act of 1995 (Pub.L. 104-13, 44 U.S.C. Chapter 35.) This notice announces that the Information Collection Request (ICR) abstracted below has been forwarded to the Office of Management and Budget (OMB) for review and comment. The ICR describes the nature of the information collections and their expected burden. Comments should be directed to the Office of Information and Regulatory Affairs, Office of Management and Budget, 725-17th Street, NW., Washington, DC 20503, Attention NHTSA Desk Officer.

DATES: OMB approval has been requested by January 30, 2001.

FOR FURTHER INFORMATION CONTACT:

Jennifer T. Timian, NHTSA 400 Seventh Street, SW., Room 5219, NCC-10, Washington, DC 20590. Ms. Timian's telephone number is (202) 366-5263.

SUPPLEMENTARY INFORMATION:

National Highway Traffic Safety Administration

Title: Reporting of Sale or Lease of Defective or Noncompliant Tires.

OMB Control Number: None Assigned to Date.

Frequency: Occasional.

Affected Public: Any person who knowingly and willfully sells or leases a defective or noncompliant tire for use on a motor vehicle with actual knowledge that the manufacturer of the tire has notified dealers of the defect or noncompliance. Persons who sell or lease new or used motor vehicles equipped with defective or noncompliant tires not subject to this reporting requirement with respect to vehicle sales. Motor vehicle lessors and rental companies are also excluded.

Abstract: This information collection is statutorily-mandated. NHTSA anticipates using the information collected to inform purchasers of those defective or noncompliant tires of the existence of the defect or noncompliance, to investigate sales and leases of new tires that are defective or noncompliant, and/or facilitate the providing of a remedy to the purchasers of such new tires. Respondents are expected to be tire dealers and retailers.

Estimated Annual Burden: 4.5 hours annually.

Number of Respondents: 9 annually.

Issued on: December 18, 2000.

Frank Seales, Jr.,

Chief Counsel.

[FR Doc. 00-32580 Filed 12-20-00; 8:45 am]

BILLING CODE 4910-59-P

DEPARTMENT OF TRANSPORTATION

National Highway Traffic Safety Administration

Reports, Forms and Record Keeping Requirements; Agency Information Collection Activity Under OMB Review

AGENCY: National Highway Traffic Safety Administration, DOT.

ACTION: Emergency Federal Register Notice.

SUMMARY: The Department of Transportation has submitted the following request for emergency processing of a public information collection to the Office of Management and Budget for review and clearance under the Paperwork Reduction Act of 1995 (Pub. L. 104-13, 44 U.S.C. Chapter 35.) This notice announces that the Information Collection Request (ICR) abstracted below has been forwarded to

the Office of Management and Budget (OMB) for review and comment. The ICR describes the nature of the information collections and their expected burden.

Comments: Comments should be directed to the Office of Information and Regulatory Affairs, Office of Management and Budget, 725-17th Street, NW., Washington, DC 20503, Attention NHTSA Desk Officer.

Type of Request: New.

Form Number: This proposed collection of information would not use any standard forms.

DATES: OMB approval has been requested by January 30, 2001.

FOR FURTHER INFORMATION CONTACT: Steven Cohen, NHTSA 400 Seventh Street, SW., Rm 5219 (NCC-10), Washington, DC 20590. Telephone number: (202) 366-5263.

SUPPLEMENTARY INFORMATION:

National Highway Traffic Safety Administration

Title: Criminal Penalty Safe Harbor Provision.

OMB Control Number: None assigned.

Frequency: We believe that there will be very few criminal prosecutions under section 30170, given its elements. Accordingly, it is not likely to be a substantial motivating force for a submission of a proper report. We estimate that no more than 9 persons a year would be subject to this new collection of information, and we do not anticipate receiving more than one report a year from any particular person.

Affected Public: This collection of information would apply to any person who seeks a "safe harbor" from potential criminal liability under 49 U.S.C. 30170. Thus, the collection of information could apply to the manufacturers, any officers or employees thereof, and other persons who respond or have a duty to respond to an information provision requirement pursuant to 49 U.S.C. 30166 or a regulation, requirement, request or order issued thereunder.

Abstract: NHTSA is publishing a rule related to "reasonable time" and sufficient manner of "correction," as they apply to the safe harbor from criminal penalties, as required by Section 5 of the Transportation Recall Enhancement, Accountability, and Documentation (TREAD) Act (Pub. L. 106-414), enacted November 1, 2000.

Estimated Annual Burden: Using the above estimate of 9 respondents a year, with an estimated two hours of preparation to collect and provide the information, at an assumed rate of \$20 an hour, the annual, estimated cost of

collecting and preparing the information necessary for 9 complete "safe harbor" corrections is about \$360. Adding in a postage cost of \$3.06 (9 reports at a cost of 34 cents to mail each one), we estimate that it will cost \$363.06 a year for persons to prepare and submit the information necessary to satisfy the safe harbor provision of 49 U.S.C. 30170.

Since nothing in this rule would require those persons who submit reports pursuant to this rule to keep copies of any records or reports submitted to us, the cost imposed to keep records would be zero hours and zero costs.

Number of Respondents: We estimate that there will be no more than 9 per year.

Summary of The Collection of Information: Any person seeking protection from criminal liability under 49 U.S.C. 30170 related to an improper report or failure to report pursuant to 49 U.S.C. 30166, or a regulation, requirement, request or order issued thereunder, will be required to report the following information to NHTSA: (1) each previous improper item of information or document and each failure to report that was required under 49 U.S.C. 30166, or a regulation, requirement, request or order issued thereunder, (2) the specific predicate under which each improper or omitted report should have been provided, and (3) the complete and correct reports, including all information that was improperly submitted or that should have been submitted and all relevant documents that were not previously submitted to NHTSA or, if the person cannot provide this, then a full detailed description of that information or of the content of those documents and the reason why the individual cannot provide them to NHTSA.

Issued on: December 18, 2000.

Frank Seales, Jr.,

Chief Counsel.

[FR Doc. 00-32581 Filed 12-20-00; 8:45 am]

BILLING CODE 4910-59-P

DEPARTMENT OF TRANSPORTATION

Surface Transportation Board

[STB Docket No. AB-33 (Sub-No. 164X)]

Union Pacific Railroad Company— Abandonment Exemption—in Bonne Terre, MO

Union Pacific (UP) has filed a notice of exemption under 49 CFR 1152 Subpart F—*Exempt Abandonments and Discontinuances* to abandon a 1.10-mile line of railroad between milepost 31.20

and milepost 30.10 (the Bonne Terre Industrial Lead) in Bonne Terre, St. Francois County, MO. The line traverses United States Postal Service Zip Code 63628.

UP has certified that: (1) No local traffic has moved over the line for at least 2 years; (2) there is no overhead traffic on the line; (3) no formal complaint filed by a user of rail service on the line (or by a state or local government entity acting on behalf of such user) regarding cessation of service over the line either is pending with the Surface Transportation Board (Board) or with any U.S. District Court or has been decided in favor of complainant within the 2-year period; and (4) the requirements at 49 CFR 1105.7 (environmental reports), 49 CFR 1105.8 (historic reports), 49 CFR 1105.11 (transmittal letter), 49 CFR 1105.12 (newspaper publication), and 49 CFR 1152.50(d)(1) (notice to governmental agencies) have been met.

As a condition to this exemption, any employee adversely affected by the abandonment shall be protected under *Oregon Short Line R. Co.—Abandonment—Goshen*, 360 I.C.C. 91 (1979). To address whether this condition adequately protects affected employees, a petition for partial revocation under 49 U.S.C. 10502(d) must be filed.

Provided no formal expression of intent to file an offer of financial assistance (OFA) has been received, this exemption will be effective on January 20, 2001, unless stayed pending reconsideration. Petitions to stay that do not involve environmental issues,¹ formal expressions of intent to file an OFA under 49 CFR 1152.27(c)(2),² and trail use/rail banking requests under 49 CFR 1152.29 must be filed by January 2, 2001. Petitions to reopen or requests for public use conditions under 49 CFR 1152.28 must be filed by January 10, 2001, with: Surface Transportation Board, Office of Secretary, Case Control Unit, 1925 K Street, NW., Washington, DC 20423.

A copy of any petition filed with the Board should be sent to applicant's representative: James P. Gatlin, Union

¹ The Board will grant a stay if an informed decision on environmental issues (whether raised by a party or by the Board's Section of Environmental Analysis in its independent investigation) cannot be made before the exemption's effective date. See *Exemption of Out-of-Service Rail Lines*, 5 I.C.C. 2d 377 (1989). Any request for a stay should be filed as soon as possible so that the Board may take appropriate action before the exemption's effective date.

² Each offer of financial assistance must be accompanied by the filing fee, which currently is set at \$1000. See 49 CFR 1002.2(f)(25).

Pacific Railroad Company, 1416 Dodge Street, Room 830, Omaha, NE 68179.

If the verified notice contains false or misleading information, the exemption is void *ab initio*.

UP has filed an environmental report which addresses the abandonment's effects, if any, on the environment and historic resources. The Section of Environmental Analysis (SEA) will issue an environmental assessment (EA) by December 26, 2000.

Interested persons may obtain a copy of the EA by writing to SEA (Room 500, Surface Transportation Board, Washington, DC 20423) or by calling SEA, at (202) 565-1545. Comments on environmental and historic preservation matters must be filed within 15 days after the EA becomes available to the public.

Environmental, historic preservation, public use, or trail use/rail banking conditions will be imposed, where appropriate, in a subsequent decision.

Pursuant to the provisions of 49 CFR 1152.29(e)(2), UP shall file a notice of consummation with the Board to signify that it has exercised the authority granted and fully abandoned the line. If consummation has not been effected by UP's filing of a notice of consummation by December 21, 2001, and there are no legal or regulatory barriers to consummation, the authority will automatically expire.

Board decisions and notices are available on our website at "WWW.STB.DOT.GOV."

Decided: December 8, 2000.

By the Board, David M. Konschnik,
Director, Office of Proceedings.

Vernon A. Williams,

Secretary.

[FR Doc. 00-31909 Filed 12-20-00; 8:45 am]

BILLING CODE 4915-00-P

DEPARTMENT OF TRANSPORTATION

Surface Transportation Board

[STB Docket No. AB-277 (Sub-No. 1X)]

West Virginia Northern Railroad Company—Abandonment Exemption— in Preston County, WV

West Virginia Northern Railroad Company (WVN) has filed a notice of exemption under 49 CFR 1152 Subpart F—*Exempt Abandonments* to abandon its entire line of railroad between milepost 0.0 in Tunnelton and the end of the line at milepost 10.13 near Kingwood, in Preston County, WV, a distance of 10.13 miles. The line traverses United States Postal Service Zip Codes 26444 and 26537.

WVN has certified that: (1) No local traffic has moved over the line for at least 2 years; (2) any overhead traffic can be rerouted over other lines; (3) no formal complaint filed by a user of rail service on the line (or by a state or local government entity acting on behalf of such user) regarding cessation of service over the line either is pending with the Surface Transportation Board (Board) or with any U.S. District Court or has been decided in favor of complainant within the 2-year period; and (4) the requirements at 49 CFR 1105.7 (environmental reports), 49 CFR 1105.8 (historic reports), 49 CFR 1105.11 (transmittal letter), 49 CFR 1105.12 (newspaper publication), and 49 CFR 1152.50(d)(1) (notice to governmental agencies) have been met.

Where, as here, the carrier is abandoning its entire line, the Board does not normally impose labor protection under 49 U.S.C. 10505(g) unless the evidence indicates the existence of a corporate affiliate that will: (1) Continue rail operations; or (2) realize significant benefits in addition to being relieved of the burden of deficit operations by its affiliated railroad. *See T and P Railway—Abandonment—in Shawnee, Jefferson and Atchison Counties, KS*, Docket No. AB-381, *et al.* (ICC served Apr. 27, 1993). Because these conditions do not appear to exist here, employee protection conditions will not be imposed.

Provided no formal expression of intent to file an offer of financial assistance (OFA) has been received, this exemption will be effective on January 20, 2001, unless stayed pending reconsideration. Petitions to stay that do not involve environmental issues,¹ formal expressions of intent to file an OFA under 49 CFR 1152.27(c)(2),² and trail use/rail banking requests under 49 CFR 1152.29 must be filed by January 2, 2001. Petitions to reopen or requests for public use conditions under 49 CFR 1152.28 must be filed by January 10, 2001, with: Surface Transportation Board, Office of the Secretary, Case Control Unit, 1925 K Street, NW., Washington, DC 20423.

A copy of any petition filed with the Board should be sent to applicant's

representative: Fritz R. Kahn, 1920 N Street, NW. (8th Floor), Washington, DC 20036-1601.

If the verified notice contains false or misleading information, the exemption is void *ab initio*.

WVN has filed an environmental report which addresses the effects, if any, of the abandonment on the environment and historic resources. The Section of Environmental Analysis (SEA) will issue an environmental assessment (EA) by December 26, 2000. Interested persons may obtain a copy of the EA by writing to SEA (Room 500, Surface Transportation Board, Washington, DC 20423) or by calling SEA, at (202) 565-1545. Comments on environmental and historic preservation matters must be filed within 15 days after the EA becomes available to the public.

Environmental, historic preservation, public use, or trail use/rail banking conditions will be imposed, where appropriate, in a subsequent decision.

Pursuant to the provisions of 49 CFR 1152.29(e)(2), WVN shall file a notice of consummation with the Board to signify that it has exercised the authority granted and fully abandoned its line. If consummation has not been effected by WVN's filing of a notice of consummation by December 21, 2001, and there are no legal or regulatory barriers to consummation, the authority to abandon will automatically expire.

Board decisions and notices are available on our website at "WWW.STB.DOT.GOV."

Decided: December 8, 2000.

By the Board, David M. Konschnik, Director, Office of Proceedings.

Vernon A. Williams,

Secretary.

[FR Doc. 00-31908 Filed 12-20-00; 8:45 am]

BILLING CODE 4915-00-P

DEPARTMENT OF TRANSPORTATION

Bureau of Transportation Statistics

Reports, Forms and Recordkeeping Requirements Activity Under OMB Review; Airline Service Quality Performance

AGENCY: Bureau of Transportation Statistics (BTS), DOT.

ACTION: Notice.

SUMMARY: In compliance with the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*), this notice announces that the Information Collection Request (ICR) abstracted below has been forwarded to the Office of Management and Budget (OMB) for

extension of currently approved collections. The ICR describes the nature of the information collection and its expected burden. The **Federal Register** Notice with a 60-day comment period soliciting comments on the following collection of information was published on September 22, 2000 (65 FR vol. 185, page 57426).

DATES: Written comments should be submitted by January 22, 2001.

FOR FURTHER INFORMATION CONTACT: Bernie Stankus, Office of Airline Information, K-25, Room 4125, Bureau of Transportation Statistics, 400 Seventh Street, SW., Washington, DC 20590-0001, Telephone Number (202) 366-4387, Fax Number (202) 366-3383 or EMAIL bernard.stankus@bts.gov.

SUPPLEMENTARY INFORMATION:

Bureau of Transportation Statistics (BTS)

Title: Report of Passengers Denied Confirmed Space.

Type of Request: Extension of a currently approved collection.

OMB Control Number: 2138-0018.

Forms: BTS Form 251.

Affected Public: U.S. and foreign air carriers that provide scheduled passenger service.

Abstract: BTS Form 251 is a one-page report on the number of passengers denied boarding voluntarily and involuntarily, whether the bumped passengers were provided alternate transportation and/or compensation, and the amount of the payment. U.S. and foreign air carriers that operate scheduled passenger service with large aircraft (over 60 seats) must submit Form 251. However, carriers do not report data from inbound international flights because the protections of Part 250 *Oversales* do not apply to these flights. The report allows the Department to monitor the effectiveness of its oversales rule and take enforcement action when necessary. The involuntary denied-boarding rate has decreased over the years from 4.38 per 10,000 passengers in 1980 to 1.15 for the nine months ended September 2000. The improvement has been made in a period when load factors and passenger enplanements have risen. These statistics demonstrate the effectiveness of the 'volunteer provision'. The publishing of the air carriers' individual denied boarding rates has negated the need for more intrusive regulation. The rate of denied boarding can be examined as a continuing fitness factor. This rate provides an insight into a carrier's policy of treating passengers and its compliance disposition. A rapid

¹ The Board will grant a stay if an informed decision on environmental issues (whether raised by a party or by the Board's Section of Environmental Analysis in its independent investigation) cannot be made before the exemption's effective date. *See Exemption of Out-of-Service Rail Lines*, 5 I.C.C.2d 377 (1989). Any request for a stay should be filed as soon as possible so that the Board may take appropriate action before the exemption's effective date.

² Each offer of financial assistance must be accompanied by the filing fee, which currently is set at \$1000. *See* 49 CFR 1002.2(f)(25).

sustained increase in the rate of denied boarding often is an indicator of operational difficulty. Because the rate of denied boarding is released quarterly, travelers and travel agents can select carriers with low bumping incidents when booking a trip. This information is made available to the public in the *Air Travel Consumer Report* and on the web at <http://www.dot.gov/airconsumer>. The *Air Travel Consumer Report* is also sent to newspapers, magazines, and trade journals. Without Form 251, determining the effectiveness of the Department's oversales rules, would be an uncertainty.

Estimated Annual Burden Hours: 2,200 hours.

ADDRESSES: Send comments to the Office of Information and Regulatory Affairs, Office of Management and Budget, 725—17th Street, NW., Washington, DC 20503, Attention BTS Desk Officer.

Comments are invited on: whether the proposed collection of information is necessary for the proper performance of the functions of the Department concerning consumer protection. Comments should address whether the information will have practical utility; the accuracy of the Department's estimate of the burden of the proposed information collection; ways to enhance the quality, utility and clarity of the information to be collected; and ways to minimize the burden of the collection of information on respondents, including the use of automated collection techniques or other forms of information technology.

Donald W. Bright,

Assistant Director, Office of Airline Information.

[FR Doc. 00-32529 Filed 12-20-00; 8:45 am]

BILLING CODE 4910-FE-P

DEPARTMENT OF THE TREASURY

Submission for OMB Review; Comment Request

December 14, 2000.

The Department of Treasury has submitted the following public information collection requirement(s) to OMB for review and clearance under the Paperwork Reduction Act of 1995, Public Law 104-13. Copies of the submission(s) may be obtained by calling the Treasury Bureau Clearance Officer listed. Comments regarding this information collection should be addressed to the OMB reviewer listed and to the Treasury Department Clearance Officer, Department of the

Treasury, Room 2110, 1425 New York Avenue, NW., Washington, DC 20220.

DATES: Written comments should be received on or before January 22, 2001 to be assured of consideration.

Financial Management Service (FMS)

OMB Number: 1510-0066.

Form Number: None.

Type of Review: Extension.

Title: 31 CFR Part 208—Management of Federal Agency Disbursements; Final Rule.

Description: This regulation requires that most Federal payments be made by Electronic Funds Transfer (EFT); sets forth waiver requirements; and provides for a low-cost Treasury designated account to individuals at a financial institution who offers such accounts.

Respondents: Business or other for-profit, Individuals or households, Not-for-profit institutions.

Estimated Number of Respondents: 1,300.

Estimated Burden Hours Per

Respondent: 15 minutes.

Estimated Total Reporting Burden: 325 hours.

Clearance Officer: Juanita Holder, Financial Management Service, 3700 East West Highway, Room 144, PGP II, Hyattsville, MD 20782.

OMB Reviewer: Alexander T. Hunt, (202) 395-7860, Office of Management and Budget, Room 10202, New Executive Office Building, Washington, DC 20503.

Lois K. Holland,

Departmental Reports Management Officer.

[FR Doc. 00-32490 Filed 12-20-00; 8:45 am]

BILLING CODE 4810-35-P

DEPARTMENT OF THE TREASURY

Submission for OMB Review; Comment Request

December 12, 2000.

The Department of Treasury has submitted the following public information collection requirement(s) to OMB for review and clearance under the Paperwork Reduction Act of 1995, Public Law 104-13. Copies of the submission(s) may be obtained by calling the Treasury Bureau Clearance Officer listed. Comments regarding this information collection should be addressed to the OMB reviewer listed and to the Treasury Department Clearance Officer, Department of the Treasury, Room 2110, 1425 New York Avenue, NW., Washington, DC 20220.

DATES: Written comments should be received on or before January 22, 2001 to be assured of consideration.

Internal Revenue Service (IRS)

OMB Number: 1545-1450.

Regulation Project Number: FI-59-91 Final.

Type of Review: Extension.

Title: Debt Instructions With Original Issue Discount; Anti-Abuse Rule.

Description: The regulations provide definitions, general rules, and reporting requirements for debt instruments that provide for contingent payments. The regulations also provide definitions, general rules, and recordkeeping requirements for integrated debt instruments.

Respondents: Individuals or households, Business or other for-profit, State, Local or Tribal Government.

Estimated Number of Respondents/Recordkeepers: 180,000.

Estimated Burden Hours Per

Respondent/Recordkeeper: 30 minutes.

Frequency of Response: Annually.

Estimated Total Reporting/Recordkeeping Burden: 89,000 hours.

OMB Number: 1545-1573.

Regulation Project Number: REG-209463-82 NPRM.

Type of Review: Extension.

Title: Required Distributions from Qualified Plans and Individual Retirement Plans.

Description: The regulation permits a taxpayer to name a trust as the beneficiary of the employee's benefits under a retirement plan and use the life expectancies of the beneficiaries of the trust to determine the required minimum distribution, if certain conditions are satisfied.

Respondents: Individuals or households.

Estimated Number of Respondents: 1,000.

Estimated Burden Hours Per

Respondent: 20 minutes.

Frequency of Response: On occasion.

Estimated Total Reporting Burden: 333 hours.

OMB Number: 1545-1583.

Regulation Project Number: REG-209322-82 Final.

Type of Review: Extension.

Title: Return of Partnership Income.

Description: Information is required to enable the IRS to verify that a taxpayer is reporting the correct amount of income or gain or claiming the correct amount of losses, deductions, or credits from that taxpayer's interest in the partnership.

Respondents: Business or other for-profit, Farms.

Estimated Number of Respondents: 1.

Estimated Burden Hours Per

Respondent: 1 hour.

Frequency of Response: Annually.

Estimated Total Reporting Burden: 1 hour.

Clearance Officer: Garrick Shear, Internal Revenue Service, Room 5244, 1111 Constitution Avenue, NW., Washington, DC 20224.

OMB Reviewer: Alexander T. Hunt, (202) 395-7860, Office of Management and Budget, Room 10202, New Executive Office Building, Washington, DC 20503.

Lois K. Holland,

Departmental Reports Management Officer.
[FR Doc. 00-32491 Filed 12-20-00; 8:45 am]
BILLING CODE 4830-01-P

DEPARTMENT OF THE TREASURY

Submission for OMB Review; Comment Request

December 14, 2000.

The Department of Treasury has submitted the following public information collection requirement(s) to OMB for review and clearance under the Paperwork Reduction Act of 1995, Public Law 104-13. Copies of the submission(s) may be obtained by calling the Treasury Bureau Clearance Officer listed. Comments regarding this information collection should be addressed to the OMB reviewer listed and to the Treasury Department Clearance Officer, Department of the Treasury, Room 2110, 1425 New York Avenue, NW., Washington, DC 20220.

DATES: Written comments should be received on or before January 22, 2001 to be assured of consideration.

Internal Revenue Service (IRS)

OMB Number: 1545-1299.

Regulation Project Number: IA-54-90 Final.

Type of Review: Extension.

Title: Settlement Funds.

Description: The reporting requirements affect taxpayers that are qualified settlement funds; they will be required to file income tax returns, estimated income tax returns, and withholding tax returns. The information will facilitate taxpayer examinations.

Respondents: Business or other for-profit, Individuals or households, Not-for-profit institutions, Farms, Federal Government, State, Local or Tribal Government.

Estimated Number of Respondents: 1,500.

Estimated Burden Hours Per

Respondent: 2 hours, 22 minutes.

Frequency of Response: Annually.

Estimated Total Reporting Burden: 3,542 hours.

OMB Number: 1545-1451.

Revenue Project Number: REG-248900-96 Final.

Type of Review: Extension.

Title: Definition of Private Activity Bonds.

Description: Section 103 provides generally that interest on certain State or local bonds is excluded from gross income. However, under sections 103(b)(1) and 141, interest on private activity bonds (other than qualified bonds) is not excluded. The regulations provide rules, for purposes of section 141, to determine how bond proceeds are measured and used and how debt service for those bonds is paid or secured.

Respondents: State, Local or Tribal Government.

Estimated Number of Respondents: 10,100.

Estimated Burden Hours Per

Respondent: 2 hours, 59 minutes.

Frequency of Response: On occasion.

Estimated Total Reporting Burden: 30,100 hours.

OMB Number: 1545-1559.

Revenue Procedure Number: Revenue Procedures 98-46 and 97-44.

Type of Review: Extension.

Title: LIFO Conformity Requirement.

Description: Revenue Procedure 97-44 permits automobile dealers that comply with the terms of the revenue procedure to continue using the LIFO inventory method despite previous violations of the LIFO inventory method despite previous violations of the LIFO conformity requirements of section 472(c) or (e)(2). Revenue Procedure 98-46 modifies Revenue Procedure 97-44 by allowing medium- and heavy-duty truck dealers to take advantage of the favorable relief provided in Revenue Procedure 97-44.

Respondents: Business or other for-profit.

Estimated Number of Respondents: 5,000.

Estimated Burden Hours Per

Respondent: 20 hours.

Frequency of Response: Annually.

Estimated Total Reporting Burden: 100,000 hours.

OMB Number: 1545-1562.

Revenue Procedure Number: Revenue Procedure 97-48.

Type of Review: Extension.

Title: Automatic Relief for Late S Corporation Elections.

Description: The Small Business Job Protection Act of 1996 provides the IRS with the authority to grant relief for late S corporation elections. This revenue procedure provides that, in certain situations, taxpayers whose S corporation election was filed late can obtain by filing Form 2553 and attaching a statement explaining that the requirements of the revenue procedure have been met.

Respondents: Business or other for-profit.

Estimated Number of Respondents: 100.

Estimated Burden Hours Per

Respondent: 1 hour.

Frequency of Response: Other (once).

Estimated Total Reporting Burden: 100 hours.

OMB Number: 1545-1582.

Regulation Project Number: REG-209373-81 Final.

Type of Review: Extension.

Title: Election to Amortize Start-Up Expenditures for Active Trade or Business.

Description: The information is needed to comply with section 195 of the Internal Revenue Code, which requires taxpayers to make an election in order to amortize start-up expenditures. The information will be used for compliance and audit purposes.

Respondents: Business or other for-profit.

Estimated Number of Respondents: 150,000.

Estimated Burden Hours Per

Respondent: 15 minutes.

Frequency of Response: Other (one-time election).

Estimated Total Reporting Burden: 37,500 hours.

OMB Number: 1545-1704.

Revenue Procedure Number: Revenue Procedure 2000-41.

Type of Review: Extension.

Title: Change in Minimum Funding Method.

Description: This revenue procedure provides a mechanism whereby a plan sponsor or plan administrator may obtain a determination from the Internal Revenue Service that its proposed change in the method of funding its pension plan(s) meets the standards of section 412 of the Internal Revenue Code.

Respondents: Business or other for-profit, Not-for-profit institutions, State, Local or Tribal Government.

Estimated Number of Respondents: 300.

Estimated Burden Hours Per

Respondent: 18 hours.

Frequency of Response: On occasion.

Estimated Total Reporting Burden: 5,400 hours.

Clearance Officer: Garrick Shear, Internal Revenue Service, Room 5244, 1111 Constitution Avenue, NW, Washington, DC 20224.

OMB Reviewer: Alexander T. Hunt, (202) 395-7860, Office of Management and Budget, Room 10202, New

Executive Office Building, Washington, DC 20503.

Lois K. Holland,

Departmental Reports Management Officer.

[FR Doc. 00-32492 Filed 12-20-00; 8:45 am]

BILLING CODE 4830-01-U

DEPARTMENT OF THE TREASURY

Office of the Comptroller of the Currency

Agency Information Collection Activities: Submission for OMB Review; Comment Request

AGENCY: Office of the Comptroller of the Currency (OCC), Treasury.

ACTION: Submission for OMB review; comment request.

SUMMARY: The OCC, as part of its continuing effort to reduce paperwork and respondent burden, invites the general public and other Federal agencies to take this opportunity to comment on a continuing information collection, as required by the Paperwork Reduction Act of 1995. The OCC may not conduct or sponsor, and a respondent is not required to respond to, an information collection that has been extended, revised, or implemented unless it displays a currently valid Office of Management and Budget (OMB) control number. Currently, the OCC is soliciting comments concerning an extension, without change, of an information collection titled Disclosure of Financial and Other Information by National Banks—12 CFR Part 18. The OCC also gives notice that it has sent the information collection to OMB for review.

DATES: You should submit your written comments to both OCC and the OMB Reviewer by January 22, 2001.

ADDRESSES: You should send your written comments to the Public Information Room, Office of the Comptroller of the Currency, 250 E Street, SW., Attention: 1557-0182, Mailstop 1-5, Washington, DC 20219. In addition, you can send comments by facsimile transmission to (202) 874-4448, or by electronic mail to regs.comments@occ.treas.gov. You can inspect and photocopy the comments at the OCC's Public Reference Room, 250 E Street SW., Washington, DC 20219 on business days. You can make an appointment to inspect the comments by calling (202)874-5043.

FOR FURTHER INFORMATION CONTACT: You may request additional information from Thomas Ramsey, (202) 874-5586, Core Policy Development Division, or a

copy of the collection and supporting documentation submitted to OMB from Jessie Dunaway, Clearance Officer, or Camille Dixon, (202) 874-5090, Legislative and Regulatory Activities Division (1557-0182), Office of the Comptroller of the Currency, 250 E Street, SW., Washington, DC 20219.

SUPPLEMENTARY INFORMATION: The OCC is proposing to extend OMB approval of the following information collection:

Title: Disclosure of Financial and Other Information by National Banks—12 CFR 18.

OMB Number: 1557-0182.

Form Numbers: None.

Abstract: This submission covers an existing regulation and involves no change to the regulation or to the information collections embodied in the regulation. The OCC requests only that OMB renew its approval of the information collections in the current regulation.

This disclosure of information is needed to facilitate informed decisionmaking by existing and potential customers and investors by improving public understanding of, and confidence in, the financial condition of an individual national bank. The disclosed information is used by depositors, security holders, and the general public in evaluating the condition of, and deciding whether to do business with, a particular national bank. Disclosure and increased public knowledge complements OCC's efforts to promote the safety and soundness of national banks and the national banking system.

The information collections contained in part 18 are found in §§ 18.4(c) and 18.8. Section 18.4(c) permits a bank to prepare an optional narrative for inclusion in its annual disclosure statement. Section 18.8 requires that a national bank promptly furnish materials in response to a request.

Type of Review: Extension, without change, of a currently approved collection.

Affected Public: Businesses or other for-profit.

Estimated Number of Respondents: 2,450.

Estimated Total Annual Responses: 2,450.

Frequency of Response: Annual.

Estimated Total Annual Burden: 1,225 burden hours.

OMB Reviewer: Alexander Hunt, (202) 395-7340, Paperwork Reduction Project 1557-0182, Office of Management and Budget, Room 10226, New Executive Office Building, Washington, DC 20503.

Dated: December 15, 2000.

Mark J. Tenhundfeld,

Assistant Director, Legislative & Regulatory Activities Division.

[FR Doc. 00-32541 Filed 12-20-00; 8:45 am]

BILLING CODE 4810-33-P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

Proposed Collection; Comment Request for Form 8831

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Notice and request for comments.

SUMMARY: The Department of the Treasury, as part of its continuing effort to reduce paperwork and respondent burden, invites the general public and other Federal agencies to take this opportunity to comment on proposed and/or continuing information collections, as required by the Paperwork Reduction Act of 1995, Public Law 104-13 (44 U.S.C. 3506(c)(2)(A)). Currently, the IRS is soliciting comments concerning Form 8831, Excise Taxes on Excess Inclusions of REMIC Residual Interests.

DATES: Written comments should be received on or before February 20, 2001, to be assured of consideration.

ADDRESSES: Direct all written comments to Garrick R. Shear, Internal Revenue Service, room 5244, 1111 Constitution Avenue NW., Washington, DC 20224.

FOR FURTHER INFORMATION CONTACT: Requests for additional information or copies of the form and instructions should be directed to Martha R. Brinson, (202) 622-3869, Internal Revenue Service, room 5244, 1111 Constitution Avenue NW., Washington, DC 20224.

SUPPLEMENTARY INFORMATION:

Title: Excise Taxes on Excess Inclusions of REMIC Residual Interests.

OMB Number: 1545-1379.

Form Number: 8831.

Abstract: Form 8831 is used by a real estate mortgage investment conduit (REMIC) to figure its excise tax liability under Internal Revenue Code sections 860E(e)(1), 860E(e)(6), and 860E(e)(7). IRS uses the information to determine the correct tax liability of the REMIC.

Current Actions: There are no changes being made to the form at this time.

Type of Review: Extension of a currently approved collection.

Affected Public: Business or other for-profit organizations.

Estimated Number of Respondents: 31.

Estimated Time Per Respondent: 7 hr., 39 min.

Estimated Total Annual Burden Hours: 237.

The following paragraph applies to all of the collections of information covered by this notice:

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless the collection of information displays a valid OMB control number. Books or records relating to a collection of information must be retained as long as their contents may become material in the administration of any internal revenue law. Generally, tax returns and tax return information are confidential, as required by 26 U.S.C. 6103.

Request for Comments: Comments submitted in response to this notice will be summarized and/or included in the request for OMB approval. All comments will become a matter of public record. Comments are invited on: (a) Whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology; and (e) estimates of capital or start-up costs and costs of operation, maintenance, and purchase of services to provide information.

Approved: December 14, 2000.

Garrick R. Shear,

IRS Reports Clearance Officer.

[FR Doc. 00-32480 Filed 12-20-00; 8:45 am]

BILLING CODE 4830-01-U

DEPARTMENT OF THE TREASURY

Internal Revenue Service

Proposed Collection; Comment Request for Form 973

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Notice and request for comments.

SUMMARY: The Department of the Treasury, as part of its continuing effort to reduce paperwork and respondent burden, invites the general public and other Federal agencies to take this opportunity to comment on proposed and/or continuing information collections, as required by the Paperwork Reduction Act of 1995,

Public Law 104-13 (44 U.S.C. 3506(c)(2)(A)). Currently, the IRS is soliciting comments concerning Form 973, Corporation Claim for Deduction for Consent Dividends.

DATES: Written comments should be received on or before February 20, 2001, to be assured of consideration.

ADDRESSES: Direct all written comments to Garrick R. Shear, Internal Revenue Service, room 5244, 1111 Constitution Avenue NW., Washington, DC 20224.

FOR FURTHER INFORMATION CONTACT: Requests for additional information or copies of the form and instructions should be directed to Martha R. Brinson, (202) 622-3869, Internal Revenue Service, room 5244, 1111 Constitution Avenue NW., Washington, DC 20224.

SUPPLEMENTARY INFORMATION:

Title: Corporation Claim for Deduction for Consent Dividends.

OMB Number: 1545-0044

Form Number: 973

Abstract: Corporations file Form 973 to claim a deduction for dividends paid. If shareholders consent and the IRS approves, the corporation may claim a deduction for dividends paid, which reduces the corporation's tax liability. IRS uses Form 973 to determine if shareholders have included the dividend in gross income.

Current Actions: There are no changes being made to the form at this time.

Type of Review: Extension of a currently approved collection.

Affected Public: Business or other for-profit organizations.

Estimated Number of Respondents: 500

Estimated Time Per Respondent: 5 hr., 10 min.

Estimated Total Annual Burden Hours: 2,580

The following paragraph applies to all of the collections of information covered by this notice:

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless the collection of information displays a valid OMB control number. Books or records relating to a collection of information must be retained as long as their contents may become material in the administration of any internal revenue law. Generally, tax returns and tax return information are confidential, as required by 26 U.S.C. 6103.

Request for comments: Comments submitted in response to this notice will be summarized and/or included in the request for OMB approval. All comments will become a matter of public record. Comments are invited on: (a) Whether the collection of information is necessary for the proper

performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology; and (e) estimates of capital or start-up costs and costs of operation, maintenance, and purchase of services to provide information.

Approved: December 14, 2000.

Garrick R. Shear,

IRS Reports Clearance Officer.

[FR Doc. 00-32481 Filed 12-20-00; 8:45 am]

BILLING CODE 4830-01-U

DEPARTMENT OF THE TREASURY

Internal Revenue Service

Proposed Collection; Comment Request for Form 9452

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Notice and request for comments.

SUMMARY: The Department of the Treasury, as part of its continuing effort to reduce paperwork and respondent burden, invites the general public and other Federal agencies to take this opportunity to comment on proposed and/or continuing information collections, as required by the Paperwork Reduction Act of 1995, Public Law 104-13 (44 U.S.C. 3506(c)(2)(A)). Currently, the IRS is soliciting comments concerning Form 9452, Filing Assistance Program (Do you have to file a tax return?).

DATES: Written comments should be received on or before February 20, 2001 to be assured of consideration.

ADDRESSES: Direct all written comments to Garrick R. Shear, Internal Revenue Service, room 5244, 1111 Constitution Avenue NW., Washington, DC 20224.

FOR FURTHER INFORMATION CONTACT: Requests for additional information or copies of the form and instructions should be directed to Carol Savage, (202) 622-3945, Internal Revenue Service, room 5242, 1111 Constitution Avenue NW., Washington, DC 20224.

SUPPLEMENTARY INFORMATION:

Title: Filing Assistance Program (Do you have to file a tax return?).

OMB Number: 1545-1316.

Form Number: 9452.

Abstract: Form 9452 aids individuals in determining whether it is necessary to file a Federal tax return. Form 9452 will not be collected by the IRS; it is to be used by individuals at their discretion. Form 9452 is used by the Service's taxpayer assistance programs. It is also available on the Internet, and it is distributed in an annual mailout to taxpayers.

Current Actions: There are no changes being made to the form at this time.

Type of Review: Extension of a currently approved collection.

Affected Public: Individuals or households.

Estimated Number of Respondents: 1,650,000.

Estimated Time Per Response: 30 minutes.

Estimated Total Annual Burden Hours: 825,000.

The following paragraph applies to all of the collections of information covered by this notice:

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless the collection of information displays a valid OMB control number.

Books or records relating to a collection of information must be retained as long as their contents may become material in the administration of any internal revenue law. Generally, tax returns and tax return information are confidential, as required by 26 U.S.C. 6103.

Request for Comments: Comments submitted in response to this notice will be summarized and/or included in the request for OMB approval. All comments will become a matter of public record.

Comments are invited on: (a) Whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology; and (e) estimates of capital or start-up costs and costs of operation, maintenance, and purchase of services to provide information.

Approved: December 15, 2000.

Garrick R. Shear,

IRS Reports Clearance Officer.

[FR Doc. 00-32604 Filed 12-20-00; 8:45 am]

BILLING CODE 4830-01-U

DEPARTMENT OF THE TREASURY

Internal Revenue Service

Proposed Collection; Comment Request for Announcement 97-122

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Notice and request for comments.

SUMMARY: The Department of the Treasury, as part of its continuing effort to reduce paperwork and respondent burden, invites the general public and other Federal agencies to take this opportunity to comment on proposed and/or continuing information collections, as required by the Paperwork Reduction Act of 1995, Public Law 104-13 (44 U.S.C. 3506(c)(2)(A)). Currently, the IRS is soliciting comments concerning Announcement 97-122, Interim Guidance for Roth Individual Retirement Accounts.

DATES: Written comments should be received on or before February 20, 2001 to be assured of consideration.

ADDRESSES: Direct all written comments to Garrick R. Shear, Internal Revenue Service, room 5244, 1111 Constitution Avenue NW., Washington, DC 20224.

FOR FURTHER INFORMATION CONTACT: Requests for additional information or copies of the announcement should be directed to Carol Savage, (202) 622-3945, Internal Revenue Service, room 5242, 1111 Constitution Avenue NW., Washington, DC 20224.

SUPPLEMENTARY INFORMATION:

Title: Interim Guidance for Roth Individual Retirement Accounts.

OMB Number: 1545-1568.

Announcement Number: Announcement 97-122.

Abstract: Announcement 97-122 provides interim guidance concerning the establishment of Roth Individual Retirement Accounts (described in section 408A of the Internal Revenue Code as added by section 302 of the Taxpayer Relief Act of 1997). The guidance is directed mainly at banks, etc., that will market prototype Roth IRAs to the public.

Current Actions: There are no changes being made to the announcement at this time.

Type of Review: Extension of a currently approved collection.

Affected Public: Business or other for-profit organizations, and not-for-profit institutions.

Estimated Number of Respondents: 4,000.

Estimated Time Per Respondent: 2 hours.

Estimated Total Annual Burden Hours: 8,000.

The following paragraph applies to all of the collections of information covered by this notice:

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless the collection of information displays a valid OMB control number.

Books or records relating to a collection of information must be retained as long as their contents may become material in the administration of any internal revenue law. Generally, tax returns and tax return information are confidential, as required by 26 U.S.C. 6103.

Request for Comments: Comments submitted in response to this notice will be summarized and/or included in the request for OMB approval. All comments will become a matter of public record.

Comments are invited on: (a) Whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology; and (e) estimates of capital or start-up costs and costs of operation, maintenance, and purchase of services to provide information.

Approved: December 15, 2000.

Garrick R. Shear,

IRS Reports Clearance Officer.

[FR Doc. 00-32605 Filed 12-20-00; 8:45 am]

BILLING CODE 4830-01-U

DEPARTMENT OF THE TREASURY

Internal Revenue Service

[REG-115795-97]

Proposed Collection; Comment Request for Regulation Project

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Notice and request for comments.

SUMMARY: The Department of the Treasury, as part of its continuing effort to reduce paperwork and respondent burden, invites the general public and other Federal agencies to take this

opportunity to comment on proposed and/or continuing information collections, as required by the Paperwork Reduction Act of 1995, Public Law 104-13 (44 U.S.C. 3506(c)(2)(A)). Currently, the IRS is soliciting comments concerning an existing final regulation, REG-115795-97 (TD 8870), General Rules for Making and Maintaining Qualified Electing Fund Elections (§§ 1.1295-1 and 1.1295-3).

DATES: Written comments should be received on or before February 20, 2001 to be assured of consideration.

ADDRESSES: Direct all written comments to Garrick R. Shear, Internal Revenue Service, room 5244, 1111 Constitution Avenue NW., Washington, DC 20224.

FOR FURTHER INFORMATION CONTACT: Requests for additional information or copies of the regulation should be directed to Carol Savage, (202) 622-3945, Internal Revenue Service, room 5242, 1111 Constitution Avenue NW., Washington, DC 20224.

SUPPLEMENTARY INFORMATION:

Title: General Rules for Making and Maintaining Qualified Electing Fund Elections.

OMB Number: 1545-1555.

Regulation Project Number: REG-115795-97.

Abstract: This regulation provides guidance to a passive foreign investment company (PFIC) shareholder that makes the election under Code section 1295 to treat the PFIC as a qualified electing fund (QEF), and for PFIC shareholders that wish to make a section 1295 election that will apply on a retroactive basis. Guidance is also provided on revoking such elections.

Current Actions: There is no change to this existing regulation.

Type of Review: Extension of a currently approved collection.

Affected Public: Individuals or households, business or other for-profit organization, and not-for-profit institutions.

Estimated Number of Respondents: 1,290.

Estimated Time Per Respondent: 29 minutes.

Estimated Total Annual Burden Hours: 623.

The following paragraph applies to all of the collections of information covered by this notice:

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless the collection of information displays a valid OMB control number. Books or records relating to a collection of information must be retained as long as their contents may become material

in the administration of any internal revenue law. Generally, tax returns and tax return information are confidential, as required by 26 U.S.C. 6103.

Request for Comments: Comments submitted in response to this notice will be summarized and/or included in the request for OMB approval. All comments will become a matter of public record. Comments are invited on: (a) Whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology; and (e) estimates of capital or start-up costs and costs of operation, maintenance, and purchase of services to provide information.

Approved: December 15, 2000.

Garrick R. Shear,

IRS Reports Clearance Officer.

[FR Doc. 00-32606 Filed 12-20-00; 8:45 am]

BILLING CODE 4830-01-U

DEPARTMENT OF THE TREASURY

Internal Revenue Service

[EE-178-78]

Proposed Collection; Comment Request for Regulation Project

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Notice and request for comments.

SUMMARY: The Department of the Treasury, as part of its continuing effort to reduce paperwork and respondent burden, invites the general public and other Federal agencies to take this opportunity to comment on proposed and/or continuing information collections, as required by the Paperwork Reduction Act of 1995, Public Law 104-13 (44 U.S.C. 3506(c)(2)(A)). Currently, the IRS is soliciting comments concerning an existing final regulation, EE-178-78 (TD 7898), Employers' Qualified Educational Assistance Programs (Section 1.127-2).

DATES: Written comments should be received on or before February 20, 2001 to be assured of consideration.

ADDRESSES: Direct all written comments to Garrick R. Shear, Internal Revenue

Service, room 5244, 1111 Constitution Avenue NW., Washington, DC 20224.

FOR FURTHER INFORMATION CONTACT:

Requests for additional information or copies of the regulation should be directed to Martha R. Brinson, (202) 622-3869, Internal Revenue Service, room 5244, 1111 Constitution Avenue NW., Washington, DC 20224.

SUPPLEMENTARY INFORMATION:

Title: Employers' Qualified Educational Assistance Programs.

OMB Number: 1545-0768.

Regulation Project Number: EE-178-78.

Abstract: Internal Revenue Code section 127(a) provides that the gross income of an employee does not include amounts paid or expenses incurred by an employer if furnished to the employee pursuant to a qualified educational assistance program. This regulation requires that a qualified educational assistance program must be a separate written plan of the employer and that employees must be notified of the availability and terms of the program. Also, substantiation may be required to verify that employees are entitled to exclude from their gross income amounts paid or expenses incurred by the employer.

Current Actions: There is no change to this existing regulation.

Type of Review: Extension of a currently approved collection.

Affected Public: Business or other for-profit organizations, and individuals or households.

Estimated Number of Respondents: 5,200.

Estimated Time Per Respondent: 7 minutes.

Estimated Total Annual Burden Hours: 615.

The following paragraph applies to all of the collections of information covered by this notice:

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless the collection of information displays a valid OMB control number. Books or records relating to a collection of information must be retained as long as their contents may become material in the administration of any internal revenue law. Generally, tax returns and tax return information are confidential, as required by 26 U.S.C. 6103.

Request for Comments: Comments submitted in response to this notice will be summarized and/or included in the request for OMB approval. All comments will become a matter of public record.

Comments are invited on: (a) Whether the collection of information is

necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology; and (e) estimates of capital or start-up costs and costs of operation, maintenance, and purchase of services to provide information.

Approved: December 15, 2000.

Garrick R. Shear,

IRS Reports Clearance Officer.

[FR Doc. 00-32607 Filed 12-20-00; 8:45 am]

BILLING CODE 4830-01-U

DEPARTMENT OF THE TREASURY

Internal Revenue Service

Proposed Collection; Comment Request for Form 8038-T

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Notice and request for comments.

SUMMARY: The Department of the Treasury, as part of its continuing effort to reduce paperwork and respondent burden, invites the general public and other Federal agencies to take this opportunity to comment on proposed and/or continuing information collections, as required by the Paperwork Reduction Act of 1995, Public Law 104-13 (44 U.S.C. 3506(c)(2)(A)). Currently, the IRS is soliciting comments concerning Form 8038-T, Arbitrage Rebate and Penalty in Lieu of Arbitrage Rebate.

DATES: Written comments should be received on or before February 20, 2001 to be assured of consideration.

ADDRESSES: Direct all written comments to Garrick R. Shear, Internal Revenue Service, room 5244, 1111 Constitution Avenue NW., Washington, DC 20224.

FOR FURTHER INFORMATION CONTACT: Requests for additional information or copies of the form and instructions should be directed to Carol Savage, (202) 622-3945, Internal Revenue Service, room 5242, 1111 Constitution Avenue NW., Washington, DC 20224.

SUPPLEMENTARY INFORMATION:

Title: Arbitrage Rebate and Penalty in Lieu of Arbitrage Rebate.

OMB Number: 1545-1219.

Form Number: 8038-T.

Abstract: Form 8038-T is used by issuers of tax exempt bonds to report and pay the arbitrage rebate and to elect and/or pay various penalties associated with arbitrage bonds. The issuers include state and local governments.

Current Actions: There are no changes being made to the form at this time.

Type of Review: Extension of a currently approved collection.

Affected Public: State, local or tribal governments.

Estimated Number of Respondents: 2,500.

Estimated Time Per Response: 29 hours, 27 minutes.

Estimated Total Annual Burden Hours: 73,625.

The following paragraph applies to all of the collections of information covered by this notice:

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless the collection of information displays a valid OMB control number. Books or records relating to a collection of information must be retained as long as their contents may become material in the administration of any internal revenue law. Generally, tax returns and tax return information are confidential, as required by 26 U.S.C. 6103.

Request for Comments: Comments submitted in response to this notice will be summarized and/or included in the request for OMB approval. All comments will become a matter of public record. Comments are invited on: (a) Whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology; and (e) estimates of capital or start-up costs and costs of operation, maintenance, and purchase of services to provide information.

Approved: December 15, 2000.

Garrick R. Shear,

IRS Reports Clearance Officer.

[FR Doc. 00-32608 Filed 12-20-00; 8:45 am]

BILLING CODE 4830-01-U

DEPARTMENT OF THE TREASURY

Internal Revenue Service

[LR-100-78]

Proposed Collection; Comment Request for Regulation Project

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Notice and request for comments.

SUMMARY: The Department of the Treasury, as part of its continuing effort to reduce paperwork and respondent burden, invites the general public and other Federal agencies to take this opportunity to comment on proposed and/or continuing information collections, as required by the Paperwork Reduction Act of 1995, Public Law 104-13 (44 U.S.C. 3506(c)(2)(A)). Currently, the IRS is soliciting comments concerning an existing final regulation, LR-100-78 (T.D. 7918), Creditability of Foreign Taxes (§§ 1.901-2 and 1.901-2A).

DATES: Written comments should be received on or before February 20, 2001 to be assured of consideration.

ADDRESSES: Direct all written comments to Garrick R. Shear, Internal Revenue Service, room 5244, 1111 Constitution Avenue NW., Washington, DC 20224.

FOR FURTHER INFORMATION CONTACT: Requests for additional information or copies of the information collection should be directed to Larnice Mack, (202) 622-3179, Internal Revenue Service, room 5244, 1111 Constitution Avenue NW., Washington, DC 20224.

SUPPLEMENTARY INFORMATION:

Title: Creditability of Foreign Taxes.

OMB Number: 1545-0746.

Regulation Project Number: LR-100-

78.

Abstract: Section 1.901-2A of the regulation contains special rules that apply to taxpayers engaging in business transactions with a foreign government that is also taxing them. In general, such taxpayers must establish what portion of a payment made pursuant to a foreign levy is actually tax and not compensation for a economic benefit received from the foreign government. One way a taxpayer can do this is by electing to apply the safe harbor formula of section 1.901-2A by filing a statement with the IRS.

Current Actions: There is no change to this existing regulation.

Type of Review: Extension of a currently approved collection.

Affected Public: Individuals or households, and business or other for-profit organizations.

Estimated Number of Respondents: 110.

Estimated Time Per Respondent: 20 min.

Estimated Total Annual Burden Hours: 37.

The following paragraph applies to all of the collections of information covered by this notice:

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless the collection of information displays a valid OMB control number. Books or records relating to a collection of information must be retained as long as their contents may become material in the administration of any internal revenue law. Generally, tax returns and tax return information are confidential, as required by 26 U.S.C. 6103.

Request for Comments: Comments submitted in response to this notice will be summarized and/or included in the request for OMB approval. All comments will become a matter of public record. Comments are invited on: (a) Whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology; and (e) estimates of capital or start-up costs and costs of operation, maintenance, and purchase of services to provide information.

Approved: December 15, 2000.

Garrick R. Shear,

IRS Reports Clearance Officer.

[FR Doc. 00-32609 Filed 12-20-00; 8:45 am]

BILLING CODE 4830-01-P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

Proposed Collection; Comment Request for Form 2758

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Notice and request for comments.

SUMMARY: The Department of the Treasury, as part of its continuing effort to reduce paperwork and respondent burden, invites the general public and other Federal agencies to take this

opportunity to comment on proposed and/or continuing information collections, as required by the Paperwork Reduction Act of 1995, Public Law 104-13 (44 U.S.C. 3506(c)(2)(A)). Currently, the IRS is soliciting comments concerning Form 2758, Application for Extension of Time To File Certain Excise, Income, Information, and Other Returns.

DATES: Written comments should be received on or before February 20, 2001 to be assured of consideration.

ADDRESSES: Direct all written comments to Garrick R. Shear, Internal Revenue Service, room 5244, 1111 Constitution Avenue NW., Washington, DC 20224.

FOR FURTHER INFORMATION CONTACT: Requests for additional information or copies of the form and instructions should be directed to Faye Bruce, (202) 622-6665, Internal Revenue Service, room 5244, 1111 Constitution Avenue NW., Washington, DC 20224.

SUPPLEMENTARY INFORMATION:

Title: Application for Extension of Time To File Certain Excise, Income, Information, and Other Returns.

OMB Number: 1545-0148.

Form Number: 2758.

Abstract: Internal Revenue Code section 6081 allows a reasonable extension of time for filing any return, declaration, statement, or other document. Form 2758 is used by fiduciaries, trustees, and certain other organizations to request an extension of time to file their returns. The information is used to determine whether the extension should be granted.

Current Actions: There are no changes being made to the form at this time.

Type of Review: Extension of a currently approved collection.

Affected Public: Business or other for-profit organizations and not-for-profit institutions.

Estimated Number of Respondents: 70,371.

Estimated Time Per Respondent: 5 hr., 21 min.

Estimated Total Annual Burden Hours: 375,923.

The following paragraph applies to all of the collections of information covered by this notice:

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless the collection of information displays a valid OMB control number. Books or records relating to a collection of information must be retained as long as their contents may become material in the administration of any internal revenue law. Generally, tax returns and tax return information are confidential, as required by 26 U.S.C. 6103.

Request for Comments: Comments submitted in response to this notice will be summarized and/or included in the request for OMB approval. All comments will become a matter of public record. Comments are invited on: (a) Whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology; and (e) estimates of capital or start-up costs and costs of operation, maintenance, and purchase of services to provide information.

Approved: December 14, 2000.

Garrick R. Shear,

IRS Reports Clearance Officer.

[FR Doc. 00-32610 Filed 12-20-00; 8:45 am]

BILLING CODE 4830-01-P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

Proposed Collection; Comment Request for Form 1099-OID

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Notice and request for comments.

SUMMARY: The Department of the Treasury, as part of its continuing effort to reduce paperwork and respondent burden, invites the general public and other Federal agencies to take this opportunity to comment on proposed and/or continuing information collections, as required by the Paperwork Reduction Act of 1995, Public Law 104-13 (44 U.S.C. 3506(c)(2)(A)). Currently, the IRS is soliciting comments concerning Form 1099-OID, Original Issue Discount.

DATES: Written comments should be received on or before February 20, 2001 to be assured of consideration.

ADDRESSES: Direct all written comments to Garrick R. Shear, Internal Revenue Service, room 5244, 1111 Constitution Avenue NW., Washington, DC 20224.

FOR FURTHER INFORMATION CONTACT: Requests for additional information or copies of the form and instructions should be directed to Faye Bruce, (202) 622-6665, Internal Revenue Service,

room 5244, 1111 Constitution Avenue NW., Washington, DC 20224.

SUPPLEMENTARY INFORMATION:

Title: Original Issue Discount.

OMB Number: 1545-0117.

Form Number: 1099-OID.

Abstract: The form is used for reporting original issue discount as required by section 6049 of the Internal Revenue Code. It is used to verify that income earned on discount obligations is properly reported by the recipient.

Current Actions: There are no changes being made to the form at this time.

Type of Review: Extension of a currently approved collection.

Affected Public: Businesses or other for-profit organizations.

Estimated Number of Responses: 5,906,965.

Estimated Time Per Response: 12 min.

Estimated Total Annual Burden

Hours: 1,142,323.

The following paragraph applies to all of the collections of information covered by this notice:

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless the collection of information displays a valid OMB control number. Books or records relating to a collection of information must be retained as long as their contents may become material in the administration of any internal revenue law. Generally, tax returns and tax return information are confidential, as required by 26 U.S.C. 6103.

Request for Comments: Comments submitted in response to this notice will be summarized and/or included in the request for OMB approval. All comments will become a matter of public record. Comments are invited on: (a) Whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology; and (e) estimates of capital or start-up costs and costs of operation, maintenance, and purchase of services to provide information.

Approved: December 14, 2000.

Garrick R. Shear,

IRS Reports Clearance Officer.

[FR Doc. 00-32611 Filed 12-20-00; 8:45 am]

BILLING CODE 4830-01-P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

[LR-58-83]

Proposed Collection; Comment Request for Regulation Project

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Notice and request for comments.

SUMMARY: The Department of the Treasury, as part of its continuing effort to reduce paperwork and respondent burden, invites the general public and other Federal agencies to take this opportunity to comment on proposed and/or continuing information collections, as required by the Paperwork Reduction Act of 1995, Public Law 104-13 (44 U.S.C. 3506(c)(2)(A)).

Currently, the IRS is soliciting comments concerning an existing final regulation, LR-58-83 (TD 7959), Related Group Election With Respect to Qualified Investments in Foreign Base Company Shipping Operations (§§ 1.955A-2 and 1.955A-3).

DATES: Written comments should be received on or before February 20, 2001 to be assured of consideration.

ADDRESSES: Direct all written comments to Garrick R. Shear, Internal Revenue Service, room 5244, 1111 Constitution Avenue NW., Washington, DC 20224.

FOR FURTHER INFORMATION CONTACT: Requests for additional information or copies of the information collection should be directed to Faye Bruce, (202) 622-6665, Internal Revenue Service, room 5244, 1111 Constitution Avenue NW., Washington, DC 20224.

SUPPLEMENTARY INFORMATION:

Title: Related Group Election With Respect to Qualified Investments in Foreign Base Company Shipping Operations.

OMB Number: 1545-0755.

Regulation Project Number: LR-58-83.

Abstract: This regulation concerns the election made by a related group of controlled foreign corporations to determine foreign base company shipping income and qualified investments in foreign base company shipping operations on a related group basis. The information required is necessary to assure that the U.S. shareholder correctly reports any shipping income of its controlled foreign corporations which is taxable to the shareholder.

Current Actions: There is no change to this existing regulation.

Type of Review: Extension of a currently approved collection.

Affected Public: Business or other for-profit organizations.

Estimated Number of Respondents: 100.

Estimated Time Per Respondent: 2 hours, 3 minutes.

Estimated Total Annual Burden

Hours: 205.

The following paragraph applies to all of the collections of information covered by this notice:

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless the collection of information displays a valid OMB control number. Books or records relating to a collection of information must be retained as long as their contents may become material in the administration of any internal revenue law. Generally, tax returns and tax return information are confidential, as required by 26 U.S.C. 6103.

Request for Comments: Comments submitted in response to this notice will be summarized and/or included in the request for OMB approval. All comments will become a matter of public record. Comments are invited on: (a) whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology; and (e) estimates of capital or start-up costs and costs of operation, maintenance, and purchase of services to provide information.

Approved: December 14, 2000.

Garrick R. Shear,

IRS Reports Clearance Officer.

[FR Doc. 00-32612 Filed 12-20-00; 8:45 am]

BILLING CODE 4830-01-P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

Special Enrollment Examination Advisory Committee

AGENCY: Internal Revenue Service, Office of Director of Practice, Treasury.

ACTION: Notice of invitation to submit nominations for advisory committee membership.

SUMMARY: The Director of Practice invites individuals and organizations to nominate candidates for membership on the Special Enrollment Examination Advisory Committee.

DATES: Submit nominations on or before January 22, 2001.

ADDRESSES: Mail, fax, or e-mail nominations to: Internal Revenue Service; Office of Director of Practice; N:C:SC; Attn: Kathy Hughes; 1111 Constitution Avenue, NW, Washington, DC 20224; fax number 202-694-1934; e-mail Kathy.E.Hughes@IRS.Gov.

FOR FURTHER INFORMATION CONTACT: Kathy Hughes, Designated Federal Officer, Special Enrollment Examination Advisory Committee, at 202-694-1851 or Kathy.E.Hughes@IRS.Gov.

SUPPLEMENTARY INFORMATION: The Special Enrollment Examination Advisory Committee ("SEEAC"), which was formerly known as the "Advisory Committee on the Special Enrollment Examination," was established in 1999 under the terms of the Federal Advisory Committee Act, 5 U.S.C. App. The SEEAC's charter expires February 5, 2001. It is expected that the SEEAC will be renewed for another two-year period. Therefore, the Director of Practice invites individuals and organizations to nominate candidates for membership.

Section 330 of 31 U.S.C. authorizes the Secretary of the Treasury to require that representatives before the Department demonstrate their "competency to advise and assist persons in presenting their cases." Pursuant to that statute, the Secretary has promulgated the regulations governing practice before the Internal Revenue Service, which are found at 31 CFR part 10 and are separately published in pamphlet form as Treasury Department Circular No. 230 (to order call 1-800-829-3676).

The regulations provide that enrolled agents are among the classes of individuals eligible to practice before the Internal Revenue Service. The regulations also authorize the Director of Practice to pass upon applications for enrollment and to grant enrollment to applicants who demonstrate special competence in tax matters by written examination administered by the Internal Revenue Service. This written examination is the Special Enrollment Examination ("SEE"). More information concerning the SEE may be found on the Director of Practice Webpage: (1) Go to IRS Digital Daily, www.irs.gov; (2) at the bottom of the page, click *Tax Info For Business*; (3) click *Tax Professionals' Corner*; and (4) click *Director of Practice, Enrolled Agent Program*.

The objective of the SEEAC is to propose, on an annual basis, an examination testing the special competence in Federal tax matters of individuals who have applied for enrolled agent status. In meeting this objective, non-Federal members of the SEEAC shall represent the various segments of the tax practitioner community. The SEEAC's advisory functions will include, but will not necessarily be limited to: (1) Considering areas of Federal tax knowledge that should be treated on the examination; (2) developing examination questions; and (3) recommending passing scores.

FACA mandates that the membership of the Committee be fairly balanced in terms of the points of view presented and the functions to be performed. To that end, the Director of Practice will consider nominations of all individuals who: (1) Are qualified to represent the views of a segment of the tax practitioner community; (2) possess professional or academic accomplishments sufficient to allow contributions to the SEEAC's advisory functions; (3) are of good character and good reputation; and (4) are in compliance with the Federal tax laws. Current or former status as an enrolled agent is not a requirement for SEEAC membership.

Individuals may nominate themselves; an individual may nominate other individuals; or professional associations or other organizations may nominate individuals. A nomination may be in any format, but it must include: (1) A statement of which segment of the tax practitioner community the nominee is qualified to represent; (2) a description of the nominee's professional accomplishments, academic accomplishments, or both; and (3) a statement that the nominee is willing to accept an appointment to the SEEAC. Nominations may include copies of articles from professional journals or other relevant publications, but such items cannot be returned.

Appointment to the Committee will be for a two-year term, providing that a member continues to fulfill his or her Committee responsibilities. The Committee is expected to meet up to four times a year. Members should be prepared to devote from 125 to 175 hours per year, including meetings, to the Committee's work. Members will be reimbursed, in accordance with Government regulations, for expenses (transportation, meals, and lodging) incurred in connection with Committee meetings.

If the SEE is to provide objective and fair indicia of special competence in Federal taxation, the SEE's specific topics and questions must not become publicly available prior to administration of the examination. Consequently, sessions of SEEAC meetings dealing with specific SEE topics and questions will be closed to public participation. With respect to such closed sessions, SEEAC members must be prepared to maintain the confidentiality of their deliberations and advice.

Dated: December 13, 2000.

Patrick W. McDonough,
Director of Practice.

[FR Doc. 00-32483 Filed 12-20-00; 8:45 am]

BILLING CODE 4830-01-P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

Quarterly Publication of Individuals, Who Have Chosen To Expatriate, as Required by Section 6039G

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Notice.

SUMMARY: This notice is provided in accordance with IRC section 6039G, as amended, by the Health Insurance Portability and Accountability Act (HIPAA) of 1996. This listing contains the name of each individual losing United States citizenship (within the meaning of section 877(a)) with respect to whom the Secretary received information during the quarter ending September 30, 2000.

Last name	First name	Middle name
Alvear	Lars	Mikael
An	Suk	Hyun
Aurstad	Marit	Arleen
Avaznia	Natasha.	
Baarsden	Espen.	
Bailey	Chong	Cha
Barili	Ok	Pun
Boeck	George	Henry
Borel	Didier.	
Canellopoulos ..	Takis	P.
Chang	David	Hak
Cheung	Karen	Tih Loh
Chippis	Myong	Suk
Cihla	Peter	Ernst
Cipriano	Robert	James
Conmy	Kevin	Francis
Cooper	Bryan	Patrick
Corbett Jr.	Charles	Frederick
Crook	Howard	Alan
Dahl	Anne.	
Dublin-Poulos ..	Suri	E.
Emery	Mary	Elizabeth
Emeryiii	Roland	Scott
Feliciano	Eun	Ye

Last name	First name	Middle name
Foote	Charlotte	Maria
Freeman	Derrick	Blair
Fuerniss	Elisabeth	Julia
Gates-Robert ..	Diane.	
Halter	Cornelia	Adriana, Maria
Halter	Pieter.	
Han	Jung-Sook.	
Headford	June	Carol
Henderson	Teresa	Micheile
Hillgard	Elsie	Marie- Brigitte
Hobden	John	Andrew
Homann- Herimberg.	Claude	Marie
Hsue	Glen	Jen
Hughes	Linda	Joans
Jimenez	Carmen	Dora
Jimenez	Enrique	Manuel
Jimenez	Maria	Elena
Jimenez	Olga	Maria
Johnson Jr.	Glenn	Elwood
Jones	Juergen	Richard
Keller	Peter	John
Kim	Ki	Sun
Kim	Ted	Yong
Ko	Miguel.	
Lan Ng	Macy	Yuen
Lawrence	Deborah	S.
Malms	Christoph	P.
Malone	Nancy	Isolde
Mansfield	Patricia	Joan
Marcus	Mary	Ellen
Marias	Kim	Irene
Mc Kenna	Joanne	Marie
Mccarthy	Mary.	
Michael- Beerbaum.	Meredith	True
Oye	Bradford.	
Park	Choon	Duk
Peterson	Theodosius ..	Nicholas
Pfister	Gustav	R.
Porrino	Ano	Jason
Poulos	Darrel.	
Rush	Wayne	Alan
Salhab	Tanja.	
Salisbury	Gerald	Allen
Sanford-Nydes	Robin.	
Sayre	Heidi	Bachem
Schoch	Charles	Rolf
Seda	Jessica	Choe
Sevo	Mike.	
Shih	Choon	Fong
Shin	Kyung	Hee
Smith-Scott	Jennifer	Cameron
So	Yong	Sin
Tang	Daisy	Lee
Tepper	Elisabeth	Connie
Thorpe	Ozey	Lee
Thorsen	Johannes ..	Martin
Thorvaldsen	Anne	Lisa
Tobias	Roy	Michael
Tung Lee	Richard	Char
Vedilago	John	David
Walton	Keth	Patrick-Pol- lard'
Weber	Yvonne.	
Wong	Shing	Kwan
Zivy	Andrew	Henry

Approved: November 15, 2000.

Doug Rogers,*Chief, Special Projects, Compliance Area 15,
Small Business/Self Employed, Territory 3
(Support).*

[FR Doc. 00-32487 Filed 12-20-00; 8:45 am]

BILLING CODE 4830-01-P**DEPARTMENT OF THE TREASURY****Internal Revenue Service****Meeting of the Pacific-Northwest
Citizen Advocacy Panel****ACTION:** Notice.**SUMMARY:** An open meeting of the Pacific-Northwest Citizen Advocacy Panel will be held in Honolulu, Hawaii.**DATES:** The meeting will be held Friday January 12, 2001 and Saturday January 13, 2001.**FOR FURTHER INFORMATION CONTACT:** Judi L. Nicholas at 1-888-912-1227 or 206-220-6096.

SUPPLEMENTARY INFORMATION: Notice is hereby given pursuant to Section 10(a)(2) of the Federal Advisory Committee Act, 5 U.S.C. App. (1988) that an open meeting of the Citizen Advocacy Panel will be held Friday January 12, 2001, 9 a.m. to Noon at the HEI Training Center located at Pacific Tower, Room 805, 1001 Bishop Street, Honolulu, HI 96813; 1:30 p.m. to 4:30 p.m. at the Internal Revenue Service Federal Building located at 300 Ala Moana Blvd., Honolulu, HI 96813 and Saturday January 13, 2001, 8 a.m. to Noon at the Internal Revenue Service Federal Building located at 300 Ala Moana Blvd., Honolulu, HI 96813. The public is invited to make oral comments. Individual comments will be limited to 10 minutes. If you would like to have the CAP consider a written statement, please call 1-888-912-1227 or 206-220-6096, or write Judi L. Nicholas, CAP Office, 915 2nd Avenue, Room 442, Seattle, WA 98174. Due to limited conference space, notification of intent to attend the meeting must be made with Judi L. Nicholas. Ms. Nicholas can be reached at 1-888-912-1227 or 206-220-6096.

The Agenda will include the following: various IRS issue updates and reports by the CAP sub-groups.

Note: Last minute changes to the agenda are possible and could prevent effective advance notice.

Dated: December 13, 2000.

Cathy VanHorn,*Director, Citizen Advocacy Panel,
Communications and Liaison.*

[FR Doc. 00-32482 Filed 12-20-00; 8:45 am]

BILLING CODE 4830-01-U**DEPARTMENT OF THE TREASURY****Internal Revenue Service****Open Meeting of Citizen Advocacy
Panel, Midwest District****AGENCY:** Internal Revenue Service (IRS), Treasury**ACTION:** Notice.**SUMMARY:** A meeting of the Midwest Citizen Advocacy Panel will be held in Milwaukee, Wisconsin.**DATES:** The meeting will be held Thursday, January 18, 2001, and Friday, January 19, 2001.**FOR FURTHER INFORMATION CONTACT:** Sandra McQuin at 1-888-912-1227, or 414-297-1604.

SUPPLEMENTARY INFORMATION: Notice is hereby given pursuant to Section 10(a)(2) of the Federal Advisory Committee Act, 5 U.S.C. App. (1988) that an open meeting of the Citizen Advocacy Panel (CAP) will be held Thursday, January 18, 2001, from 9 a.m. to 4 p.m. and Friday, January 19, 2001, from 8 a.m. to noon at the Howard Johnson at 176 West Wisconsin Avenue, Milwaukee, WI 53203. The Citizen Advocacy Panel is soliciting public comment, ideas, and suggestions on improving customer service at the Internal Revenue Service. Written comments can be submitted to the panel by fax to (414) 297-1623, or by mail to Citizen Advocacy Panel, Mail Stop 1006 MIL, 310 West Wisconsin Avenue, Milwaukee, WI 53203-2221.

The Agenda will include the following: Reports by the CAP sub-groups, presentation of taxpayer issues by individual members, and discussion of issues.

Note: Last minute changes to the agenda are possible and could prevent effective advance notice.

Dated: December 12, 2000.

M. Cathy VanHorn,*Director, Citizen Advocacy Panel,
Communication & Liaison.*

[FR Doc. 00-32484 Filed 12-20-00; 8:45 am]

BILLING CODE 4830-01-P**DEPARTMENT OF THE TREASURY****Internal Revenue Service****Open Meeting of South Florida Citizen
Advocacy Panel****ACTION:** Notice.**SUMMARY:** An open meeting of the South Florida Citizen Advocacy Panel will be held in Sunrise, Florida.

DATES: The meeting will be held Friday, January 26, 2001 and Saturday, January 27, 2001.

FOR FURTHER INFORMATION CONTACT:

Nancy Ferree at 1-888-912-1227, or 954-423-7973.

SUPPLEMENTARY INFORMATION: Notice is hereby given pursuant to Section 10(a)(2) of the Federal Advisory Committee Act, 5 U.S.C. app. (1988) that an open meeting of the Citizen Advocacy Panel will be held Friday, January 26, 2001 from 6 pm to 9 pm and Saturday, January 27, 2001 from 9 am to 12 pm, in Room 225, CAP Office, 7771 W. Oakland Park Blvd., Sunrise, Florida 33351. The public is invited to make oral comments. Individual comments will be limited to 10 minutes. If you would like to have the CAP consider a written statement, please call 1-800-912-1226 or 954-423-7973, or write Nancy Ferree, CAP Office, 7771 W. Oakland Park Blvd., Rm 225, Sunrise, FL 33351. Due to limited conference space, notification of intent to attend the meeting must be made with Nancy Ferree. Ms. Ferree can be reached at 1-800-912-1227 or 954-423-7973.

The agenda will include the following: various IRS issue updates and reports by the CAP sub-groups.

Note: Last minute changes to the agenda are possible and could prevent effective advance notice.

Dated: December 12, 2000.

Cathy VanHorn,

*Director, Citizen Advocacy Panel,
Communications, and Liaison.*

[FR Doc. 00-32485 Filed 12-20-00; 8:45 am]

BILLING CODE 4830-01-M

DEPARTMENT OF THE TREASURY

Internal Revenue Service

Open Meeting of Citizen Advocacy Panel, Brooklyn District

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Notice.

SUMMARY: An open meeting of the Brooklyn District Citizen Advocacy Panel will be held in Brooklyn, New York.

DATES: The meeting will be held Thursday, January 18, 2001.

FOR FURTHER INFORMATION CONTACT:

Eileen Cain at 1-888-912-1227 or 718-488-3555.

SUPPLEMENTARY INFORMATION: Notice is hereby given pursuant to section 10(a)(2) of the Federal Advisory

Committee Act, 5 U.S.C. App. (1988) that an operational meeting of the Citizen Advocacy Panel will be held Thursday, January 18, 2001 6 p.m. to 9:20 p.m. at the Internal Revenue Service Brooklyn Building located at 625 Fulton Street, Brooklyn, NY 11201. For more information or to confirm attendance, notification of intent to attend the meeting must be made with Eileen Cain. Mrs. Cain can be reached at 1-888-912-1227 or 718-488-3555. The public is invited to make oral comments from 8:30 p.m. to 9:20 p.m. on Thursday, January 18, 2001.

Individual comments will be limited to 5 minutes. If you would like to have the CAP consider a written statement, please call 1-888-912-1227 or 718-488-3555, or write Eileen Cain, CAP Office, P.O. Box R, Brooklyn, NY, 11201. The Agenda will include the following: various IRS issues.

Note: Last minute changes to the agenda are possible and could prevent effective advance notice.

Dated: December 12, 2000.

M. Cathy VanHorn,

*Director, Citizen Advocacy Panel,
Communication & Liaison.*

[FR Doc. 00-32486 Filed 12-20-00; 8:45 am]

BILLING CODE 4830-01-P

Corrections

Federal Register

Vol. 65, No. 246

Thursday, December 21, 2000

This section of the FEDERAL REGISTER contains editorial corrections of previously published Presidential, Rule, Proposed Rule, and Notice documents. These corrections are prepared by the Office of the Federal Register. Agency prepared corrections are issued as signed documents and appear in the appropriate document categories elsewhere in the issue.

COMMODITY FUTURES TRADING COMMISSION

17 CFR Part 1

RIN 3038-AB55

A New Regulatory Framework for Multilateral Transaction Execution Facilities, Intermediaries and Clearing Organizations

Correction

In rule document 00-30267 beginning on page 77962 in the issue of Wednesday, December 13, 2000, make the following correction:

§§1.43, 1.45 and 1.50 [Corrected]

On page 77979, in the second column, in amendatory instruction 4., after “are” remove “proposed to be”.

[FR Doc. C0-30267 Filed 12-20-00; 8:45 am]

BILLING CODE 1505-01-D

CORPORATION FOR NATIONAL AND COMMUNITY SERVICE

Availability of Funds for National Service-Learning Clearinghouse

Correction

In notice document 00-31534 beginning on page 77595, in the issue of Tuesday, December 12, 2000, make the following correction:

On page 77597, in the second column, in the second full paragraph, in the last line, “ <http://umn.edu/serve>.” should read “ <http://umn.edu/~serve>.”.

[FR Doc. C0-31534 Filed 12-20-00; 8:45 am]

BILLING CODE 1505-01-D

DEPARTMENT OF LABOR

Pension and Welfare Benefits Administration

Prohibited Transaction Exemption 2000-63; [Exemption Application No. D-10651, et al.] Grant of Individual Exemptions; Merrill Lynch & Co., Inc. (ML&Co.)

Correction

In notice document 00-31018, beginning on page 76306, in the issue of Wednesday, December 6, 2000, make the following correction:

On page 76308, in the third column, under the heading **FOR FURTHER**

INFORMATION CONTACT:, in the 10th line, “ 2000-64” should read “2000-65”.

[FR Doc. C0-31018 Filed 12-20-00; 8:45 am]

BILLING CODE 1505-01-D

DEPARTMENT OF THE TREASURY

Customs Service

19 CFR Parts 12 and 113

[T.D. 00-87]

RIN 1515-AC43

Amended Bond Procedures for Articles Subject to an Exclusion Order Issued by the U.S. International Trade Commission

Correction

In rule document 00-31699 beginning on page 77813 in the issue of Wednesday, December 13, 2000, make the following correction:

§12.39 [Corrected]

1. On page 77815, in the third column, in §12.39(b)(2), in the fourth line, remove “9”.

Appendix B to Part 113 [Corrected]

2. On page 77816, in the first column, in appendix B to part 113, in the third line, remove “11”.

[FR Doc. C0-31699 Filed 12-20-00; 8:45 am]

BILLING CODE 1505-01-D



Federal Register

**Thursday,
December 21, 2000**

Part II

Architectural and Transportation Barriers Compliance Board

36 CFR Part 1194

**Electronic and Information Technology
Accessibility Standards; Final Rule**

ARCHITECTURAL AND TRANSPORTATION BARRIERS COMPLIANCE BOARD

36 CFR Part 1194

[Docket No. 2000-01]

RIN 3014-AA25

Electronic and Information Technology Accessibility Standards

AGENCY: Architectural and
Transportation Barriers Compliance
Board.

ACTION: Final rule.

SUMMARY: The Architectural and Transportation Barriers Compliance Board (Access Board) is issuing final accessibility standards for electronic and information technology covered by section 508 of the Rehabilitation Act Amendments of 1998. Section 508 requires the Access Board to publish standards setting forth a definition of electronic and information technology and the technical and functional performance criteria necessary for such technology to comply with section 508. Section 508 requires that when Federal agencies develop, procure, maintain, or use electronic and information technology, they shall ensure that the electronic and information technology allows Federal employees with disabilities to have access to and use of information and data that is comparable to the access to and use of information and data by Federal employees who are not individuals with disabilities, unless an undue burden would be imposed on the agency. Section 508 also requires that individuals with disabilities, who are members of the public seeking information or services from a Federal agency, have access to and use of information and data that is comparable to that provided to the public who are not individuals with disabilities, unless an undue burden would be imposed on the agency.

DATES: *Effective Date:* February 20, 2001.

FOR FURTHER INFORMATION CONTACT:
Doug Wakefield, Office of Technical and
Information Services, Architectural and
Transportation Barriers Compliance
Board, 1331 F Street, NW., suite 1000,
Washington, DC 20004-1111.
Telephone number (202) 272-5434
extension 139 (voice); (202) 272-5449
(TTY). Electronic mail address:
wakefield@access-board.gov.

SUPPLEMENTARY INFORMATION:

Availability of Copies and Electronic Access

Single copies of this publication may be obtained at no cost by calling the Access Board's automated publications order line (202) 272-5434, by pressing 2 on the telephone keypad, then 1, and requesting publication S-40 (Electronic and Information Technology Accessibility Standards Final Rule). Persons using a TTY should call (202) 272-5449. Please record a name, address, telephone number and request publication S-40. This document is available in alternate formats upon request. Persons who want a copy in an alternate format should specify the type of format (cassette tape, Braille, large print, or computer disk). This document is also available on the Board's Internet site (<http://www.access-board.gov/sec508/508standards.htm>).

Background

On August 7, 1998, the President signed into law the Workforce Investment Act of 1998, which includes the Rehabilitation Act Amendments of 1998. Section 508 of the Rehabilitation Act Amendments, as amended by the Workforce Investment Act of 1998, requires that when Federal agencies develop, procure, maintain, or use electronic and information technology, they shall ensure that the electronic and information technology allows Federal employees with disabilities to have access to and use of information and data that is comparable to the access to and use of information and data by Federal employees who are not individuals with disabilities, unless an undue burden would be imposed on the agency.¹ Section 508 also requires that individuals with disabilities, who are members of the public seeking information or services from a Federal agency, have access to and use of information and data that is comparable to that provided to the public who are not individuals with disabilities.

Section 508(a)(2)(A) requires the Architectural and Transportation Barriers Compliance Board (Access Board)² to publish standards setting

¹ Section 508 does not apply to national security systems, as that term is defined in section 5142 of the Clinger-Cohen Act of 1996 (40 U.S.C. 1452).

² The Access Board is an independent Federal agency established by section 502 of the Rehabilitation Act (29 U.S.C. 792) whose primary mission is to promote accessibility for individuals with disabilities. The Access Board consists of 25 members. Thirteen are appointed by the President from among the public, a majority of who are required to be individuals with disabilities. The other twelve are heads of the following Federal agencies or their designees whose positions are

forth a definition of electronic and information technology and the technical and functional performance criteria necessary for accessibility for such technology. If an agency determines that meeting the standards, when procuring electronic and information technology, imposes an undue burden, it must explain why meeting the standards creates an undue burden.

On March 31, 2000, the Access Board issued a notice of proposed rulemaking (NPRM) in the **Federal Register** (65 FR 17346) proposing standards for accessible electronic and information technology. The proposed standards were based on recommendations of the Electronic and Information Technology Access Advisory Committee (EITAAC). The EITAAC was convened by the Access Board in September 1998 to assist the Board in fulfilling its mandate under section 508. It was composed of 27 members including representatives of the electronic and information technology industry, organizations representing the access needs of individuals with disabilities, and other persons affected by accessibility standards for electronic and information technology. Representatives of Federal agencies, including the departments of Commerce, Defense, Education, Justice, Veterans Affairs, the Federal Communications Commission, and the General Services Administration, served as ex-officio members or observers of the EITAAC.

The public comment period for the proposed rule ended on May 30, 2000. Over 100 individuals and organizations submitted comments on the proposed standards. Comments were submitted by Federal agencies, representatives of the information technology industry, disability groups, and persons with disabilities. Approximately 35 percent of the comments came from Federal agencies. Fifteen percent came from individual companies and industry trade associations. Approximately 30 percent of the comments were from individuals with disabilities and organizations representing persons with disabilities. Eight states responded to the proposed rule and the remaining comments were from educational or research organizations.

The proposed standards covered various products, including computers, software, and electronic office

Executive Level IV or above: The departments of Health and Human Services, Education, Transportation, Housing and Urban Development, Labor, Interior, Defense, Justice, Veterans Affairs, and Commerce; the General Services Administration; and the United States Postal Service.

equipment in the Federal sector. They provided technical criteria specific to various types of technologies and performance-based requirements, which focus on the functional capabilities of covered technologies. Specific criteria covered controls, keyboards, and keypads; software applications and operating systems (non-embedded); web-based information or applications; telecommunications functions; video or multi-media products; and information kiosks and transaction machines. Also covered was compatibility with adaptive equipment that people with disabilities commonly use for information and communication access.

General Issues

This section of the preamble addresses general issues raised by comments filed in response to the NPRM. Individual provisions of the rule are discussed in detail under the Section-by-Section Analysis below.

Effective Date for the Enforcement of Section 508

Section 508(a)(2)(A) required the Board to publish final standards for accessible electronic and information technology by February 7, 2000. Section 508(a)(3) provides that within six months after the Board publishes its standards, the Federal Acquisition Regulatory Council is required to revise the Federal Acquisition Regulation (FAR), and each Federal agency is required to revise the Federal procurement policies and directives under its control to incorporate the Board's standards.³

Because of the delay in publishing the standards, the proposed rule sought comment on making the standards effective six months after publication in the **Federal Register** to provide Federal agencies an opportunity to more fully understand the new standards and allow manufacturers of electronic and information technology time to ensure that their products comply with the standards before enforcement actions could be initiated. The NPRM noted that postponing the effective date of the Board's standards could not affect the right of individuals with disabilities to file complaints for electronic and information technology procured after August 7, 2000 since that right was established by the statute.

Comment. There was a general consensus that a delay in the effective

date of the standards was warranted to provide a reasonable period of time for industry to bring their products into compliance with the Board's standards.

Response. On July 13, 2000, President Clinton signed into law the Military Construction Appropriations Act for Fiscal Year 2001 (Public Law 106-246) which included an amendment to section 508 of the Rehabilitation Act. Under the amendment, the effective date for the enforcement of section 508 was delayed to allow for additional time for compliance with the Board's final standards. As originally written, the enforcement provisions of section 508 would have taken effect on August 7, 2000. The amendment in Public Law 106-246 revises the enforcement date to 6 months from publication of the Board's final standards, consistent with the law's intent. As a result of the amendment, there is no need to delay the effective date of the standards. The effective date for the standards is largely an administrative provision and does not affect the date by which complaints may be filed under section 508. Complaints and lawsuits may be filed 6 months from the date of publication of these standards in the **Federal Register**.

Technical and Functional Performance Criteria

Section 508 (a)(2)(A)(ii) requires the Board to develop technical and functional performance criteria necessary to implement the requirements of section 508.

Comment. The Information Technology Association of America (ITAA) commented that the specificity of many of the proposed provisions go beyond what may be characterized as technical and functional performance criteria. ITAA commented that the statute intended that the standards be set forth in terms of technical and functional performance criteria as opposed to technical design requirements. Performance criteria are intended to give discretion in achieving the required end result. ITAA commented that product developers, who have a broad understanding of their own products, industry standards, and future trends need this discretion to meet the requirements of section 508 and that it is impossible to predict accurately future technological advances. Design requirements, they added, inhibit development and innovation. ITAA was concerned that many of the proposed provisions would impede technological advancements because they were too specific. On the other hand, ITAA supported proposed § 1194.5, Equivalent Facilitation,

because it would lessen the adverse impact of the specific requirements.

Response. According to administration policy, performance standards are generally to be preferred to engineering or design standards because performance standards provide the regulated parties the flexibility to achieve the regulatory objective in a more cost-effective way. The Board was given the responsibility to develop technical and functional performance criteria necessary to implement the requirements of section 508. Thus, the standards provide technical requirements as well as functional performance criteria. The standards reflect the need to be as descriptive as possible because procurement officials and others need to know when compliance with section 508 has been achieved and because the failure to meet the standards can result in an enforcement action. Several provisions, such as those regarding time-out features, have been revised in the final rule to be more performance oriented rather than specific design standards.

Section-by-Section Analysis

This section of the preamble summarizes each of the provisions of the final rule and the comments received in response to the proposed rule. Where the provision in the final rule differs from that of the proposed rule, an explanation of the modification is provided. The text of the final rule follows this section.

Subpart A—General

Section 1194.1 Purpose

This section describes the purpose of the standards which is to implement section 508 of the Rehabilitation Act of 1973, as amended by the Workforce Investment Act of 1998. No substantive comments were received and no changes have been made to this section in the final rule.

Section 1194.2 Application

This section specifies what electronic and information technology is covered by the standards. Electronic and information technology covered by section 508 must comply with each of the relevant sections of this part. For example, a computer and its software programs would be required to comply with § 1194.26, Desktop and portable computers, § 1194.21, Software applications and operating systems, and the functional performance criteria in § 1194.31. Paragraph (a) states the general statutory requirement for electronic and information technology that must comply with the standards

³ Whenever the Access Board revises its standards, the Federal Acquisition Regulatory Council is required to revise the FAR, and each appropriate Federal agency is required to revise its procurement policies and directives within six months to incorporate the revisions.

unless doing so would result in an undue burden. The term "undue burden" is defined at § 1194.4 (Definitions) and is discussed in the preamble under that section.

Paragraph (a)(1) states the statutory obligation of a Federal agency to make information and data available by an alternative means when complying with the standards would result in an undue burden. For example, a Federal agency wishes to purchase a computer program that generates maps denoting regional demographics. If the agency determines that it would constitute an undue burden to purchase an accessible version of such a program, the agency would be required to make the information provided by the program available in an alternative means to users with disabilities. In addition, the requirements to make reasonable accommodations for the needs of an employee with a disability under section 501 and to provide overall program accessibility under section 504 of the Rehabilitation Act also apply.

Comment. The National Federation of the Blind (NFB) suggested that additional language be added that would require agencies to provide information by an alternative means at the same time the information and data are made available to others.

Response. This paragraph restates the general statutory requirement to provide an alternative means of providing an individual the use of the information and data. Providing individuals with information and data by an alternative means necessarily requires flexibility and will generally be dealt with on a case-by-case approach. Although, the Board agrees that information provided by an alternative means should be provided at generally the same time as the information is made available to others, the provision provides the needed flexibility to ensure that agencies can make case-by-case decisions. No substantive changes were made in the final rule.

Paragraph (a)(2) sets forth the statutory requirement for an agency to document any claim of undue burden in a procurement. Such documentation must explain in detail which provision or provisions of this rule impose an undue burden and the extent of such a burden. The agency should discuss each of the factors considered in its undue burden analysis.

Comment. The General Services Administration was concerned that this provision was too limiting because it only referred to products which are procured by the Federal Government and did not include products which are developed, maintained, or used. The

American Council of the Blind (ACB) recommended that the requirement for documentation apply when agencies claim the lack of commercially available accessible equipment or software. The NFB commented that there should be a requirement for agencies to explain the specific alternate means to be used to provide information or data. Without such a requirement, they argued, persons with disabilities must be knowledgeable enough to inquire about an alternate means after first discovering that the product used for the information and data is not accessible. Although agencies would be expected to know in advance when products will not be accessible, persons with disabilities will not have this information until encountering the problem.

Response. Paragraph (a)(2) addresses the documentation of undue burden. By statute, the requirement to document an undue burden applies only to procurements. This rule does not prescribe the needed documentation of a finding of an undue burden but merely restates the statutory requirement that a finding be documented. The FAR is expected to address the needed documentation. No substantive changes have been made in the final rule.

Paragraph (b) states that procurement of products complying with this part is subject to commercial availability. The concept of commercial availability is based on existing provisions in the FAR (see 48 CFR 2.101, Definitions of Words and Terms: Commercial item).

The proposed rule provided that the standards applied to products which were available in the commercial marketplace; would be available in time to meet an agency's delivery requirements through advances in technology or performance; or were developed in response to a Government solicitation. As noted in the preamble, this language was derived from the definition for "commercial item" in the FAR cited above. The preamble to the proposed rule stated that the determination of commercial availability is to be applied on a provision by provision basis.

Comment. A number of commenters sought further clarification of this provision. Several commenters from the information technology industry and some Federal agencies were concerned that the concept of what is commercially available was more appropriately within the jurisdiction of the Federal Acquisition Regulatory Council. The American Foundation for the Blind (AFB) and the ACB wanted agencies to document their determination that a product was not

commercially available similar to what is required under undue burden. The ITAA commented that commercial availability should not be applied on a provision by provision basis.

Response. The Board agrees that the FAR is the appropriate venue for addressing commercial availability. The Board believes that the concept of commercial availability is captured in the FAR definition of "commercial item".

With respect to documentation, Federal agencies may choose to document a determination that a product is not available in the commercial marketplace in anticipation of a subsequent inquiry. However, such documentation is not required by section 508.

Similar to an undue burden analysis, agencies cannot claim that a product as a whole is not commercially available because no product in the marketplace meets all the standards. If products are commercially available that meet some but not all of the standards, the agency must procure the product that best meets the standards. The final rule has been modified to clarify this application.

Paragraph (c) applies this rule to electronic and information technology developed, procured, maintained, or used by an agency directly or used by a contractor pursuant to a contract with an agency.

Comment. The ITAA commented that this provision conflicts with section 508. For example, they commented that if a contract required a vendor to purchase and maintain a specific computer system for the purpose of gathering and relaying certain data to an agency, the standards would apply to such a computer system even if the system would be used only by vendor employees. In addition, ITAA commented that this is not a technical and functional performance criterion, and should be addressed by the FAR.

Response. Consistent with section 5002(3)(C) of the Clinger-Cohen Act of 1996 (40 U.S.C. 1452) and as further discussed in section 1194.3(b) below, products used by a contractor which are incidental to a contract are not covered by this rule. For example, a Federal agency enters into a contract to have a web site developed for the agency. The contractor uses its own office system to develop the web site. The web site is required to comply with this rule since the web site is the purpose of the contract, however, the contractor's office system does not have to comply with these standards, since the equipment used to produce the web site is incidental to the contract. See section

1194.3(b) below. No changes were made to this provision in the final rule.

Section 1194.3 General Exceptions

This section provides general exceptions from the standards. Paragraph (a) provides an exception for telecommunications or information systems operated by agencies, the function, operation, or use of which involves intelligence activities, cryptologic activities related to national security, command and control of military forces, equipment that is an integral part of a weapon or weapons system, or systems which are critical to the direct fulfillment of military or intelligence missions. This exception is statutory under section 508 and is consistent with a similar exception in section 5142 of the Clinger-Cohen Act of 1996. This exception does not apply to a system that is to be used for routine administrative and business applications (including payroll, finance, logistics, and personnel management applications). For example, software used for payroll, word processing software used for production of routine documents, ordinary telephones, copiers, fax machines, and web applications must still comply with the standards even if they are developed, procured, maintained, or used by an agency engaged in intelligence or military activities. The Board understands that the Department of Defense interprets this to mean that a computer designed to provide early missile launch detection would not be subject to these standards, nor would administrative or business systems that must be architecturally tightly coupled with a mission critical, national security system, to ensure interoperability and mission accomplishment. No substantive comments were received and no changes have been made to this section in the final rule.

Paragraph (b) provides an exception for electronic and information technology that is acquired by a contractor incidental to a Federal contract. That is, the products a contractor develops, procures, maintains, or uses which are not specified as part of a contract with a Federal agency are not required to comply with this part. For example, a consulting firm that enters into a contract with a Federal agency to produce a report is not required to procure accessible computers and word processing software to produce the report regardless of whether those products were used exclusively for the government contract or used on both government and non-government related activities since the purpose of

the contract was to procure a report. Similarly, if a firm is contracted to develop a web site for a Federal agency, the web site created must be fully compliant with this part, but the firm's own web site would not be covered. No substantive comments were received and no changes have been made to this section in the final rule.

Paragraph (c) clarifies that, except as required to comply with these standards, this part does not require the installation of specific accessibility-related software or the attachment of an assistive technology device at a workstation of a Federal employee who is not an individual with a disability. Specific accessibility related software means software which has the sole function of increasing accessibility for persons with disabilities to other software programs (e.g., screen magnification software). The purpose of section 508 and these standards is to build as much accessibility as is reasonably possible into general products developed, procured, maintained, or used by agencies. It is not expected that every computer will be equipped with a refreshable Braille display, or that every software program will have a built-in screen reader. Such assistive technology may be required as part of a reasonable accommodation for an employee with a disability or to provide program accessibility. To the extent that such technology is necessary, products covered by this part must not interfere with the operation of the assistive technology. No substantive comments were received and no changes have been made to this section in the final rule.

Paragraph (d) specifies that when agencies provide access to information or data to the public through electronic and information technology, agencies are not required to make equipment owned by the agency available for access and use by individuals with disabilities at a location other than that where the electronic and information technology is provided to the public, or to purchase equipment for access and use by individuals with disabilities at a location other than that where the electronic and information technology is provided to the public. For example, if an agency provides an information kiosk in a Post Office, a means to access the kiosk information for a person with a disability need not be provided in any location other than at the kiosk itself.

Comment. The ACB commented that where a location is not accessible, an agency must provide the information in a location that is accessible to people with disabilities.

Response. This paragraph restates the general statutory requirement that when agencies provide access to information or data to the public through electronic and information technology, the agencies are not required to make equipment owned by the agency available for access and use by individuals with disabilities at a location other than that where the electronic and information technology is provided to the public, or to purchase equipment for access and use by individuals with disabilities at a location other than that where the electronic and information technology is provided to the public. The accessibility of the location would be addressed under section 504 of the Rehabilitation Act or other Federal laws. No substantive changes were made in the final rule.

Paragraph (e) states that compliance with this part does not require a fundamental alteration in the nature of a product or service or its components.

Comment. The AFB commented that fundamental alteration is not an appropriate factor to include in this rule since the statute provides undue burden as the proper protection and allowing a fundamental alteration exemption weakens the intent of the statute and its high expectations of government. If the concept of fundamental alteration is maintained, AFB recommended that it be part of an explanation of undue burden. The Department of Commerce agreed that the inclusion of a fundamental alteration exception would negate the purpose of section 508. The Trace Research and Development Center said that the term should be defined.

The Information Technology Industry Council (ITIC) commented that the Board should expand the concept of fundamental alteration by stating that an agency should not be required to fundamentally alter the nature of a program or service that the agency offers.

Response. Fundamental alteration is an appropriate exception for inclusion in the standards. It means a change in the fundamental characteristic or purpose of the product or service, not merely a cosmetic or aesthetic change. For example, an agency intends to procure pocket-sized pagers for field agents for a law enforcement agency. Adding a large display to a small pager may fundamentally alter the device by significantly changing its size to such an extent that it no longer meets the purpose for which it was intended, that is to provide a communication device which fits in a shirt or jacket pocket. For some of these agents, portability of electronic equipment is a paramount

concern. Generally, adding access should not change the basic purpose or characteristics of a product in a fundamental way.

Comment. The ITAA commented that telecommunications equipment switches, servers, and other similar "back office" equipment which are used for equipment maintenance and administration functions should be exempt from the standards. For example, in the case of telecommunications equipment, technicians might need to configure service databases, remove equipment panels to replace components, or run tests to verify functionality. ITAA commented that section 508 should not apply to these types of products since applying requirements to such products would have serious design and cost ramifications.

Response. The Board agrees and has provided an exception that products located in spaces frequented only by service personnel for maintenance, repair, or occasional monitoring of equipment are not required to comply with this part. This exception is consistent with a similar exception in the Board's guidelines under the Americans with Disabilities Act (ADA) (§ 4.1.1(5)(b) 36 CFR part 1191) and the Architectural Barriers Act (§ 4.1.2(5) exception, Uniform Federal Accessibility Standards Appendix A to 41 CFR part 101–19.6).

Section 1194.4 Definitions

Accessible. The term accessible was defined in the proposed rule in terms of compliance with the standards in this part, as is common with other accessibility standards. As proposed, if a product complies with the standards in this part, it is "accessible"; if it does not comply, it is not accessible.

Comment. The Trace Research and Development Center (Trace Center) and the General Services Administration commented that the proposed definition of accessible would mean that products can be declared "accessible" if they are merely compatible with assistive technology and that the definition of accessible was being used as a measure of compliance. The Trace Center commented that the problem with this approach is that a product could have few or no accessibility features because it was an undue burden and still be considered accessible.

Response. Although the term accessible was used sparingly in the proposed rule, the Board agrees that the definition may be problematic. The term as used in the proposed rule was in fact addressing products which comply with the standards. Products covered by this

part are required to comply with all applicable provisions of this part. Accordingly, the definition has been eliminated in the final rule and the term accessible is not used in the text of the final rule. A product is compliant with the requirements of section 508 of the Rehabilitation Act of 1973 (as amended by the Workforce Investment Act of 1998) by meeting all the applicable provisions of part 1194.

Agency. The term agency includes any Federal department or agency, including the United States Postal Service. No substantive comments were received regarding this definition and no changes have been made in the final rule.

Alternate formats. Certain product information is required to be made available in alternate formats to be usable by individuals with various disabilities. Consistent with the Board's Telecommunications Act Accessibility Guidelines (36 CFR part 1193), the proposed rule defined alternate formats as those formats which are usable by people with disabilities. The proposed definition noted that the formats may include Braille, ASCII text, large print, recorded audio, and accessible internet programming or coding languages, among others. ASCII refers to the American Standard Code for Information Interchange, which is an American National Standards Institute (ANSI) standard defining how computers read and write commonly used letters, numbers, punctuation marks, and other codes.

Comment. One commenter was concerned that the term "accessible internet programming or coding languages" used in the description of acceptable alternate formats was somewhat ambiguous and recommended using the term "accessible internet formats".

Response. The Board agrees that the term "accessible internet programming or coding languages" may be vague. In addition, as noted above, the final rule will not include the term "accessible". The definition for alternate formats has been modified to refer to "electronic formats which comply with this part". This change will permit, for instance, alternate formats to include a computer file (either on the internet or saved on a computer disk) that can be viewed by a browser and which complies with the standards for web pages. No other changes have been made to the definition in the final rule.

Alternate methods. The proposed rule used the term "alternate modes" which was defined as different means of providing information to users of products, including product

documentation, such as voice, fax, relay service, TTY, internet posting, captioning, text-to-speech synthesis, and audio description.

Comment. One commenter suggested that "alternate methods" would be a better term to describe the different means of providing information. The commenter was concerned that the term alternate modes would be confused with alternate modes of operation of the product itself which does not necessarily refer to how the information is provided.

Response. The Board agrees that the term alternate methods is a more descriptive and less confusing term than the term alternate modes. Other than the change in terminology from alternate modes to alternate methods, no other changes have been made to the definition in the final rule.

Assistive technology. Assistive technology is defined as any item, piece of equipment, or system, whether acquired commercially, modified, or customized, that is commonly used to increase, maintain, or improve functional capabilities of individuals with disabilities. The definition was derived from the definition of assistive technology in the Assistive Technology Act of 1998 (29 U.S.C. 3002). The preamble to the proposed rule noted that assistive technology may include screen readers which allow persons who cannot see a visual display to either hear screen content or read the content in Braille, specialized one-handed keyboards which allow an individual to operate a computer with only one hand, and specialized audio amplifiers that allow persons with limited hearing to receive an enhanced audio signal. No substantive comments were received regarding this definition and no changes have been made in the final rule.

Electronic and information technology. This is the statutory term for the products covered by the standards in this part. The statute explicitly required the Board to define this term, and required the definition to be consistent with the definition of information technology in the Clinger-Cohen Act of 1996. The Board's proposed definition of information technology was identical to that in the Clinger-Cohen Act. Electronic and information technology was defined in the proposed rule to include information technology, as well as any equipment or interconnected system or subsystem of equipment, that is used in the creation, conversion, or duplication of data or information.

Information technology includes computers, ancillary equipment, software, firmware and similar

procedures, services (including support services), and related resources. Electronic and information technology includes information technology products like those listed above as well as telecommunications products (such as telephones), information kiosks and transaction machines, World Wide Web sites, multimedia, and office equipment such as copiers, and fax machines.

Consistent with the FAR,⁴ the Board proposed that electronic and information technology not include any equipment that contains embedded information technology that is used as an integral part of the product, but the principal function of which is not the acquisition, storage, manipulation, management, movement, control, display, switching, interchange, transmission, or reception of data or information. For example, HVAC (heating, ventilation, and air conditioning) equipment such as thermostats or temperature control devices, and medical equipment where information technology is integral to its operation, are not information technology.

Comment. Several commenters recommended that the exception for HVAC control devices and medical equipment be revised in the final rule. The commenters were concerned that the exception was too broad in that it exempted equipment such as medical diagnostic equipment that they felt should be covered by the rule. In addition, the National Association of the Deaf (NAD) requested that public address systems, alarm systems, and two-way communications systems such as intercoms be expressly included as electronic and information technology.

Response. The exemption is consistent with existing definitions for information technology in the FAR. Public address systems, alarm systems, and two-way communications systems are already addressed by the Americans with Disabilities Act Accessibility Guidelines and will be addressed in more detail in the Board's guidelines under the Architectural Barriers Act which apply to Federal facilities. No changes have been made to the definition in the final rule.

Information technology. The definition of information technology is identical to that in the Clinger-Cohen Act, that is, any equipment or interconnected system or subsystem of equipment, that is used in the automatic acquisition, storage, manipulation, management, movement, control, display, switching, interchange,

transmission, or reception of data or information. Information technology includes computers, ancillary equipment, software, firmware and similar procedures, services (including support services), and related resources. No substantive comments were received regarding this definition and no changes have been made in the final rule.

Operable controls. The proposed rule defined operable controls as those components of a product that require physical contact for normal operation of the device. Examples of operable controls were provided, including on/off switches, buttons, dials and knobs, mice, keypads and other input devices, copier paper trays (both for inserting paper to be copied and retrieving finished copies), coin and card slots, card readers, and similar components. The proposed rule also clarified that operable controls do not include voice-operated controls.

Comment. One commenter was concerned that the term paper trays was confusing and interpreted it to mean the large trays on a copier which are loaded with reams of paper for copying. The commenter suggested that the term input and output trays be used instead.

Response. The Board agrees that input and output trays are more descriptive. The final rule reflects this change which is intended to apply to products in their normal operation rather than when the product may be used for maintenance, repair, or occasional monitoring. For example, a user should be able to add paper to a desktop laser printer. No other changes have been made to this definition.

Product. The term product is used in the rule as a shorthand for electronic and information technology. No substantive comments were received regarding this definition and no changes have been made in the final rule.

Self contained, closed products. This term was not used in the proposed rule and is provided in the final rule as a result of the reorganization of the standards. Self contained, closed products, are those that generally have embedded software and are commonly designed in such a fashion that a user cannot easily attach or install assistive technology. These products include, but are not limited to, information kiosks and information transaction machines, copiers, printers, calculators, fax machines, and other similar types of products.

Telecommunications. The definition for telecommunications is consistent with the definition in the Board's Telecommunications Act Accessibility Guidelines and the definition of telecommunications in the

Telecommunications Act. No substantive comments were received regarding this definition and no changes have been made in the final rule.

TTY. TTYS are machinery or equipment that employ interactive text based communications through the transmission of coded signals across the telephone network.

Comment. The Trace Center recommended adding the word "baudot" to the definition of TTY to clarify that the term is not meant to be broader than baudot TTYS. The NAD and other consumer groups, however, supported the Board's definition and encouraged the Board to use the same definition consistently.

Response. The definition for the term TTY is consistent with the definition of TTY in the Board's ADA Accessibility Guidelines and Telecommunications Act Accessibility Guidelines. No changes have been made to the definition in the final rule.

Undue burden. The final rule defines the term undue burden as "significant difficulty or expense." In determining what is a significant difficulty or expense, each agency must consider the resources available to the program or component for which the product is being developed, maintained, used or procured. The proposed rule defined undue burden as an action that would result in significant difficulty or expense considering all agency resources available to the agency or component. The Board sought comment in the NPRM on two additional factors (identified as factor (2) and factor (3) in the preamble) for agencies to consider in assessing a determination of an undue burden. Factor (2) addressed the compatibility of an accessible product with the agency's or component's infrastructure, including security, and the difficulty of integrating the accessible product. Factor (3) concerned the functionality needed from the product and the technical difficulty involved in making the product accessible.

Comment. The ITAA, ITIC and the Oracle Corporation opposed the inclusion of a definition for undue burden in the final rule. Both the ITAA and the ITIC commented that defining undue burden was beyond the Board's authority. Oracle suggested that the concept of undue burden under section 508 was beyond the Board's expertise in that it was a procurement matter. The commenters were also concerned that the Board's definition was too narrow. Alternatively, if the Board was to adopt a definition for undue burden, the ITAA favored adoption of the factors associated with undue burden and

⁴ 48 CFR Chapter 1, part 2, § 2.101 Definitions Information Technology (c).

undue hardship in the ADA and section 504 of the Rehabilitation Act. In particular, the ITAA recommended adoption of the "nature and cost" of the accommodation as a factor for consideration. ITIC favored adoption of the employment factors in title I of the ADA if the Board were to include a definition of undue burden. Both the ITAA and the ITIC also favored the adoption of factors (2) and (3) identified in the NPRM if undue burden was to be addressed in the final rule.

The remainder and majority of the commenters did not address the issue of whether the Board should adopt a definition of undue burden, but rather how to define it. At least two Federal agencies and 10 organizations representing persons with disabilities opposed the inclusion of factors (2) and (3) suggested in the NPRM. The Department of Commerce and a majority of advocacy organizations representing people with disabilities opposed factors (2) and (3) on the grounds that the factors would create a loophole for agencies to avoid compliance with section 508. The Department of Veterans Affairs opposed factor (3) as it considered that factor to be more about job assignment than undue burden. Several commenters including Sun Microsystems and Adobe Systems favored adopting factors (2) and (3) in the definition of undue burden. The Social Security Administration (SSA) and the Department of Health and Human Services, Administration for Children and Families, sought guidance as to the amount of increased cost of a product that would not constitute undue burden regardless of an agency's overall budget. Citing the example of a product that would cost 25 percent more to comply with the standards, the SSA questioned whether that would be undue or would 10 percent or 50 percent be considered undue. The General Services Administration recommended basing the financial resources available to an agency on a program basis.

Response. The term undue burden is based on caselaw interpreting section 504 of the Rehabilitation Act (*Southeastern Community College v. Davis*, 442 U.S. 397 (1979)), and has been included in agency regulations issued under section 504 since the *Davis* case. See, e.g., 28 CFR 39.150. The term undue burden is also used in Title III of the ADA, 42 U.S.C. 12182(b)(2)(A)(iii). The legislative history of the ADA states that the term undue burden is derived from section 504 and the regulations thereunder, and is analogous to the term "undue hardship" in Title I of the ADA, which Congress defined as "an action

requiring significant difficulty or expense." 42 U.S.C. 12111(10)(A). See, H. Rept. 101-485, pt. 2, at 106. In the NPRM, the Board proposed adoption of "significant difficulty or expense" as the definition for undue burden. No changes were made to that aspect of the definition in the final rule.

Title I of the ADA lists factors to be considered in determining whether a particular action would result in an undue hardship. 42 U.S.C. 12111(10)(B)(i)-(iv). However, since title I of the ADA addresses employment and the individual accommodation of employees, not all of the factors are directly applicable to section 508 except for the financial resources of the covered facility or entity which is necessary to a determination of "significant difficulty or expense." Unlike title I, section 508 requires that agencies must procure accessible electronic and information technology regardless of whether they have employees with disabilities. Requiring agencies to purchase accessible products at the outset eliminates the need for expensive retrofitting of an existing product when requested by an employee or member of the public as a reasonable accommodation at a later time.

In determining whether a particular action is an undue burden under section 508, the proposed rule provided that the resources "available" to an "agency or component" for which the product is being developed, procured, maintained, or used is an appropriate factor to consider. The language was derived from the section 504 federally conducted regulations. Those regulations limited the consideration of resources to those resources available to a "program". The preamble to the proposed rule noted that an agency's entire budget may not be available for purposes of complying with section 508. Many parts of agency budgets are authorized for specific purposes and are thus not available to other programs or components within the agency. The definition of undue burden has been clarified in the final rule to more clearly reflect this limitation. The provision now states that "agency resources available to a program or component" are to be considered in determining whether an action is an undue burden. Because available financial resources vary greatly from one agency to another, what constitutes an undue burden for a smaller agency may not be an undue burden for another, larger agency having more resources to commit to a particular procurement. Each procurement would necessarily be determined on a case-by-case basis. Because a determination of

whether an action would constitute an undue burden is made on a case-by-case basis, it would be inappropriate for the Board to assess a set percentage for the increased cost of a product that would be considered an undue burden in every case.

The Board has not included factors (2) and (3) in the text of the final rule. While the Board acknowledges that these may be appropriate factors for consideration by an agency in determining whether an action is an undue burden, factors (2) and (3) were not based on established caselaw or existing regulations under section 504. Further, the Board recognizes that undue burden is determined on a case-by-case basis and that factors (2) and (3) may not apply in every determination. Agencies are not required to consider these factors and may consider other appropriate factors in their undue burden analyses.

Comment. Adobe Systems questioned whether a product which does not meet a provision based on a finding of undue burden, has to comply with the remaining provisions.

Response. The undue burden analysis is applied on a provision by provision basis. A separate undue burden analysis must be conducted and, in the case of procurements, be documented for each applicable provision.

Section 1194.5 Equivalent Facilitation

This section allows the use of designs or technologies as alternatives to those prescribed in this part provided that they result in substantially equivalent or greater access to and use of a product for people with disabilities. This provision is not a "waiver" or "variance" from the requirement to provide accessibility, but a recognition that future technologies may be developed, or existing technologies could be used in a particular way, that could provide the same functional access in ways not envisioned by these standards. In evaluating whether a technology results in "substantially equivalent or greater access," it is the functional outcome, not the form, which is important. For example, an information kiosk which is not accessible to a person who is blind might be made accessible by having a telephone handset that connects to a computer that responds to touch-tone commands and delivers the same information audibly. In addition, voice recognition and activation are progressing rapidly so that voice input soon may become a reasonable substitute for some or all keyboard input functions. For example, already some telephones can be dialed by voice. In effect, compliance with the performance

criteria of § 1194.31 is the test for equivalent facilitation.

Comment. Commenters supported the Board in its recognition that accessibility may sometimes be attained through products that do not strictly comply with design standards. Several commenters supported this concept because they believed that it will result in the development of better access solutions for individuals with disabilities.

Response. No changes have been made to this provision in the final rule.

Subpart B—Technical Standards (Formerly Subpart B—Accessibility Standards in the NPRM)

Comment. Subpart B of the proposed rule contained four sections: § 1194.21 (General Requirements); § 1194.23 (Component Specific Standards); § 1194.25 Standards for Compatibility; and § 1194.27 (Functional Performance Criteria). The Board sought comment in the proposed rule on the organization of Subpart B in general and § 1194.21 (General Requirements), § 1194.23 (Component Specific Requirements) and § 1194.25 (Requirements for Compatibility) in particular. A number of commenters found the application of the proposed rule to be confusing due to the manner in which the rule was organized. Commenters questioned whether a specific product need only comply with the provisions under a specific heading in § 1194.23 (Component Specific Requirements) or whether they must also look to the provisions in § 1194.21 (General Requirements), as well as § 1194.25 (Compatibility). Commenters further questioned whether multiple provisions within a specific section would apply. For example, making electronic forms accessible was addressed under § 1194.23(b) (Non-embedded software applications and operating systems). Provisions for web sites were addressed separately in § 1194.23(c) (Web-based information or applications). Since electronic forms are becoming very popular on web sites, the commenters questioned whether the provisions for electronic forms under the software section should also be applied to web sites even though the section on web sites did not specifically address electronic forms. Another commenter pointed out that some provisions under § 1194.21 (General Requirements) actually addressed specific components such as touch screens, which were addressed under General Requirements in the proposed rule. Finally, other commenters noted that several provisions under § 1194.23 (Component Specific Requirements) were really

compatibility concerns, such as § 1194.23(b) (Non-embedded software).

Response. A product must comply with the provisions under each applicable section in Subpart B. For example, a telecommunications product that has computer, software and operating systems, a keyboard, and web browser will have to comply with each of the relevant sections in Subpart B. The Board has reorganized Subpart B in the final rule as follows:

The title of Subpart B has been changed from “Accessibility Standards” to “Technical Standards”.

Subpart B has been reorganized so that each section addresses specific products. For example, § 1194.21 addresses software applications, § 1194.22 addresses web-based intranet and internet information and applications, and so on. Each technical provision that applies to a product is located under that product heading. As a result, there is some redundancy in this section. However, the Board believes that this format will help clarify the application of the standards for each type of product. For example, the provision prohibiting the use of color alone to indicate an action applies not only to web page design, but also to software design and certain operating systems. In the final rule, it is addressed in § 1194.21(i) (Software applications and operating systems), § 1194.22(c) (Web-based intranet and internet information and applications), as well as § 1194.25(g) (Self contained, closed products).

The provisions contained in § 1194.21 (General Requirements), § 1194.23 (Component Specific Requirements) and § 1194.25 (Requirements for Compatibility with Assistive Technology) of the proposed rule have been moved to the new subpart B (Technical Standards) in the final rule.

Also, the provisions in the proposed rule under § 1194.27 (Functional Performance Criteria) have been redesignated as Subpart C (Functional Performance Criteria) in the final rule. Subpart C provides functional performance criteria for overall product evaluation and for technologies or components for which there is no specific provision in subpart B. The substance of each of the provisions in the final rule are discussed below.

Section 1194.21 Software Applications and Operating Systems

Paragraphs (a) through (l) address provisions for software applications and operating systems. Electronic and information technology products operate by following programming instructions referred to as software.

Software refers to a set of logical steps (or programming instructions) that control the actions or operations of most forms of electronic and information technology products. For instance, when a pager receives a radio signal, the software embedded inside the pager determines whether the signal is a “page” and how it should display the information it receives. The circuitry inside the pager, including the display unit, merely follows the instructions encoded in the software. Software can be divided into two broad categories: Software that is embedded in a chip mounted in a product and non-embedded software that is loaded onto a storage device such as a hard disk and can be erased, replaced, or updated. For instance, a word processing program that is installed onto a computer’s hard drive and which may be easily erased, replaced, or updated is typically “non-embedded” software. By contrast, the set of instructions installed on a chip inside a pager and which cannot be erased, replaced, or updated is typically embedded software. The proposed rule included provisions for non-embedded software. However, as pointed out by commenters, as technology changes, the distinction between embedded software and non-embedded software is increasingly becoming less clear. These provisions apply to all software products.

Paragraph (a) requires that when software is designed to run on a system that has a keyboard, the software shall provide a way to control features which are identifiable by text, from the keyboard. For example, if a computer program included a “print” command or a “save” command (both can be readily discerned textually), the program must provide a means of invoking these commands from the keyboard. For people who cannot accurately control a mouse, having access to the software’s controls through keyboard alternatives is essential. For example, rather than pointing to a particular selection on the screen, a user may move through the choices in a dialogue box by pressing the tab key. (See § 1194.23(a)(4) and § 1194.23(b)(1) in the NPRM.)

Comment. The NPRM required that products must provide logical navigation among interface elements through the use of keystrokes. Commenters questioned the meaning of “logical” and whether the provisions, as proposed, were requiring that each system have a keyboard. Commenters were concerned that requiring that all features of every software program be accessible from a keyboard was not feasible because some programs that

allow an individual to draw lines and create designs using a mouse could not be replicated with keystrokes.

Response. This provision applies to products which are intended to be run on a system with a keyboard. It does not require that a keyboard be added. The term "logical navigation" has been deleted. Only those actions which can be discerned textually are required to be executable from a keyboard. For example, most of the menu functions in common drawing programs that allow a user to open, save, size, rotate, and perform other actions on a graphic image can all be performed from the keyboard. However, providing keyboard alternatives for creating an image by selecting a paintbrush, picking a color, and actually drawing a design would be extremely difficult. Such detailed procedures require the fine level of control afforded by a pointing device (e.g., a mouse) and thus cannot be discerned textually without a lengthy description. Accordingly, in the final rule, keyboard alternatives are required when the function (e.g., rotate figure) or the result of performing a function (e.g., save file confirmation) can be represented with words.

Paragraph (b) prohibits applications from disrupting or disabling activated features of other products that are identified as accessibility features, where those features are developed and documented according to industry standards. Applications also shall not disrupt or disable activated features of any operating system that are identified as accessibility features where the application programming interface for those accessibility features has been documented by the manufacturer of the operating system and is available to the product developer. The application programming interface refers to a standard way for programs to communicate with each other, including the operating system, and with input and output devices. For instance, the application programming interface affects how programs have to display information on a monitor or receive keyboard input via the operating system.

Many commercially available software applications and operating systems have features built-into the program that are labeled as access features. These features can typically be turned on or off by a user. Examples of these features may include, reversing the color scheme (to assist people with low vision), showing a visual prompt when an error tone is sounded (to assist persons who are deaf or hard of hearing), or providing "sticky keys" that allow a user to press key combinations

(such as control-C) sequentially rather than simultaneously (to assist persons with dexterity disabilities). This provision prohibits software programs from disabling these features when selected. (See § 1194.23(b)(2) in the NPRM.)

Comment. The proposed rule only specified that software not interfere with features that affect the usability for persons with disabilities. Commenters from industry noted that the provision in the NPRM did not provide any method of identifying what features are considered access features and further stated that this provision was not achievable. These commenters pointed out that it was impossible for a software producer to be aware of all of the features in all software packages that could be considered an access feature by persons with disabilities. Sun Microsystems recommended that this provision address access features that have been developed using standard programming techniques and that have been documented by the manufacturer.

Response. This provision has been modified in the final rule to reference access features which have been developed and documented according to industry standards. No other changes have been made in the final rule.

Paragraph (c) requires that software applications place on the screen a visual indication of where some action may occur if a mouse click or keystroke takes place. This point on a screen indicating where an action will take place is commonly referred to as the "focus". This provision also requires that the focus be readable by other software programs such as screen readers used by computer users who are blind. (See § 1194.23(b)(3) in the NPRM.) No substantive comments were received and no changes have been made to this section in the final rule.

Paragraph (d) requires that software programs, through the use of program code, make information about the program's controls readable by assistive technology. Simply stated, this paragraph requires that information that can be delivered to or received from the user must be made available to assistive technology, such as screen reading software. Examples of controls would include button checkboxes, menus, and toolbars. For assistive technology to operate efficiently, it must have access to the information about a program's controls to be able to inform the user of the existence, location, and status of all controls. If an image is used to represent a program function, the information conveyed by the image must also be available in text. (See § 1194.23(b)(4) and § 1194.23(b)(5) in the NPRM.) No

substantive comments were received and no changes have been made to this section, other than editorial changes.

Paragraph (e) requires that when bitmap images are used by a program to identify programmatic features, such as controls, the meaning of that image shall not change during the operation of a program. "Bitmap images" refer to a type of computer image commonly used in "icons" (e.g., a small picture of a printer to activate the print command). Most screen reading programs allow users to assign text names to bitmap images. If the bitmap image changes meaning during a program's execution, the assigned identifier is no longer valid and is confusing to the user. (See § 1194.23(b)(6) in the NPRM.)

Comment. As proposed, this provision did not identify which images had to remain consistent during the application. The AFB commented that the provision should be modified to indicate the type of image that needs to hold a consistent meaning during the running of an application. AFB noted that this provision should apply only to those bitmaps that represent a program function, and not to all images.

Response. The final rule applies the provision to those images which are used to identify controls, status indicators, or other programmatic elements. No other changes have been made to this section in the final rule.

Paragraph (f) provides that software programs use the functions provided by an operating system when displaying text. The operating system is the "core" computer software that controls basic functions, such as receiving information from the keyboard, displaying information on the computer screen, and storing data on the hard disk. Other software programs use the standard protocols dictated by the operating system for displaying their own information or processing the output of other computer programs. When programs are written using unique schemes for writing text on the screen or use graphics, other programs such as software for assistive technology may not be able to interpret the information. This provision does not prohibit or limit an application programmer from developing unique display techniques. It requires that when a unique method is used, the text be consistently written throughout the operating system. (See § 1194.23(b)(7) in the NPRM.)

Comment. The proposed rule did not specify that software programs must use the functions provided by an operating system when displaying text. The NPRM required that the text would be provided through an application programming interface that supported

interaction with assistive technology or that it would use system text writing tools. Commenters raised several concerns regarding this provision. Some commenters were concerned that without a recognized interface standard, there was no assurance that assistive technology would be able to access the text provided by an application. Software producers felt that the provision should not unduly restrict how programs create or display text. Baum Electronics and GW Micro pointed out that the only way to ensure that both assistive technology and applications are using a common interface, was to use the text displaying functions of the operating system.

Response. The Board agrees that using operating system functions is one approach that would be available to all programmers. The final rule has been modified to require that textual information be provided through the operating system functions so that it will be compatible with assistive technology. This provision does not restrict programmers from developing unique methods of displaying text on a screen. It requires that when those methods are used, the software also sends the information through the operating systems functions for displaying text.

Paragraph (g) prohibits applications from overriding user selected contrast and color selections and other individual display attributes. As described above, the operating system provides the basic functions for receiving, displaying, transmitting, or receiving information in a computer or similar product. Thus, the operating system would appear the logical choice for "system-wide" settings that would be respected by all computer programs on a computer. Many modern operating systems incorporate the ability to make settings system-wide as an accessibility feature. This permits, for instance, users to display all text in very large characters. Often, persons with disabilities prefer to select color, contrast, keyboard repeat rate, and keyboard sensitivity settings provided by an operating system. When an application disables these system-wide settings, accessibility is reduced. This provision allows the user to select personalized settings which cannot be disabled by software programs. (See § 1194.23(b)(9) in the NPRM.) No substantive comments were received and no changes have been made to this section in the final rule.

Paragraph (h) addresses animated text or objects. The use of animation on a screen can pose serious access problems for users of screen readers or other

assistive technology applications. When important elements such as push-buttons or relevant text are animated, the user of assistive technology cannot access the application. This provision requires that in addition to the animation, an application provide the elements in a non-animated form. (See § 1194.23(b)(11) in the NPRM.) No substantive comments were received and no changes have been made to this section in the final rule.

Paragraph (i) prohibits the use of color as the single method for indicating important information. For instance, a computer program that requires a user to distinguish between otherwise identical red and blue squares for different functions (e.g., printing a document versus saving a file) would not comply with this provision. Relying on color as the only method for identifying screen elements or controls poses problems, not only for people with limited or no vision, but also for those people who are color blind. This provision does not prohibit the use of color to enhance identification of important features. It does, however, require that some other method of identification, such as text labels, be combined with the use of color. (See § 1194.21(a) in the NPRM.) No substantive comments were received and no changes have been made to this section in the final rule.

Paragraph (j) requires software applications to provide users with a variety of color settings that can be used to set a range of contrast levels. (See § 1194.23(b)(8) in the NPRM.)

Comment. The NPRM specified a minimum number of color settings. Some commenters were concerned that the proposed provision was too specific, while others felt it was too general because it failed to measure how different levels of contrast would be produced. Several commenters suggested requiring "a wide variety" of color settings as recommended by the EITAAC. One commenter noted that, as proposed, the provision forbids a monochrome display. Commenters also stated that some systems do not provide users with color selection capabilities.

Response. The provision in the final rule is limited to those circumstances where the system allows a user to select colors. This provision requires more than just providing color choices. The available choices must also allow for different levels of contrast. Many people experience a high degree of sensitivity to bright displays. People with this condition cannot focus on a bright screen for long because they will soon be unable to distinguish individual letters. An overly bright background

causes a visual "white-out". To alleviate this problem, the user must be able to select a softer background and appropriate foreground colors. The provision has been revised as a performance standard rather than a specific design standard by removing the requirement for 8 foreground and 8 background color selections.

Paragraph (k) limits the flashing or blinking rate of screen items. (See § 1194.21(c) in the NPRM.)

Comment. The Trace Center expressed concern that research supported a limit of 3 Hz, not 2 Hz as described in the NPRM. Trace suggested that the flash or blink rate avoid any flickering between (but not including) 3 Hz and 55 Hz, which is the power frequency for Europe.

Response. This provision is necessary because some individuals with photosensitive epilepsy can have a seizure triggered by displays which flicker or flash, particularly if the flash has a high intensity and is within certain frequency ranges. The 2 Hz limit was chosen to be consistent with proposed revisions to the ADA Accessibility Guidelines which, in turn, are being harmonized with the International Code Council (ICC)/ANSI A117 standard, "Accessible and Usable Buildings and Facilities", ICC/ANSI A117.1-1998 which references a 2 Hz limit. The Board agrees that an upper limit is needed, since all electrically powered equipment, even an incandescent light bulb, has a "flicker" due to the alternating current line voltage frequency (60 Hz in the U.S., 55 Hz in Europe). There does not appear to be any significant incidence of photosensitive seizures being induced by the line voltage frequency of ordinary lights. Therefore, the provision has been changed to prohibit flash or blink frequencies between 2 Hz and 55 Hz.

Paragraph (l) requires that people with disabilities have access to electronic forms. This section is a result of the reorganization of the final rule and is identical to section 1194.22(n) discussed below. (See § 1194.23(b)(10) in the NPRM.)

Section 1194.22 Web-based Intranet and Internet Information and Applications

In the proposed rule, the Board indicated that the EITAAC had recommended that the Board's rule directly reference priority one and two checkpoints of the World Wide Web Consortium's (W3C) Web Accessibility Initiative's (WAI) Web Content Accessibility Guidelines 1.0 (WCAG 1.0). Rather than reference the WCAG 1.0, the proposed rule and this final rule

include provisions which are based generally on priority one checkpoints of the WCAG 1.0, as well as other agency documents on web accessibility and additional recommendations of the EITAAC.

Comment. A number of comments were received from the WAI and others expressing concern that the Board was creating an alternative set of standards that would confuse developers as to which standards should be followed. WAI was further concerned that some of the provisions and preamble language in the NPRM were inaccurate. On the other hand, a number of commenters, including the ACB and several members of the EITAAC, supported the manner in which web access issues were addressed in the proposed rule.

Response. The final rule does not reference the WCAG 1.0. However, the first nine provisions in § 1194.22, paragraphs (a) through (i), incorporate the exact language recommended by the WAI in its comments to the proposed rule or contain language that is not substantively different than the WCAG 1.0 and was supported in its comments.

Paragraphs (j) and (k) are meant to be consistent with similar provisions in the WCAG 1.0, however, the final rule uses language which is more consistent with enforceable regulatory language. Paragraphs (l), (m), (n), (o), and (p) are different than any comparable provision in the WCAG 1.0 and generally require a higher level of access or prescribe a more specific requirement.

The Board did not adopt or modify four of the WCAG 1.0 priority one checkpoints. These include WCAG 1.0 Checkpoint 4.1 which provides that web pages shall “[c]learly identify changes in the natural language of a document’s text and any text equivalents (e.g., captions).”; WCAG 1.0 Checkpoint 14.1 which provides that web pages shall “[u]se the clearest and simplest language appropriate for a site’s content.”; WCAG 1.0 Checkpoint 1.3 which provides that “[u]ntil user agents can automatically read aloud the text equivalent of a visual track, provide an auditory description of the important information of the visual track of a multimedia presentation.”; and WCAG 1.0 Checkpoint 6.2 which provides that web pages shall “[e]nsure that equivalents for dynamic content are updated when the dynamic content changes.”

Section 1194.23(c)(3) of the proposed rule required that web pages alert a user when there is a change in the natural language of a page. The “natural language” referred to the spoken language (e.g., English or French) of the web page content. The WAI pointed out

that the preamble to the NPRM misinterpreted this provision. The preamble suggested that a statement such as “the following paragraph is in French” would meet the provision. WAI responded by noting that this was not the intent of the provision. The WCAG 1.0 recommend that web page authors embed a code or markup language in a document when the language changes so that speech synthesizers and Braille displays could adjust output accordingly.

The Trace Center advised that only two assistive technology programs could interpret such coding or markup language, Homepage Reader from IBM and PwWebspeak from Isound. These programs contain the browser, screen reading functions, and the speech synthesizer in a single highly integrated program. However, the majority of persons who are blind use a mainstream browser such as Internet Explorer or Netscape Navigator in conjunction with a screen reader. There are also several speech synthesizers in use today, but the majority of those used in the United States do not have the capability of switching to the processing of foreign language phonemes. As a result, the proposed provision that web pages alert a user when there is a change in the natural language of a page has been deleted in the final rule.

The Board also did not adopt WCAG 1.0 Checkpoint 14.1 which provides that web pages shall “[u]se the clearest and simplest language appropriate for a site’s content.” While a worthwhile guideline, this provision was not included because it is difficult to enforce since a requirement to use the simplest language can be very subjective.

The Board did not adopt WCAG 1.0 Checkpoint 1.3 which provides that “[u]ntil user agents can automatically read aloud the text equivalent of a visual track, provide an auditory description of the important information of the visual track of a multimedia presentation.” Although the NPRM did not propose addressing this issue in the web section, there was a similar provision in the multi-media section of the NPRM.

The Board did not adopt WCAG 1.0 Checkpoint 6.2 which provide that web pages shall “[e]nsure that equivalents for dynamic content are updated when the dynamic content changes.” The NPRM had a provision that stated “web pages shall update equivalents for dynamic content whenever the dynamic content changes.” The WAI stated in its comments that there was no difference in meaning between the NPRM and WCAG 1.0 Checkpoint 6.2. The NPRM

provision has been deleted in the final rule as the meaning of the provision is unclear.

A web site required to be accessible by section 508, would be in complete compliance if it met paragraphs (a) through (p) of these standards. It could also comply if it fully met the WCAG 1.0, priority one checkpoints and paragraphs (l), (m), (n), (o), and (p) of these standards. A Federal web site that was in compliance with these standards and that wished to meet all of the WCAG 1.0, priority one checkpoints would also have to address the WAI provision regarding using the clearest and simplest language appropriate for a site’s content (WCAG 1.0 Checkpoint 14.1), the provision regarding alerting a user when there is a change in the natural language of the page (WCAG 1.0 Checkpoint 4.1), the provision regarding audio descriptions (WCAG 1.0 Checkpoint 1.3), and the provision that web pages shall “ensure that equivalents for dynamic content are updated when the dynamic content changes (WCAG 1.0 Checkpoint 6.2).

The Board has as one of its goals to take a leadership role in the development of codes and standards for accessibility. We do this by working with model code organizations and voluntary consensus standards groups that develop and periodically revise codes and standards affecting accessibility. The Board acknowledges that the WAI has been at the forefront in developing international standards for web accessibility and looks forward to working with them in the future on this vitally important area. However, the WCAG 1.0 were not developed within the regulatory enforcement framework. At the time of publication of this rule, the WAI was developing the Web Content Accessibility Guidelines 2.0. The Board plans to work closely with the WAI in the future on aspects regarding verifiability and achievability of the Web Content Accessibility Guidelines 2.0.

Paragraph (a) requires that a text equivalent for every non-text element shall be provided. As the Internet has developed, the use of photographs, images, and other multimedia has increased greatly. Most web pages are created using HTML, or “HyperText Markup Language.” A “page” in HTML is actually a computer file that includes the actual text of the web page and a series of “tags” that control layout, display images (which are actually separate computer files), and essentially provide all content other than text. The tags are merely signals to the browser that tell it how to display information and many tags allow web designers to

include a textual description of the non-textual content arranged by the tag. The provision is necessary because assistive technology cannot describe pictures, but can convey the text information to the user. Currently, most web page authoring programs already provide a method for web designers to associate words with an image and associating text with non-textual content is easy for anyone familiar with HTML. This provision requires that when an image indicates a navigational action such as "move to the next screen" or "go back to the top of the page," the image must be accompanied by actual text that states the purpose of the image, in other words, what the image is telling you to do. This provision also requires that when an image is used to represent page content, the image must have a text description accompanying it that explains the meaning of the image. Associating text with these images makes it possible, for someone who cannot see the screen to understand the content and navigate a web page. (See § 1194.23(c)(1) in the NPRM.)

Comment. In the NPRM, § 1194.23(c)(1) required text to be associated with all non-textual elements, and prescribed the use of specific techniques, such as "alt" and "longdesc," to accomplish that requirement. WAI commented that, while the use of specific techniques was provided in WCAG 1.0 as examples of methods to use, the proposed rule was limiting the manner in which text could be associated with non-textual elements to two techniques. The result was that other approaches to providing text tags in web languages other than HTML were prohibited.

Other commenters pointed out that many images on a web page do not need text tags. They noted that some images are used to create formatting features such as spacers or borders and that requiring text identification of these images adds nothing to the comprehension of a page. These images were, in their view, textually irrelevant. One commenter suggested that this provision should address "every non-text element" because such features as buttons, checkboxes, or audio output were covered by other provisions in the proposed rule.

Response. This provision incorporates the exact language recommended by the WAI in their comments to the proposed rule. Non-text element does not mean all visible elements. The types of non-text elements requiring identification is limited to those images that provide information required for comprehension of content or to facilitate navigation. Web page authors often utilize

transparent graphics for spacing. Adding text to identify these elements would produce unnecessary clutter for users of screen readers.

The Board also interprets this provision to require that when audio presentations are available on a web page, because audio is a non-textual element, text in the form of captioning must accompany the audio, to allow people who are deaf or hard of hearing to comprehend the content. (See § 1194.23(c)(1) in the NPRM.)

Paragraph (b) provides that equivalent alternatives for any multimedia presentation shall be synchronized with the presentation. This would require, for example, that if an audio portion of a multi-media production was captioned as required in paragraph (a), the captioning must be synchronized with the audio. (See § 1194.23(c)(12) and (e)(3) in the NPRM.)

Comment. Comments from organizations representing persons who are deaf or hard of hearing strongly supported this provision. One commenter from the technology industry raised a concern that this provision would require all live speeches broadcast on the Internet by a Federal agency to be captioned. The commenter noted that an alternative might be to provide a transcript of the speech which could be saved, reviewed, and searched.

Response. This provision uses language that is not substantively different than the WCAG 1.0 and was supported in the WAI comments to the proposed rule. There are new techniques for providing realtime captioning which are supported by new versions of programs like RealAudio. Providing captioning does not preclude posting a transcript of the speech for people to search or download. However, commenters preferred the realtime captioning over the delay in providing a transcript. No substantive changes have been made to this provision in the final rule.

Paragraph (c) prohibits the use of color as the single method for indicating important information on a web page. When colors are used as the sole method for identifying screen elements or controls, persons who are color blind as well as those people who are blind or have low vision may find the web page unusable. This provision does not prohibit the use of color to enhance identification of important features. It does, however, require that some other method of identification, such as text labels, must be combined with the use of color. (See § 1194.23(c)(2) in the NPRM.)

Comment. The WAI expressed concern that as proposed, the provision did not capture the intent of the provision as addressed in the WCAG 1.0. The intent of such a requirement, according to WAI, was to have web page designers use methods other than color to indicate emphasis such as bold text.

Response. This provision incorporates the exact language recommended by the WAI in their comments to the proposed rule. This provision addresses not only the problem of using color to indicate emphasized text, but also the use of color to indicate an action. For example, a web page that directs a user to "press the green button to start" should also identify the green button in some other fashion than simply by color.

Paragraph (d) provides that documents must be organized so they are readable without requiring browser support for style sheets. Style sheets are a relatively new technology that lets web site designers make consistent appearing web pages that can be easily updated. For instance, without style sheets, making headings appear in large font while not affecting the surrounding text requires separate tags hidden in the document to control font-size and boldface. Each heading would require a separate set of tags. Using style sheets, however, the web site designer can specify in a single tag that all headings in the document should be in large font and boldface. Because style sheets can be used to easily affect the entire appearance of a page, they are often used to enhance accessibility and this provision does not prohibit the use of style sheets. This provision requires that web pages using style sheets be able to be read accurately by browsers that do not support style sheets and by browsers that have disabled the support for style sheets. (See § 1194.23(c)(4) in the NPRM.) This requirement is based on the fact that style sheets are a relatively new technology and many users with disabilities may either not have computer software that can properly render style sheets or because they may have set their own style sheet for all web pages that they view.

Comment. The WAI commented that while the provision was consistent with WCAG 1.0, the preamble inaccurately noted that this provision would prohibit the use of style sheets that interfere with user defined style sheets. The WAI noted that a browser running on a user's system determines whether or not style sheets associated with pages will be downloaded.

Response. The WAI correctly noted that this provision does not prohibit the use of style sheets that interfere with user-defined style sheets because the

use of style sheets is controlled by a user's browser. This provision uses language that is not substantively different than WCAG 1.0 and was supported in the WAI comments to the proposed rule. No substantive changes have been made to this provision in the final rule.

Paragraph (e) requires web page designers to include redundant text links for each active region of a server-side image map on their web pages. An "image map" is a picture (often a map) on a web page that provides different "links" to other web pages, depending on where a user clicks on the image. There are two basic types of image maps: "client-side image maps" and "server-side image maps." With client-side image maps, each "active region" in a picture can be assigned its own "link" (called a URL or "uniform resource locator") that specifies what web page to retrieve when a portion of the picture is selected. HTML allows each active region to have its own alternative text, just like a picture can have alternative text. See § 1194.22(a). By contrast, clicking on a location of a server-side image map only specifies the coordinates within the image when the mouse was depressed—which link or URL is ultimately selected must be deciphered by the computer serving the web page. When a web page uses a server-side image map to present the user with a selection of options, browsers cannot indicate to the user the URL that will be followed when a region of the map is activated. Therefore, the redundant text link is necessary to provide access to the page for anyone not able to see or accurately click on the map. (See § 1194.23(c)(6) in the NPRM.) No substantive changes have been made to this provision in the final rule.

Paragraph (f) provides that client-side image maps shall be provided instead of server-side image maps except where the regions cannot be defined with an available geometric shape. As discussed above, there are two general categories of image maps: client-side image maps and server-side image maps. When a web browser retrieves a specific set of instructions from a client-side image map, it also receives all the information about what action will happen when a region of the map is pressed. For this reason, client-side image maps, even though graphical in nature, can display the links related to the map, in a text format which can be read with the use of assistive technology. (See § 1194.23(c)(7) in the NPRM.)

Comment. The WAI suggested that the final rule include an exception for those regions of a map which cannot be

defined with an available geometric shape.

Response. This provision incorporates the exact language recommended by the WAI in their comments to the proposed rule.

Paragraphs (g) and (h) permit the use of tables, but require that the tables be coded according to the rules for developing tables of the markup language used. When tables are coded inaccurately or table codes are used for non-tabular material, some assistive technology cannot accurately read the content. Many assistive technology applications can interpret the HTML codes for tables and will most likely be updated to read the table coding of new markup languages. (See § 1194.23(c)(8–9) in the NPRM.) The Board will be developing technical assistance materials on how tables can comply with this section. In addition to these specific provisions, the technical assistance materials will address all of the provisions in this part.

Comment. Commenters were concerned by the preamble discussion in the NPRM which advised against the use of table tags for formatting of non-tabular material.

Response. The Board understands that there are currently few alternatives to the use of tables when trying to place items in predefined positions on web pages. These provisions do not prohibit the use of table codes to format non-tabular content. They require that when a table is created, appropriate coding should be used. Paragraph (g) incorporates the exact language recommended by the WAI in their comments to the proposed rule. Paragraph (h) uses language that is not substantively different than WCAG 1.0 and was supported in the WAI comments to the proposed rule. No substantive changes have been made to this provision in the final rule.

Paragraph (i) addresses the use of frames and requires that they be titled with text to identify the frame and assist in navigating the frames. "Frames" are a technique used by web designers to create different "portions" or "frames" of their screen that serve different functions. When a web site uses frames, often only a single frame will update with information while the other frames remain intact. Because using frames gives the user a consistent portion of the screen, they are often used for navigational toolbars for web sites. They are also often faster because only a portion of the screen is updated, instead of the entire screen. Frames can be an asset to users of screen readers and other assistive technology if the labels on the frames are explicit. Labels such

as top, bottom, or left, provide few clues as to what is contained in the frame. However, labels such as "navigation bar" or "main content" are more meaningful and facilitate frame identification and navigation. (See § 1194.23(c)(10) in the NPRM.) This provision uses language that is not substantively different than WCAG 1.0. No substantive changes have been made to this provision in the final rule.

Paragraph (j) sets limits on the blink or flicker rate of screen elements. This section is a result of the reorganization of the final rule and is similar to section 1194.21(k) discussed above. (See § 1194.21(c) in the NPRM.) This provision is meant to be consistent with WCAG 1.0 Checkpoint 7.1 which provides that, "[u]ntil user agents allow users to control flickering, avoid causing the screen to flicker." This provision uses language which is more consistent with enforceable regulatory language.

Paragraph (k) requires that a text-only web page shall only be provided as a last resort method for bringing a web site into compliance with the other requirements in § 1194.22. Text-only pages must contain equivalent information or functionality as the primary pages. Also, the text-only page shall be updated whenever the primary page changes. This provision is meant to be consistent with WCAG 1.0 Checkpoint 11.4 which provides that "[i]f, after best efforts, you cannot create an accessible page, provide a link to an alternative page that uses W3C technologies, is accessible, has equivalent information (or functionality), and is updated as often as the inaccessible (original) page."

Paragraph (l) requires that when web pages rely on special programming instructions called "scripts" to affect information displayed or to process user input, functional text shall be provided. It also requires that the text be readable by assistive technology such as screen reading software. Scripts are widely used by web sites as an efficient method to create faster or more secure web communications. A script is a programmatic set of instructions that is downloaded with a web page and permits the user's computer to share the processing of information with the web server. Without scripts, a user performs some action while viewing a web page, such as selecting a link or submitting a form, a message is sent back to the "web server", and a new web page is sent back to the user's computer. The more frequently an individual computer has to send and receive information from a web server, the greater chance there is for errors in the data, loss of speed, and possible violations of security. Also,

when many users are simultaneously viewing the same web page, the demands on the web server may be huge. Scripts allow more work to be performed on the individual's computer instead of on the web server. And, the individual computer does not have to contact the web server as often. Scripts can perform very complex tasks such as those necessary to complete, verify, and submit a form and verify credit information. The advantage for the user is that many actions take place almost instantly, because processing takes place on the user's computer and because communication with the web server is often not necessary. This improves the apparent speed of a web page and makes it appear more dynamic. Currently, JavaScript, a standardized object-oriented programming language, is the most popular scripting language, although certain plug-ins (see below) support slightly different scripting languages. This provision requires web page authors to ensure that all the information placed on a screen by a script shall be available in a text form to assistive technology. (See § 1194.23(c)(11) in the NPRM.)

Comment. The NPRM was more specific in its application, providing that pages must be usable when scripts, applets, or other programmatic objects are turned off or are not supported. The NPRM permitted the use of an alternative accessible page. Several commenters found the proposed provision too restrictive. They noted that, as proposed, it could severely discourage innovation both for web page developers and for designers of assistive technology. It was argued that if producers of assistive technology know that a web page would never require access to scripts, there would be no incentive to develop better access to these features. It was also pointed out that discussing scripts, applets, and plug-ins in the same provision was not appropriate, because plug-ins were actual programs that run on a user's machine and do not necessarily originate on the web page. Scripts, on the other hand, are downloaded to a user's system from the web page (or an associated file) and, unlike applets or plug-ins, operate completely inside the browser without any additional software. Therefore, as scripts directly affect the actual content of a web page, the web page designer has control over designing a script but does not have control over which plug-in a user may select to process web content.

Response. The final rule has two separate provisions for scripts (l), and applets and plug-ins (m). Web page

authors have a responsibility to provide script information in a fashion that can be read by assistive technology. When authors do not put functional text with a script, a screen reader will often read the content of the script itself in a meaningless jumble of numbers and letters. Although this jumble is text, it cannot be interpreted or used. For this reason, the provision requires that functional text, that is text that when read conveys an accurate message as to what is being displayed by the script, be provided. For instance, if a web page uses a script only to fill the contents of an HTML form with basic default values, the web page will likely comply with this requirement, as the text inserted into the form by the script may be readable by a screen reader. By contrast, if a web page uses a script to create a graphic map of menu choices when the user moves the pointer over an icon, the web site designer may be required to incorporate "redundant text links" that match the menu choices because functional text for each menu choice cannot be rendered to the assistive technology. Determining whether a web page meets this requirement may require careful testing by web site designers, particularly as both assistive technology and the JavaScript standard continue to evolve.

Paragraph (m) is, in part, a new provision developed in response to comments received on § 1194.23(c)(11) of the NPRM and discussed in the preceding paragraph. While most web browsers can easily read HTML and display it to the user, several private companies have developed proprietary file formats for transmitting and displaying special content, such as multimedia or very precisely defined documents. Because these file formats are proprietary, they cannot ordinarily be displayed by web browsers. To make it possible for these files to be viewed by web browsers, add-on programs or "plug-ins" can be downloaded and installed on the user's computer that will make it possible for their web browsers to display or play the content of the files. This provision requires that web pages which provide content such as Real Audio or PDF files, also provide a link to a plug-in that will meet the software provisions. It is very common for a web page to provide links to needed plug-ins. For example, web pages containing Real Audio almost always have a link to a source for the necessary player. This provision places a responsibility on the web page author to know that a compliant application exists, before requiring a plug-in. (See § 1194.21(c)(11) in the NPRM.)

Paragraph (n) requires that people with disabilities have access to interactive electronic forms. Electronic forms are a popular method used by many agencies to gather information or permit a person to apply for services, benefits, or employment. The 1998 Government Paperwork Elimination Act requires that Federal agencies make electronic versions of their forms available on-line when practicable and allows individuals and businesses to use electronic signatures to file these forms electronically. (See § 1194.23(b)(10) in the NPRM.) At present, the interaction between form controls and screen readers can be unpredictable, depending upon the design of the page containing these controls. Some developers place control labels and controls in different table cells; others place control labels in various locations in various distances from the controls themselves, making the response from a screen reader less than accurate many times.

Comment. Adobe Systems expressed concern that completing some forms requires a script or plug-in and interpreted the proposed rule as prohibiting such items. They pointed out that there are other methods of completing a form that would not require scripts or plug-ins, but those methods require the constant transfer of information between the client and server computers. Adobe noted that that method can be extremely inefficient and can pose a security risk for the individual's personal data.

Response. This provision does not forbid the use of scripts or plug-ins and many of the existing products support these features. If a browser does not support these features, however, paragraphs (l) and (m) require that some other method of working with the web page must be provided. As assistive technologies advance, it is anticipated that the occasions when the use of scripts and plug-ins are not supported will diminish significantly. No substantive changes have been made to this provision in the final rule.

Paragraph (o) provides that a method be used to facilitate the easy tracking of page content that provides users of assistive technology the option to skip repetitive navigation links. (See § 1194.23(c)(13) in the NPRM.) No substantive comments were received on this provision and no changes were made, other than editorial changes.

Paragraph (p) addresses the accessibility problems that can occur if a web page times-out while a user is completing a form. Web pages can be designed with scripts so that the web page disappears or "expires" if a

response is not received within a specified amount of time. Sometimes, this technique is used for security reasons or to reduce the demands on the computer serving the web pages. A disability can have a direct impact on the speed with which a person can read, move around, or fill in a web form. For this reason, when a timed response is required, the user shall be alerted and given sufficient time to indicate that additional time is necessary. (See § 1194.21(d) in the NPRM.)

Comment. The proposed rule prescribed specific settings for increasing the time-out limit based on a default setting. The Board sought comment on whether a system was commercially available that would allow a user to adjust the time-out. The Board also sought information on whether the proposed provision would compromise security. Commenters responded that security would be an issue if the time-out period was extended for too long and information with personal data was left exposed. Other commenters raised the point that specifying specific multiples of the default was unrealistic and arbitrary. The Multimedia Telecommunications Association (MMTA) stated that the default was not built-into a system. Rather, it was generally something that was set by an installer or a system administrator. They also noted that in order for a user to know that more time is needed, the user must be alerted that time is about to run out.

Response. The provision has been revised as a performance standard rather than a specific design standard by removing the reference to a specified length of time for users to respond. The Board agrees that it would be difficult for a user to know how much more time is needed even if the time-out could be adjusted. The final rule requires only that a user be notified if a process is about to time-out and be given an opportunity to answer a prompt asking whether additional time is needed.

Section 1194.23 Telecommunications Products

Paragraph (a) requires that telephone equipment shall provide a standard non-acoustic connection point for TTYs. A TTY is a device that includes a keyboard and display that is used to transmit and receive text over a telephone line using sound. Originally, TTY's used acoustic connections and the user placed the telephone handset on the TTY to transfer the sound signals between the TTY and the telephone. Handsets on many modern telephones do not fit well with many TTY acoustic couplers, allowing interference from

outside noise. Individuals who use TTYs to communicate must have a non-acoustic way to connect TTYs to telephones in order to obtain clear TTY connections, such as through a direct RJ-11 connector, a 2.5 mm audio jack, or other direct connection. When a TTY is connected directly into the network, it must be possible for the acoustic pickup (microphone) to be turned off (automatically or manually) to avoid having background noise in a noisy environment mixed with the TTY signal. Since some TTY users make use of speech for outgoing communications, the microphone on/off capability must be automatic or easy to switch back and forth or a push-to-talk mode should be provided. In the Telecommunications Act Accessibility Guidelines (36 CFR Part 1193), the Board recognized that direct-connect TTYs are customer premises equipment (CPE) subject to section 255 of that Act. Since CPE is a subset of electronic and information technology, it is similarly covered by this rule. This provision was adopted from the Board's Telecommunications Act Accessibility Guidelines so that manufacturers of telecommunications and customer premises equipment covered by section 255 of the Telecommunications Act wishing to sell products to the Federal government would have a consistent set of requirements. (See § 1194.23(d)(1) in the NPRM.)

Comment. The MMTA commented that providing a direct connection to an analog telephone may be as simple as providing an RJ-11 jack, but that digital phones pose additional problems. It noted that most multi-line business phones operating through a PBX are digital phones. However, it also stated that TTY connectivity can be accomplished by adding an analog line similar to what would be provided for a fax machine. The MMTA further suggested that TTY manufacturers should share the burden for compatibility. Another comment suggested that the Board require the provision of a shelf and outlet for a TTY.

Response. In some cases, the addition of an RJ-11 connector will be the easiest solution. In other cases, the addition of a "smart" adapter may be necessary, similar to the dataports available on many hotel phones. Some adapters and converters have circuitry which determines the nature of the line and plug-in equipment and makes the adjustment automatically while others are manual. There is merit, however, in viewing this provision from the standpoint of the capabilities of a system as opposed to the capabilities of

a single desktop unit. There may be cases in which the connection is best made at the PBX level by installing analog phone lines where necessary. The final provision has been modified to allow for either option.

With respect to the suggestion that the standards require a shelf and outlet for a TTY, these standards apply to the electronic and information technology products themselves, not the furniture they occupy. Therefore, these standards do not address auxiliary features such as shelves and electrical outlets.

Paragraph (b) requires that products providing voice communication functionality be able to support use of all commonly used cross-manufacturer, non-proprietary, standard signals used by TTYs. Some products compress or alter the audio signal in such a manner that standard signals used by TTYs are not transmitted properly, preventing successful TTY communication. This provision is consistent with the Telecommunications Act Accessibility Guidelines. (See § 1194.23(d)(2) in the NPRM.)

Comment. Comments from industry suggested that the Board should clarify the standard referred to as U.S. standard Baudot communications protocol. They noted that there are several standards in use in Europe. Some European products support more than one of these standards, but not the common U.S. standard. The comments said that such products would arguably comply with the provision but would not meet the intent of section 508.

Response. The proposed rule required that products must support all cross-manufacturer, non-proprietary protocols, not just one or two. Of course, that included the common U.S. Baudot protocol (ANSI/TIA/EIA 825). ASCII is also used, especially on dual mode TTYs, but it is less common. Compliance with international standard ITU-T Recommendation V.18 would meet this provision, but products complying with the ITU standard may not be commercially available. It is important that products and systems support the protocol used by most TTYs currently in use to avoid a disenfranchisement of the majority of persons who are deaf or hard of hearing. However, the intent of this provision is to require support of more than just Baudot or just ASCII. At present, only these two are commonly used in the U.S., but others may come into use later. While the Board does not want to disenfranchise users of current devices, neither does it want to exclude those who buy newer equipment, as long as such devices use protocols which are not proprietary and are supported by

more than one manufacturer. Of course, like all the requirements of these standards, this provision is subject to commercial availability. Accordingly, the provision has been changed in the final rule by adding the phrase "commonly used."

Paragraph (c) provides that TTY users be able to utilize voice mail, auto-attendant, and interactive voice response telecommunications systems. Voice mail systems are available which allow TTY users to retrieve and leave TTY messages. This provision does not require that phone systems have voice to text conversion capabilities. It requires that TTY users can retrieve and leave TTY messages and utilize interactive systems. (See § 1194.23(d)(3) in the NPRM.)

Comment. One commenter suggested that the Board encourage developers to build-in direct TTY decoding so that external TTYs are not required. For example, if an employee had voice mail with TTY functionality built-in, that employee would be able to read TTY messages through the computer system directly, without needing to attach an external TTY. The commenter noted that this would be beneficial to Federal agencies having telephone communication with members of the public who have speech or hearing disabilities. The agency could then have direct communication rather than being required to use an external TTY device or utilizing a relay service. Another said telecommunications systems should be required to have TTY decoding capability built-in, to the maximum extent possible. Another commenter pointed out that voice mail, voice response, and interactive systems depend on DTMF "touch tones" for operation and that many TTYs do not provide this function. Also, one commenter noted that automatic speech recognition (ASR) is not yet mature, but requested that a requirement for ASR be reviewed every two years to determine the feasibility of including such capabilities in products based on the rapid change of technology.

Response. This provision requires that voice mail, auto-attendant, and interactive voice response systems be usable with TTYs. It is desirable that computers have built-in TTY capability and there are currently systems which can add such functionality to computers. This provision is a performance requirement and the Board does not feel it would be useful to be more specific at this time. The current problems with voice mail and voice response systems are not necessarily susceptible to a single solution and there are several ways to comply,

including voice recognition in some cases, depending on the system. Many voice mail systems could record a TTY message, just like a voice message, but the outgoing message needs to include a TTY prompt letting TTY users to know when to start keying. A requirement for a quick response to menu choices is the most frequently reported barrier for relay users. The ability to "opt out" of a menu and connect with an operator or transfer to a TTY system are also ways to make these services available and usable without highly sophisticated decoding technology.

Paragraph (d) addresses access problems that can arise when telecommunications systems require a response from a user within a certain time. Due to the nature of the equipment, users of TTYs may need additional time to read and respond to menus and messages. This provision is identical to section 1194.22(p) discussed above. (See § 1194.21(d)(4) in the NPRM.)

Comment. The proposed rule prescribed specific settings for increasing the time-out limit based on a default setting. Commenters raised the point that specifying specific multiples of the default was unrealistic and arbitrary. The MMTA stated that the default was not built-into a system. Rather it was generally something that was set by an installer or a system administrator. It also noted that in order for users to know that more time is needed, they must be alerted that time is about to run out.

Response. The provision has been changed to a performance standard rather than a specific design standard by removing the reference to a specified length of time for users to respond. The Board agrees that it would be difficult for a user to know how much more time is needed even if the time-out could be adjusted. The final rule requires only that a user be notified if a process is about to time-out and be given an opportunity to answer a prompt asking whether additional time is needed.

Paragraph (e) requires that functions such as caller identification must be accessible for users of TTYs, and for users who cannot see displays. (See § 1194.23(d)(5) in the NPRM.)

Comment. One commenter thought the reference to telecommunications relay services in the NPRM implied that caller identification information must somehow be transmitted directly to the end-user.

Response. Since the end-users in a telecommunications relay service are not directly connected, passing along caller identification information is not

commonly done, therefore, the reference to relay services has been deleted to avoid confusion.

Paragraph (f) requires products to be equipped with volume control that provides an adjustable amplification up to a minimum of 20 dB of gain. If a volume adjustment is provided that allows a user to set the level anywhere from 0 to the upper requirement of 20 dB, there is no need to specify a lower limit. If a stepped volume control is provided, one of the intermediate levels must provide 12 dB of gain. The gain applies to the voice output. (See § 1194.23(d)(6) in the NPRM.)

Comment. Several commenters supported the provision for a 20 dB gain, but some supported a 25 dB requirement, pointing out that many persons who are hard of hearing need more than 20 dB amplification. Others urged the Board to adopt the current Federal Communications Commission's (FCC) requirement for a minimum of 12 dB and a maximum of 18 dB. Some commenters said amplifying a poor quality signal would not be useful and that the amplification may itself introduce distortion.

Response. The proposed level of amplification was different from that required under the FCC regulations implementing the Hearing Aid Compatibility Act (47 CFR 68.317 (a)). The FCC requires volume control that provides, through the receiver in the handset or headset of the telephone, 12 dB of gain minimum and up to 18 dB of gain maximum, when measured in terms of Receive Objective Loudness Rating.

The Board's provision is consistent with the 1998 ANSI A117.1 document, "Accessible and Usable Buildings and Facilities." ANSI is the voluntary standard-setting body which issues accessibility standards used by the nation's model building codes. The Board has issued a separate NPRM to harmonize the existing ADAAG provision with the ANSI standard. The FCC originally selected its requirement to be consistent with the ADA Accessibility Guidelines now being proposed for amendment. This provision is consistent with the proposed ADA and Architectural Barriers Act Accessibility Guidelines and the Telecommunications Act Accessibility Guidelines. No changes were made to this provision in the final rule.

Paragraph (g) requires that an automatic reset be installed on any telephone that allows the user to adjust the volume higher than the normal level. This is a safety feature to protect people from suffering damage to their

hearing if they accidentally answer a telephone with the amplification turned too high. (See § 1194.23(d)(7) in the NPRM.)

Comment. Most commenters supported the provision for an automatic reset. One commenter said the reset would be a problem for an individual user who would be required to constantly readjust his or her telephone to a usable level.

Response. The provision is adopted from the ADA Accessibility Guidelines, where it applies to public phones used by many people. The FCC's Part 68 rules require an automatic reset when the phone is hung up if the volume exceeds 18 dB gain. To provide the ability to override the reset function would require a waiver from the FCC since the standards require a 20 dB gain. No changes have been made to this section in the final rule.

Paragraph (h) requires telephones, or other products that provide auditory output by an audio transducer normally held up to the ear, to provide a means for effective wireless coupling to hearing aids. Many hearing aids incorporate "T-coils" that generate sounds based on magnetic signals received from earpieces that can generate the appropriate magnetic field. Generally, this provision means the earpiece generates sufficient magnetic field strength to induce an appropriate field in a hearing aid T-coil. The output in this case is the direct voice output of the transmission source, not the "machine language" such as tonal codes transmitted by TTYs. For example, a telephone must generate a magnetic output so that the hearing aid equipped with a T-coil can accurately receive the message. This provision is consistent with the Telecommunications Act Accessibility Guidelines. (See § 1194.23(d)(8) in the NPRM.) No substantive comments were received and no changes have been made to this section in the final rule.

Paragraph (i) requires that interference to hearing technologies be reduced to the lowest possible level that allows a user of hearing technologies to utilize a telecommunications product. Individuals who are hard of hearing use hearing aids and other assistive listening devices, but they cannot be used if products introduce noise into the listening aids because of electromagnetic interference. (See § 1194.23(d)(9) in the NPRM.)

Comment. The American National Standards Institutes (ANSI) is developing methods of measurement and defining the limits for hearing aid compatibility and accessibility to wireless telecommunications. At the

time of the proposed rule, the ANSI C63.19 ANSI/IEEE Standard for Hearing Aid Compatibility with Wireless Devices was not completed. The NPRM noted that the Board may ultimately incorporate the standard when it is completed. Several commenters recommended referencing the work of the ANSI committee.

Response. The ANSI committee has recently completed its work. No changes have been made to this provision in the final rule and the provision continues to be a performance standard rather than a specific design standard. However, compliance with the ANSI C63.19 ANSI/IEEE Standard for Hearing Aid Compatibility with Wireless Devices would meet this provision.

Paragraph (j) provides that all products that act as a transport or conduit for information or communication shall pass all codes, translation protocols, formats, or any other information necessary to provide information or communication in a usable format. In particular, signal compression technologies shall not remove information needed for access or shall restore it upon decompression. Some transmissions include codes or tags embedded in "unused" portions of the signal to provide accessibility. For example, closed captioning information is usually included in portions of a video signal not seen by users without decoders. This section prohibits products from stripping out such information or requires the information to be restored at the end point. (See § 1194.25(a) in the NPRM.) No substantive comments were received and no changes have been made to this section in the final rule.

Paragraph (k) addresses controls that require some physical force to activate. It is the application of force to these controls that distinguishes them from touch sensitive controls where the mere presence of a hand or finger is detected and reacted to by the product. (See § 1194.23(a) in the NPRM.)

Comment. As proposed, this provision addressed mechanically operated controls, keyboard, and keypads. Commenters were concerned that the provisions were too general. Some commenters said that it was possible to interpret this section as applying to touchscreens, and that making touchscreen controls compliant with these provisions was not possible. Commenters also raised the question of whether the proposed standards would require every product to have a keyboard.

Response. This provision has been amended to clarify its application to mechanically operated controls. The

provision only applies to products which have mechanically operated controls or keys and therefore does not require every product to have a keyboard. This provision was not intended to apply to touchscreens as touchscreens do not have mechanically operated controls.

Paragraph (k)(1) provides that mechanically operated controls and keys shall be tactilely discernible without activating the controls or keys. Tactilely discernible means that individual keys can be located and distinguished from adjacent keys by touch. To comply with this provision, controls that must be touched to activate, must be distinguishable from each other. This can be accomplished by using various shapes, spacing, or tactile markings. Because touch is necessary to discern tactile features, this provision provides that the control should not be activated by mere contact. For example, the standard desktop computer keyboard would meet this provision because the tactile mark on the "j" and "f" keys permits a user to locate all other keys tactilely. The geographic spacing of the function, "numpad" and cursor keys make them easy to locate by touch. In addition, most keyboards require some pressure before they transmit a keystroke. Conversely, "capacitance" keyboards that react as soon as they are touched and have no raised marks or actual keys would not meet this provision. A "membrane" keypad with keys that must be pressed can be made tactilely discernible by separating keys with raised ridges so that individual keys can be distinguished by touch. (See § 1194.23(a)(1) in the NPRM.) No substantive comments were received and no changes have been made to this section in the final rule.

Paragraph (k)(2) provides that mechanically operated controls shall be accessible to persons with limited dexterity. Individuals with tremor, cerebral palsy, paralysis, arthritis, or artificial hands may have difficulty operating systems which require fine motor control, assume a steady hand, or require two hands or fingers to be used simultaneously for operation. Individuals with high spinal cord injuries, arthritis, and other conditions may have difficulty operating controls which require significant strength. The provision limits the force required to five pounds and is based on § 4.27.4 of the ADA Accessibility Guidelines and is consistent with the Telecommunications Act Accessibility Guidelines. (See § 1194.23(a)(3) in the NPRM.)

Comment. The ITIC was concerned about requiring that all controls be easily activated. They pointed out that on many pieces of equipment the on/off switch is purposely set so that it is hard to activate. This is done to prevent accidental shut-down of equipment such as with a network server. They felt it was unreasonable to require changing that type of control.

Response. The Board has addressed this issue by adding § 1194.3(f) which exempts such controls from these standards. The on/off switch on a network server for example, would be operated only when maintenance of the equipment was required and would not be for normal operation. No changes have been made to this section in the final rule.

Paragraph (k)(3) establishes provisions for key repeat rate where an adjustable keyboard repeat rate is supported. It requires that the keyboard delay before repeat shall be adjustable to at least two seconds per character. (See § 1194.23(a)(5) in the NPRM.) No substantive comments were received and no changes have been made to this section in the final rule.

Paragraph (k)(4) provides that the status of toggle controls such as the "caps lock" or "scroll lock" keys be determined by both visual means and by touch or sound. For example, adding audio patterns such as ascending and descending pitch tones that indicate when a control is turned on or off would alleviate the problem of a person who is blind inadvertently pressing the locking or toggle controls. Also, buttons which remain depressed when activated or switches with distinct positions would meet this provision. (See § 1194.23(a)(2) in the NPRM.) No substantive comments were received and no changes have been made to this section in the final rule.

Section 1194.24 Video and Multimedia Products

Paragraph (a) requires that television displays 13 inches and larger, and computer equipment that includes television receiver or display circuitry be equipped with the capacity to decode and display captioning for audio material. (See § 1194.23(e)(1) in the NPRM.)

Comment. Commenters supported this provision in general, but provided suggestions for clarification. They noted that the FCC defines "television receiver" as a device that can receive and display signals from broadcast, satellite, cable transmission, or other similar transmission sources. The commenters recommended that the provision should also address television monitors that are used with video

cassette recorders (VCRs), digital video disks (DVDs), or direct video input, but do not include tuners. These non-receiver displays are commonly used throughout the government and in educational institutions and therefore, should have the capability to decode closed captions. According to commenters, the provision should reference analog television's "line-21, NTSC" or "EIA-608" caption data decoding capabilities. Many DVD presentations already include line-21 captions and commenters expressed frustration with their inability to see these captions on their desktop or laptop computers. Commenters noted that subtitles are not a substitute for captions, as captions convey more than just dialog. One commenter stated that the provision should apply to screens 10 inches or larger; while another said that digital television (DTV) will allow usable captions on smaller screens and the Board should reference the digital captioning standard EIA-708.

Response. This provision has been clarified to cover all television displays, not just those defined as a receiver under the FCC definition. The 13-inch display size was chosen because it is consistent with the Television Decoder Circuitry Act of 1990. The term "analog" added to this provision clarifies the application of the provision.

At the time of the issuance of the NPRM, the FCC was considering a rule on digital television, but had not completed its rulemaking. On July 21, 2000, the FCC issued an order on decoder circuitry standards for DTV. That standard will take effect on July 1, 2002. Devices covered under the FCC rules include DTV sets with integrated "widescreen" displays measuring at least 7.8 inches vertically, DTV sets with conventional displays measuring at least 13 inches vertically, and stand-alone DTV tuners, whether or not they are marketed with display screens. The provision in the final rule has been changed to reflect the FCC regulation.

Paragraph (b) requires that television tuners, including tuner cards for use in computers, have the ability to handle a secondary audio track used for audio description of visual material. The secondary audio channel is commonly used for audio description. An "audio description" is a verbal description of the visual content of a presentation. Audio descriptions are important for persons who are blind or who have low vision because they provide a description of the visual content of a presentation synchronized with verbal information. (See § 1194.23(e)(2) in the NPRM.) No substantive comments were

received and no changes have been made to this section in the final rule.

Paragraph (c) requires the captioning of audio material in certain multimedia presentations. (See § 1194.23(e)(3) in the NPRM.)

Comment. The NPRM limited the provision for captioning to productions that were procured or developed for repeated showings to audiences that may include people who are deaf or hard of hearing. Commenters were concerned that agencies would avoid this provision by saying that they did not anticipate having members of the audience who were deaf or hard of hearing. Commenters noted that in many instances providing an interpreter may not be a suitable alternative. They also pointed out that subtitles are not an effective substitute for captioning multimedia presentations because subtitles do not display the environmental sounds, descriptions of music, or additional text that conveys a richer content than mere translation of the spoken dialogue.

Response. As proposed, the provision was intended to require captioning whenever the audience might include a person who was deaf or hard of hearing. The final rule has been modified to require that all training and informational video and multimedia presentations that contain speech or other audio information necessary for the comprehension of the content and which supports an agency's mission, shall be open or closed captioned regardless of the anticipated audience. This provision would not require that a videotape recorded by a field investigator to document a safety violation be captioned or audio described, for example. On the other hand, if such a videotape were subsequently used as part of a training or informational presentation, it would have to be captioned and audio described. A video of a retirement celebration would not be in support of an agency's mission and would thus not be required to be captioned. Also, this provision applies only to video and multimedia presentations which contain speech or other audio information necessary for the comprehension of the content. A video that is not narrated would not be required to be captioned since it does not contain speech. The NPRM asked a question about the availability of software products that could be used to provide captioning or description to multimedia computer presentations. Information supplied by commenters suggests such products are readily available.

Paragraph (d) requires that certain multimedia presentations provide an

audio description of visual material. (See § 1194.23(e)(4) in the NPRM.)

Comment. The proposed rule limited the provision for audio description to productions that were procured or developed for repeated showings to audiences that may include people who are blind or who have low vision. Similar to (c) above, commenters were concerned that agencies may use the limitation to avoid providing the audio description.

Response. This provision has been modified to require audio description regardless of the anticipated audience. The final rule has been modified to require that all training and informational video and multimedia productions which support the agency's mission, regardless of format, that contain visual information necessary for the comprehension of the content, shall be audio described. A video or multimedia presentation that does not support an agency's mission would not be required to be audio described. Also, this provision applies only to videos or multimedia presentations which contain visual information necessary for the comprehension of the content. A "talking heads" video does not generally contain visual information necessary for the comprehension of the content and would therefore not be required to be audio described.

Paragraph (e) provides that the captioning and audio description required in (c) and (d) above must be user selectable unless permanent. (See § 1194.23(e)(5) in the NPRM.)

Comment. The National Center for Accessible Media (NCAM) at public television station WGBH indicated that unlike captioning, audio descriptions can only be hidden and then activated on request on broadcast or cablecast video. The videotape format VHS commonly used by consumers and many companies cannot encode audio description for later activation like closed captions. Videos in the VHS format must have their descriptions permanently recorded as part of the main audio program. As a result, the audio descriptions on VHS cannot be turned off. As a solution, NCAM suggested that it may be desirable to have a separate videotape available that was not described, along with a described version to allow a user to choose which version they wish to present. Unlike the VHS format, CD-ROMs, DVDs and other multimedia can support alternate audio channels for descriptions (or alternate languages). The means of choosing those alternate tracks varies by the medium, but usually involves selection from an on-screen menu. Those menus must be made

audible or otherwise readily selectable so that people who are blind or visually impaired can independently select and gain access to those audio descriptions.

Response. While the displaying of captioning is user selectable, there may be instances where the audio description would be considered permanent. The provision provides that when permanent, the user selectability provision does not apply. No changes have been made to this section in the final rule.

Section 1194.25 Self Contained, Closed Products

Sections 1194.25 (a) through (j) apply to those products that generally have embedded software and are commonly designed in such a fashion that a user cannot easily attach or install assistive technology. This section is a result of the reorganization of the final rule. In some instances, a personal computer with a touch-screen will be enclosed in a display and used as an "information kiosk". Self contained, closed products include, but are not limited to, information kiosks and information transaction machines, copiers, printers, calculators, fax machines, and other similar types of products. A definition of self contained, closed products has also been added.

Paragraph (a) provides that access features must be built-into a self contained, closed product rather than requiring users to attach an assistive device to the product. Personal headsets are not considered assistive technology and may be required to use the product. (See § 1194.23(f)(1) in the NPRM.)

Comment. Though discussed in the preamble, the text of the proposed rule did not address the issue of personal headsets. The preamble noted that personal headsets were not considered assistive technology. The ITIC urged the Board to make this clear in the text of the rule.

Response. The Board has modified this provision by clarifying that personal headsets are not considered assistive technology. No other changes were made to this provision.

Paragraph (b) addresses access problems that can arise when self contained, closed products require a response from a user within a certain time and is identical to § 1194.22(p) and § 1194.23(d) which are discussed in detail above. (See § 1194.21(d) in the NPRM.) The final rule requires only that a user be notified if a process is about to time-out and be given an opportunity to answer a prompt asking whether additional time is needed.

Paragraph (c) requires that when a product utilizes touchscreens or

contact-sensitive controls, a method of operating the product be provided that complies with the provisions for controls in § 1194.23(k)(1) through (4). (See § 1194.21(f) in the NPRM.)

Comment. The proposed rule required that touchscreens or touch-operated controls be operable without requiring body contact or close human body proximity. Commenters found the proposed provision to be confusing. One commenter noted that the proposed rule required all touchscreens to be operable by a remote control. Several commenters expressed concern that accessibility to touchscreens for individuals who are blind or who have low vision was not adequately addressed.

Response. Touchscreens and other controls that operate by sensing a person's touch pose access problems for a range of persons with disabilities. This provision does not prohibit the use of touchscreens and contact sensitive controls, but, as modified, the final rule requires a redundant set of controls that can be used by persons who have access problems with touchscreens.

Paragraph (d) addresses the use of biometric controls. Biometric controls refer to controls that are activated only if particular biological features (*e.g.*, fingerprint, retina pattern, etc.) of the user matches specific criteria. Using retinal scans or fingerprint identification may become a common practice as a method of allowing an individual to gain access to personal data from an information transaction type of machine. (See § 1194.21(e) in the NPRM.)

Comment. In the proposed rule, the Board sought comment on the best approach to accessibility issues raised by biometric forms of identification and controls. Commenters responded that asking a system to have multiple forms of biometric identification could be prohibitively expensive. Most commenters were in agreement that biometric controls provide the most security. However, they also agreed that when such a system needs to be accessed by a person with a disability and that disability prohibits the use of a specific biometric feature, a non-biometric alternative should be provided that does not compromise security.

Response. The provision does not require a specific alternative. That selection is left up to the agency, which may choose a less expensive form of identification. No changes were made to this provision in the final rule.

Paragraph (e) requires that when products use audio as a way to communicate information, the auditory

signal will be available through an industry standard connector at a standard signal level. Individuals using personal headphones, amplifiers, audio couplers, and other audio processing devices need a place to plug these devices into the product in a standard fashion. This gives the user the ability to listen privately to the information. The product must also provide a method to pause, restart, and interrupt the flow of information. (See § 1194.23(f)(2) and § 1194.25(d) in the NPRM.) No substantive comments were received on this provision and no changes were made, other than editorial changes.

Paragraph (f) provides that when products deliver voice output, they shall provide incremental volume control with output amplification up to a level of at least 65 dB. Where the ambient noise level of the environment is above 45 dB, a volume gain of at least 20 dB above the ambient level shall be user selectable. According to the Occupational Safety and Health Administration, and the American Speech, Language, and Hearing Association, 65 dB is the volume level for normal speech. This provision requires that audio output from a kiosk type product shall have a minimum level of 65 dB. For people with reduced hearing, voice levels must be 20 dB above the surround sound level to be understandable. This means that as long as the noise level in the surrounding environment is below 45 dB, the 65 dB output level would be sufficient. If the product is in an environment with a high noise level, the user must be able to raise the volume to a setting of 20 dB higher than the ambient level. (See § 1194.23(f)(3) in the NPRM.) A feature has been required to automatically reset the volume to the default level after every use. This is consistent with a similar provision addressing telecommunications products. No substantive comments were received and no other changes have been made to this section in the final rule.

Paragraph (g) addresses the use of color prompting and is identical to section 1194.21(i) discussed above. (See § 1194.21(a) in the NPRM.) No substantive comments were received and no changes have been made to this section in the final rule.

Paragraph (h) addresses color selection and contrast settings and is identical to section 1194.21(j) discussed above. (See § 1194.23(b)(8) in the NPRM.)

Paragraph (i) addresses the use of flashing objects and is identical to section 1194.21(k) discussed above. (See § 1194.21(c) in the NPRM.)

Paragraphs (j)(1) through (4) provide provisions for the physical characteristics of large office equipment including reach ranges and the general physical accessibility of controls and features. Examples of these products, include but are not limited to, copiers, information kiosks and floor standing printers. These provisions are based on the Americans with Disabilities Act Accessibility Guidelines (ADAAG 4.2 Space Allowance and Reach Ranges). Two figures are provided to help explain the application of these provisions. (See § 1194.21(b)(1) through (4) in the NPRM.) No substantive comments were received on these provisions and no changes were made in the final rule.

Section 1194.26 Desktop and Portable Computers

This section is a result of the reorganization of the final rule. Paragraphs (a) through (d) contain provisions that apply to desktop and portable computers. The provisions in § 1194.21 for software address the accessibility of programs and operating systems that run on a computer. In contrast, the provisions in this section address physical characteristics of computer systems including the design of controls and the use of connectors. This section was previously addressed in § 1194.21 (General requirements), § 1194.23 (Component specific requirements) and § 1194.25 (Requirements for compatibility with assistive technology) in the NPRM.

Paragraph (a) addresses keyboards and other mechanically operated controls. These provisions are addressed further in sections 1194.23(k)(1) through (4) above. (See § 1194.23(a) in the NPRM.)

Paragraph (b) provides that systems using touchscreen technology must also provide controls that comply with sections 1194.23(k)(1) through (4) discussed above. (See § 1194.21(f) in the NPRM.) Similar to § 1194.25(c), this provision was modified in the final rule to require redundant controls.

Paragraph (c) requires that when biometric forms of identification are used, an alternative must also be available. This provision is identical to § 1194.25 (d) discussed above.

Paragraph (d) requires that products have standard ports and connectors. This means that the connection points on a system must comply with a standard specification that is available to other manufacturers. This provision assures that the designers of assistive technology will have access to information concerning the design of system connections and thus be able to

produce products that can utilize those connections. (See § 1194.25(b) in the NPRM.)

Comment. In the proposed rule, this provision was addressed in § 1194.25(b) under the requirements for compatibility with assistive technology. A commenter noted that this provision was more specific to computer products and not to all products.

Response. As noted, this provision has been modified to apply to computer products.

Subpart C—Functional Performance Criteria

Section 1194.31 Functional Performance Criteria

This section provides functional performance criteria for overall product evaluation and for technologies or components for which there is no specific requirement under other sections. These criteria are also intended to ensure that the individual accessible components work together to create an accessible product. This section requires that all product functions, including operation and information retrieval, be operable through at least one mode addressed in each of the following paragraphs.

Comment. The ITIC requested clarification as to how a manufacturer would determine the type and number of assistive technology devices for which support must be provided by a product.

Response. Manufacturers do not need to be aware of the universe of assistive technology products on the market. Each provision specifies the type of assistive technology that must be supported. For example, § 1194.31(a) addresses those assistive technology devices which provide output to persons who cannot see the screen. Such devices may include screen readers, Braille displays and speech synthesizers. There are numerous resources available to manufacturers to assist them in identifying specific types of assistive technology which would be used to access their product.

Paragraph (a) provides that at least one mode of operation and information retrieval that does not require user vision shall be provided, or support for assistive technology used by people who are blind or visually impaired shall be provided. It is not expected that every software program will be self-voicing or have its own built-in screen reader. Software that complies with § 1194.21 would also satisfy this provision. (See § 1194.27(a) in the NPRM.) No substantive comments were

received regarding this provision and no changes were made in the final rule.

Paragraph (b) provides that at least one mode of operation and information retrieval that does not require visual acuity greater than 20/70 (when corrected with glasses) must be provided in audio and enlarged print output that works together or independently. In the alternative, support for assistive technology used by people who are blind or who have low vision must be provided. Although visual acuity of 20/200 is considered "legally blind," there are actually millions of Americans with vision below the 20/200 threshold who can still see enough to operate and get output from technology, often with just a little additional boost in contrast or font size. This paragraph requires either the provision of screen enlargement and voice output or, that the product support assistive technology. (See § 1194.27(b) in the NPRM.) No substantive comments were received regarding this provision and no changes were made in the final rule.

Paragraph (c) provides that at least one mode of operation and information retrieval that does not require user hearing must be provided, or support for assistive technology used by people who are deaf or hard of hearing shall be provided. This provision is met when a product provides visual redundancy for any audible cues or audio output. If this redundancy cannot be built-into a product then the product shall support the use of assistive technology. (See § 1194.27(c) in the NPRM.) No substantive comments were received regarding this provision and no changes were made in the final rule.

Paragraph (d) requires that audio information important for the use of a product, must be provided in an enhanced auditory fashion by allowing for an increase in volume and/or altering the tonal quality or increasing the signal-to-noise ratio. For example, increasing the output would assist persons with limited hearing to receive information. Audio information that is important for the use of a product includes, but is not limited to, error tones, confirmation beeps and tones, and verbal instructions. (See § 1194.27(d) in the NPRM.) No substantive comments were received regarding this provision. The final provision has been amended editorially to provide that support for assistive hearing devices may be provided in place of built-in enhanced audio features.

Paragraph (e) provides that at least one mode of operation and information retrieval which does not require user

speech must be provided, or support for assistive technology shall be provided. Most products do not require speech input. However, if speech input is required to operate a product, this paragraph requires that at least one alternative input mode also be provided. For example, an interactive telephone menu that requires the user to say or press "one" would meet this provision. (See § 1194.27(e) in the NPRM.) No substantive comments were received regarding this provision and no changes were made in the final rule.

Paragraph (f) provides that at least one mode of operation and information retrieval that does not require fine motor control or simultaneous actions and which is operable with limited reach and strength must be provided. (See § 1194.27(f) in the NPRM.) No substantive comments were received regarding this provision and no changes were made in the final rule.

Subpart D—Information, Documentation, and Support

Section 1194.41 Information, Documentation, and Support

In order for a product to be fully usable by persons with disabilities, the information about the product and product support services must also be usable by persons with disabilities. These issues are addressed in this section.

Paragraph (a) states that when an agency provides end-user documentation to users of technology, the agency must ensure that the documentation is available upon request in alternate formats. Alternate formats are defined in § 1194.4, Definitions. Except as provided in paragraph (b) below, this provision does not require alternate formats of documentation that is not provided by the agency to other users of technology. (See § 1194.31(a) in the NPRM.) No substantive comments were received regarding this provision and no changes other than editorial changes were made in the final rule.

Paragraph (b) requires that agencies supply end-users with information about accessibility or compatibility features that are built-into a product, upon request. (See § 1194.31(b) in the NPRM.) No substantive comments were received regarding this provision and, other than an editorial revision substituting "methods" for "modes", and general editorial changes, no other changes were made in the final rule.

Paragraph (c) provides that help desks and other support services serving an agency must be capable of accommodating the communications needs of persons with disabilities. For

example, an agency help desk may need to communicate through a TTY. The help desk or support service must also be familiar with such features as keyboard access and other options important to people with disabilities. (See § 1194.31(a) in the NPRM.) No substantive comments were received regarding this provision and no changes other than editorial changes were made in the final rule.

Regulatory Process Matters

Executive Order 12866: Regulatory Planning and Review and Congressional Review Act

This final rule is an economically significant regulatory action under Executive Order 12866 and has been reviewed by the Office of Management and Budget (OMB). The final rule is also a major rule under the Congressional Review Act. The Board has prepared a regulatory assessment for the final rule which has been placed in the docket and is available for public inspection. The regulatory assessment is also available on the Board's Internet site (<http://www.access-board.gov/sec508/assessment.htm>). In the NPRM, the Board sought comment on the regulatory assessment which was prepared in conjunction with the proposed rule. The Board received four comments that specifically addressed concerns with that economic assessment. A summary of the comments received and the Board's responses can be found in Chapter Six of the Board's final regulatory assessment.

Section 508 covers the development, procurement, maintenance or use of electronic and information technology by Federal agencies. Exemptions are provided by statute for national security systems and for instances where compliance would impose an undue burden on an agency. The final rule improves the accessibility of electronic and information technology used by the Federal government and will affect Federal employees with disabilities, as well as members of the public with disabilities who seek to use Federal electronic and information technologies to access information. The final rule is based largely on the recommendations of the Electronic and Information Technology Access Advisory Committee.

The standards in the final rule will be incorporated into the Federal Acquisition Regulation (FAR). Failure of a Federal agency to comply with the standards may result in a complaint under the agency's existing complaint procedures under section 504 of the

Rehabilitation Act or a civil action seeking to enforce compliance with the standards.

Estimated Baseline of Federal Spending for Electronic and Information Technology

According to OMB figures, Federal government expenditures for information technology products was \$37.6 billion in fiscal year 1999. The defense agencies appear to have the highest information technology budgets, while civilian agency budgets are expected to increase rapidly. It was not possible however, to disaggregate this data such that it was useful for purposes of a regulatory assessment. Instead, the regulatory assessment uses annual sales data collected from the General Services Administration (GSA) as a proxy for the actual number of products in each applicable technology category. Using the GSA data, the regulatory assessment estimates that the Federal government spends approximately \$12.4 billion annually on electronic and information technology products covered by the final rule. This estimate likely understates the actual spending by the Federal government because it is limited to the GSA data. Agencies are not required to make purchases through the GSA supply service, thus many items are purchased directly from suppliers. As a result, the government costs for software and compatible hardware products may actually be higher than estimates would indicate.

The regulatory assessment also examines historical budgetary obligations for information technology tracked by OMB until fiscal year 1998. Two scenarios were examined to

develop an upper and lower bound to represent the proportion expected to be potentially affected by the final rule. During a five year period from fiscal year 1994 through fiscal year 1998, the average proportion of the total information technology obligations potentially covered by the final rule ranged between 25 percent and 50 percent. The \$12.4 billion GSA estimate falls within this range, representing 33 percent of the total fiscal year 1999 information technology obligations of \$37.6 billion. One limitation of these ranges is that they are based on gross classifications of information technology obligations and do not provide the level of disaggregation necessary to parallel the GSA data assessment. As a result, the two scenarios likely include expenditures on products and services that would not be effected by the final rule to a higher degree than the data obtained from GSA.

The degree to which the potential understatement of baseline spending leads to an understatement of the cost of the final rule is unclear. Some of the components of the estimated cost of the final rule rely heavily on the level of Federal spending while others are independent of this number.

Estimated Cost of the Final Rule

The regulatory assessment includes both direct and opportunity costs associated with the final rule. Major sources of cost include:

- Costs of modifying electronic and information technology to meet the substantive requirements of the standards;
- Training of staff, both Federal and manufacturers, to market, support, and

use technologies modified in response to the standards; and

- Translation of documentation and instructions into alternate formats.

The direct costs that were quantified are shown in Table 1. The total quantified costs to society range from \$177 million to \$1,068 million annually. The Federal proportion of these costs is estimated to range between \$85 million and \$691 million. The ability of manufacturers, especially software manufacturers, to distribute these costs over the general consumer population will determine the actual proportion shared by the Federal government. Assuming that the addition of accessibility features add value to the products outside the Federal government, it is expected that the costs will be distributed across society thereby setting a lower bound cost to the Federal government of \$85 million. If manufacturers do not distribute the costs across society, the upper bound of the Federal cost will increase to an estimated \$1,068 million. These costs must be placed in appropriate context by comparing them with the total Federal expenditures for information technology. By comparison, the lower and upper bound of the incremental costs represent a range of 0.23 percent to 2.8 percent of the \$37.6 billion spent by the Federal government on information technology in fiscal year 1999. Although the regulatory assessment does not analyze the timing of expenditures or reductions in costs over time, it is expected that the costs will decrease over time as a proportion of total electronic and information technology spending.

TABLE 1

Electronic and information technology	Lower bound cost estimates (millions)	Upper bound cost estimates (millions)
General Office Software	\$110	\$456
Mission Specific Software	10	52
Compatible Hardware Products		337
Document Management Products	56	222
Microphotographic Products	0.1	0.4
Other Miscellaneous Products	0.2	1
Total Social Cost	177	1,068
Estimated Federal Proportion	85	¹ 691

¹ As noted above, if manufacturers do not distribute the costs across society, the upper bound of the Federal cost will increase to an estimated \$1,068 million.

Accessible alternatives are available to satisfy the requirements of the final rule for many types of electronic and information technologies, particularly computers and software products. Some

electronic and information technology products will require modifications to meet the requirements of the final standards.

For many types of electronic and information technology, the final rule focuses on compatibility with existing and future assistive devices, such as screen readers. The final rule does not

require that assistive technologies be provided universally. Provision of assistive technologies is still governed by the reasonable accommodation requirements contained in sections 501 and 504 of the Rehabilitation Act. Section 508 does not require that assistive devices be purchased, but it does require that covered electronic and information technology be capable of having such devices added at some later time as necessary.

Software products represent the largest part of the estimated costs. The regulatory assessment assumes that Federal software expenditures can be divided into two major subcategories: general office applications and mission-specific applications. Internet applications are assumed to be represented within each of these subcategories. General office applications include operating systems, wordprocessors, and spreadsheets, and are assumed to represent 80 percent of the total software category. The remaining 20 percent covers mission-specific or proprietary applications that have limited distribution outside the Federal government. Within each subcategory, the estimated costs of the final rule are distributed according to the level or degree of accessibility already being achieved in the private sector.

The general office application subcategory is broken into three groups based on discussions with several industry experts. The first 30 percent is expected to require very little modification to satisfy the final standards and therefore no incremental cost is associated with this group. The middle 40 percent is expected to require minor to medium alterations to satisfy the final rule. The cost of modifying a particular general office application in this category is estimated to be in the range of 0.4 percent to 1 percent based on discussions with several manufacturers. This assumption is based on the ratio of employees dedicated to accessibility issues. The methodology uses employee classification as a proxy for cost or expense of accessibility research and development, labor, and design that are all factored into the final product cost. The remaining 30 percent is expected to require significant modifications to meet the requirements of the final rule, which is estimated to cost in the range of 1 percent to 5 percent based on discussion with industry experts.

The regulatory assessment assumes that the remaining 20 percent of the software products purchased by the Federal government represent proprietary or mission-specific software

with limited distribution outside the government. These products will require significant modification to satisfy the final rule. Based on discussions with industry experts, the cost increase associated with achieving the level of accessibility required by the final rule is estimated to range from 1 percent to 5 percent.

Estimated Benefits of the Final Rule

The benefits associated with the final rule results from increased access to electronic and information technology for Federal employees with disabilities and members of the public seeking Federal information provided using electronic and information technology. This increased access reduces barriers to employment in the Federal government for persons with disabilities, reduces the probability that Federal employees with disabilities will be underemployed, and increases the productivity of Federal work teams. The final standards may also have benefits for people outside the Federal workforce, both with and without disabilities, as a result of spillover of technology from the Federal government to the rest of society.

Two methods are presented in the regulatory assessment for evaluating the quantifiable benefits of the final rule. The first is a wage gap analysis that attempts to measure the difference in wages between the general Federal workforce and Federal workers with targeted and reportable disabilities. While this analysis is limited to white collar Federal workers due to data constraints, the potential change in productivity is measured by the difference between the weighted average salary for all white collar Federal employees and the average within the two disability classes. This assumes that an increase in accessibility will help diminish this wage gap by increasing worker productivity.

The alternative is a team based approach for measuring the productivity of Federal workers. This approach is based on the assumption that a Federal workers wage rate reflects their productivity and the scarcity of their skills in the labor market. However this may not apply to Federal wage rates, thus the average productivity of a Federal team is assumed to be equivalent to the average Federal wage rate. Based on this average rate, it is assumed that the final rule will produce an increase in productivity ranging between 5 percent and 10 percent.

Since no data have been identified to support the increase in productivity in the team based approach, the wage gap analysis is used to represent the benefits generated by the final rule shown in

Table 2. Keeping in mind certain data limitations with this analysis, the benefits derived from the wage gap method do not account for benefits that may be accrued by the general public or other Federal workers due to spillover effects of increased accessibility resulting from the final standards.

TABLE 2

Productivity increase	Aggregate benefits range (millions)
Lower Bound	
Upper Bound	\$466

Not all government policies are based on maximizing economic efficiency. Some policies are based on furthering the rights of certain classes of individuals to achieve more equitable results, regardless of the effect on economic efficiency. Accessibility to electronic information and technology is an essential component of civil rights for persons with disabilities. The final rule will ensure that Federal employees with disabilities will have access to electronic and information technology used by the Federal government that is comparable to that of Federal employees without disabilities; and that members of the public with disabilities will have comparable access to information and services provided to members of the public without disabilities through the use of Federal electronic and information technology.

Based on Bureau of Census statistics from 1994, 20.6 percent or 54 million persons in the United States have some level of disability. By increasing the accessibility of electronic and information technology used by the Federal government, the final rule may also improve future employment opportunities in the Federal government for persons with disabilities currently employed by the Federal government, and for persons that are working in the private sector or are classified as not being active in the labor force. Increasing the accessibility of electronic and information technology increases the productivity and mobility of the disabled sector of the labor pool that, under existing conditions, may face barriers to their employment and advancement within the Federal workforce and in the private sector. The standards will allow other Federal workers who become temporarily disabled to maintain their productivity during their illness. In addition, accessible features of electronic and information technology may also enhance the productivity of Federal

workers without disabilities and therefore be a benefit to the workforce in general.

Regulatory Flexibility Act

The Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*), as amended, generally requires Federal agencies to conduct a regulatory flexibility analysis describing the impact of the regulatory action on small entities. However, section 605(b) of the RFA, provides that a regulatory flexibility analysis is not required if the rule will not have a significant economic impact on a substantial number of small entities. This final rule imposes requirements only on the Federal Government and the Board certifies that it does not impose any requirements on small entities. As a result, a regulatory flexibility analysis is not required.

Executive Order 13132: Federalism

By its terms, this rule applies to the development, procurement, maintenance or use by Federal agencies of electronic and information technology. As such, the Board believes that it does not have federalism implications within the meaning of Executive Order 13132. In the proposed rule, the Board referred to the Department of Education's interpretation of the Assistive Technology Act (the "AT Act"), 29 U.S.C. 3001. The Board received approximately five responses from various State organizations regarding the relationship between the AT Act and Section 508 of the Rehabilitation Act. The Department of Education, the agency responsible for administering the AT Act, has advised the Board that it plans to work with States to address the relationship between the AT Act and section 508, and specifically how the Board's standards would apply to the States for purposes of the AT Act. As part of this process, the Department of Education will address issues raised in the five responses the Board received on the relationship between the AT Act and section 508 of the Rehabilitation Act.

Unfunded Mandates Reform Act

The Unfunded Mandates Reform Act does not apply to proposed or final rules that enforce constitutional rights of individuals or enforce any statutory rights that prohibit discrimination on the basis of race, color, sex, national origin, age, handicap, or disability. Since the final rule is issued under the authority of section 508, part of title V of the Rehabilitation Act of 1973 which establishes civil rights protections for individuals with disabilities, an

assessment of the rule's effects on State, local, and tribal governments, and the private sector is not required by the Unfunded Mandates Reform Act.

List of Subjects in 36 CFR Part 1194

Civil rights, Communications equipment, Computer technology, Electronic products, Government employees, Government procurement, Individuals with disabilities, Reporting and recordkeeping requirements, Telecommunications.

Thurman M. Davis, Sr.,

Chair, Architectural and Transportation Barriers Compliance Board.

For the reasons set forth in the preamble, the Board adds part 1194 to Chapter XI of title 36 of the Code of Federal Regulations to read as follows:

PART 1194—ELECTRONIC AND INFORMATION TECHNOLOGY ACCESSIBILITY STANDARDS

Subpart A—General

Sec.

- 1194.1 Purpose.
- 1194.2 Application.
- 1194.3 General exceptions.
- 1194.4 Definitions.
- 1194.5 Equivalent facilitation.

Subpart B—Technical Standards

- 1194.21 Software applications and operating systems.
- 1194.22 Web-based intranet and internet information and applications.
- 1194.23 Telecommunications products.
- 1194.24 Video and multimedia products.
- 1194.25 Self contained, closed products.
- 1194.26 Desktop and portable computers.

Subpart C—Functional Performance Criteria

- 1194.31 Functional performance criteria.

Subpart D—Information, Documentation, and Support

- 1194.41 Information, documentation, and support.

Figures to Part 1194

Authority: 29 U.S.C. 794d.

Subpart A—General

§ 1194.1 Purpose.

The purpose of this part is to implement section 508 of the Rehabilitation Act of 1973, as amended (29 U.S.C. 794d). Section 508 requires that when Federal agencies develop, procure, maintain, or use electronic and information technology, Federal employees with disabilities have access to and use of information and data that is comparable to the access and use by Federal employees who are not individuals with disabilities, unless an undue burden would be imposed on the agency. Section 508 also requires that

individuals with disabilities, who are members of the public seeking information or services from a Federal agency, have access to and use of information and data that is comparable to that provided to the public who are not individuals with disabilities, unless an undue burden would be imposed on the agency.

§ 1194.2 Application.

(a) Products covered by this part shall comply with all applicable provisions of this part. When developing, procuring, maintaining, or using electronic and information technology, each agency shall ensure that the products comply with the applicable provisions of this part, unless an undue burden would be imposed on the agency.

(1) When compliance with the provisions of this part imposes an undue burden, agencies shall provide individuals with disabilities with the information and data involved by an alternative means of access that allows the individual to use the information and data.

(2) When procuring a product, if an agency determines that compliance with any provision of this part imposes an undue burden, the documentation by the agency supporting the procurement shall explain why, and to what extent, compliance with each such provision creates an undue burden.

(b) When procuring a product, each agency shall procure products which comply with the provisions in this part when such products are available in the commercial marketplace or when such products are developed in response to a Government solicitation. Agencies cannot claim a product as a whole is not commercially available because no product in the marketplace meets all the standards. If products are commercially available that meet some but not all of the standards, the agency must procure the product that best meets the standards.

(c) Except as provided by § 1194.3(b), this part applies to electronic and information technology developed, procured, maintained, or used by agencies directly or used by a contractor under a contract with an agency which requires the use of such product, or requires the use, to a significant extent, of such product in the performance of a service or the furnishing of a product.

§ 1194.3 General exceptions.

(a) This part does not apply to any electronic and information technology operated by agencies, the function, operation, or use of which involves intelligence activities, cryptologic activities related to national security,

command and control of military forces, equipment that is an integral part of a weapon or weapons system, or systems which are critical to the direct fulfillment of military or intelligence missions. Systems which are critical to the direct fulfillment of military or intelligence missions do not include a system that is to be used for routine administrative and business applications (including payroll, finance, logistics, and personnel management applications).

(b) This part does not apply to electronic and information technology that is acquired by a contractor incidental to a contract.

(c) Except as required to comply with the provisions in this part, this part does not require the installation of specific accessibility-related software or the attachment of an assistive technology device at a workstation of a Federal employee who is not an individual with a disability.

(d) When agencies provide access to the public to information or data through electronic and information technology, agencies are not required to make products owned by the agency available for access and use by individuals with disabilities at a location other than that where the electronic and information technology is provided to the public, or to purchase products for access and use by individuals with disabilities at a location other than that where the electronic and information technology is provided to the public.

(e) This part shall not be construed to require a fundamental alteration in the nature of a product or its components.

(f) Products located in spaces frequented only by service personnel for maintenance, repair, or occasional monitoring of equipment are not required to comply with this part.

§ 1194.4 Definitions.

The following definitions apply to this part:

Agency. Any Federal department or agency, including the United States Postal Service.

Alternate formats. Alternate formats usable by people with disabilities may include, but are not limited to, Braille, ASCII text, large print, recorded audio, and electronic formats that comply with this part.

Alternate methods. Different means of providing information, including product documentation, to people with disabilities. Alternate methods may include, but are not limited to, voice, fax, relay service, TTY, Internet posting, captioning, text-to-speech synthesis, and audio description.

Assistive technology. Any item, piece of equipment, or system, whether acquired commercially, modified, or customized, that is commonly used to increase, maintain, or improve functional capabilities of individuals with disabilities.

Electronic and information technology. Includes information technology and any equipment or interconnected system or subsystem of equipment, that is used in the creation, conversion, or duplication of data or information. The term electronic and information technology includes, but is not limited to, telecommunications products (such as telephones), information kiosks and transaction machines, World Wide Web sites, multimedia, and office equipment such as copiers and fax machines. The term does not include any equipment that contains embedded information technology that is used as an integral part of the product, but the principal function of which is not the acquisition, storage, manipulation, management, movement, control, display, switching, interchange, transmission, or reception of data or information. For example, HVAC (heating, ventilation, and air conditioning) equipment such as thermostats or temperature control devices, and medical equipment where information technology is integral to its operation, are not information technology.

Information technology. Any equipment or interconnected system or subsystem of equipment, that is used in the automatic acquisition, storage, manipulation, management, movement, control, display, switching, interchange, transmission, or reception of data or information. The term information technology includes computers, ancillary equipment, software, firmware and similar procedures, services (including support services), and related resources.

Operable controls. A component of a product that requires physical contact for normal operation. Operable controls include, but are not limited to, mechanically operated controls, input and output trays, card slots, keyboards, or keypads.

Product. Electronic and information technology.

Self Contained, Closed Products. Products that generally have embedded software and are commonly designed in such a fashion that a user cannot easily attach or install assistive technology. These products include, but are not limited to, information kiosks and information transaction machines, copiers, printers, calculators, fax

machines, and other similar types of products.

Telecommunications. The transmission, between or among points specified by the user, of information of the user's choosing, without change in the form or content of the information as sent and received.

TTY. An abbreviation for teletypewriter. Machinery or equipment that employs interactive text based communications through the transmission of coded signals across the telephone network. TTYs may include, for example, devices known as TDDs (telecommunication display devices or telecommunication devices for deaf persons) or computers with special modems. TTYs are also called text telephones.

Undue burden. Undue burden means significant difficulty or expense. In determining whether an action would result in an undue burden, an agency shall consider all agency resources available to the program or component for which the product is being developed, procured, maintained, or used.

§ 1194.5 Equivalent facilitation.

Nothing in this part is intended to prevent the use of designs or technologies as alternatives to those prescribed in this part provided they result in substantially equivalent or greater access to and use of a product for people with disabilities.

Subpart B—Technical Standards

§ 1194.21 Software applications and operating systems.

(a) When software is designed to run on a system that has a keyboard, product functions shall be executable from a keyboard where the function itself or the result of performing a function can be discerned textually.

(b) Applications shall not disrupt or disable activated features of other products that are identified as accessibility features, where those features are developed and documented according to industry standards. Applications also shall not disrupt or disable activated features of any operating system that are identified as accessibility features where the application programming interface for those accessibility features has been documented by the manufacturer of the operating system and is available to the product developer.

(c) A well-defined on-screen indication of the current focus shall be provided that moves among interactive interface elements as the input focus changes. The focus shall be

programmatically exposed so that assistive technology can track focus and focus changes.

(d) Sufficient information about a user interface element including the identity, operation and state of the element shall be available to assistive technology. When an image represents a program element, the information conveyed by the image must also be available in text.

(e) When bitmap images are used to identify controls, status indicators, or other programmatic elements, the meaning assigned to those images shall be consistent throughout an application's performance.

(f) Textual information shall be provided through operating system functions for displaying text. The minimum information that shall be made available is text content, text input caret location, and text attributes.

(g) Applications shall not override user selected contrast and color selections and other individual display attributes.

(h) When animation is displayed, the information shall be displayable in at least one non-animated presentation mode at the option of the user.

(i) Color coding shall not be used as the only means of conveying information, indicating an action, prompting a response, or distinguishing a visual element.

(j) When a product permits a user to adjust color and contrast settings, a variety of color selections capable of producing a range of contrast levels shall be provided.

(k) Software shall not use flashing or blinking text, objects, or other elements having a flash or blink frequency greater than 2 Hz and lower than 55 Hz.

(l) When electronic forms are used, the form shall allow people using assistive technology to access the information, field elements, and functionality required for completion and submission of the form, including all directions and cues.

§ 1194.22 Web-based intranet and internet information and applications.

(a) A text equivalent for every non-text element shall be provided (*e.g.*, via "alt", "longdesc", or in element content).

(b) Equivalent alternatives for any multimedia presentation shall be synchronized with the presentation.

(c) Web pages shall be designed so that all information conveyed with color is also available without color, for example from context or markup.

(d) Documents shall be organized so they are readable without requiring an associated style sheet.

(e) Redundant text links shall be provided for each active region of a server-side image map.

(f) Client-side image maps shall be provided instead of server-side image maps except where the regions cannot be defined with an available geometric shape.

(g) Row and column headers shall be identified for data tables.

(h) Markup shall be used to associate data cells and header cells for data tables that have two or more logical levels of row or column headers.

(i) Frames shall be titled with text that facilitates frame identification and navigation.

(j) Pages shall be designed to avoid causing the screen to flicker with a frequency greater than 2 Hz and lower than 55 Hz.

(k) A text-only page, with equivalent information or functionality, shall be provided to make a web site comply with the provisions of this part, when compliance cannot be accomplished in any other way. The content of the text-only page shall be updated whenever the primary page changes.

(l) When pages utilize scripting languages to display content, or to create interface elements, the information provided by the script shall be identified with functional text that can be read by assistive technology.

(m) When a web page requires that an applet, plug-in or other application be present on the client system to interpret page content, the page must provide a link to a plug-in or applet that complies with § 1194.21(a) through (l).

(n) When electronic forms are designed to be completed on-line, the form shall allow people using assistive technology to access the information, field elements, and functionality required for completion and submission of the form, including all directions and cues.

(o) A method shall be provided that permits users to skip repetitive navigation links.

(p) When a timed response is required, the user shall be alerted and given sufficient time to indicate more time is required.

Note to § 1194.22: 1. The Board interprets paragraphs (a) through (k) of this section as consistent with the following priority 1 Checkpoints of the Web Content Accessibility Guidelines 1.0 (WCAG 1.0) (May 5, 1999) published by the Web Accessibility Initiative of the World Wide Web Consortium:

Section 1194.22 paragraph	WCAG 1.0 checkpoint
(a)	1.1
(b)	1.4
(c)	2.1
(d)	6.1
(e)	1.2
(f)	9.1
(g)	5.1
(h)	5.2
(i)	12.1
(j)	7.1
(k)	11.4

2. Paragraphs (l), (m), (n), (o), and (p) of this section are different from WCAG 1.0. Web pages that conform to WCAG 1.0, level A (*i.e.*, all priority 1 checkpoints) must also meet paragraphs (l), (m), (n), (o), and (p) of this section to comply with this section. WCAG 1.0 is available at <http://www.w3.org/TR/1999/WAI-WEBCONTENT-19990505>.

§ 1194.23 Telecommunications products.

(a) Telecommunications products or systems which provide a function allowing voice communication and which do not themselves provide a TTY functionality shall provide a standard non-acoustic connection point for TTYs. Microphones shall be capable of being turned on and off to allow the user to intermix speech with TTY use.

(b) Telecommunications products which include voice communication functionality shall support all commonly used cross-manufacturer non-proprietary standard TTY signal protocols.

(c) Voice mail, auto-attendant, and interactive voice response telecommunications systems shall be usable by TTY users with their TTYs.

(d) Voice mail, messaging, auto-attendant, and interactive voice response telecommunications systems that require a response from a user within a time interval, shall give an alert when the time interval is about to run out, and shall provide sufficient time for the user to indicate more time is required.

(e) Where provided, caller identification and similar telecommunications functions shall also be available for users of TTYs, and for users who cannot see displays.

(f) For transmitted voice signals, telecommunications products shall provide a gain adjustable up to a minimum of 20 dB. For incremental volume control, at least one intermediate step of 12 dB of gain shall be provided.

(g) If the telecommunications product allows a user to adjust the receive volume, a function shall be provided to automatically reset the volume to the default level after every use.

(h) Where a telecommunications product delivers output by an audio transducer which is normally held up to the ear, a means for effective magnetic wireless coupling to hearing technologies shall be provided.

(i) Interference to hearing technologies (including hearing aids, cochlear implants, and assistive listening devices) shall be reduced to the lowest possible level that allows a user of hearing technologies to utilize the telecommunications product.

(j) Products that transmit or conduct information or communication, shall pass through cross-manufacturer, non-proprietary, industry-standard codes, translation protocols, formats or other information necessary to provide the information or communication in a usable format. Technologies which use encoding, signal compression, format transformation, or similar techniques shall not remove information needed for access or shall restore it upon delivery.

(k) Products which have mechanically operated controls or keys, shall comply with the following:

(1) Controls and keys shall be tactilely discernible without activating the controls or keys.

(2) Controls and keys shall be operable with one hand and shall not require tight grasping, pinching, or twisting of the wrist. The force required to activate controls and keys shall be 5 lbs. (22.2 N) maximum.

(3) If key repeat is supported, the delay before repeat shall be adjustable to at least 2 seconds. Key repeat rate shall be adjustable to 2 seconds per character.

(4) The status of all locking or toggle controls or keys shall be visually discernible, and discernible either through touch or sound.

§ 1194.24 Video and multimedia products.

(a) All analog television displays 13 inches and larger, and computer equipment that includes analog television receiver or display circuitry, shall be equipped with caption decoder circuitry which appropriately receives, decodes, and displays closed captions from broadcast, cable, videotape, and DVD signals. As soon as practicable, but not later than July 1, 2002, widescreen digital television (DTV) displays measuring at least 7.8 inches vertically, DTV sets with conventional displays measuring at least 13 inches vertically, and stand-alone DTV tuners, whether or not they are marketed with display screens, and computer equipment that includes DTV receiver or display circuitry, shall be equipped with caption decoder circuitry which appropriately receives, decodes, and

displays closed captions from broadcast, cable, videotape, and DVD signals.

(b) Television tuners, including tuner cards for use in computers, shall be equipped with secondary audio program playback circuitry.

(c) All training and informational video and multimedia productions which support the agency's mission, regardless of format, that contain speech or other audio information necessary for the comprehension of the content, shall be open or closed captioned.

(d) All training and informational video and multimedia productions which support the agency's mission, regardless of format, that contain visual information necessary for the comprehension of the content, shall be audio described.

(e) Display or presentation of alternate text presentation or audio descriptions shall be user-selectable unless permanent.

§ 1194.25 Self contained, closed products.

(a) Self contained products shall be usable by people with disabilities without requiring an end-user to attach assistive technology to the product. Personal headsets for private listening are not assistive technology.

(b) When a timed response is required, the user shall be alerted and given sufficient time to indicate more time is required.

(c) Where a product utilizes touchscreens or contact-sensitive controls, an input method shall be provided that complies with § 1194.23 (k) (1) through (4).

(d) When biometric forms of user identification or control are used, an alternative form of identification or activation, which does not require the user to possess particular biological characteristics, shall also be provided.

(e) When products provide auditory output, the audio signal shall be provided at a standard signal level through an industry standard connector that will allow for private listening. The product must provide the ability to interrupt, pause, and restart the audio at anytime.

(f) When products deliver voice output in a public area, incremental volume control shall be provided with output amplification up to a level of at least 65 dB. Where the ambient noise level of the environment is above 45 dB, a volume gain of at least 20 dB above the ambient level shall be user selectable. A function shall be provided to automatically reset the volume to the default level after every use.

(g) Color coding shall not be used as the only means of conveying information, indicating an action,

prompting a response, or distinguishing a visual element.

(h) When a product permits a user to adjust color and contrast settings, a range of color selections capable of producing a variety of contrast levels shall be provided.

(i) Products shall be designed to avoid causing the screen to flicker with a frequency greater than 2 Hz and lower than 55 Hz.

(j) Products which are freestanding, non-portable, and intended to be used in one location and which have operable controls shall comply with the following:

(1) The position of any operable control shall be determined with respect to a vertical plane, which is 48 inches in length, centered on the operable control, and at the maximum protrusion of the product within the 48 inch length (see Figure 1 of this part).

(2) Where any operable control is 10 inches or less behind the reference plane, the height shall be 54 inches maximum and 15 inches minimum above the floor.

(3) Where any operable control is more than 10 inches and not more than 24 inches behind the reference plane, the height shall be 46 inches maximum and 15 inches minimum above the floor.

(4) Operable controls shall not be more than 24 inches behind the reference plane (see Figure 2 of this part).

§ 1194.26 Desktop and portable computers.

(a) All mechanically operated controls and keys shall comply with § 1194.23(k)(1) through (4).

(b) If a product utilizes touchscreens or touch-operated controls, an input method shall be provided that complies with § 1194.23 (k) (1) through (4).

(c) When biometric forms of user identification or control are used, an alternative form of identification or activation, which does not require the user to possess particular biological characteristics, shall also be provided.

(d) Where provided, at least one of each type of expansion slots, ports and connectors shall comply with publicly available industry standards.

Subpart C—Functional Performance Criteria

§ 1194.31 Functional performance criteria.

(a) At least one mode of operation and information retrieval that does not require user vision shall be provided, or support for assistive technology used by people who are blind or visually impaired shall be provided.

(b) At least one mode of operation and information retrieval that does not

require visual acuity greater than 20/70 shall be provided in audio and enlarged print output working together or independently, or support for assistive technology used by people who are visually impaired shall be provided.

(c) At least one mode of operation and information retrieval that does not require user hearing shall be provided, or support for assistive technology used by people who are deaf or hard of hearing shall be provided.

(d) Where audio information is important for the use of a product, at least one mode of operation and information retrieval shall be provided in an enhanced auditory fashion, or support for assistive hearing devices shall be provided.

(e) At least one mode of operation and information retrieval that does not require user speech shall be provided, or support for assistive technology used by people with disabilities shall be provided.

(f) At least one mode of operation and information retrieval that does not require fine motor control or simultaneous actions and that is operable with limited reach and strength shall be provided.

Subpart D—Information, Documentation, and Support

§ 1194.41 Information, documentation, and support.

(a) Product support documentation provided to end-users shall be made

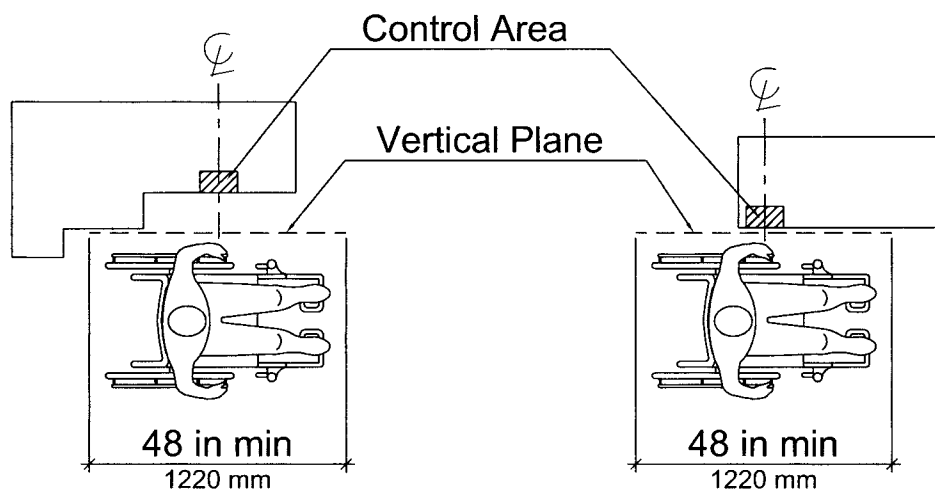
available in alternate formats upon request, at no additional charge.

(b) End-users shall have access to a description of the accessibility and compatibility features of products in alternate formats or alternate methods upon request, at no additional charge.

(c) Support services for products shall accommodate the communication needs of end-users with disabilities.

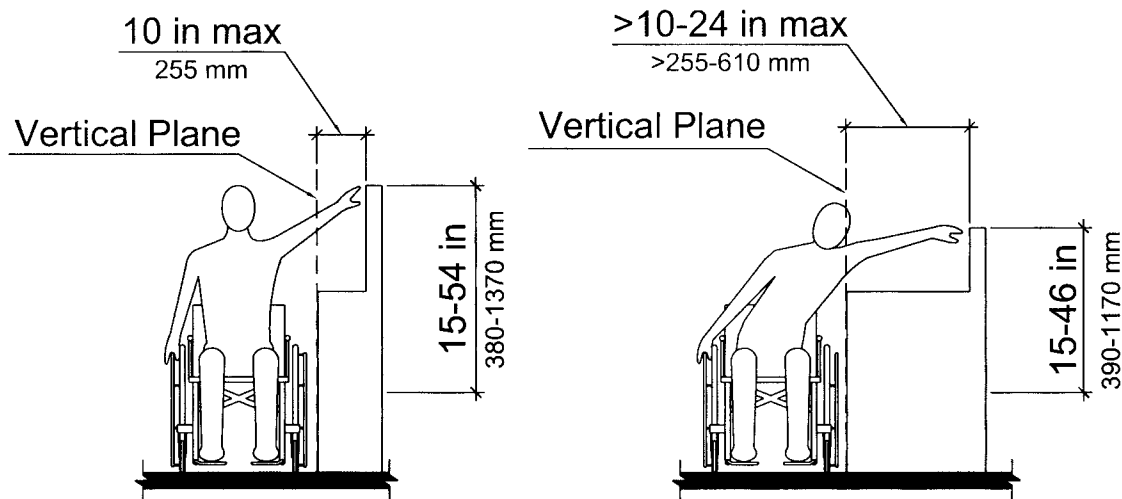
Figures to Part 1194

BILLING CODE 8150-01-P



Vertical Plane Relative to the Operable Control

Figure 1



Height of Operable Control Relative to the Vertical Plane

Figure 2



Federal Register

**Thursday,
December 21, 2000**

Part III

Department of Transportation

Research and Special Programs Administration

49 CFR Part 195

Pipeline Safety; Areas Unusually Sensitive to Environmental Damage; Final Rule

DEPARTMENT OF TRANSPORTATION**Research and Special Programs Administration****49 CFR Part 195****[Docket RSPA-99-5455; Amdt. 195-71]****RIN 2137-AC34****Pipeline Safety: Areas Unusually Sensitive to Environmental Damage****AGENCY:** Research and Special Programs Administration (RSPA), DOT.**ACTION:** Final Rule.

SUMMARY: This final rule defines drinking water and ecological areas that are unusually sensitive to environmental damage if there is a hazardous liquid pipeline release. We refer to these areas as unusually sensitive areas (USAs). RSPA created this definition through a series of public workshops, pilot testing, a technical review of the pilot test results, and extensive collaboration with a wide-range of federal, state, public, and industry stakeholders. This final rule does not require specific action by pipeline operators but will be used in existing and future regulations.

DATES: Effective February 20, 2001.

FOR FURTHER INFORMATION CONTACT: Christina Sames at (202) 366-4561 or christina.sames@rspa.dot.gov. Copies of this document or other material in the docket can be obtained from the Dockets Facility, U.S. DOT, Room #PL-401, 400 Seventh Street, SW, Washington, DC 20590-0001. The Dockets Facility is open from 9:00 a.m. to 5:00 p.m., Monday through Friday, except on Federal holidays when the facility is closed. The public may review material in the docket by accessing the Docket Management System's home page at <http://dms.dot.gov>. An electronic copy of any document published in the **Federal Register** may be downloaded from the Government Printing Office Electronic Bulletin Board Service at (202) 512-1661.

SUPPLEMENTARY INFORMATION: RSPA began its process to define unusually sensitive areas in 1992, when Congress amended the federal pipeline safety statute. The amended statute (49 U.S.C. 60109) required the Secretary of Transportation (Secretary) to prescribe regulations that establish criteria for identifying each hazardous liquid pipeline facility and gathering line located in an area that the Secretary describes as unusually sensitive to environmental damage if there is a hazardous liquid pipeline accident. We refer to these unusually sensitive areas

as USAs for short. In 1996, Congress again amended the statute to require the Secretary to consider areas where a pipeline rupture would likely cause permanent or long-term environmental damage. We described these legislative mandates in more detail in the notice of proposed rulemaking (NPRM) (64 FR 73464; December 30, 1999) to define USAs.

To fulfill the legislative mandate, RSPA began a series of public meetings and workshops to gather information to help us establish criteria for identifying USAs. We held meetings with other federal agencies and the pipeline industry to work out a definition. We held a series of public workshops to openly discuss draft definitions for USAs. These workshops helped develop guiding principles for determining which resources to concentrate on, a model of how the USA process could work, and helped define terms used to describe USAs. The workshops also identified drinking water and ecological resources that are of great importance to the nation and filtering criteria to identify those resources that could sustain permanent or long term damage if affected by a release. Participants at these meetings and workshops included representatives from the U.S. Coast Guard; the Departments of Interior, Agriculture, and Commerce; the Environmental Protection Agency (EPA); the American Waterworks Association; The Nature Conservancy; academia; the hazardous liquid pipeline industry and the public. Greater discussion on these workshops and meetings is found in the NPRM.

Notice of Proposed Rulemaking

On December 30, 1999, RSPA issued a NPRM to define USAs (64 FR 73464). The NPRM focused on drinking water and ecological resources. Cultural resources, recreational resources, and economic resource areas were not considered in the NPRM. RSPA determined that these areas should be addressed as a separate risk factor and under separate regulations.

The NPRM proposed to identify USAs through a process that began by designating and assessing environmentally sensitive areas (ESAs), determining which ESAs are potentially more susceptible to permanent or long term damage from a hazardous liquid release (areas of primary concern), and finally identifying filtering criteria to determine which areas of primary concern can sustain permanent or long-term damage or are necessary for uninterrupted drinking water consumption by the human population.

The areas that resulted from this process were the proposed USAs.

Under the proposed USA definition, drinking water areas of primary concern are a subset of all surface intakes and groundwater-based drinking water supplies that provide potable water for domestic, commercial, and industrial users. These include public water systems, wellhead protection areas, and sole source aquifers. Definitions for these resources can be found in the NPRM and at the end of this final rule. Proposed filtering criteria included the depth and geology of a drinking water resource and if the public water system has an adequate alternative drinking water supply. Additional information on the proposed filter criteria can be found in the NPRM.

The proposed ecological USA candidates focused on the characteristics of rarity, imperilment, or the potential for loss of large segments of an abundant population during periods of migratory concentration. These included threatened and endangered (T&E) species, critically imperiled and imperiled species, depleted marine mammals, and migratory waterbird concentration areas. Definitions for these resources can be found in the NPRM and at the end of this final rule. Proposed filtering criteria included the extent to which a species is vulnerable to extinction, areas that are critical to multiple sensitive species, and areas where a large percent of a species population could be impacted. Additional information on the proposed ecological filter criteria can be found in the NPRM.

How RSPA Will Use the USA Definition

RSPA will use the USA definition in current and future pipeline safety regulations. Any regulatory application of this definition will be aimed at ensuring that operators implement appropriate additional protective measures for pipelines that could affect USAs. We anticipate using the USA definition in the following regulations.

- **Integrity Management Rule.** RSPA issued a final rule titled "Pipeline Safety: Pipeline Integrity Management in High Consequence Areas (Hazardous Liquid Operators with 500 or more miles of pipeline)" on November 3, 2000, and it was published in the **Federal Register** on December 1, 2000 (65 FR 75378). The rule establishes new requirements to provide additional protection to high consequence areas. High consequence areas include USAs, populated areas, and commercially navigable waterways. The rule requires hazardous liquid pipeline operators who own or operate 500 or more miles

of pipeline to assess, evaluate, repair, and validate through analysis the integrity of any pipeline segment that could affect a high consequence area. Operators must develop and follow an integrity management program that provides for continually assessing the integrity of all pipeline segments that could affect any high consequence area, through internal inspection, pressure testing, or other equally effective assessment means. The program must also provide for periodically evaluating the pipeline segments through comprehensive information analysis, promptly remediating potential problems found through the assessment and evaluation, and ensuring additional protection to the segments and high consequence areas through preventative and mitigative measures.

This integrity management rule was the first in a series of rulemakings that ultimately will require all regulated pipeline operators to have integrity management programs. This initial action covers about 87% of all the hazardous liquid pipelines in the U.S. These pipelines have the greatest potential to adversely affect critical areas, based on the volume they transport. RSPA is now preparing a NPRM with similar requirements for the remaining hazardous liquid pipelines currently regulated under 49 CFR Part 195. RSPA will then issue proposed integrity management program requirements for natural gas pipeline operators.

- *Risk-based Alternative to Pressure Testing Older Hazardous Liquid and Carbon Dioxide Pipelines.* Operators may elect a risk-based alternative in lieu of hydrostatically testing certain older pipelines (49 CFR 195.303). The alternative establishes test priorities based on the inherent risk of a given pipeline segment. One of the risk factors is to determine the pipeline segment's proximity to environmentally sensitive areas. In the preamble to the final rule, RSPA explained that it would consider defining the environmental factor in a future rulemaking once a definition of environmentally sensitive areas was finalized.

- *Response Plans for Onshore Oil Pipelines under 49 CFR part 194.* Operators must consider areas of environmental importance that are in or adjacent to navigable waters for spill response planning. RSPA intends to amend the definition of environmental importance to include USAs. These regulations were mandated by the Federal Water Pollution Control Act as amended by the Oil Pollution Act of 1990 (OPA).

- *Area Contingency Plans.* 49 CFR part 194 also requires operators ensure their spill response plans are consistent with applicable Area Contingency Plans (ACPs). ACPs establish response strategies and priorities for a given area based on a local community assessment of all sensitive zones within that area. ACPs are created by Area Committees that are established under the U.S. Coast Guard in the coastal zone and by the U.S. Environmental Protection Agency in the inland zone. Area Committees base response priority and strategy determinations on environmental sensitivity, along with social, cultural, political, and economic sensitivities. Not all areas identified by the ACPs are USAs. The USA definition is not intended to dictate how a specific response should be undertaken, rather the definition provides a national perspective on environmental sensitivity considerations. We expect that pipeline operators and Area Committees will work cooperatively to consider the USA information when validating existing plans or revising plans during the normal 5-year planning cycle.

- *Low Stress Pipelines.* On July 12, 1999, RSPA issued a final rule extending part 195 regulations to certain pipelines operating at 20% specified minimal yield strength (SMYS) or less (39 FR 35465). In that final rule, RSPA deferred proposing to regulate non-volatile liquid low stress pipelines in rural sensitive areas since these areas had not been defined. We stated that we would reconsider the issue once there was a sensitive area definition.

USA Pilot Test, Public Workshop and Technical Review

RSPA conducted a pilot test to determine if the proposed USA definition could be used to identify and locate unusually sensitive drinking water and ecological resources using available data from government agencies and environmental organizations. Texas, California, and Louisiana were the states chosen to test the proposed USA definition. These states contain approximately 45% of the nation's hazardous liquid pipelines and considerable drinking water and ecological resources.

RSPA collected drinking water, ecological, and base map data for the pilot test. Computer models were created from the proposed USA definition to process the collected data. RSPA used a geographic information system (GIS) to run the computer models and create maps of the USAs. The results of the pilot test can be found

on the following web site: <http://ops.dot.gov/pilotresults.htm>.

The pilot test verified that the proposed USA definition could be used to identify and locate USAs. The pilot helped identify the types of data and the data attributes needed to run the computer models and what data are currently available in the pilot states. The pilot also helped in testing and modifying the model where incomplete data were not available.

On April 27–28, 2000, RSPA conducted a public workshop to discuss the pilot test results and begin a technical review of those results. Workshop participants included drinking water and ecological resource experts from federal and state agencies, academia, environmental groups, and the public. RSPA also solicited drinking water and ecological experts to provide a formal technical review of the pilot results. These technical reviewers included the Department of the Interior's Fish and Wildlife Service, the Department of Agriculture's Forest Service, the Department of Commerce's National Marine Fisheries Service, the U.S. Environmental Protection Agency (EPA) Office of Groundwater and Drinking Water, Louisiana Department of Environmental Quality, Louisiana Natural Heritage Program, Texas Natural Resource Conservation Commission, Railroad Commission of Texas' Environmental Services Division, California Department of Fish and Game, University of California Davis, Colorado State University, University of Alabama, Dartmouth College, and The Nature Conservancy.

Discussions at the workshop included background on the USA initiative, the proposed drinking water and ecological definitions, models that were used to apply the proposed definition, data that was gathered, how the data was processed using a GIS, and maps of the resulting USAs. Presentations from the workshop and a detailed summary of the workshop can be viewed from RSPA's USA Internet page: <http://ops.dot.gov/init.htm#usa>. Workshop participants also submitted their comments to the docket on this rulemaking.

Discussion of Comments Received From the Public Workshop and Technical Review

The formal technical reviewers and other workshop participants stated the proposed USA definition and the computer model created from the proposed definition are reasonable and a significant start to defining USAs. They offered various suggestions for improving the proposed USA definition,

the computer model created from the proposed definition, and the process used to create USA maps.

Drinking Water Recommendations

1. *Replace wellhead protection areas (WHPAs) with source water protection areas (SWPAs), specifically the areas of primary influence.*

A WHPA is an area surrounding a water well or well field that supplies a public water system through which contaminants are likely to pass and eventually reach the water well or well field. SWPAs are being created under a new EPA program, the Source Water Assessment Program (SWAP). The SWAP expands EPA's Wellhead Protection Program to cover surface water and places where groundwater interacts with surface water, in response to the 1996 Amendments to the Safe Drinking Water Act. State agencies are obtaining additional information than the data used to create the WHPAs in order to create SWPAs.

Under SWAP, state agencies must perform a source water assessment for each public water system to analyze existing and potential threats to the quality of the public water. As part of the assessment, the state must delineate the SWPA for the public water system. All source water assessments and SWPAs must be completed by May 2003.

The NPRM proposed that a WHPA for a community water system or a non-transient non-community water system that obtains its water supply from a Class I or Class IIA aquifer and does not have an adequate alternative source of water for a backup be considered a USA. The NPRM discussed community water systems, non-transient non-community water systems, and Class I and IIA aquifers in detail. Definitions for these terms can be found in the NPRM and at the end of this final rule.

The formal technical reviewers and other workshop participants agreed that RSPA should replace WHPAs with SWPAs. These commenters stated that SWPAs are more appropriate since they are an expansion of the WHPAs and the SWPAs should be more accurate than the WHPAs. In addition, states are focusing their attention away from WHPAs and onto SWPAs. Therefore, the WHPAs may become obsolete over time.

Since the SWAP is a new program, commenters suggested that RSPA continue to use WHPAs where SWPAs have not yet been identified. However, RSPA found that a few SWPAs have already been delineated as of August 2000.

RSPA agrees with the commenters and in the final rule has replaced WHPAs with SWPAs. Where SWPAs

have not been created, WHPAs will be used to identify USAs.

2. *Replace the Pettyjohn et al. Aquifer Classification Scheme with SWPAs.*

In the NPRM, RSPA proposed to use the Pettyjohn et al. aquifer classification scheme as a way to determine which ground water sources are more susceptible to contamination from a hazardous liquid release. The Pettyjohn et al. aquifer classification scheme can be found in EPA Report 600/2-91/043, "Regional Assessment to Aquifer Vulnerability and Sensitivity in the Conterminous United States," August 1991. Under this classification scheme, aquifers are ranked as Class I (a-d), II (a-c), III, or U. Class I aquifers are surficial or shallow, are permeable, and are highly vulnerable to contamination. Class II aquifers are consolidated bedrock aquifers that are moderately vulnerable to contamination. Class III aquifers are consolidated or unconsolidated aquifers that are overlain by more than 50 feet of low permeability material and have a low vulnerability to contamination. Class U aquifers are undifferentiated aquifers where several lithologic and hydrologic conditions exist.

One technical reviewer stated that it may be appropriate to replace the Pettyjohn et al. aquifer classification scheme used in the NPRM with SWPAs. Under the Source Water Protection Program, there are three components of source water assessment: (1) Delineating the boundaries of areas providing source waters to public water supplies (the SWPA); (2) identifying, to the extent practical, the origins of certain unregulated contaminants in the water supplies; and (3) determining the susceptibility of the source waters of the public water system(s) to contamination.

For groundwater supplies, the SWPA delineation methods are very similar to the WHPA delineation methods, and many States are using previously delineated WHPAs as SWPAs for groundwater supplies. However, delineation of a SWPA is only the first step in the assessment process. The susceptibility analysis is a critical component of the program to identify those SWPAs that are most susceptible to contamination, and it has not been completed for most of the country.

The Pettyjohn et al. aquifer classification scheme is a similar approach to determine the susceptibility of an aquifer to contamination. Since states will not complete their source water assessments until May 2003, RSPA considers it appropriate to continue to use the Pettyjohn approach that was characterized in the NPRM. RSPA will consider replacing the

Pettyjohn et al. aquifer classification scheme with completed source water assessment data in the future. If we determine the SWPAs are an appropriate replacement to the Pettyjohn et al. aquifer classification scheme, we will issue a NPRM seeking comment on revising the USA definition.

3. *Make a preliminary drinking water USA a USA unless it is verified that an adequate alternative drinking water source exists. Change the adequate alternative drinking water source definition to extend the amount of time needed for the backup water source from one month to six months for groundwater systems.*

In the computer model created from the proposed USA definition, a drinking water resource passes through a series of filtering criteria to determine if the resource is susceptible to contamination from a pipeline release. Drinking water intakes and WHPAs that pass these filtering criteria are called preliminary drinking water USAs. All preliminary drinking water USAs are put through a final filter criterion—Is there an adequate alternative drinking water source that the preliminary drinking water USA can pull from? The NPRM proposed that an adequate alternative drinking water source be defined as a source of water that currently exists, can be used almost immediately with a minimal amount of effort and cost, will meet the short-term (at least one month) consumptive and hygiene requirements of the existing population of impacted customers, involves no perceptible change in water quality, and is temporary (until a long term alternative can be put in place, if necessary).

During the pilot test, RSPA telephoned public water suppliers to determine if an adequate alternative drinking water source existed for preliminary drinking water USAs. If the public water supplier stated that an adequate alternative drinking water source existed, the drinking water resource did not become a USA. If the public water supplier could not be reached or if the information received from the supplier was too ambiguous to decipher, the preliminary drinking water source stayed as a preliminary drinking water USA and did not become a final USA. In the pilot states, the success rate for determining whether there was an adequate alternative drinking water source varied widely, from only 45 percent for California, to nearly 85 percent for Louisiana.

The formal technical reviewers and workshop participants recommended that RSPA modify how the computer

model created from the proposed USA definition processes adequate alternative drinking water sources. Commenters stated that all preliminary drinking water USAs should be treated as USAs unless the public water supplier states that an adequate alternative drinking water source exists. Most reviewers commented that, if it was not feasible to determine whether there was an adequate alternative drinking water source, the default assumption should be that there is no adequate alternative source.

Participants and reviewers also recommended that RSPA change the proposed adequate alternative drinking water source definition to extend the amount of time needed for the backup water source for groundwater systems. Commenters stated that, in their experience, most spills that have affected surface water intakes resulted in short-term shutdowns of the intakes and that one month would be appropriate for surface water intakes. However, for groundwater systems, one month would not be enough time. Contamination to a groundwater system may take longer than a month to clean up and new wells might have to be drilled and connected to the water distribution system. Therefore, commenters suggested that the backup time be changed from one month to six—twelve months for groundwater systems.

RSPA agrees with both recommendations and has incorporated them into the final rule. RSPA believes that six months is a sufficient amount of time for an adequate alternative drinking water source for a groundwater system.

4. Remove the doubling of WHPAs in sole source aquifers.

In the NPRM, RSPA proposed as USAs an area twice that of the WHPAs if the following conditions existed:

- The WHPA was in a sole source aquifer,
- The sole source aquifer was a Class I or IIa aquifer as determined by the Pettyjohn, et al., aquifer classification scheme, and
- There was not an adequate alternative drinking water source available.

EPA defines a sole or principal source aquifer as one which supplies at least 50 percent of the drinking water consumed in the area overlying the aquifer. These areas can have no alternative drinking water source(s) which could physically, legally, and economically supply all those who depend on the aquifer for drinking water.

Workshop participants and technical reviewers stated that RSPA should rely

on the analysis conducted by a state and should not second guess a state by doubling the WHPA. Each state has set up delineation programs that include scientific analytical methods to determine the appropriate size of the WHPA. Therefore, the states can most competently determine the correct protection area that should be used.

RSPA agrees with these comments. The final definition does not double the SWPAs or WHPAs in sole source aquifers.

5. Update the definition for a Community Water System.

In the NPRM, RSPA proposed to define a community water system as “a public water system that provides water to the same population year round.” RSPA agrees that the final USA definition should use EPA’s current definition for a community water system, as defined by statute. The current definition is “A public water system that serves at least 15 service connections used by year-round residents of the area served by the system or regularly serves at least 25 year-round residents.”

6. Change the Filter Criteria to Consider All Class II Aquifers, Not Just Class IIa.

In the NPRM, RSPA proposed that the WHPAs for community water systems or non-transient non-community water systems that obtain their water from a Class I or IIa aquifer and do not have an adequate alternative source of water for a backup be considered USAs. Class II aquifers are consolidated bedrock aquifers that are moderately vulnerable to contamination. They include the following sub-classes:

Class IIa: Higher Yield Bedrock Aquifers. Consist of fairly coarse sandstone or conglomerate that contain lesser amounts of interbedded fine-grained clastics and occasionally carbonate units. In general, well yields must exceed 50 gallons per minute (gpm) to be included in this class.

Class IIb: Lower Yield Bedrock Aquifers. Consist of the same clastic rock types present in the higher yield systems. Well yields are commonly less than 50 gpm.

Class IIc: Covered Bedrock Aquifers. Consist of Class IIa and IIb aquifers that are overlain by less than 50 feet of unconsolidated material of low permeability.

One technical reviewer recommended that all Class II aquifers (Pettyjohn *et al.*, 1991) be considered. We are not adopting this recommendation. RSPA believes that class IIb and IIc are not significantly at risk of contamination from a release from a hazardous liquid pipeline. The USA delineation process

is intended to identify those resources that are unusually sensitive to damage from a pipeline release. Lower-yield aquifers are at less risk of contamination because response actions should be effective in containing and cleaning up the spilled oil before the well becomes contaminated.

7. Include sole source aquifers that are karst in nature USAs.

One technical reviewer recommended that RSPA include all sole source aquifers that are karst in nature as USAs. Another reviewer recommended that the final USA definition include the recharge areas of the sole source aquifers that are karst in nature. Karst aquifers are composed of limestone or dolomite where the porosity is derived from connected solution cavities. They are often cavernous, with high rates of flow. These types of aquifers are very susceptible to contamination and EPA’s data show at least one case of significant contamination in a karst aquifer as a result of a hazardous liquid pipeline release in the recharge area of the aquifer.

The recharge area is the area contributing to the groundwater that may flow to the aquifer over a long time. Recharge areas for karst aquifers often include sinkholes, disappearing streams, etc. where surface contaminants can directly enter the aquifer. Even rapid and effective spill response is not likely to prevent groundwater contamination in these areas.

RSPA agrees that the recharge area of karst aquifers are highly susceptible to contamination from a hazardous liquid pipeline release. RSPA does not agree that the entire karst aquifer is unusually sensitive. Although contaminants, once introduced, will flow rapidly within the aquifer, they cannot readily be introduced in non-recharge areas. According to the Pettyjohn et al. aquifer classification system, if there are 50 feet or more of imperious material overlying the aquifer, it is a Class III aquifer and is of low susceptibility of contamination, even if it is karst in nature.

In the NPRM, RSPA proposed that the WHPAs for community water systems or non-transient non-community water systems that obtain their water from a Class I or IIa aquifer and do not have an adequate alternative source of water for a backup be considered USAs. A recharge area of a sole source aquifer that is karst in nature would be considered part of a Class I aquifer. The NPRM proposed that WHPAs be doubled for sole source aquifers to provide additional protection. While RSPA did not propose to include the

entire recharge area for sole source aquifers that are karst in nature, RSPA did show intent to provide these areas with additional protection.

RSPA has conducted a national review of sole source aquifers that are karst in nature and has determined that including the recharge areas for these aquifers would only cause a minor increase in the amount of land mass identified as a USA. Therefore, RSPA has included the recharge areas of sole source aquifers that are karst in nature in the final USA definition.

8. *Where possible, consider artificial penetrations from abandoned wells, injection wells, seismic shot holes, etc.*

Three technical reviewers and several workshop participants expressed concern that artificial penetrations into an aquifer would provide a pathway for aquifer contamination that was unaccounted for in the Pettyjohn et al. aquifer classification. Artificial penetrations include abandoned wells, monitoring wells, injection wells, seismic shot holes, and improperly constructed water wells that allow groundwater interflow among aquifers. Artificial penetrations are of particular concern in many areas, including those with oil and gas exploration and production. In spite of the concern of the technical reviewers and workshop participants, the lack of data on the locations of these artificial penetrations makes it impossible to consider them in state or regional mapping applications or risk assessments at this time.

Ecological Recommendations

1. *Include in the USA definition all resources RSPA was asked to consider in the federal pipeline safety statute.*

One technical reviewer recommended that USAs include all resources that RSPA was asked to consider in 49 U.S.C. § 60109. These resources include critical wetlands, riverine or estuarine systems, national parks, wilderness areas, wildlife preservation areas or refuges, wild and scenic rivers, and critical habitat for threatened and endangered species.

RSPA has determined that not all of these resources should be considered USAs at this time. Congress required RSPA to establish criteria defining locations where unusually sensitive resources might incur permanent or long-term "environmental" damage in the event of an oil spill. Congress added the words "permanent" and "long-term" when it amended the USA identification requirements in 1996 (49 U.S.C. 60109). As we explained in the NPRM, rather than focus on the geographic boundaries of these areas, we focused on particular ecological

species and drinking water resources in these areas that could suffer irreparable harm from a hazardous liquid release. We believe that protecting those particular species and resources now will concentrate prevention, mitigation, and response resources on areas that are most susceptible to permanent or long-term damage.

We believe that this approach satisfies the statutory mandate. We ran computer models that tested including various categories of resources, including all resources listed in the statutory mandate, for which existing data bases permitted computer modeling. Based on our analysis of all information currently available, we believe that by focusing on the particular ecological species and drinking water resources that could suffer irreparable harm, we will pick up a substantial extent of resources within the National Parks, National Wildlife Refuges, National Wilderness Areas, National Forests, and other resources that do not meet the filtering criteria being used in this rulemaking. Based on information currently available, it is not possible at this time to determine the extent of coverage in these nationally important resources areas.

Although we have not included these other areas in this rulemaking, RSPA will consider extending protection to other environmentally sensitive and vital resources through future rulemaking. Other areas that will be considered include the National Parks, National Wildlife Refuges, National Wilderness Areas, National Forests, and other cultural and sensitive environmental resources that do not meet the filtering criteria being used in this rulemaking.

The following provides additional information on some of the particular resources listed in the federal pipeline safety statute:

Critical Wetlands

RSPA has not been able to find a strict definition of critical wetlands or a consistent program that identifies critical wetlands that could be applied to the ecological USA program. "Critical wetland" in many cases is a generally applied term used in a wide variety of situations.

The most prevalent use of this term is in relation to issuance of permits for impacts to wetlands under Section 404 of the Clean Water Act. Some states have developed special conditions, mainly related to water quality criteria, that limit use of nationwide and other general permits in certain waters. The term "critical wetland" is used by a few states in this regard, however, the types

of wetlands considered as "critical" differ from state to state.

The term "critical wetland," when used in permitting programs, tends to require additional scrutiny to permit applications. It does not preclude the approval of permits. Indeed, permits are approved for these "critical wetlands," subjecting these areas to environmental impacts.

Although the USA definition does not use the term "critical wetlands," the definition does include wetlands that are represented in the Ramsar program (Wetlands of International Importance) and the Western Hemisphere Shorebird Reserve Network (WHSRN) program. These wetlands include the Florida Everglades, the Okefenokee Swamp in Georgia, Cheyenne Bottoms in Kansas, and Ash Meadows in Nevada. The protection of rare and endangered species in ecological USAs also contributes to the protection of wetland habitats. For aquatic and wetland species, the computer model created from the proposed and final USA definition identifies potentially larger polygonal areas as USAs (using a five mile radius around the species occurrence locations, as well as a one-fourth mile buffer into adjacent upland habitats), relative to terrestrial species (using a one mile radius), increasing the amount of wetland or aquatic area protected.

Finally, as a result of technical reviewer and workshop participant comments and other public comments to the NPRM, RSPA has revised the USA definition to include all occurrences of aquatic and aquatic-dependent USA candidate species. This will further increase the number and extent of wetlands captured as USAs. Our discussion about including these species is found later in this document.

Riverine or Estuarine Systems

Rivers and estuaries are extensive geographic features. Although all rivers and estuaries are important national resources, RSPA has decided to focus on the most sensitive portions that contain critically imperiled, imperiled, and threatened and endangered species.

Many rivers and estuaries are captured in whole or part by the final definition. Areas such as the Chesapeake Bay estuary, the Delaware Bay estuary, San Francisco Bay, Florida Bay (in Everglades National Park), the Copper River delta in Alaska and the Altamaha River in Georgia will be captured as USAs due to their recognition in the Ramsar and/or WHSRN programs. USAs formed due to the presence of rare and endangered species also result in the protection of

estuaries and rivers. As an example, many estuaries, rivers, and streams in the California pilot test became ecological USAs because they contained critically imperiled salmon populations. Also, much of the Pearl River in the Louisiana pilot became a USA because it contained three or more occurrences of endangered and imperiled species.

National Parks, Wildlife Refuges, Wildlife Preserves, Wilderness Areas and Wild and Scenic Rivers

We refer to these areas collectively as management areas, since they are managed primarily by the Departments of Interior and Agriculture. All of these areas are very important national resources. Rather than focus on the geographic boundaries of these areas, the proposed USA definition focuses on many areas within the boundaries as potential ecological USAs because of the presence of other protected species or natural communities.

Management areas tend to receive more USA designations because there is more information on the ecological resources in these areas. Endangered and rare species surveys, migratory waterbird surveys and enhancement projects, and detailed natural resource mapping efforts are much more prevalent in management areas compared to lands under other types of ownership and management. Accordingly, under this rule, large portions of our national parks, wildlife refuges, etc. are likely to be identified and protected as USAs even without explicitly including these important national resources as a USA. Based on data currently available for our analysis, it is not possible to determine the exact extent of coverage with the boundaries.

Designated Critical Habitat for Threatened or Endangered Species

During the public workshops that were held to help identify USAs, designated critical habitats (DCH) were considered as possible ecological USA candidates. RSPA chose to focus on the locations of the species rather than DCH because the location is a more focused identification of where the rare species currently exists. RSPA expects large areas of DCH to be USAs based on the presence of rare species. Due to the way in which critical habitats are described for some species, converting the DCH text descriptions to geographic boundaries would be difficult and, in some cases, impossible. We believe that protecting those particular species and resources now will concentrate prevention, mitigation and response resources to areas that are most

susceptible to permanent or long-term damage.

As new ecological information becomes available to RSPA and we identify and locate additional USAs, the operator has responsibility to apply this new information in its integrity management program.

2. Include additional species concentration areas, such as rookeries.

Four technical reviewers and workshop participants recommended that the USA definition include additional species congregation areas, such as migratory, breeding, calving, spawning, and nursery areas. Congregation areas are currently covered in the proposed definition through inclusion of Ramsar and Western Hemisphere Shorebird Reserve Network (WHSRN) sites. These sites protect highly significant migratory waterbird concentration areas and habitats. In these areas, a very large percent of a water bird species population concentrate, creating a situation where a relatively abundant species might have a large percentage of its population impacted by a petroleum spill. One of the best examples of this type of concentration area is the portion of Delaware Bay where 80–90 percent of the red knot (a shorebird) population stops-over to feed during migration.

RSPA researched additional species aggregation and concentration areas and found standard definitions, classifications, and databases do not exist or are not complete enough to include them in the USA model. Of our three pilot states, only the eastern portion of Louisiana had additional species concentration data.

From our research, we concluded that we should consider adding two programs to the ecological component of the USA definition when complete data is available: Colonial waterbird nesting sites and Important Bird Areas. Colonial waterbirds include seabirds and wading birds, such as herons, egrets, ibises, pelicans, gulls, and terns. Colonial waterbird nesting data are currently collected by many state resource agencies. States collect the data in a relatively standardized way, but the type of information collected and its format, quality, availability, etc. varies widely between states and even within individual states. This variability makes identifying unusually sensitive or highly significant colonies very difficult to impossible on a national or range-wide basis.

To address the variability problem, two related national programs spearheaded by the USGS Biological Resources Division (BRD) are currently under development. One effort is to

establish a national monitoring program for colonial waterbirds and a centralized database. The other is to develop a management plan for colonial waterbirds throughout North America. The USGS BRD's Patuxent Wildlife Research Center can be contacted for more information about these programs (<http://www.pwrc.usgs.gov/> or phone: 301/497–5753).

Important Bird Areas (IBAs) is a relatively new program headed by the American Bird Conservancy and the National Audubon Society to identify unusual or highly significant concentration bird areas. Criteria established for certain types of sites in the IBA program might be comparable to criteria used in the Ramsar and WHSRN programs. IBAs include wintering, breeding, and migratory sites and also cover additional species groups (IBA is not limited to migratory waterbirds). However, the exact criteria used to determine IBAs are not currently available and supporting data for different sites are still in development, making it difficult to evaluate sites for inclusion in the USA model. Furthermore, geographic information and/or maps to delineate IBA locations do not exist. A published account of the most significant IBAs for each state is expected in the near future. For more information about IBAs, contact the American Bird Conservancy (<http://www.abcbirds.org/> or phone: 540/253–5780).

Once complete data are available, RSPA will evaluate the data and determine whether to include these programs in the USA definition. If we determine that these programs should be included as USAs, RSPA will issue a NPRM seeking public comment on revising the USA definition.

3. Add rare ecological communities (habitats), such as California's vernal pools.

Five technical reviewers and various workshop participants recommended that RSPA add rare ecological communities (habitats) to the USA definition. RSPA carefully considered including rare ecological communities when developing the proposed USA definition. RSPA did not include them in the proposed definition because of the quality of the rare ecological community data at the time these resources were being considered. At that time, data providers indicated that the classification systems, nomenclature, conservation status ranks, etc. for the ecological community data were still in development and were not consistent.

RSPA was concerned that different state groups and other data providers were using different classification

schemes, different naming conventions, inconsistent status ranks, etc. Therefore, RSPA did not include rare ecological communities in the proposed definition. Since that time, data standards for the natural community data have greatly improved.

RSPA agrees that critically imperiled and imperiled rare ecological communities should now be included as ecological USA candidates, with the caveat that the natural community data must match recent nomenclature and conservation status rank conventions. RSPA believes including these resources in the final definition is consistent with our expressed intent to focus on resources that are susceptible to permanent or long term damage if affected by a release. All the same filtering criteria will be applied.

RSPA tested a modification of the proposed definition that included rare communities. In our pilot states, adding rare communities increased the amount of land mass by less than 1% in Louisiana and California. It did not increase the land mass covered in Texas.

4. *Make imperiled, threatened and endangered, and depleted marine*

mammal species that are aquatic or aquatic dependent or are terrestrial and have a limited range USAs.

Several technical reviewers and workshop participants recommended that RSPA modify the proposed definition to increase the USA species representation. For USAs, increasing species representation would increase the percent of critically imperiled, imperiled, threatened and endangered, and depleted marine mammal species that are covered as USAs.

Technical reviewers and workshop participants discussed several ways to increase representation. One suggestion was to add as USAs all species that are aquatic or aquatic dependent and species that are terrestrial with a limited range (occupying a small area or can not move far). These species are more susceptible to permanent or long term damage since they are less likely or less able to avoid or leave an impacted area. These species are more likely to have all or a large part of the area they occupy or use as habitat or food sources disturbed, impacted, or destroyed during a spill.

RSPA tested a modified USA definition that included aquatic or

aquatic dependent species and species that are terrestrial and have a limited range. For terrestrial species, RSPA reviewed the ecological databases for the pilot states to determine an appropriate value for "limited range." RSPA determined that five acres was an appropriate value. Five acres or less seemed to successfully discriminate between those terrestrial species that have small ranges versus those that are easily recognized as wide-ranging species. Rare terrestrial species with limited ranges include most critically imperiled, imperiled and threatened and endangered plants and invertebrates.

The following table compares the representation statistics that were achieved for imperiled species and threatened and endangered species with the proposed rule and the statistics achieved when we add aquatic, aquatic dependent, and limited range species. The representation statistics for critically imperiled species were 100% for both the proposed definition and the modified definition since all critically imperiled species are USAs.

	Imperiled species	Threatened & endangered species
Proposed rule	TX: 70% representation LA: 30% representation CA: 93% representation	TX: 90% representation. LA: 60% representation. CA: 98% representation.
With changes	TX: 99% representation LA: 97% representation CA: 100% representation	TX: 90% representation. LA: 92% representation. CA: 100% representation.

RSPA agrees with the technical reviewers that these species should be made USAs. Adding these species is consistent with our intent in the proposed definition to provide additional protection to species in or near water. In the computer model created from the proposed USA definition, species that are aquatic or aquatic dependent are given a five mile buffer instead of the one mile buffer given to species that are terrestrial. In the pilot states, adding aquatic, aquatic dependent, and limited range species increased the amount of land mass by

less than 2% in Texas, 4% in California, and 13% in Louisiana.

5. *Change multi-species protection areas (MSPAs) from three overlapping species to two overlapping species. Also, change MSPA to "multi-species assemblage areas."*

In the proposed USA definition, a MSPA is defined as an area where three or more different critically imperiled or imperiled species, threatened or endangered species, depleted marine mammals, or migratory waterbird concentrations co-occur. Several technical reviewers and workshop participants recommended that MSPAs

be changed from three overlapping species to two overlapping species to increase representation.

The following table compares the representation statistics that the proposed rule achieved for imperiled species and threatened and endangered species with the proposed rule and the statistics achieved when we change MSPAs from three overlapping species to two overlapping species. The representation statistics for critically imperiled species were 100% for both the proposed definition and the modified definition since all critically imperiled species are USAs.

	Imperiled species	Threatened & endangered species
Proposed rule	TX: 70% representation LA: 30% representation CA: 93% representation	TX: 90% representation. LA: 60% representation. CA: 98% representation.
With MSPA changes	TX: 84% representation LA: 63% representation CA: 97% representation	TX: 96% representation. LA: 80% representation. CA: 99% representation.

Comparing the representation statistics when adding aquatic, aquatic dependent, and limited terrestrial species with changing MSPAs from three overlapping species to two shows greater representation is achieved by adding aquatic, aquatic dependent, and limited terrestrial species. This modification will result in covering larger assemblage of species vulnerable to extinction and provides greater species protection. Therefore, in the final USA definition, RSPA chose to include the aquatic, aquatic dependent, and limited terrestrial species. RSPA did not change MSPAs from three overlapping species to two.

Various workshop participants and technical reviewers also recommended that we change the term "multi-species protection area" to "multi-species assemblage areas." RSPA agrees that this would be a more accurate portrayal of these areas and has changed the term in the final rule.

6. *Add species and ecological community occurrences that are in the best condition and are therefore the most viable, as identified by the Natural Heritage Programs' element occurrence rank (EORANK) or some other measure.*

One technical reviewer recommended that RSPA consider including those rare species and ecological community occurrences that are in the best condition and are therefore the most viable. The Natural Heritage Programs assign EORANKs to species and ecological community occurrences based on a population's size, condition, and landscape context. An EORANK of A means the species or community occurrence is in excellent condition and an EORANK of B means it is in good condition. EORANKs of C and D refer to occurrences that are marginal or poor. EORANKs of H and X refer to historical and extirpated occurrences.

Rare species and ecological community occurrences with an EORANK of C or D are considered in other areas. All critically imperiled species and community occurrences are USAs, regardless of their EORANK. Imperiled species and ecological community occurrences, threatened and endangered species occurrences, and depleted marine mammal species occurrences that have an EORANK of C or D are USAs if the species is aquatic, aquatic dependent, or has a limited terrestrial range, or if it is part of a MSPA or migratory waterbird concentration area.

RSPA agrees that rare species and community occurrences that are in the best condition and are therefore the most viable should be added as USAs. Adding these rare species and

community occurrences ensures that the highest quality or most important occurrences for the remaining rare species and community occurrences (those that are not aquatic or aquatic dependent, or part of a multi-species assemblage area) are included as USAs. Accordingly, RSPA has added to the USA definition imperiled, threatened or endangered, or depleted marine mammal species occurrences and imperiled ecological community occurrences that have an EORANK of A or B. All critically imperiled species and community occurrences are already treated as automatic USAs.

RSPA tested a modification of the proposed definition that included the most viable rare species and ecological community occurrences. In our pilot states, adding rare communities increased the amount of land mass by less than 1% in Texas, by 2% in California, and by 4% in Louisiana.

7. *Use the state conservation status ranks (S-ranks) to exclude extinct and historic species.*

One technical reviewer recommended that RSPA use the state conservation status ranks to remove species that are historical or extirpated. RSPA agrees to remove the species and ecological communities with an S-rank of SX in the computer model that will be created from the final USA definition. RSPA will not remove the species or communities with an SH ranking because there is sufficient variability in how this ranking is used and a possibility that the occurrence is still present that RSPA elects to err on the side of including SH occurrences.

8. *Include only occupied habitat for terrestrial species with large ranges.*

One technical reviewer recommended that RSPA include only those areas designated as being occupied for terrestrial species that have large ranges. This concept is already incorporated into the computer model created from the proposed USA definition. For species with large ranges that are mapped as polygons, areas described as "potentially" containing a species are not used in the computer model. Also, large polygonal distributions that are not classified as "occupied habitat" or "specific bounded areas" (e.g., areas where the specific boundaries of the species occurrence were mapped) are not used in the computer model.

9. *Include state listed threatened and endangered species and state priorities.*

Two technical reviewers recommended that RSPA consider including state listed threatened and endangered species and resources that the state considers important. RSPA considered including these species and

resources, but found that state listings do not always reflect the nationwide, or range-wide, abundance of a species. In many cases, a species may be ranked or listed in a state because it is near the edge of its range and is therefore rare within that state. The species may be relatively abundant in the adjacent states. State rankings and listings can also be highly variable due to differences among states in ranking and listing procedures and regulations. For these reasons, RSPA does not agree that these resources should be included.

Miscellaneous Recommendations

The technical reviewers and workshop participants also provided recommendations that apply to both the drinking water and ecological portion of the proposed rule, or to items that were not proposed in the NPRM. These include the following:

1. *Include cultural and Indian tribal concerns, economic, and recreational areas as USAs.*

One technical reviewer recommended that RSPA include the above resources as USAs. The proposed definition concentrated on drinking water and ecological resources. The NPRM did not propose to include other sensitive resource areas. Before proposing the USA definition, we sought extensive comment from drinking water experts, ecological resource experts, and interested public parties. We would not want to include these other areas now without an opportunity for public comment and evaluation by experts. RSPA intends to define other sensitive resource areas that need additional protection in a future rulemaking and will consider cultural and Indian tribal concerns, economic and recreational areas as a part of this process.

2. *Update USAs on a periodic basis, possibly every 4-5 years.*

Several technical reviewers and workshop participants stated that USAs need to be updated on a regular basis or they would become obsolete over time. RSPA agrees. RSPA intends to identify the locations of USAs through a comprehensive collection and analysis of drinking water and ecological resource data, contingent on the availability of funding and resources. These areas will be mapped using the National Pipeline Mapping System. Operators, other government agencies and the public will have access to these maps through the Internet. Individuals will be able to view maps of USAs and other high consequence areas nationally or by state, county, zip code, or zooming in or out of a particular area. Operators will then be able to use the maps as a guide to determine which areas of their

pipeline could affect USAs. Operators may need to contact resource agencies to obtain additional information on a particular species or drinking water intake in a USA. Nothing in this mapping, however, changes the definition of an USA in this rule.

RSPA will map USA locations on a state by state basis, beginning with the states that have the largest number of liquid pipeline miles. RSPA expects to complete the first ten states by the end of the year. These states include Texas, Oklahoma, Kansas, Louisiana, Illinois, Wyoming, New Mexico, California, Missouri, and Montana. The remaining states are expected to be completed by the end of 2001.

RSPA recognizes that inventories and maps of USAs have to be updated on a periodic basis to incorporate new information and databases. RSPA intends to update the USA maps every five years, contingent on the availability of funding and resources. RSPA will review new or revised drinking water and ecological programs and databases at that time and will incorporate new databases into the computer model created from the final USA definition at that time. RSPA will announce in the **Federal Register** and through other communication networks when revised USA maps are available.

RSPA will also analyze new, revised, or refined drinking water and ecological programs every five years to determine if other programs should be added to the USA definition. RSPA will propose any revisions to the USA definition in a notice of proposed rulemaking.

3. Create a petitioning process to correct, add, or remove USA designations.

The pipeline safety regulations (49 CFR 190.331) allow interested persons to petition the Associate Administrator for Pipeline Safety to establish, amend, or repeal a substantive regulation. There is no need to create a separate process for USAs.

4. Use regional, state, and local data sets, not just data sets that meet national standards.

Various technical reviewers and workshop participants recommended that RSPA use regional, state, and local data sets when processing the computer model created from the USA definition. RSPA uses state databases as the primary data source for the USA computer model.

The drinking water USA computer model relies on data solely provided by the states. State aquifer maps are used to determine aquifer classifications. State data on the well location, depth, source, etc. are used to identify the aquifers used by the wells. Source-water

and wellhead protection programs are implemented at the state and local level.

The ecological USA computer model uses data from the state Natural Heritage Programs (NHP) on rare and endangered species locations. The Environmental Sensitivity Index (ESI) and related ecological data sets are also used to augment the NHP data in coastal and marine areas. ESI data are developed primarily by federal agencies, although some states have their own ESI programs (e.g., Texas, Maine, Florida, Alabama). Regardless of the managing authority, the content of the ESI data sets are derived primarily from state agency sources.

National programs often provide the guidance for these state-implemented programs. RSPA considers it important that USAs be defined in a consistent manner nationwide. This requires data that conform to some common standard. The NHP and ESI data sources both conform to published national standards. The fact that they are nationally standardized also makes the application of the USA computer model much more uniform across states. Attempting to obtain, organize, and validate data that are not nationally standardized would require significant effort, time, and money well beyond RSPA's limited resources. Each additional data set would need to be evaluated for consistency and accuracy. Independently evaluating a wide variety of local, state, and regional data sets would not be feasible and could impede the creation of USA maps for the nation.

Other local, state, and regional groups may submit their data to the appropriate state NHPs. This would assure that their information will be considered when revised USA maps are generated in future updates. Local, state, and regional groups may also participate in U.S. Coast Guard area planning meetings, or they may contact the NOAA Scientific Support Coordinator or the appropriate state contact in their area so that they can be identified as potential data providers when ESI data sets are developed and updated.

Discussion of Comments in Response to NPRM

In addition to the technical review and workshop comments, RSPA received 24 additional comments to the NPRM. Most of these comments mirrored those received from the technical reviewers. RSPA received comments from ten government agencies (EPA Office of Emergency and Remedial Response; EPA Regions 3 and 8; U.S. Department of the Interior; U.S. Department of Commerce; U.S. Department of Energy; State of Missouri,

Department of Natural Resources; State of Wyoming, Department of Environmental Quality; Hill Country Underground Water Conservation District; and the City of Austin), six advocacy groups (The Working Group on Community Right to Know, Environmental Defense, Friends of the Aquifer, Fuel Safe Washington, McHenry County Defenders, and STOP), two trade associations (American Water Works Association and the American Petroleum Institute), three pipeline operators (Equilon, Tosco, and BP Explorer), two separate comments from Argonne National lab, and one additional member of the public (Ruth Ellen Schelhaus). Most commenters expressed support for the proposed rule.

Drinking Water Recommendations

The following briefly discusses the public comments (those not from the technical reviewers or workshop participants) to the drinking water portion of the proposed rule that mirrored those received from technical reviewers and workshop participants. Our rationale for accepting or rejecting these recommendations is discussed in more detail in the previous section on technical reviewer comments.

1. Replace WHPAs with SWPAs.

Nine commenters recommended that RSPA replace WHPAs with SWPAs. RSPA agrees and has made this change to the final rule.

2. Replace the Pettyjohn et al. Aquifer Classification Scheme with SWPAs.

Two commenters recommended that RSPA consider replacing the Pettyjohn et al. aquifer classification scheme used in the NPRM with SWPAs. Since states will not complete their source water assessments until May 2003, RSPA considers the approach proposed in the NPRM to be appropriate at this time. RSPA will consider replacing the Pettyjohn et al. aquifer classification scheme with completed source water assessment data in the future. RSPA will issue a NPRM seeking comment on revising the USA definition if we determine the SWPAs are an appropriate replacement to the Pettyjohn et al. aquifer classification scheme.

3. Make a preliminary drinking water USA a USA unless it is verified that an adequate alternative drinking water source exists. Change the adequate alternative drinking water source definition to extend the amount of time needed for the backup water source from one month to six months for groundwater systems.

Various commenters recommended that RSPA modify how the model processes adequate alternative drinking

water sources. They stated RSPA should treat a preliminary drinking water USA as a USA unless the public water supplier states that an adequate alternative drinking water source exists. Commenters also recommended that RSPA change the adequate alternative drinking water source definition to extend the amount of time needed for the backup water source for groundwater systems from one month to six—twelve months for groundwater systems. RSPA agrees with these recommendations and has incorporated them into the final rule.

4. Remove the doubling of WHPAs in sole source aquifers.

Five commenters recommended that RSPA rely on the WHPA analysis conducted by the States and not double the WHPAs. RSPA agrees and has removed the doubling.

5. Update the Community Water System definition.

RSPA agrees and has included EPA's most current definition.

6. Include sole source aquifers that are karst in nature as USAs.

One commenter recommended that RSPA include all sole source aquifers that are karst in nature as USAs. RSPA does not agree that the entire karst aquifer is unusually sensitive but does agree that the recharge areas of these aquifers are. RSPA has included the recharge areas of sole source aquifers that are karst in nature as USAs.

7. Where possible, consider artificial penetrations from abandoned wells, injection wells, seismic shot holes, etc.

One commenter urged us to consider artificial penetrations into the aquifer. RSPA agrees that artificial penetration is a concern, but the lack of data on the locations of these artificial penetrations makes it impossible to consider this factor at the current time. RSPA will reconsider revising the USA definition to include this factor when better information is available.

The following discusses comments on drinking water resources received to the NPRM that the technical reviewers did not address:

1. Make all drinking water areas of primary concern USAs. Do not use filtering criteria.

In the proposed USA definition, drinking water areas of primary concern are identified. These areas are a subset of all surface intakes and groundwater-based drinking water supplies that provide potable water for domestic, commercial, and industrial users. Filtering criteria are applied to the areas of primary concern to determine which areas are more susceptible to contamination from a hazardous liquid release. Proposed filter criteria include

the depth and geology of a drinking water resource and if the public water system has an adequate alternative drinking water supply.

Eight commenters recommended that RSPA remove the proposed drinking water filter criteria and make all drinking water areas of primary concern USAs. RSPA does not agree with this recommendation. The majority of the technical reviewers and workshop participants agreed that certain drinking water resources are more susceptible to permanent or long term damage than others. Removing the filter criteria would make drinking water resources that have a very low or no probability of becoming contaminated from a release USAs.

2. Remove the adequate alternative drinking water source filter.

In the proposed USA definition, drinking water areas of primary concern do not become USAs if an adequate alternative drinking water source exists. Five commenters recommended that RSPA remove this filtering criterion. The commenters stated that these alternatives may not always be available, pipeline operators do not have the expertise to determine if an alternate source exists, and available water supply and demand are subject to dramatic change over time.

Removing this filter criterion would make all water intakes and WHPAs for community water systems and non-transient non-community water systems USAs. RSPA does not agree that this filter should be removed. Drinking water USAs are areas where a hazardous liquid release could represent an imminent threat to human health, due to contamination of community drinking water supplies. If an alternate source of drinking water is available, there is no immediate threat to human health. A community could switch to the alternative source and the alternative water source would provide the same water quality for essential uses.

RSPA will determine if an adequate alternative drinking water supply is available by contacting operators of community water supplies that have been determined to be preliminary USAs. Pipeline operators will not make this determination. RSPA will also reassess the adequate alternative drinking water supplies when USAs maps are updated.

3. Add industrial water intakes as drinking water USAs.

One commenter asked us to consider industrial water intakes as USAs. RSPA does not agree. Threats to industrial water intakes do not, by themselves, pose an imminent threat to human

health. Temporary shut-down of an industrial surface water intake poses more of an economic impact than a health impact. While such impacts are real and their avoidance is desirable, economic reasons alone do not justify treating industrial intakes as an unusually sensitive area.

4. Include all aquifers as drinking water USAs.

One commenter asked us to consider treating all aquifers as USAs. RSPA researched the impact of including all aquifers as USAs and determined that this addition would make the majority of the United States a USA. This would dilute RSPA's and the industry's ability to focus additional prevention, mitigation, and response measures on those areas most in need of additional protection from a hazardous liquid release. In addition, not all aquifers have the ability to be impacted by a hazardous liquid release. Some aquifers are so deep or are of such geology that a hazardous liquid release could not reach and consequently impact the aquifer. Therefore, RSPA does not agree with the commenter.

5. Include the entire aquifer of all sole source aquifers as drinking water USAs.

Two commenters recommended that RSPA include all sole source aquifers as drinking water USAs. RSPA does not agree. RSPA researched EPA's guidance on sole source aquifers. EPA notes that the ground water's vulnerability to contamination can vary considerably within an aquifer. Therefore, EPA does not endorse using sole source aquifer status as the determining factor in making land use decisions that may impact ground water quality. EPA recommends that site-specific hydrogeological assessments be considered along with other factors to determine the vulnerability of the area to contamination.

RSPA has followed EPA's guidance. RSPA has used the EPA aquifer vulnerability classification of Pettyjohn et al. (1991) to identify those ground water wells that are at risk of contamination from a pipeline release. RSPA has defined as USAs the SWPA or WHPA around each well to represent the USA for the vulnerable aquifers. States designate these areas to protect wells from a broad range of chemical contaminants. These state delineations consider the hydrogeological features important in determining the well's vulnerability to contamination. RSPA believes this is the best approach to identify the drinking water intakes most susceptible or unusually sensitive to a pipeline release.

6. *Include aquifer recharge zones as drinking water USAs.*

Three commenters recommended that RSPA include aquifer recharge zones as drinking water USAs. RSPA does not agree. The recharge zone is the entire area contributing to groundwater that may replace water drawn from an aquifer, such as by a community water supply. The time periods for water (and contaminant) transport in this zone can be very long, sometimes on the order of hundreds to thousands of years. RSPA believes that the WHPAs and SWPAs are the more appropriate areas to focus USAs. When designating WHPAs and SWPAs, states consider the ability of contaminants to reach and affect the public water supply within 2–5 years.

RSPA has revised the USA definition to add the recharge zones of sole source aquifers in karst areas. Aquifers in karst areas are very susceptible to contamination if a hazardous liquid release occurs in the area. Sole source aquifers are the sole or primary drinking water source for an area and have no adequate backup water source. Because these areas can suffer long-term damage from a pipeline release, we have included them as USAs.

Ecological Recommendations

The following briefly discusses the public comments (those not from the technical reviewers or workshop participants) to the ecological portion of the proposed rule that mirrored those received from technical reviewers and workshop participants. Our rationale for accepting or rejecting these recommendations is discussed in greater detail in the section on the technical experts' comments.

1. *Include all resources RSPA was asked to consider in the federal pipeline safety statute as USAs.*

Seven commenters recommended that RSPA include all resources listed for consideration in 49 U.S.C. § 60109 as USAs. These resources include critical wetlands, riverine or estuarine systems, national parks, wilderness areas, wildlife preservation areas or refuges, wild and scenic rivers, and critical habitat for threatened and endangered species.

RSPA has not included them. Congress required us to establish criteria defining locations where unusually sensitive resources might incur permanent or long-term environmental damage in the event of an oil spill. Congress added the words "permanent" and "long-term" when it amended the USA identification requirements in 1996. Not all areas and resources listed in the statute are subject to permanent or long term environmental damage.

RSPA believes Congress intended that RSPA focus on protecting those areas where additional prevention, mitigation, and response measures are most needed. Including all areas RSPA was asked to consider in the mandate would divert resources to areas that are not susceptible to permanent or long-term damage. All areas that are sensitive cannot be defined as "unusually sensitive" if the expected focusing of attention is to occur. Thus, instead of including all listed areas at this time, we decided to focus on the drinking water and ecological resources within these areas that would likely suffer irreparable harm if affected by a release. Although RSPA has not included these other areas in this rulemaking, we will consider extending protection to other environmentally sensitive and vital resources through future rulemaking.

2. *Include additional species concentration areas, such as rookeries and Important Bird Areas.*

Four commenters recommended that RSPA include additional species congregation areas, such as migratory, breeding, calving, spawning, and nursery areas. RSPA researched additional species aggregation and concentration areas and found standard definitions, classifications, and databases do not exist or are not currently in a format that would support their inclusion in the USA model. Two programs that RSPA will consider in the future are the colonial waterbird nesting sites and Important Bird Areas.

3. *Add rare ecological communities (habitats).*

Five commenters recommended that RSPA add rare ecological communities (habitats) to the USA definition. RSPA agrees and has revised the final rule to add these resources. The natural community data will be treated the same as the rare and endangered species data, in that critically imperiled and imperiled natural communities will be USA candidates and filtering criteria will be applied.

4. *Make species that are aquatic or aquatic dependent and species that are terrestrial and have a limited range USAs.*

One commenter recommended that RSPA modify the proposed rule to increase species representation by adding all aquatic or aquatic dependent species and terrestrial species with a limited ranges as USAs. These species are more susceptible to permanent or long-term damage since they are less likely or unable to avoid or leave an impacted area. These species are more likely to have all or a large part of the area they occupy or use as habitat or food sources disturbed, impacted, or

destroyed during a spill. RSPA agrees and has added these species as USAs.

5. *Change multi-species protection areas (MSPAs) from three overlapping species to two overlapping species.*

Three commenters recommended that RSPA modify the NPRM to increase species representation by changing the MSPAs from three overlapping species to two overlapping species. RSPA tested this change and found that the representation statistics improved when we added aquatic, aquatic dependent, and limited terrestrial species as USAs. Therefore, RSPA decided to include the aquatic, aquatic dependent, and limited terrestrial species as USAs and did not change MSPAs from three overlapping species to two.

6. *Add species and ecological community occurrences that are in the best condition and are therefore the most viable, as identified by The Natural Heritage Program's element occurrence rank (EORANK) or some other measure.*

Three commenters recommended that RSPA include rare species and ecological communities that are in the best condition and are therefore the most viable as USAs. RSPA has made this change to the final rule.

7. *Include only the occupied habitat for terrestrial species with large ranges.*

Three commenters recommended that RSPA include only those areas designated as being occupied for terrestrial species that have large ranges. This concept is already incorporated into the computer model created from the proposed USA definition.

8. *Include state listed threatened and endangered species and state priorities.*

Seven commenters recommended that RSPA include state listed threatened and endangered species and resources important to the state. RSPA considered including these species and resources, but state listings do not always reflect the nationwide, or range-wide, abundance of a species. State rankings and listings can also be highly variable due to differences among states in ranking and listing procedures and regulations. For these reasons, RSPA does not agree that these resources should be included.

The following discusses comments on ecological resources received to the NPRM that were not addressed by the technical reviewers:

1. *Include all environmentally sensitive areas.*

Three commenters recommended that RSPA make all environmentally sensitive areas USAs. RSPA does not agree. Environmentally sensitive areas are part of the USA definition and identification process in that we

considered and evaluated these areas to determine USA candidates. Not all environmentally sensitive areas are unusually sensitive. Making all environmentally sensitive areas USAs would divert prevention, mitigation and response resources to areas that are not susceptible to permanent or long-term damage. To do so would not be consistent with the statutory mandate in 49 U.S.C. 60109.

2. Include all resources in the oil spill Area Contingency Plans (ACPs) and areas subject to soil erosion or subsidence.

One commenter recommended that RSPA include all ACP resources as USAs. RSPA does not agree and has not included these areas in the final definition. Ecological resources identified in the ACPs comprise all environmentally sensitive areas. Including all environmentally sensitive areas would divert prevention, mitigation and response resources to areas that are not susceptible to permanent or long-term damage. This final rule does not decrease the status of any ecological resource identified in the ACPs, nor does it decrease the amount of protection afforded these areas under the Oil Pollution Act of 1990.

The commenter also recommended that RSPA include all areas subject to soil erosion and subsidence. Soil erosion and subsidence are risk assessment factors that are related to pipeline vulnerability (the likelihood of a pipeline release). They have no direct relationship to ecological sensitivity (how sensitive a resource is to a disturbance or impact).

3. Make all ecological candidates USAs. Do not use filtering criteria.

Six commenters recommended that RSPA remove the filtering criteria used to identify ecological USAs. The majority of the technical reviewers and workshop participants agreed that certain species are more susceptible to permanent or long term damage. Likewise, most technical reviewers and workshop participants accepted that all individual occurrences of all candidate species do not need to be USAs. Therefore, RSPA will continue to use filter criteria.

RSPA has not filtered imperiled species since these species are closest to the brink of extinction. RSPA has also not filtered aquatic, aquatic dependent, or limited terrestrial species since they are the most vulnerable and sensitive to spill impacts. In addition, the most viable species occurrences are not filtered. This ensures that the best examples of each candidate species are protected as USAs. Finally, clusters or "hot spots" of species vulnerable to

extinction are not filtered. The multi-species USAs provide protection to unique areas where groups of species vulnerable to extinction co-occur.

4. Include vulnerable species as USAs or USA candidates.

Three commenters recommended that RSPA include vulnerable species as USAs. Vulnerable species are defined by The Nature Conservancy as rare species, typically with 21 to 100 occurrences or 3,000 to 10,000 individuals.

RSPA considered including vulnerable species as USA candidates. RSPA held detailed discussions with experts in the field of conservation biology, including representatives from The Nature Conservancy. Through these conversations, we decided that USA candidates should be limited to critically imperiled and imperiled species. If a pipeline release impacts a critically imperiled or imperiled species, it could eliminate 5% to 100% of the known occurrences for that species. If a pipeline release impacts a vulnerable species, the largest impact would be an elimination of less than 5% of the known occurrences for that species. Vulnerable species are picked up in part by the USA definition since several of these species are also federally listed threatened or endangered species. RSPA will consider including vulnerable species and other sensitive resources in a future rulemaking.

Miscellaneous Recommendations

The following briefly discusses the public comments (those not from the technical reviewers or workshop participants) that mirrored those received from technical reviewers and workshop participants. Our rationale for accepting or rejecting these recommendations is discussed in more detail in the previous section on technical reviewer comments.

1. Include cultural and Indian tribal concerns, economic, and recreational areas as USAs.

Eleven additional commenters recommended that RSPA include the above resources as USAs. The proposed definition focused on drinking water and ecological resources that needed additional protection. We would not want to now include other areas not proposed without an opportunity for public comment and technical review. RSPA intends to define other sensitive resource areas that need additional protection in a future rulemaking and will consider cultural and Indian tribal concerns, economic and recreational areas as a part of this process.

2. Update USAs on a periodic basis, possibly every 4–5 years.

Six commenters stated that USAs need to be updated on a regular basis or they would become obsolete over time. RSPA agrees. RSPA intends to identify the locations of USAs and to map these areas. RSPA will update the USA maps every five years, contingent on the availability of funding and resources. RSPA will review new or revised drinking water and ecological programs and databases at that time and will incorporate new databases into the computer model created from the final USA definition at that time. RSPA will announce in the **Federal Register** and through communication networks when revised USA maps are available.

RSPA will also analyze new, revised, or refined drinking water and ecological programs every five years to determine if other programs should be added to the USA definition. RSPA will propose any revisions to the USA definition in a notice of proposed rulemaking.

3. Create a petitioning process to correct, add, or remove USA designations.

Eight commenters recommended that RSPA create a petitioning process to add, modify, or appeal a USA designation. The pipeline safety regulations (49 CFR 190.331) allow interested persons to petition the Associate Administrator for Pipeline Safety to establish, amend, or repeal a substantive regulation. There is no need to create a separate process for USAs.

4. Use regional, state, and local data sets, not just data sets that meet national standards.

Two commenters recommended that RSPA use regional, state, and local data sets when creating USAs. RSPA agrees and uses state databases as the primary data source for the USA computer model created from the proposed definition. However, RSPA considers it important that USAs be defined in a consistent manner nationwide. This requires data that conform to some common standard. Attempting to obtain, organize, and validate data that are not nationally standardized would require significant effort, time, and money well beyond RSPA's limited resources. Each additional data set would need to be evaluated for consistency and accuracy. Independently evaluating a wide variety of local, state, and regional data sets would not be feasible and could impede the creation of USA maps for the nation.

The following discusses miscellaneous comments received to the NPRM that technical reviewers did not address:

1. Consider short-term damage caused by a release.

Seven commenters recommended that RSPA consider the short-term effects of

a hazardous liquid pipeline release. Several of these commenters recommended that RSPA specifically consider the short term effects of a release on waterways and fish. Short term effects are those that are reversible or can be mitigated by interim actions.

RSPA does not agree that short term effects should be a major consideration when designating USAs. However, RSPA has placed high priority on protecting human health, even in the short term, in defining an adequate alternative drinking water source as one that must be readily available, of the same water quality, and must be able to supply the community for at least a one month period of time for surface water intakes and for at least six months for ground water wells. In addition, RSPA has added all species vulnerable to extinction that rely on water or are terrestrial and can not move far. Including all resources that could suffer short-term injuries would cover the majority of the U.S.

2. RSPA should designate and map USAs.

Four commenters stated that RSPA should designate and map USAs. As mentioned above, RSPA intends to identify, designate, and map the locations of USAs through a comprehensive collection and analysis of drinking water and ecological resource data, contingent on the availability of funding and resources. These areas will be mapped using the National Pipeline Mapping System. Operators, other government agencies and the public will have access to these maps through the Internet. Individuals will be able to view USAs nationally or by state, county, zip code, or zooming in or out of a particular area. Operators will then be able to determine which areas of their pipeline could impact USAs. Operators may need to contact resource agencies to obtain additional information on a particular species or drinking water intake in a USA.

Discussion of Comments and Modifications Received From the Technical Hazardous Liquid Pipeline Safety Standards Committee

On May 3–4, 2000, the Technical Hazardous Liquid Pipeline Safety Standards Committee (THLPSSC) met to discuss and vote on the USA proposed rule. The THLPSSC is RSPA's statutory advisory committee for hazardous liquid pipeline safety. The Committee has 15 members representing industry, government, and the public. Each proposed hazardous liquid pipeline safety standard must be submitted to the THLPSSC for the Committee's view as to its technical feasibility,

reasonableness, cost-effectiveness, and practicability. During the May meeting, the THLPSSC deferred from voting on the USA proposed rule stating the members of the committee would like the results of the technical review before voting.

On September 11, 2000, the THLPSSC again convened by teleconference to discuss and vote on the proposed rule. A transcript of the meeting is in the docket. Nine Committee members voted the proposed rule and its regulatory analysis as technically feasible, reasonable, cost-effective, and practical, with modifications. One THLPSSC member abstained from the vote. Most of the suggested modifications mirrored those received from the technical reviewers. RSPA has added to the final rule all of the THLPSSC's recommended changes that passed a majority vote. The following discusses each recommended change:

1. Modify the NPRM to add the most viable USA candidate occurrences (critically imperiled, imperiled, threatened and endangered, and depleted marine mammals occurrences) as USAs.

The THLPSSC voted 10 to 1 in favor of this recommendation. The committee member that voted against the proposal stated the vote was negative because she would be voting yes on a motion to include all USA candidates as USAs.

2. Modify the NPRM to add rare communities.

The THLPSSC voted unanimously in favor of this recommendation.

3. Modify the NPRM to make the USA candidate species that are aquatic or aquatic dependent or are terrestrial and have a limited range USAs.

The THLPSSC voted 7 to 4 in favor of this recommendation. One THLPSSC member abstained from the vote.

4. Include in the preamble to the final rule that RSPA intends to consider in a future rulemaking the inclusion of vulnerable species as USAs.

The THLPSSC voted unanimously for RSPA to add to the preamble of this final rule that we will consider adding vulnerable species as USAs in a future rulemaking.

5. Replace WHPAs with SWPAs.

The THLPSSC voted unanimously in favor of this recommendation.

6. Change the adequate alternative drinking water source definition to extend the amount of time needed for the backup water source from one month to six months for groundwater systems. Make preliminary drinking water USAs interim USAs when it can not be verified that an adequate alternative drinking water source exists. Interim USAs would be treated like all

other USAs and this would give a quality code to individuals looking at the data.

The THLPSSC voted 10 to 2 in favor of this recommendation. One THLPSSC member abstained from the vote. One voter against the proposal stated the vote was negative because she would be voting for the removal of the adequate alternative drinking water filter later.

7. Modify the adequate alternative drinking water source definition to include the ability of the alternative source to provide fire fighting capabilities.

The THLPSSC voted 6 to 5 in favor of this recommendation.

8. Remove the doubling of WHPAs in sole source aquifers.

The THLPSSC voted unanimously in favor of this recommendation.

9. Make the recharge areas of sole source aquifers that are karst in nature USAs.

The THLPSSC voted unanimously in favor of this recommendation.

In addition to the THLPSSC's recommendations that passed a majority vote, the Committee also discussed other recommendations. These include the following:

- Include colonial waterbird data, which are additional species concentration areas,
- Remove the USA filtering criteria,
- Create a simultaneous rule that would cover cultural and other natural resource areas,
- Change the adequate alternative drinking water source definition to extend the amount of time needed for the backup water source from one month to six months for surface water systems,
- Make preliminary drinking water USAs final USAs when it can not be verified that an adequate alternative drinking water source exists.
- Remove the adequate alternative drinking water source filter criterion, and
- Make all sole source aquifer recharge areas USAs.

None of these recommendations passed a majority vote and RSPA has not included them in this final rule.

Resources Not Included in the Final Rule

There are many other resources that government agencies, environmental organizations, and others consider sensitive to a hazardous liquid pipeline release. These include national parks, wetlands, wildlife preservation areas, refuges, fish hatcheries, vulnerable species, cultural resources, recreation areas, and economic resource areas. RSPA currently protects these resources

under 49 CFR parts 194 and 195. RSPA will consider extending protection to other environmentally sensitive and vital resources through future rulemaking and will consider the above listed resources as a part of this process.

Mapping of USAs

RSPA intends to identify the locations of USAs through a comprehensive collection and analysis of drinking water and ecological resource data, contingent on the availability of funding and resources. These areas will be mapped using the National Pipeline Mapping System. Operators, other government agencies and the public will have access to these maps through the internet. Individuals will be able to view USAs and other high consequence areas nationally or by state, county, zip code, or zooming in or out of a particular area. Operators will then be able to determine which areas of their pipeline have the ability to impact USAs. Operators may need to contact resource agencies to obtain additional information on a particular species or drinking water intake in a USA.

As additional ecological and drinking water resource information becomes available, and RSPA identifies and locates additional USAs, the operator has the responsibility to apply this new information in its integrity management program.

RSPA will map USA locations on a state by state basis, beginning with the states that have the largest number of liquid pipeline miles. RSPA expects to complete the first ten states by the end of the year. These states include Texas, Oklahoma, Kansas, Louisiana, Illinois, Wyoming, New Mexico, California, Missouri, and Montana. The remaining states are expected to be completed by the end of 2001.

RSPA recognizes that inventories and maps of USAs have to be updated on a periodic basis to incorporate new information and databases. RSPA intends to update the USA maps at least every five years, contingent on the availability of funding and resources. RSPA will review new or revised drinking water and ecological programs and databases and will incorporate new databases into the computer model created from the final USA definition. RSPA will announce in the **Federal Register** and through other communication networks, including during inspections, when revised USA maps are available.

Regulatory Analyses and Notices

A. Executive Order 12866 and DOT Policies and Procedures

The Department of Transportation considers this action to be a significant regulatory action under section 3(f) of Executive Order 12866 (58 FR 51735; October 4, 1993). Therefore, it was forwarded to the Office of Management and Budget. This final rule is significant under Department of Transportation's regulatory policies and procedures (44 FR 11034; February 26, 1979) because of its significant public and government interest.

This final rule has no cost impact on the pipeline industry or the public because it is only a definition.

The USA definition is used in the "Pipeline Safety: Pipeline Integrity Management in High Consequence Areas (Hazardous Liquid Operators with 500 or more miles of pipeline)" (65 FR 75378; December 1, 2000) final rule and potentially other current or future regulations. A cost-benefit analysis has been prepared for the Integrity Management rulemaking. RSPA will perform a cost-benefit analysis on any other rulemakings that require operators to take specific actions on pipelines that could affect USAs.

B. Regulatory Flexibility Act

This final rule will not impose additional requirements on pipeline operators, including small entities that operate regulated pipelines. Based on the above information showing that there is no economic impact of this rulemaking, I certify, pursuant to Section 605 of the Regulatory Flexibility Act (5 U.S.C. 605), that this final rulemaking would not have a significant economic impact on a substantial number of small entities.

C. Federalism Assessment

This final rule has been analyzed in accordance with the principles and criteria contained in Executive Order 13132 ("Federalism"). This final rule does not adopt any regulation that:

- (1) has substantial direct effects on the States, the relationship between the national government and the States, or the distribution of power and responsibilities among the various levels of government;
- (2) imposes substantial direct compliance costs on State and local governments; or
- (3) preempts state law.

Therefore, the consultation and funding requirements of Executive Order 13132 (64 FR 43255; August 10, 1999) do not apply. Nevertheless, RSPA worked with state government

representatives from Texas, California, and Louisiana to review our USA pilot test results. RSPA also conducted an aggressive communication plan to notify interested parties, including states, of our USA work.

D. Executive Order 13084

The final rule has been analyzed in accordance with the principles and criteria contained in Executive Order 13084, "Consultation and Coordination with Indian Tribal Governments." Because the final rule does not significantly or uniquely affect the communities of the Indian tribal governments and does not impose substantial direct compliance costs, the funding and consultation requirements of Executive Order 13084 do not apply.

E. Paperwork Reduction Act

On December 30, 1999 (64 FR 73463) RSPA published the USA NPRM. In the NPRM, RSPA stated "This proposed rulemaking contains no information collection that is subject to review by OMB under the Paperwork Reduction Act of 1995." No comments were received on this issue. Therefore, RSPA concludes that this final rule contains no paperwork burden and is not subject to OMB review under the Paperwork Reduction Act of 1995.

This final rule, like the proposed rule, is simply a definition. The USA definition is used in the "Pipeline Safety: Pipeline Integrity Management in High Consequence Areas (Hazardous Liquid Operators with 500 or more miles of pipeline)" (65 FR 75378; December 1, 2000) final rule and potentially other current or future regulations. A paperwork burden analysis has been prepared for the Integrity Management rulemaking. RSPA will perform a paperwork burden analysis on any other rulemakings that require operators to take specific actions on pipelines that could affect USAs.

F. Unfunded Mandates Reform Act of 1995

This final rule does not impose unfunded mandates under the Unfunded Mandates Reform Act of 1995. It does not result in costs of \$100 million or more to either State, local, or tribal governments, in the aggregate, or to the private sector, and is the least burdensome alternative that achieves the objective of the rule.

G. National Environmental Policy Act

RSPA has analyzed the final rule defining USAs in accordance with section 102(2)(c) of the National Environmental Policy Act (42 U.S.C. Section 4332), the Council on

Environmental Quality regulations (40 CFR Parts 1500–1508), and DOT Order 5610.1D. An Environmental Assessment was prepared for the initial USA definitions proposed in a Notice of Proposed Rulemaking (64 FR 73464). RSPA did not receive any public comment on the Environmental Assessment. We have revised the Environmental Assessment to evaluate the USA definition changes made in response to public and other agency comments. Both the Environmental Assessment and modifications are available in the Docket.

The Environmental Assessment provides sufficient evidence to determine that the provisions of the final rule are expected to have no significant impact on the environment. Therefore, in accordance with 40 CFR Section 1508.13, RSPA has made a Finding of No Significant Impact (FONSI) for the final rule defining USAs. The FONSI is available in the Docket. The basis for arriving at this conclusion is summarized below.

The final rule establishes definitions delineating how specific drinking water and ecological resources that are unusually sensitive to environmental damage will be identified. These definitions alone do not pose any new requirements on pipeline operators, and thus have no impact on the environment. However, in the Environmental Assessment, RSPA examined current and potential future regulations to project what future environmental impacts might be expected.

RSPA has recently published a final rule on Pipeline Integrity Management in High Consequence Areas (65 FR 75378; December 1, 2000). This rule establishes new requirements for operators operating 500 or more miles of hazardous liquid pipeline to provide additional protection for high consequence areas, which include USAs. This rule specifies new requirements to assess, evaluate, repair, and validate the integrity of pipelines that could affect high consequence areas. As part of this rulemaking, RSPA prepared an Environmental Assessment to understand the impacts of these requirements (available in Docket No. 99–6355). RSPA concluded that the combined impacts of the integrity management rule provisions to protect high consequence areas will result in positive environmental impacts. The number of incidents and the environmental damage from failures in and near high consequence areas are likely to be reduced. However, from a national perspective, the impact is not expected to be significant for the

pipeline operators covered by the final rule. RSPA has issued a FONSI for the integrity management rule (also available on the Docket).

RSPA also examined other regulatory requirements which could be impacted by the definition and identifications of USAs. These are:

- Integrity Management in High Consequence Areas for Operators Operating less than 500 Miles of Pipeline. This rule is expected to be similar to the new rule for larger pipeline operators described above.
- Risk-based Alternative to Pressure Testing Older Hazardous Liquid and Carbon Dioxide Pipelines (49 CFR 195.303). Environmental sensitivity is a risk factor to be considered in setting pressure test schedules. RSPA may clarify that USAs must be considered in identifying areas of environmental sensitivity.
- Response Plans for Onshore Oil Pipelines (49 CFR 194). Areas of environmental importance are to be addressed in response plans. RSPA may amend the definition of environmental importance to include USAs. Area Committees and OPS may use the USA definition in reviewing and validating response plans and response plan revisions.
- Jurisdiction of Rural Low Stress Pipelines. Currently pipelines operating at low stress in rural areas are exempt from compliance with 49 CFR 195 requirements. RSPA may consider removing this exemption for low stress lines that could impact USAs.

RSPA's initial assessment is that each of the above changes would have some positive environmental impacts in reducing the likelihood of pipeline spills and/or minimizing the consequences should a spill occur. However, without specification of the particular regulatory requirements, projections of the expected benefits are highly uncertain. When RSPA establishes specific requirements in these areas, Environmental Assessments will be performed to fully understand the impacts and guide decision-making.

List of Subjects in 49 CFR Part 195

Anhydrous ammonia, Carbon dioxide, Hazardous liquids, Petroleum, Pipeline safety, Reporting and recordkeeping requirements.

In consideration of the foregoing, RSPA hereby amends 49 CFR part 195 as follows:

PART 195—[AMENDED]

1. The authority citation for part 195 continues to read as follows:

Authority: 49 U.S.C. 5103, 60102, 60104, 60108, 60109, 60118; and 49 CFR 1.53.

2. Section 195.2 is amended by adding a new definition in alphabetical order to read as follows:

§ 195.2 Definitions.

* * * * *

Unusually sensitive area (USA) means a drinking water or ecological resource area that is unusually sensitive to environmental damage from a hazardous liquid pipeline release, as identified under § 195.6.

3. Section 195.6 is added to read as follows:

§ 195.6 Unusually Sensitive Areas (USAs).

As used in this part, a USA means a drinking water or ecological resource area that is unusually sensitive to environmental damage from a hazardous liquid pipeline release.

(a) An USA drinking water resource is:

(1) The water intake for a Community Water System (CWS) or a Non-transient Non-community Water System (NTNCWS) that obtains its water supply primarily from a surface water source and does not have an adequate alternative drinking water source;

(2) The Source Water Protection Area (SWPA) for a CWS or a NTNCWS that obtains its water supply from a Class I or Class IIA aquifer and does not have an adequate alternative drinking water source. Where a state has not yet identified the SWPA, the Wellhead Protection Area (WHPA) will be used until the state has identified the SWPA; or

(3) The sole source aquifer recharge area where the sole source aquifer is a karst aquifer in nature.

(b) An USA ecological resource is:

(1) An area containing a critically imperiled species or ecological community;

(2) A multi-species assemblage area;

(3) A migratory waterbird concentration area;

(4) An area containing an imperiled species, threatened or endangered species, depleted marine mammal species, or an imperiled ecological community where the species or community is aquatic, aquatic dependent, or terrestrial with a limited range; or

(5) An area containing an imperiled species, threatened or endangered species, depleted marine mammal species, or imperiled ecological community where the species or community occurrence is considered to be one of the most viable, highest quality, or in the best condition, as

identified by an element occurrence ranking (EORANK) of A (excellent quality) or B (good quality).

(c) As used in this part—

Adequate Alternative Drinking Water Source means a source of water that currently exists, can be used almost immediately with a minimal amount of effort and cost, involves no decline in water quality, and will meet the consumptive, hygiene, and fire fighting requirements of the existing population of impacted customers for at least one month for a surface water source of water and at least six months for a groundwater source.

Aquatic or Aquatic Dependent Species or Community means a species or community that primarily occurs in aquatic, marine, or wetland habitats, as well as species that may use terrestrial habitats during all or some portion of their life cycle, but that are still closely associated with or dependent upon aquatic, marine, or wetland habitats for some critical component or portion of their life-history (*i.e.*, reproduction, rearing and development, feeding, etc).

Class I Aquifer means an aquifer that is surficial or shallow, permeable, and is highly vulnerable to contamination. Class I aquifers include:

(1) *Unconsolidated Aquifers (Class Ia)* that consist of surficial, unconsolidated, and permeable alluvial, terrace, outwash, beach, dune and other similar deposits. These aquifers generally contain layers of sand and gravel that, commonly, are interbedded to some degree with silt and clay. Not all Class Ia aquifers are important water-bearing units, but they are likely to be both permeable and vulnerable. The only natural protection of these aquifers is the thickness of the unsaturated zone and the presence of fine-grained material;

(2) *Soluble and Fractured Bedrock Aquifers (Class Ib)*. Lithologies in this class include limestone, dolomite, and, locally, evaporitic units that contain documented karst features or solution channels, regardless of size. Generally these aquifers have a wide range of permeability. Also included in this class are sedimentary strata, and metamorphic and igneous (intrusive and extrusive) rocks that are significantly faulted, fractured, or jointed. In all cases groundwater movement is largely controlled by secondary openings. Well yields range widely, but the important feature is the potential for rapid vertical and lateral ground water movement along preferred pathways, which result in a high degree of vulnerability;

(3) *Semiconsolidated Aquifers (Class Ic)* that generally contain poorly to moderately indurated sand and gravel

that is interbedded with clay and silt. This group is intermediate to the unconsolidated and consolidated end members. These systems are common in the Tertiary age rocks that are exposed throughout the Gulf and Atlantic coastal states. Semiconsolidated conditions also arise from the presence of intercalated clay and caliche within primarily unconsolidated to poorly consolidated units, such as occurs in parts of the High Plains Aquifer; or

(4) *Covered Aquifers (Class Id)* that are any Class I aquifer overlain by less than 50 feet of low permeability, unconsolidated material, such as glacial till, lacustrine, and loess deposits.

Class IIa aquifer means a Higher Yield Bedrock Aquifer that is consolidated and is moderately vulnerable to contamination. These aquifers generally consist of fairly permeable sandstone or conglomerate that contain lesser amounts of interbedded fine grained clastics (shale, siltstone, mudstone) and occasionally carbonate units. In general, well yields must exceed 50 gallons per minute to be included in this class. Local fracturing may contribute to the dominant primary porosity and permeability of these systems.

Community Water System (CWS) means a public water system that serves at least 15 service connections used by year-round residents of the area or regularly serves at least 25 year-round residents.

Critically imperiled species or ecological community (habitat) means an animal or plant species or an ecological community of extreme rarity, based on The Nature Conservancy's Global Conservation Status Rank. There are generally 5 or fewer occurrences, or very few remaining individuals (less than 1,000) or acres (less than 2,000). These species and ecological communities are extremely vulnerable to extinction due to some natural or man-made factor.

Depleted marine mammal species means a species that has been identified and is protected under the Marine Mammal Protection Act of 1972, as amended (MMPA) (16 U.S.C. 1361 *et seq.*). The term "depleted" refers to marine mammal species that are listed as threatened or endangered, or are below their optimum sustainable populations (16 U.S.C. 1362). The term "marine mammal" means "any mammal which is morphologically adapted to the marine environment (including sea otters and members of the orders Sirenia, Pinnipedia, and Cetacea), or primarily inhabits the marine environment (such as the polar bear)" (16 U.S.C. 1362). The order Sirenia includes manatees, the order Pinnipedia

includes seals, sea lions, and walruses, and the order Cetacea includes dolphins, porpoises, and whales.

Ecological community means an interacting assemblage of plants and animals that recur under similar environmental conditions across the landscape.

Element occurrence rank (EORANK) means the condition or viability of a species or ecological community occurrence, based on a population's size, condition, and landscape context. EORANKs are assigned by the Natural Heritage Programs. An EORANK of A means an excellent quality and an EORANK of B means good quality.

Imperiled species or ecological community (habitat) means a rare species or ecological community, based on The Nature Conservancy's Global Conservation Status Rank. There are generally 6 to 20 occurrences, or few remaining individuals (1,000 to 3,000) or acres (2,000 to 10,000). These species and ecological communities are vulnerable to extinction due to some natural or man-made factor.

Karst aquifer means an aquifer that is composed of limestone or dolomite where the porosity is derived from connected solution cavities. Karst aquifers are often cavernous with high rates of flow.

Migratory waterbird concentration area means a designated Ramsar site or a Western Hemisphere Shorebird Reserve Network site.

Multi-species assemblage area means an area where three or more different critically imperiled or imperiled species or ecological communities, threatened or endangered species, depleted marine mammals, or migratory waterbird concentrations co-occur.

Non-transient Non-community Water System (NTNCWS) means a public water system that regularly serves at least 25 of the same persons over six months per year. Examples of these systems include schools, factories, and hospitals that have their own water supplies.

Public Water System (PWS) means a system that provides the public water for human consumption through pipes or other constructed conveyances, if such system has at least 15 service connections or regularly serves an average of at least 25 individuals daily at least 60 days out of the year. These systems include the sources of the water supplies—*i.e.*, surface or ground. PWS can be community, non-transient non-community, or transient non-community systems.

Ramsar site means a site that has been designated under The Convention on Wetlands of International Importance

Especially as Waterfowl Habitat program. Ramsar sites are globally critical wetland areas that support migratory waterfowl. These include wetland areas that regularly support 20,000 waterfowl; wetland areas that regularly support substantial numbers of individuals from particular groups of waterfowl, indicative of wetland values, productivity, or diversity; and wetland areas that regularly support 1% of the individuals in a population of one species or subspecies of waterfowl.

Sole source aquifer (SSA) means an area designated by the U.S. Environmental Protection Agency under the Sole Source Aquifer program as the "sole or principal" source of drinking water for an area. Such designations are made if the aquifer's ground water supplies 50% or more of the drinking water for an area, and if that aquifer were to become contaminated, it would pose a public health hazard. A sole source aquifer that is karst in nature is one composed of limestone where the porosity is derived from connected solution cavities. They are often cavernous, with high rates of flow.

Source Water Protection Area (SWPA) means the area delineated by the state for a public water supply system (PWS) or including numerous PWSs, whether the source is ground water or surface water or both, as part of the state source water assessment program (SWAP)

approved by EPA under section 1453 of the Safe Drinking Water Act.

Species means species, subspecies, population stocks, or distinct vertebrate populations.

Terrestrial ecological community with a limited range means a non-aquatic or non-aquatic dependent ecological community that covers less than five (5) acres.

Terrestrial species with a limited range means a non-aquatic or non-aquatic dependent animal or plant species that has a range of no more than five (5) acres.

Threatened and endangered species (T&E) means an animal or plant species that has been listed and is protected under the Endangered Species Act of 1973, as amended (ESA73) (16 U.S.C. 1531 et seq.). "Endangered species" is defined as "any species which is in danger of extinction throughout all or a significant portion of its range" (16 U.S.C. 1532). "Threatened species" is defined as "any species which is likely to become an endangered species within the foreseeable future throughout all or a significant portion of its range" (16 U.S.C. 1532).

Transient Non-community Water System (TNCWS) means a public water system that does not regularly serve at least 25 of the same persons over six months per year. This type of water system serves a transient population

found at rest stops, campgrounds, restaurants, and parks with their own source of water.

Wellhead Protection Area (WHPA) means the surface and subsurface area surrounding a well or well field that supplies a public water system through which contaminants are likely to pass and eventually reach the water well or well field.

Western Hemisphere Shorebird Reserve Network (WHSRN) site means an area that contains migratory shorebird concentrations and has been designated as a hemispheric reserve, international reserve, regional reserve, or endangered species reserve. Hemispheric reserves host at least 500,000 shorebirds annually or 30% of a species flyway population. International reserves host 100,000 shorebirds annually or 15% of a species flyway population. Regional reserves host 20,000 shorebirds annually or 5% of a species flyway population. Endangered species reserves are critical to the survival of endangered species and no minimum number of birds is required.

Issued in Washington, DC December 8, 2000.

Kelley S. Coyner,

Administrator.

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Part IV

**Department of
Agriculture**

Agricultural Marketing Service

7 CFR Part 205

National Organic Program; Final Rule

DEPARTMENT OF AGRICULTURE**Agricultural Marketing Service****7 CFR Part 205**

[Docket Number: TMD-00-02-FR]

RIN 0581-AA40

National Organic Program**AGENCY:** Agricultural Marketing Service, USDA.**ACTION:** Final Rule with request for comments.

SUMMARY: This final rule establishes the National Organic Program (NOP or program) under the direction of the Agricultural Marketing Service (AMS), an arm of the United States Department of Agriculture (USDA). This national program will facilitate domestic and international marketing of fresh and processed food that is organically produced and assure consumers that such products meet consistent, uniform standards. This program establishes national standards for the production and handling of organically produced products, including a National List of substances approved for and prohibited from use in organic production and handling. This final rule establishes a national-level accreditation program to be administered by AMS for State officials and private persons who want to be accredited as certifying agents. Under the program, certifying agents will certify production and handling operations in compliance with the requirements of this regulation and initiate compliance actions to enforce program requirements. The final rule includes requirements for labeling products as organic and containing organic ingredients. This final rule also provides for importation of organic agricultural products from foreign programs determined to have equivalent organic program requirements. This program is authorized under the Organic Foods Production Act of 1990, as amended.

EFFECTIVE DATE: This rule becomes effective February 20, 2001.

Comments: Comments on specified aspects of the final regulations must be submitted on or before March 21, 2001.

ADDRESSES: Interested persons are invited to submit written comments on specified aspects of the final regulation to: Keith Jones, Program Manager, National Organic Program, USDA-AMS-TMP-NOP, Room 2945-So., Ag Stop 0275, P.O. Box 96456, Washington, DC 20090-6456. Comments may also be filed via the Internet through the National Organic Program's homepage

at: www.ams.usda.gov/nop. Written comments on specified aspects of the final regulations should be identified with the docket number TMD-00-02-FR. To facilitate the timely scanning and posting of comments to the NOP homepage, multiple-page comments submitted by regular mail should not be stapled or clipped.

It is our intention to have all comments to this final rule, whether mailed or submitted via the Internet, available for viewing on the NOP homepage in a timely manner. Comments submitted in response to this final rule will be available for viewing at USDA-AMS, Transportation and Marketing Programs, Room 2945-South Building, 14th and Independence Avenue, SW., Washington, DC, from 9 a.m. to 12 noon and from 1 p.m. to 4 p.m., Monday through Friday (except for official Federal holidays). Persons wanting to visit the USDA South Building to view comments received in response to this final rule are requested to make an appointment in advance by calling (202) 720-3252.

FOR FURTHER INFORMATION CONTACT: Richard Mathews, Senior Agricultural Marketing Specialist, USDA-AMS-TMP-NOP, Room 2510-So., P.O. Box 96456, Washington, DC 20090-6456; Telephone: (202) 205-7806; Fax: (202) 205-7808.

SUPPLEMENTARY INFORMATION:**Prior Documents in This Proceeding**

This final rule is issued pursuant to the Organic Food Production Act of 1990 (Act or OFPA), as amended (7 U.S.C. 6501 *et seq.*). This final rule replaces the proposed rule published in the **Federal Register** March 13, 2000. The public submitted 40,774 comments on the proposed rule. Comments to the proposed rule were considered in the preparation of this final rule.

The following notices related to the National Organic Standards Board (NOSB) and the development of this proposed regulation have been published in the **Federal Register**. Six notices of nominations for membership on the NOSB were published between April 1991 and June 2000 (56 FR 15323, 59 FR 43807, 60 FR 40153, 61 FR 33897, 64 FR 33240, 65 FR 35317). Two notices of extension of time for submitting nominations were published on September 22, 1995, and September 23, 1996 (60 FR 49246, 61 FR 49725). Twenty notices of meetings of the NOSB were published between March 1992 and November 2000 (57 FR 7094, 57 FR 27017, 57 FR 36974, 58 FR 85, 58 FR 105, 58 FR 171, 59 FR 58, 59 FR 26186, 59 FR 49385, 60 FR 51980, 60 FR 15532,

61 FR 43520, 63 FR 7389, 63 FR 64451, 64 FR 3675, 64 FR 28154, 64 FR 54858, 65 FR 11758, 65 FR 33802, 65 FR 64657). One notice of public hearings on organic livestock and livestock products was published on December 30, 1993 (58 FR 69315). Two notices specifying a procedure for submitting names of substances for inclusion on or removal from the National List of Approved and Prohibited Substances were published on March 27, 1995 (60 FR 15744), and July 13, 2000 (65 FR 43259). A rule proposing the NOP was published on December 16, 1997 (62 FR 65850). An extension of the time period for submitting comments to the proposed rule was published on February 9, 1998 (63 FR 6498). One request for comments on Issue Papers was published on October 28, 1998 (63 FR 57624). A notice of a program to assess organic certifying agencies was published on June 9, 1999 (64 FR 30861). A rule proposing the NOP was published on March 13, 2000 (65 FR 13512). A notice of public meeting and request for comments on organic production and handling of aquatic animals to be labeled as organic was published on March 23, 2000 (65 FR 15579). One advance notice of proposed rulemaking and request for comments on reasonable security for private certifying agents was published on August 9, 2000 (65 FR 48642).

This preamble includes a discussion of the final rule and supplementary information, including the Regulatory Impact Assessment, Unfunded Mandates Reform Act Statement, Regulatory Flexibility Act Analysis, Federalism Impact Statement, and Civil Justice Impact Statement. The Civil Rights Impact Analysis is not included as an attachment but may be obtained by writing to the address provided above or via the Internet through the National Organic Program's homepage at: <http://www.ams.usda.gov/nop>.

Approval of Paperwork Reduction Act Requirements for This Final Rule

The reporting requirements and recordkeeping burden imposed by this rule were published in the March 13, 2000, **Federal Register** for public comment. The Agency addressed these comments in the final rule to ensure that the least amount of the burden is placed on the public. The information collection and recordkeeping requirements have been reviewed and approved by the Office of Management and Budget under OMB Number 0581-0191, National Organic Program.

National Organic Program Overview

Subpart A—Definitions

Description of Regulations

This subpart defines various terms used in this part. These definitions are intended to enhance conformance with the regulatory requirements through a clear understanding of the meaning of key terms.

We have amended terms and definitions carried over from the proposed rule where necessary to make their wording consistent with the language used in this final rule. We have revised the definitions of the following words for greater clarity: person, practice standard, inert ingredient, processing, tolerance. We have removed the definitions for the following terms because the terms are not used in this final rule or have been determined to be unnecessary: accredited laboratory, estimated national mean, system of organic production and handling. We received comments on some of these definitions that have been deleted. We have not addressed those comments here because the relevant definitions have been deleted.

Definitions—Changes Based on Comments

This subpart differs from the proposed rule in several respects as follows:

(1) Many commenters requested changes to the definition of “excluded methods.” Comments included requests to use the more common term, “genetically modified organisms (GMO)”; to include the products of excluded methods/GMO’s in the definition; to more closely follow the NOSB definition by adding gene deletion, doubling, introduction of a foreign gene, and changing gene position; to include that excluded methods are prohibited by the Act and by the regulations in this part; to change the wording of the reference to “recombinant DNA”; and to add that the definition of excluded methods only covers “intentional use.”

We have accepted some of the comments and have modified the definition accordingly. Specifically, we have included reference to the “methods”—gene deletion, gene doubling, changing positions of genes, and introducing foreign genes—that were included in the original NOSB definition. This will make the definition even more closely parallel the NOSB recommendation. We also refer to recombinant DNA technology, which is technically more accurate than the

proposed rules reference to recombinant DNA as a “method.”

We have not accepted the comments that requested adding the products of excluded methods to the definition. The emphasis and basis of these standards is on process, not product. We have specifically structured the provisions relating to excluded methods to refer to the use of methods. Including the products of excluded methods in the definition would not be consistent with this approach to organic standards as a process-based system. For the same reason, we have retained the term, “excluded methods,” to reinforce that process-based approach.

We have also rejected comments requesting that we include the prohibition on excluded methods in the definition and, likewise, those requesting that we refer to “intentional use” of excluded methods. The final rule maintains and clarifies the prohibition on the use of excluded methods in organic production systems. The prohibition is most properly addressed in the appropriate provisions of the regulations, particularly in Section 205.105, and not in the definition. Similarly, although we recognize that a distinction between intentional and unintentional use of excluded methods may be meaningful, particularly as it pertains to issues of drift, this is an issue that is best handled in the sections of the regulation governing use of excluded methods, not in the definition. The definition for “excluded methods” now reads:

A variety of methods used to genetically modify organisms or influence their growth and development by means that are not possible under natural conditions or processes and are not considered compatible with organic production. Such methods include cell fusion, microencapsulation and macroencapsulation, and recombinant DNA technology (including gene deletion, gene doubling, introducing a foreign gene, and changing the position of genes when achieved by recombinant DNA technology). Such methods do not include the use of traditional breeding, conjugation, fermentation, hybridization, in vitro fertilization, or tissue culture.”

(2) Many commenters objected to the definition of “compost” in the proposed rule because it required that compost must be produced in a facility that was in compliance with the Natural Resource Conservation Service’s (NRCS) practice standard for a composting facility. We agree with these commenters and removed the requirement to comply with the NRCS practice standard. However, the final

rule incorporates new requirements for the production of compost that are included in the definition. The final rule requires that compost must be produced through a process that combines plant and animal materials with an initial C:N ratio of between 25:1 and 40:1. Furthermore, producers using an in-vessel or static aerated pile system must maintain the composting materials at a temperature of between 131°F and 170°F for 3 days. Producers using a windrow system must maintain the composting materials at a temperature between 131°F and 170°F for 15 days, during which time, the materials must be turned a minimum of five times. We developed the requirements in the final rule for producing an allowed composted material by integrating standards used by the Environmental Protection Agency (EPA) and USDA’s Natural Resources Conservation Service (NRCS). The requirements for the carbon-to-nitrogen (C:N) ratio for composting materials is the same as that found in the NRCS practice standard for a composting facility. The time and temperature requirements for in-vessel, static aerated pile, and window composting systems are consistent with those which EPA regulates under 40 CFR 503 for the production of Class A sewage sludge. Additionally, AMS reviewed these compost production requirements with USDA’s Agricultural Research Service (ARS). This subject is discussed further under subpart C, Crop Production, Changes Based on Comment.

(3) Some commenters stated that allowing nonagricultural or synthetic substances as feed supplements contradicted the definition for “feed supplement” in the proposed rule. These commenters stated that the definition stipulated that a feed supplement must, itself, be a feed material and that the proposed definition for “feed” did not include nonagricultural or synthetic substances. These commenters stated that the definition of “feed supplement” needed to be amended to accommodate nonagricultural or synthetic substances, or such substances should not be allowed. We agree with these commenters and amended the definition for “feed supplement” to read “a combination of feed nutrients added to livestock feed to improve the nutritional balance or performance of the total ration.” One commenter recommended modifying the definition of “feed additive” to “a substance added to feed in micro quantities to fulfill a specific nutritional need; *i.e.*, essential nutrients in the form of amino acids, vitamins,

and minerals.” We agree that this modification provides a more precise description of “feed additive” and have included the change. The changes to the definitions for “feed supplement” and “feed additive” are further discussed under item (4) of Livestock Production—Changes Based on Comments.

(4) One commenter stated that the definition for “forage” inaccurately described it as “vegetable matter,” and suggested that “vegetative matter” was a more suitable description. We agree with the suggestion and have incorporated the change.

(5) Some commenters stated that the definition for “mulch” implied that all mulch materials must either be organic or included on the National List. These commenters maintained that, if this was the intent of the proposed rule, the provision was too restrictive. They recommended revising the definition to clarify that natural but nonorganic plant and animal materials, if managed to prevent contamination from prohibited substances, could be used as mulch without being added to the National List. This was the intent in the proposed rule, and we have modified the definition to make this provision clearer.

(6) Many commenters stated that the final rule should include a definition of “organic production” that required that certified operations must preserve or protect biodiversity. These commenters stated that the preservation of biodiversity is a requirement in many existing organic certification standards, including the Codex guidelines. They also stated that the NOSB had included the requirement to preserve biodiversity in its definition of organic. We agree with the intent of these comments but prefer the term, “conserve,” to “preserve” because it reflects a more dynamic, interactive relationship between the operation and biodiversity over time. We included a definition for organic production as “a production system that is managed in accordance with the Act and regulations in this part to respond to site-specific conditions by integrating cultural, biological, and mechanical practices that foster cycling of resources, promote ecological balance, and conserve biodiversity.” We deleted the definition for “organic system of production and handling” in the final rule.

(7) Several commenters, including the NOSB, were concerned that the definition for “planting stock” as “any plant or plant tissue, including rhizomes, shoots, leaf or stem cuttings, roots, or tubers, used in plant production or propagation” was

sufficiently broad to be applied to annual seedlings. We agree that it is important to establish that annual seedlings are not covered by the definition of “planting stock” and amended the definition to exclude them. The definition for planting stock in the final rule states “any plant or plant tissue other than annual seedlings but including rhizomes, shoots, leaf or stem cuttings, roots, or tubers, used in plant production or propagation.” The final rule retains the definition for “annual seedling” from the proposed rule.

(8) Several commenters recommended that the definition of “processing” should be amended to include “distilling” as an allowed practice. We agree with this comment and added distilling as an allowed processing practice.

(9) Several commenters recommended that the final rule include a definition for “processing aid” that is consistent with the definition proposed by the NOSB and used by the Food and Drug Administration (FDA). We agree with these commenters and have included a definition for processing aid that is the same as the definition used by FDA and found in 21 CFR Part 101.100(a)(3)(ii).

(10) Many commenters questioned whether the term, “State organic certification program,” in the proposed rule included organic programs from States that did not offer certification services. These commenters stated that the final rule should include provisions for all State organic programs regardless of whether they functioned as certifying agents. We agree with these commenters and have amended the final rule by incorporating the term, “State organic program,” as “a State program that meets the requirements of section 6506 of the Act, is approved by the Secretary, and is designed to ensure that a product that is sold or labeled as organically produced under the Act is produced and handled using organic methods.” The term, “State organic program,” encompasses such programs whether they offer certification services or not.

(11) One commenter stated that the definition for “wild crop” only referred to a plant or part of a plant that was harvested from “an area of land.” This commenter was concerned that the definition would preclude the certification of operations that produce wild aquatic crops, such as seaweed, and stated that the OFPA does allow for certifying such operations. We agree with this commenter and changed the definition to refer to a plant or part of a plant harvested from a “site.”

(12) Many commenters stated that the soil fertility and crop nutrient

management practice standard lacked a definition for “manure.” These commenters maintained that the different provisions contained in the practice standard for “manure” and “compost” would be difficult to enforce without clear definitions to differentiate between the two materials. We agree with these comments and added a definition for manure as “feces, urine, other excrement, and bedding produced by livestock that has not been composted.”

(13) Some commenters stated that the National List in the final rule should include an annotation for narrow range oils to limit their use to a specific subset of such materials recommended by the NOSB. We agree with this comment but, rather than add an annotation, we have included the specifications recommended by the NOSB in a new definition for narrow range oils. Narrow range oils are defined as “petroleum derivatives, predominately of paraffinic and naphthenic fractions with a 50-percent boiling point (10 mm Hg) between 415°F and 440°F.”

(14) Many commenters maintained that the final rule needed a definition of the term, “pasture,” to describe the relationship between ruminants and the land they graze. These commenters stated that a meaningful definition of “pasture” must incorporate the nutritional component that it provides livestock, as well as the necessity to manage the land in a manner that protects the natural resources of the operation. We agree with these commenters and have added a definition of “pasture” as “land used for livestock grazing that is managed to provide feed value and maintain or improve soil, water, and vegetative sources.”

(15) Many commenters stated that a definition for “split operation” was necessary to prevent commingling between organic and nonorganic commodities on operations that produced or handled both forms of a commodity. We agree with these comments and have included a definition for “split operation” as “an operation that produces or handles both organic and nonorganic agricultural products.”

Definitions—Changes Requested But Not Made

This subpart retains from the proposed rule terms and their definitions on which we received comments as follows:

(1) Many commenters objected to the definition of “sewage sludge” because it excluded ash generated in a sewage sludge incinerator and grit and

screenings generated during preliminary treatment of domestic sewage in treatment works. We have not changed the definition for "sewage sludge" because it provides the most comprehensive and enforceable description of the types of materials that commenters wanted to prohibit. The definition for "sewage sludge" in the proposed rule arose in response to significant public comment on the first proposed rule for national organic standards (62 **Federal Register**, No. 241) that recommended prohibiting biosolids in organic production. When incorporating those comments into the proposed rule, we did not use the term, "biosolids," because it does not have a standardized definition under Federal regulations. The term, "biosolids," is commonly used to refer to "sewage sludge," which is the regulatory term established in 40 CFR part 503. We incorporated the precise definition from 40 CFR part 503, even though it does not include ash, grit, or screenings, because it provided the clearest description of the types of materials identified in public comment.

While commenters are correct that ash, grit, or screenings from the production of sewage sludge are not prohibited by this definition, these materials are prohibited elsewhere in the regulation. The soil fertility and crop nutrient management practice standard in section 205.203 establishes the universe of allowed materials and practices. These allowed materials and practices are crop rotations, cover crops, plant and animal materials (including their ash), nonagricultural, natural materials, and, under appropriate conditions, mined substances of low and high solubility and synthetic materials included on the National List. Ash, grit, or screenings from the production of sewage sludge cannot be included in any of these categories and, therefore, cannot be used in organic production. We retained the definition of "sewage sludge" because it most clearly conveys the wide array of commercially available soil amendments that might be considered for organic production but that the final rule expressly prohibits. We have not added specific exclusions for sewage sludge, ash, grit, or screenings because these materials are prohibited through other provisions in the practice standard.

(2) The proposed rule prohibited the handler of an organic handling operation from using ionizing radiation for any purpose. The vast majority of commenters agreed with this prohibition and further recommended that the term, "ionizing radiation,"

should be defined to identify the specific applications that are prohibited. Most commenters supported a definition based on the FDA requirements in 21 CFR part 179.26 for the treatment or processing of food using ionizing radiation. While agreeing with the prohibition on ionizing radiation, these commenters favored allowing certain forms of irradiation such as the use of X-rays to inspect for debris such as stones that were inadvertently commingled with organically handled food. Other commenters recommended a prohibition on all forms of irradiation, which would include X-rays for inspection purposes, ultraviolet light, and microwaves in addition to ionizing radiation. Finally, a number of commenters stated that ionizing radiation is a safe and effective process for handling food and, therefore, should not be prohibited in organic handling.

We have not added a definition for "ionizing radiation" to the final rule because we have incorporated specific references to the applications that are prohibited in the regulatory text. The final rule prohibits the handler of an organic handling operation from using ionizing radiation as specified under 21 CFR part 179.26. These are the FDA-approved uses of ionizing radiation that commenters most frequently recommended that we prohibit in organic handling operations. They include the use of cobalt-60, cesium-137, and other sources of radiation for the purpose of controlling microbial contaminants, pathogens, and pests in food or to inhibit the growth and maturation of fresh foods. At its June 2000 meeting, the NOSB recommended prohibiting ionizing radiation for the purpose of controlling microbial contaminants, pathogens, parasites, and pests in food, preserving a food, or inhibiting physiological processes such as sprouting or ripening. The final rule does not prohibit the handler of an organic handling operation from using the FDA-approved applications of X-rays for inspecting food. The prohibition on ionizing radiation in the final rule is based solely on consumer preference as reflected in the overwhelming public comment stating that organically handled foods should not be treated in that manner.

(3) Some commenters recommend that the final rule incorporate definitions for the terms, "food additives," "extraction methods," "incidental additive," and "substantially transform." However, these terms are not used in the final rule and do not require a definition.

Definitions—Clarifications

Following our review of the definitions provisions in the proposed rule, we decided to further clarify the following provision in the final rule:

We were concerned that "State entity," the meaning of which encompasses both domestic and foreign political subdivisions, may be confused with "State," the meaning of which is limited to the States of the United States, its territories, the District of Columbia, and Puerto Rico. To avoid any possible confusion as to which provisions in this final rule apply to States and which apply to the broader political subdivisions, we have replaced the term, "State entity," with the term, "governmental entity," while retaining the same definition language in the proposed rule.

Subpart B—Applicability

This subpart provides an overview of what has to be certified under the National Organic Program (NOP); describes exemptions and exclusions from certification; addresses use of the term, "organic"; addresses recordkeeping by certified production and handling operations; and addresses allowed and prohibited substances, methods, and ingredients in organic production and handling.

Description of Regulations

Except for exempt and excluded operations, each production or handling operation or specified portion of a production or handling operation that produces or handles crops, livestock, livestock products, or other agricultural products that are intended to be sold, labeled, or represented as "100 percent organic," "organic," or "made with organic (specified ingredients or food group(s))" must be certified. Certified operations must meet all applicable requirements of these regulations.

This final rule becomes effective 60 days after its publication in the **Federal Register** and will be fully implemented 18 months after its effective date. Eighteen months after the effective date, all agricultural products that are sold, labeled, or represented as "100 percent organic," "organic," or "made with * * *" must be produced and handled in compliance with these regulations. Products entering the stream of commerce prior to the effective date will not have to be relabeled. The U.S. Department of Agriculture (USDA) seal may not be affixed to any "100 percent organic" or "organic" product until 18 months after the final rule's effective date.

We anticipate that certifying agents and production and handling operations

will move as quickly as possible after the effective date of the final rule to begin operating under the national organic standards. Certifying agents must begin certifying organic production and handling operations to the national standards upon receipt of their accreditation from the Administrator. Any production or handling operation or specified portion of a production or handling operation that has been already certified by a certifying agent on the date that the certifying agent receives its accreditation under this part shall be deemed to be certified under the Act until the operation's next anniversary date of certification. We have taken this approach because we believe that such certifying agents will, upon the effective date of the final rule, demonstrate their eligibility for accreditation by applying the national standards to the certification and renewal of certification of their clients. We also believe this approach will provide relief to certified operations which might otherwise have to be certified twice within a 12-month period (prior to their certifying agent's accreditation and again following their certifying agent's accreditation). This relief will only be available to those certified operations certified by a certifying agent that receives its accreditation within 18 months from the effective date of the final rule.

Certifying agents can apply for accreditation anytime after the effective date of the rule. Applications will be processed on a first-come, first-served basis. Those certifying agents who apply for accreditation within the first 6 months after the effective date of the final rule and are determined by the Administrator to meet the requirements for accreditation will be notified of their status approximately 12 months after the final rule's effective date. This approach is being taken because of the market advantage that could be realized by accredited certifying agents if USDA did not announce the accreditations simultaneously.

Exempt and Excluded Operations

This regulation establishes several categories of exempt or excluded operations. An exempt or excluded operation does not need to be certified. However, operations that qualify as exempt or excluded operations can voluntarily choose to be certified. A production or handling operation that is exempt or excluded from obtaining certification still must meet other regulatory requirements contained in this rule as explained below.

Exempt Operations

(1) A production or handling operation that has \$5,000 or less in gross annual income from organic sales is exempt from certification. This exemption is primarily designed for those producers who market their product directly to consumers. It will also permit such producers to market their products direct to retail food establishments for resale to consumers. The exemption is not restricted to U.S. producers. However, as a practical matter, we do not envision any significant use of the exemption by foreign producers because: (1) the products from such operations cannot be used as ingredients identified as organic in processed products produced by another handling operation, and (2) it is unlikely that such operations will be selling their products directly to consumers in the United States.

An exempt producer or handler must comply with the labeling requirements of section 205.310 and the organic production and handling requirements applicable to its type of operation. For example, a producer of organic vegetables that performs no handling functions would have to comply with the labeling requirements of section 205.310 and the applicable production requirements in sections 205.202 through 205.207. The labeling and production and handling requirements protect the integrity of organically produced products.

(2) A retail food establishment or portion of a retail food establishment that handles organically produced agricultural products but does not process them is exempt from all of the requirements in these regulations.

(3) A handling operation or portion of a handling operation that handles only agricultural products containing less than 70 percent organic ingredients by total weight of the finished product (excluding water and salt) is exempt from the requirements in these regulations, except the recordkeeping provisions of section 205.101(c); the provisions for prevention of contact of organic products with prohibited substances in section 205.272; and the labeling regulations in sections 205.305 and 205.310. The recordkeeping provisions maintain an audit trail for organic products. The prevention of contact with prohibited substances and the labeling requirements protect the integrity of organically produced products.

(4) A handling operation or portion of a handling operation that uses the word, "organic," only on the information panel is exempt from the requirements

in these regulations, except the recordkeeping provisions of section 205.101(c); the provisions for prevention of contact of organic products with prohibited substances as provided in section 205.272; and the labeling regulations in sections 205.305 and 205.310. The recordkeeping provisions maintain an audit trail for organic products. The prevention of contact with prohibited substances and labeling requirements protect the integrity of organically produced products.

As noted above, exempt handling operations producing multiingredient products must maintain records as required by section 205.101(c). This would include records sufficient to: (1) Prove that ingredients identified as organic were organically produced and handled and (2) verify quantities produced from such ingredients. Such records must be maintained for no less than 3 years, and the operation must allow representatives of the Secretary and the applicable State program's governing State official access to the records during normal business hours for inspection and copying to determine compliance with the applicable regulations.

Excluded Operations

(1) A handling operation or portion of a handling operation that sells organic agricultural products labeled as "100 percent organic," "organic," or "made with * * *" that are packaged or otherwise enclosed in a container prior to being received or acquired by the operation, remain in the same package or container, and are not otherwise processed while in the control of the handling operation is excluded from the requirements in these regulations, except for the provisions for prevention of commingling and contact of organic products with prohibited substances in section 205.272. The requirements for the prevention of commingling and contact with prohibited substances protect the integrity of organically produced products.

This exclusion will avoid creating an unnecessary barrier for handlers who distribute nonorganic products and who want to offer a selection of organic products.

(2) A retail food establishment or portion of a retail food establishment that processes on the premises of the retail food establishment raw and ready-to-eat food from certified agricultural products labeled as "100 percent organic," "organic," or "made with * * *" is excluded from the requirements in these regulations, except for the provisions for prevention

of contact of organic products with prohibited substances as provided in section 205.272 and the labeling regulations in section 205.310. The prevention of commingling and contact with prohibited substances and labeling requirements protect the integrity of organically produced products.

Excluded retail food establishments include restaurants; delicatessens; bakeries; grocery stores; or any retail outlet with an in-store restaurant, delicatessen, bakery, salad bar, or other eat-in or carry-out service of processed or prepared raw and ready-to-eat food.

There is clearly a great deal of public concern regarding the handling of organic products by retail food establishments. We have not required certification of retail food establishments at this time because of a lack of consensus as to whether retail food establishments should be certified, a lack of consensus on retailer certification standards, and a concern about the capacity of existing certifying agents to certify the sheer volume of such businesses. Retail food establishments, not exempt under the Act, could at some future date be subject to regulation under the NOP. Any such regulation would be preceded by rulemaking with an opportunity for public comment.

No retailer, regardless of this exclusion and the exceptions found in the definitions for "handler" or "handling operation," may sell, label, or provide market information on a product unless such product has been produced and handled in accordance with the Act and these regulations. Any retailer who knowingly sells or labels a product as organic, except in accordance with the Act and these regulations, will be subject to a civil penalty of not more than \$10,000 per violation under this program.

Recordkeeping Requirements for Certified Operations

A certified operation must maintain records concerning the production and handling of agricultural products that are sold, labeled, or represented as "100 percent organic," "organic," or "made with * * *" sufficient to demonstrate compliance with the Act and regulations. Such records must be adapted to the particular business that the certified operation is conducting, fully disclose all activities and transactions of the certified operation in sufficient detail to be readily understood and audited, be maintained for not less than 5 years beyond their creation, and be sufficient to demonstrate compliance with the Act and regulations. Certified operations

must make the records required by this regulation available for inspection by authorized representatives of the Secretary, the applicable State organic program's (SOP) governing State official, and the certifying agent. Access to such records must be provided during normal business hours.

Examples of Records

Each exempt, excluded, and certified operation should maintain the records which demonstrate compliance with the Act and the regulations applicable to it and which it believes establish an audit trail sufficient to prove to the Secretary, the applicable SOP's governing State official, and the certifying agent that the exempt, excluded, or certified operation is and has been in compliance with the Act and regulations.

Examples of records include: application and supporting documents for certification; organic system plan and supporting documents; purchased inputs, including seeds, transplants, livestock, and substances (fertilizers, pesticides, and veterinary biologics consistent with the livestock provisions of subpart C); cash purchase receipts, receiving manifests (bills of lading), receiving tickets, and purchase invoices; field records (planting, inputs, cultivation, and harvest); storage records (bin register, cooler log); livestock records, including feed (cash purchase receipts, receiving manifests (bills of lading), receiving tickets, purchase invoices, copies of grower certificates), breeding records (calendar, chart, notebook, veterinary documents), purchased animals documentation (cash purchase receipts, receiving manifests (bills of lading), receiving tickets, purchase invoices, copies of grower certificates), herd health records (calendar, notebook, card file, veterinary records), and input records (cash purchase receipts, written records, labels); producer invoice; producer contract; receiving manifests (bills of lading); transaction certificate; producer certificate; handler certificate; weigh tickets, receipts, and tags; receiving tickets; cash purchase receipts; raw product inventory reports and records; finished product inventory reports and records; daily inventories by lot; records as to reconditioning, shrinkage, and dumping; production reports and records; shipping reports; shipping manifests (bills of lading); paid freight and other bills; car manifests; broker's contracts; broker's statements; warehouse receipts; inspection certificates; residue testing reports; soil and water testing reports; cash receipt journals; general ledgers and supporting documents; sales journals; accounts

payable journals; accounts receivable journals; cash disbursement journals; purchase invoices; purchase journals; receiving tickets; producer and handler contracts; cash sales receipts; cash purchase journals; sales invoices, statements, journals, tickets, and receipts; account sales invoices; ledgers; financial statements; bank statements; records of deposit; canceled checks; check stubs; cash receipts; tax returns; accountant's or other work papers; agreements; contracts; purchase orders; confirmations and memorandums of sales; computer data; computer printouts; and compilations of data from the foregoing.

Allowed and Prohibited Substances

A certified operation must only use allowed substances, methods, and ingredients for the production and handling of agricultural products that are sold, labeled, or represented as "100 percent organic," "organic," or made with * * *" for these products to be in compliance with the Act and the NOP regulations. Use of ionizing radiation, sewage sludge, and excluded methods are prohibited in the production and handling of organic agricultural products.

Applicability—Changes Based on Comments

This subpart differs from the proposal in several respects as follows:

(1) *Violations of the Act or Regulations.* We have amended section 205.100 by adding a new paragraph (c), which addresses violations of the Act and these regulations. A number of commenters advocated for provisions within the final rule describing what legal proceedings USDA would conduct against operations or persons that violate the NOP. We agree that this rule should include provisions addressing violations of the Act and these regulations. Accordingly, we have added at section 205.100 the misuse of label provisions and false statement provisions of section 2120 (7 U.S.C. 6519) of the Act. Specifically, section 205.100(c) provides that persons not in compliance with the labeling requirements of the Act or these regulations are subject to a civil penalty of not more than \$10,000 per violation and that persons making false statements under the Act to the Secretary, a governing State official, or an accredited certifying agent shall be subject to the provisions of section 1001 of Title 18, United States Code. The provisions of the Act and these regulations apply to all operations or persons that sell, label, or represent their agricultural product as organic.

(2) *Prohibition on Use of Excluded Methods.* We have moved section 205.600 from subpart G, Administrative, to subpart B, Applicability, and replaced paragraph (d), which referred the reader to section 205.301, with new paragraphs (d) through (g). As amended, this section, redesignated as section 205.105, includes all of the provisions covered under old section 205.600.

The vast majority of commenters strongly supported the prohibition on the use of excluded methods in organic production and handling but raised concerns that they could not point to one provision that prohibited use of excluded methods in all aspects of organic production and handling. To close what they perceived to be "loopholes" in the prohibition, commenters made several suggestions for inclusion of new provisions prohibiting use of excluded methods in particular aspects of organic production and handling that they believed were not covered in the proposed rule. Other commenters pointed to inconsistencies in the way the prohibition on use of excluded methods was described in different sections, raising concerns that these apparent inconsistencies may create confusion for organic operations, certifiers, and consumers.

Although we intended that use of excluded methods would be prohibited in all aspects of organic production and handling, the structure of the proposed rule may not have made that clear. We also share the concerns that, in attempting to identify all aspects of organic production and handling where excluded methods might be used, we may inadvertently have left out some provisions, creating confusion for organic operations, certifying agents, and consumers and creating doubt as to the scope of the prohibition on use of excluded methods. Similarly, to the extent that the prohibition on excluded methods may have been described differently in various sections of the proposed rule, we also share the concern that these inconsistencies could create confusion.

As a result of these concerns, we have created a new provision in section 205.105 that prohibits the use of excluded methods (and ionizing radiation and sewage sludge) generally. This provision should alleviate perceptions that some areas of organic production may not have been covered by the prohibitions in the proposed rule. It also allows us to eliminate from the regulation most of the individual references to the prohibition on use of these methods, thereby eliminating any potential confusion where these provisions may have appeared

inconsistent. These changes do not lift the prohibition on use of these methods in those sections. In fact, the purpose of this new provision is to make clear that use of these methods is prohibited in the production and handling of organic products.

(3) *Animal Vaccines.* The proposed rule specifically asked for public comment on the potential impact of the prohibition on use of excluded methods as it relates to animal vaccines. A number of commenters raised concerns that there may be some critical vaccines that are only available in forms produced using excluded methods. Several commenters requested that we prohibit use of animal vaccines produced using excluded methods but that we provide for a temporary exemption until such time as vaccines produced without using excluded methods are approved for use on the National List. Other commenters requested that we prohibit use of vaccines produced using excluded methods without exception.

We have concluded that the potential impact of prohibiting vaccines produced using excluded methods on animal production systems is still unknown. We do not know of any critical animal vaccine that is only available in a form produced using excluded methods, but it is unclear whether producers and certifying agents are tracking the possible use of such vaccines. There also appears to be no international consensus on the use in organic production systems of animal vaccines produced using excluded methods, although there is precedent for such an exemption. European Union regulations, for example, allow for use of animal vaccines produced using excluded methods.

Based on comments received and because the potential impact of the prohibition on use of excluded methods is still uncertain, we have created the possibility at section 205.105(e) for the NOSB to exercise one very narrow exception to allow use of animal vaccines produced using excluded methods but only if they are explicitly approved on the National List. We believe the issue of animal vaccines requires further deliberation and that it is most appropriate to consider it through the National List process, which mandates review by the NOSB and Technical Advisory Panels. Consideration of animal vaccines produced using excluded methods is appropriate for the National List review process because animal vaccines, we believe, are most appropriately considered synthetic materials. That is why the provision is structured so that

vaccines produced using excluded methods could only be used in organic production if they are affirmatively included on the National List. We do not believe that a broad-based exemption of the type suggested in some comments, even if only temporary, is appropriate.

The Act allows use of animal vaccines in organic livestock production. Given the general prohibition on the use of excluded methods, however, we believe that animal vaccines produced using excluded methods should not be allowed without an explicit consideration of such materials by the NOSB and without an affirmative determination from the NOSB that they meet the criteria for inclusion on the National List. It is for that reason that we have not granted this request of commenters but, rather, provided an opportunity for review of this narrow range of materials produced using excluded methods through the National List process.

It is important to make clear, however, that this provision does not open all potential applications of excluded methods to a case-by-case review in the context of the National List, nor are we proposing that any particular vaccines be reviewed for inclusion on the National List at this time. The prohibition on use of excluded methods applies across the board to all phases of organic production and handling. We are simply responding to comments suggesting that a narrow exception for animal vaccines may be appropriate and providing for the possibility that such an exception could be invoked upon thorough review and recommendation by the NOSB.

Applicability—Changes Requested But Not Made

This subpart retains from the proposed rule regulations on which we received comments as follows:

(1) Exemption of Handling Operations Producing Multiingredient Products.

Some commenters asserted that only certified handling operations should be allowed to identify ingredients in multiingredient products as organic. These commenters believe that consumers will be misled if noncertified handling operations are allowed to identify ingredients as organic even if the organic claim is limited to the information panel. We do not agree with these assertions and have retained the proposed rule provisions that do not require handler certification when a product only identifies ingredients as organic within the information panel. Although handling operations only making organic claims on the

information panel are exempt from certification, these operations are required to use organic product from certified operations. They are also required to prevent contact of organic products with prohibited substances as set forth in section 205.272, adhere to the labeling provisions of sections 205.305 and 205.310, and maintain records in accordance with section 205.101(c). We believe consumers will understand the distinction between products that have the organic nature of the product stated on the principal display panel and those that merely identify an ingredient as organic on the information panel.

(2) *Retailer Exclusion from Certification.* Many commenters objected to the provisions of section 205.101(b)(2) which exclude retail food establishments from certification. These commenters assert that only final retailers that do not process agricultural products should be excluded from certification. There is clearly a great deal of public concern regarding the handling of organic products by retail food establishments. We have not required certification of retail food establishments at this time because of a lack of consensus as to whether retail food establishments should be certified, a lack of consensus on retailer certification standards, and a concern about the capacity of existing certifying agents to certify the sheer volume of such businesses. In addition, most existing certification programs do not include retail food establishments, and we do not believe there is sufficient consensus to institute such a significant expansion in the scope of certification at this time. However, since a few States have established procedures for certifying retail food establishments, we will assess their experience and continue to seek consensus on this issue of establishing retailer provisions under the NOP. Any such change would be preceded by rulemaking with an opportunity for public comment. The exclusion of nonexempt retail food establishments from this final rule does not prevent a State from developing an organic retail food establishment program as a component of its SOP. However, as with any component of an SOP, the Secretary will review such components on a case-by-case basis.

(3) *Producer Exemption Level.* Several commenters advocated for an increase in the producer exemption level above the \$5,000 limit. Comments supporting the exemption suggested increasing the statutory limit for qualifying for the exemption to as high as \$75,000. Other commenters stated that all producers should be certified and opposed the

exemption even though it is required by the Act. These commenters were concerned about maintaining the integrity of the organic product and about the lack of verification of the exempt operations.

We have not increased or removed the \$5,000 producer exemption because the exemption is mandated by section 2106(d) (7 U.S.C. 6505(d)) of the Act. Our purpose is to limit the financial burdens of certification on such operations but not to exempt them from the standards for organic production and handling. Accordingly, exempt production and handling operations must comply with the applicable organic production and handling requirements of subpart C and the labeling requirements of section 205.310.

Some of the commenters wanting a change in the producer exemption level suggested that the NOP add provisions for restricting these producers to marketing at farmers markets or roadside stands. We disagree with these comments. While we believe that most producers qualifying for the exemption are indeed likely to be small producers who market their products directly to consumers, we do not believe it is in the best interest of these producers to restrict their market opportunity to a specific sales method.

A few comments suggested that we establish a sliding-scale certification fee based upon either the size of the operation or sales of agricultural product instead of the exemption. The NOP does not establish fees for certification. Certifying agents may establish a sliding-scale system as long as their fees are reasonable and applied in a consistent and nondiscriminatory manner.

Finally, some commenters expressed concern that exempt operations were forbidden from certification. This interpretation is not correct. Any production or handling operation, including an exempt operation, which makes application for certification as an organic operation and meets the requirements for organic certification may be certified.

(4) *Handler exemption.* Many commenters disagreed with the proposed rule provision providing for an exemption of \$5,000 to handlers. These commenters asked the NOP to remove the phrase, "or handlers," from the exemption provision. The commenters argue that the handler exemption is not authorized by the Act. We disagree with the commenters, and we have retained the handler exemption in the final rule. The Act states that the exemption is available to "persons"

selling not more than \$5,000 annually in value of agricultural products. The Act's definition of "persons" includes handlers. Thus, handlers grossing \$5,000 or less qualify for the exemption.

(5) *Categories of Income to Qualify for an Exemption.* Some commenters want the \$5,000 producer/handler exemption to include all sales of agricultural products, not just sales of organic agricultural products. These commenters perceive this provision to be a loophole for large, split operations. We disagree with these commenters, and we have retained the \$5,000 producer/handler exemption based upon total sales of organic agricultural products. We do not believe there is a significant number of split operations which only gross \$5,000 in annual sales of organic products and, therefore, qualify for this exemption. In setting the exemption levels, the Department sought to maximize the benefits to small producers afforded by the Act while setting a threshold level that minimizes the potential of product mislabeling.

(6) *Limiting Handler Exclusions.* Many commenters argued that brokers, distributors, warehousemen, and transporters should not be excluded from certification. We do not agree with these commenters. Brokers, distributors, warehousemen and transporters do not alter the product and, in many cases, do not take title to the product. Certifying these handlers would be an unnecessary burden on the industry. Traditionally, distributors and trucking companies have been excluded from State and private certification requirements.

(7) *Recordkeeping Requirements for Excluded Operations.* Several commenters argued that excluded operations should be required to comply with the same recordkeeping requirements as exempt operations. Some commenters expressed concern over the inability to verify compliance for either exempt or excluded operations and asked that exempt or excluded operations be subject to additional recordkeeping requirements. We disagree with these commenters and have retained the provisions from the proposed rule on recordkeeping for excluded operations. Given the nature of these excluded operations, for example, operations that only sell prepackaged organic products, we believe that extensive recordkeeping requirements would be an unwarranted regulatory burden.

(8) *Recordkeeping Burden on Small Certified Operations.* Some commenters questioned whether small certified operations have the ability to implement a recordkeeping system which complies with the provisions of section 205.103.

These commenters argue that recordkeeping requirements must be tailored to the scale of the operation. We do not believe that the recordkeeping requirements as described in section 205.103 conflict with the suggestions of the commenters. The recordkeeping requirements provide that the records must be adapted to the particular business that the certified operation is conducting and be sufficient to demonstrate compliance with the Act and regulations. It is USDA's intent that each production and handling operation decide for itself what recordkeeping scheme is appropriate, given the complexity and scope of the individual business. These provisions provide considerable latitude for each production and handling operation to decide what records are necessary to demonstrate its compliance with the Act and the NOP regulations.

(9) *Public Access to Records.* Several commenters asked that the public have full access to any certifying agent record on organic production and/or handling operations. Other commenters expressed concerns about certifying agents divulging confidential business information and asked that records containing confidential business information not be taken from the business' physical location.

We have not changed this provision. The recordkeeping requirements are designed to seek a balance between the public's right to know and a business's right to retain confidential business information. Certifying agents must have access to certain records during their review of the operation to determine the operation's compliance with the NOP. However, certifying agents are required to protect an operation's confidential business information. Requiring full public access could compromise a business' competitive position and place an unfair burden on the organic industry.

(10) *Fair Labor Practices on Organic Farms.* Many commenters asked the NOP to develop fair labor practice standards as a part of the final rule. We have not adopted these comments. Other statutes cover labor and worker safety standards. The Act does not provide the authority to include them in these regulations. However, these regulations do not prohibit certifying agents from developing a voluntary certification program, separate from organic certification, that address fair labor and worker safety standards.

(11) *"Transitional Organic" Label.* Several commenters requested that the NOP adopt regulations on the conversion of operations to organic production and create a "transitional

organic" label. We have not included provisions within the final rule that provide for "transitional organic" labeling. Although many commenters requested that we provide for transition labeling, there does not appear to be sufficient consensus to establish such a standard at this time. Given this lack of consensus, it is unclear what marketplace value such a label might have, and we are concerned that allowing such a label at this point might lead to greater consumer confusion rather than providing clarity.

Applicability—Clarifications

Clarification is given on the following issues raised by commenters as follows:

(1) *"Genetic" drift.* Many commenters raised issues regarding drift of the products of excluded methods onto organic farms. These commenters were concerned that pollen drifting from near-by farms would contaminate crops on organic operations and that, as a result, organic farmers could lose the premium for their organic products through no fault of their own. Many commenters argued that we should use this rule to somehow shift the burden to the technology providers who market the products of excluded methods or the nonorganic farming operations that use their products. Some, for example, suggested that this regulation should require that the nonorganic operations using genetically engineered varieties plant buffer strips or take other steps to avoid drift onto organic farms. Others suggested that the regulation could provide for citizens' right to sue in cases of drift.

While we understand the concerns that commenters have raised, the kind of remedies they suggested are outside the scope of the Act and this regulation. The Act only provides for the regulation of organic operations. We cannot use this regulation to impose restrictions, such as requiring buffer strips or other measures, on operations that are not covered by the Act. Similarly, while citizens may have the ability to bring suit under other laws, the Act itself does not provide for the right to bring suit as a Federal cause of action, and we could not grant it through this regulation.

Drift has been a difficult issue for organic producers from the beginning. Organic operations have always had to worry about the potential for drift from neighboring operations, particularly drift of synthetic chemical pesticides. As the number of organic farms increases, so does the potential for conflict between organic and nonorganic operations.

It has always been the responsibility of organic operations to manage

potential contact of organic products with other substances not approved for use in organic production systems, whether from the nonorganic portion of a split operation or from neighboring farms. The organic system plan must outline steps that an organic operation will take to avoid this kind of unintentional contact.

When we are considering drift issues, it is particularly important to remember that organic standards are process based. Certifying agents attest to the ability of organic operations to follow a set of production standards and practices that meet the requirements of the Act and the regulations. This regulation prohibits the use of excluded methods in organic operations. The presence of a detectable residue of a product of excluded methods alone does not necessarily constitute a violation of this regulation. As long as an organic operation has not used excluded methods and takes reasonable steps to avoid contact with the products of excluded methods as detailed in their approved organic system plan, the unintentional presence of the products of excluded methods should not affect the status of an organic product or operation.

Issues of pollen drift are also not confined to the world of organic agriculture. For example, plant breeders and seed companies must ensure genetic identity of plant varieties by minimizing any cross-pollination that might result from pollen drift. Under research conditions, small-scale field tests of genetically engineered plants incorporate various degrees of biological containment to limit the possibility of gene flow to other sexually compatible plants. Federal regulatory agencies might impose specific planting requirements to limit pollen drift in certain situations. Farmers planting nonbiotechnology-derived varieties may face similar kinds of questions if cross-pollination by biotechnology-derived varieties alters the marketability of their crop. These discussions within the broader agricultural community may lead to new approaches to addressing these issues. They are, however, outside the scope of this regulation by definition.

(2) *Additional NOP Standards for Specific Production Categories.* Many commenters asked that the NOP include in the final rule certification standards for apiculture, greenhouses, mushrooms, aquatic species, culinary herbs, pet food, and minor animal species (e.g., rabbits) food. The NOP intends to provide standards for categories where the Act provides the authority to promulgate standards.

During the 18-month implementation period, the NOP intends to publish for comment certification standards for apiculture, mushrooms, greenhouses and aquatic animals. These standards will build upon the existing final rule and will address only the unique requirements necessary to certify these specialized operations.

Some of the other questions raised by commenters are already addressed in the final rule. For example, feed for minor species is covered by livestock feed provisions within subpart C and the livestock feed labeling provisions within subpart D. The production and utilization of culinary herbs, including herbal teas, is covered by the provisions of the final rule. We do not envision needing to do additional rulemaking on these two categories.

Other requests by commenters have not been addressed. We have not addressed the labeling of pet food within this final rule because of the extensive consultation that will be required between USDA, the NOSB, and the pet food industry before any standards on this category could be considered.

(3) *Standards for Cosmetics, Body Care Products, and Dietary Supplements.* A few commenters asked that the NOP include in the final rule certification standards for cosmetics, body care products, and dietary supplements. Producers and handlers of agricultural products used as ingredients in cosmetics, body care products, and dietary supplements could be certified under these regulations. Producers and handlers of these ingredients might find an increased market value for their products because of the additional assurance afforded by certification. The ultimate labeling of cosmetics, body care products, and dietary supplements, however, is outside the scope of these regulations.

(4) *Private Label Products.* Many commenters asked about the certification status of so-called "private label products." Private label products are items for which a retailer contracts with a processor to produce the product to the retailer's specifications and to be sold under the retailer's name. Commenters believe the proposed rule was unclear on the certification requirements for these products. Any product labeled as "100 organic," "organic," or "made with * * *" must be certified regardless of the business arrangements under which the product was produced. When a retail operation contracts for the production, packaging, or labeling of organic product, it is the certified production or handling

operation that is responsible for complying with the applicable organic production or handling regulations.

(5) *State Oversight of Exempt and Excluded Operations.* Many commenters asked for clarification on the State's enforcement responsibility for exempt and excluded operations. The NOP is ultimately responsible for the oversight and enforcement of the program, including oversight of exempt and excluded operations and cases of fraudulent or misleading labeling. We expect, however, that States would want to monitor for false claims or misleading labeling under these regulations and would forward any complaints to the NOP. States that have an approved SOP which includes regulation of operations excluded under the NOP would be required to enforce those provisions.

(6) *Nonedible Fibers Products in the NOP.* Some commenters asked the NOP to clarify the certification status of fibers such as cotton and flax. The final rule allows for certification of organically produced fibers such as cotton and flax. However, the processing of these fibers is not covered by the final rule. Therefore, goods that utilize organic fibers in their manufacture may only be labeled as a "made with * * *" product; e.g., a cotton shirt labeled "made with organic cotton."

(7) *Recordkeeping for Operations That Produce Organic and Nonorganic Product.* Several commenters recommended that "split operations," which are operations producing organic and nonorganic agricultural products, be required to maintain separate records. These commenters believe that the proposed rule did not provide adequate provision for the maintenance of separate recordkeeping. The provisions within section 205.103(b)(1) and (b)(2) do indicate that operations which produce both organic and nonorganic agricultural products must maintain a recordkeeping system that differentiates the organic portion of the operations from the records related to other portions of operations.

(8) *NOP Program Manual.* A few commenters, particularly States, noted that the proposed rule made several references to program manuals as a mechanism for further clarifying certain portions of the rule. These commenters asked whether certifying agents should consider information contained in these manuals as enforceable regulations. NOP program manuals cannot be and are not intended to be the equivalent of regulations. Rather, the NOP envisions development of a program manual to serve as guidance for certifying agents regarding implementation- and certification-related issues. Material

contained within the program manual will be designed to address the organic agriculture principles of each final rule section, as appropriate, and to offer information that certifying agents should consider in making certification decisions that will be reliably uniform throughout the country. The use of program manuals as guidance to assist in developing uniform certification decisions is a standard industry practice, and the NOP has compiled examples of program manuals from both large and small certifiers. Because the NOP intends to use the examples it has acquired as the basis for any NOP guidance manual, we believe that most certifying agents will find such NOP manual, when developed, familiar and useful. Additionally, we will use the NOSB public meeting process to seek guidance from industry and the public on what information would be useful in a program manual and to provide input on the program manual as it is developed. Of course, if in developing program guidance, it appears that modifications or changes in the NOP final rule are required, such modifications would be made through notice and comment rulemaking.

(9) *Use of Products from Exempt Operations as Organic Ingredients.* A few commenters responded to the question in the proposed rule in which we asked whether handlers should be allowed to identify organically produced products produced by exempt production operations as organic ingredients. The proposed rule provided that all ingredients identified as organic in a multiingredient product must have been produced by a production or handling operation certified by an accredited certifying agent.

The commenters supported this position. These commenters believe that the potential for mislabeling outweighed any financial benefit that might accrue to exempt producers through expanded market opportunities. We concur, and, therefore, have retained the prohibition on using products produced by an exempt production or handling operation as organic ingredients.

(10) *Exemption of Handling Operations Producing Multiingredient Products.* We have amended section 205.101(a)(3) by changing "50 percent" to "70 percent" to make it consistent with the amendments to the labeling provisions. We have also edited section 205.101(a)(4) for clarification purposes. Additionally, we amended sections 205.101(a)(3) and 205.101(a)(4) by citing the labeling requirements of section 205.305. These amendments have been made to clarify that handling operations exempted under these sections are

subject to the labeling requirements of section 205.305.

(11) *Production and Handling in Compliance with Federal Statutes.* We have amended section 205.102 by removing paragraph (c). This paragraph provided that any agricultural product that is sold, labeled, or represented as "100 percent organic," "organic," or "made with organic (specified ingredients)" must be produced and handled in compliance with applicable Federal statutes and their implementing regulations. We have taken this action because the provision is an identical restatement of section 2120(f) (7 U.S.C. 6519(f)) of the Act. The Act makes clear that all production and handling operations are to comply with all applicable Federal statutes and their implementing regulations. Therefore, it is unnecessary to repeat the requirement in these regulations.

(12) *Foreign Applicants.* We have removed section 205.104, which provided that the regulations in this part, as applicable, apply equally to domestic and foreign applicants for accreditation, accredited certifying agents, domestic and foreign applicants for certification as organic production or handling operations, and certified organic production and handling operations unless otherwise specified. These regulations, as written, apply equally to all applicants for accreditation, accredited certifying agents, applicants for organic certification, and certified organic operations. Accordingly, we have determined that section 205.104 is not necessary.

Subpart C—Organic Crop, Wild Crop, Livestock, and Handling Requirements Description of Regulations

General Requirements

This subpart sets forth the requirements with which production and handling operations must comply in order to sell, label, or represent agricultural products as "100 percent organic," "organic," or "made with organic (specified ingredients or food group(s))." The producer or handler of an organic production or handling operation must comply with all applicable provisions of subpart C. Any production practice implemented in accordance with this subpart must maintain or improve the natural resources, including soil and water quality, of the operation. Production and handling operations which sell, label, or represent agricultural products as organic in any manner and which are exempt or excluded from certification must comply with the requirements of

this subpart, except for the development of an organic system plan.

Production and Handling (General)

The Organic Food Production Act of 1990 (OFPA or Act) requires that all crop, wild crop, livestock, and handling operations requiring certification submit an organic system plan to their certifying agent and, where applicable, the State organic program (SOP). The organic system plan is a detailed description of how an operation will achieve, document, and sustain compliance with all applicable provisions in the OFPA and these regulations. The certifying agent must concur that the proposed organic system plan fulfills the requirements of subpart C, and any subsequent modification of the organic plan by the producer or handler must receive the approval of the certifying agent.

The organic system plan is the forum through which the producer or handler and certifying agent collaborate to define, on a site-specific basis, how to achieve and document compliance with the requirements of certification. The organic system plan commits the producer or handler to a sequence of practices and procedures resulting in an operation that complies with every applicable provision in the regulations. Accreditation qualifies the certifying agent to attest to whether an organic system plan comports with the organic standard. The organic system plan must be negotiated, enacted, and amended through an informed dialogue between certifying agent and producer or handler, and it must be responsive to the unique characteristics of each operation.

An organic system plan contains six components. First, the organic system plan must describe the practices and procedures used, including the frequency with which they will be used, in the certified operation. Second, it must list and characterize each substance used as a production or handling input, including the documentation of commercial availability, as applicable. Third, it must identify the monitoring techniques which will be used to verify that the organic plan is being implemented in a manner which complies with all applicable requirements. Fourth, it must explain the recordkeeping system used to preserve the identity of organic products from the point of certification through delivery to the customer who assumes legal title to the goods. Fifth, the organic system plan must describe the management practices and physical barriers established to prevent commingling of organic and nonorganic

products on a split operation and to prevent contact of organic production and handling operations and products with prohibited substances. Finally, the organic system plan must contain the additional information deemed necessary by the certifying agent to evaluate site-specific conditions relevant to compliance with these or applicable State program regulations. Producers or handlers may submit a plan developed to comply with other Federal, State, or local regulatory programs if it fulfills the requirements of an organic system plan.

The first element of the organic system plan requires a narrative or other descriptive format that identifies the practices and procedures to be performed and maintained, including the frequency with which they will be performed. Practices are tangible production and handling techniques, such as the method for applying manure, the mechanical and biological methods used to prepare and combine ingredients and package finished products, and the measures taken to exclude pests from a facility. Procedures are the protocols established for selecting appropriate practices and materials for use in the organic system plan, such as a procedure for locating commercially available, organically produced seed. Procedures reflect the decision-making process used to implement the organic system plan.

By requiring information on the frequency with which production and handling practices and procedures will be performed, the final rule requires an organic system plan, to include an implementation schedule, including information on the timing and sequence of all relevant production and handling activities. The plan will include, for example, information about planned crop rotation sequences, the timing of any applications of organic materials, and the timing and location of soil tests. Livestock management practices might describe development of a rotational grazing plan or addition of mineral supplements to the feed supply. A handling operation might identify steps involved in locating and contracting with farmers who could produce organic ingredients that were in short supply.

The second element that must be included in an organic system plan is information on the application of substances to land, facilities, or agricultural products. This requirement encompasses both natural and synthetic materials allowed for use in production and handling operations. For natural materials which may be used in organic operations under specific restrictions,

the organic plan must detail how the application of the materials will comply with those restrictions. For example, farmers who apply manure to their fields must document in their organic system plans how they will prevent that application from contributing to water contamination. A producer and handler who bases the selection of seed and planting stock material under section 205.204 or an agricultural ingredient under section 205.301 on the commercial availability of that substance must provide documentation in the organic system plan.

The third element of the organic system plan is a description of the methods used to evaluate its effectiveness. Producers and handlers are responsible for identifying measurable indicators that can be used to evaluate how well they are achieving the objectives of the operation. For example, production objectives could be measured through regular tallies of bushels or pounds of product sold from the farm or in numbers of cases sold from a handling operation. Indicators that can identify changes in quality or effectiveness of management practices could be relatively simple, such as the information contained in a standard soil test. The specific indicators used to evaluate a given organic system plan will be determined by the producer or handler in consultation with the certifying agent. Thus, if the organic system plan calls for improvements in soil organic matter content in a particular field, it would include provisions for analyzing soil organic matter levels at periodic intervals. If herd health improvement is an objective, factors such as somatic cell count or observations about changes in reproductive patterns might be used as indicators.

The fourth element of the organic system plan is a description of the recordkeeping system used to verify and document an audit trail, as appropriate to the operation. For each crop or wild-crop harvested, the audit trail must trace the product from the field, farm parcel, or area where it is harvested through the transfer of legal title. A livestock operation must trace each animal from its entrance into through removal from the organic operation. A handling operation must trace each product that is handled and sold, labeled, or represented as organic from the receipt of its constituent ingredients to the sale of the processed product.

The fifth element which must be included in an organic system plan pertains to split production or handling operations. This provision requires an operation that produces both organic

and nonorganic products to describe the management practices and physical barriers established to prevent commingling of organic and nonorganic products. This requirement addresses contact of organic products, including livestock, organic field units, storage areas, and packaging to be used for organic products, with prohibited substances.

The specific requirements to be included in an organic system plan are not listed here. The accreditation process provides an assurance that certifying agents are competent to determine the specific documentation they require to review and evaluate an operation's organic system plan. Section 205.200(a)(6) allows a certifying agent to request additional information needed to determine that an organic system plan meets the requirements of this subpart. The site-specific nature of organic production and handling necessitates that certifying agents have the authority to determine whether specific information is needed to carry out their function.

Crop Production

Any field or farm parcel used to produce an organic crop must have been managed in accordance with the requirements in sections 205.203 through 205.206 and have had no prohibited substances applied to it for at least 3 years prior to harvest of the crop. Such fields and farm parcels must also have distinct, defined boundaries and buffer zones to prevent contact with the land or crop by prohibited substances applied to adjoining land.

A producer of an organic crop must manage soil fertility, including tillage and cultivation practices, in a manner that maintains or improves the physical, chemical, and biological condition of the soil and minimizes soil erosion. The producer must manage crop nutrients and soil fertility through rotations, cover crops, and the application of plant and animal materials. The producer must manage plant and animal materials to maintain or improve soil organic matter content in a manner that does not contribute to contamination of crops, soil, or water by plant nutrients, pathogenic organisms, heavy metals, or residues of prohibited substances. Plant and animal materials include raw animal manure, composted plant and animal materials, and uncomposted plant materials. Raw animal manure must either be composted, applied to land used for a crop not intended for human consumption, or incorporated into the soil at least 90 days before harvesting an edible product that does not come into contact with the soil or

soil particles and at least 120 days before harvesting an edible product that does come into contact with the soil or soil particles. Composted plant or animal materials must be produced through a process that establishes an initial carbon-to-nitrogen (C:N) ratio of between 25:1 and 40:1 and achieves a temperature between 131°F and 170°F. Composting operations that utilize an in-vessel or static aerated pile system must maintain a temperature within that range for a minimum of 3 days. Composting operations that utilize a windrow composting system must maintain a temperature within that range for a minimum of 15 days, during which time the materials must be turned five times.

In addition to these practices and materials, a producer may apply a crop nutrient or soil amendment included on the National List of synthetic substances allowed in crop production. The producer may apply a mined substance of low solubility. A mined substance of high solubility may only be applied if the substance is used in compliance with the annotation on the National List of nonsynthetic materials prohibited in crop production. Ashes of untreated plant or animal materials which have not been combined with a prohibited substance and which are not included on the National List of nonsynthetic substances prohibited for use in organic crop production may be used to produce an organic crop. A plant or animal material that has been chemically altered by a manufacturing process may be used only if it is included on the National List of synthetic substances allowed for use in organic production. The producer may not use any fertilizer or composted plant and animal material that contains a synthetic substance not allowed for crop production on the National List or use sewage sludge. Burning crop residues as a means of disposal is prohibited, except that burning may be used to suppress the spread of disease or to stimulate seed germination.

The producer must use organically grown seeds, annual seedlings, and planting stock. The producer may use untreated nonorganic seeds and planting stock when equivalent organic varieties are not commercially available, except that organic seed must be used for the production of edible sprouts. Seed and planting stock treated with substances that appear on the National List may be used when an organically produced or untreated variety is not commercially available. Nonorganically produced annual seedlings may be used when a temporary variance has been established due to damage caused by

unavoidable business interruption, such as fire, flood, or frost. Planting stock used to produce a perennial crop may be sold as organically produced planting stock after it has been maintained under a system of organic management for at least 1 year. Seeds, annual seedlings, and planting stock treated with prohibited substances may be used to produce an organic crop when the application of the substance is a requirement of Federal or State phytosanitary regulations.

The producer is required to implement a crop rotation, including but not limited to sod, cover crops, green manure crops, and catch crops. The crop rotation must maintain or improve soil organic matter content, provide for effective pest management in perennial crops, manage deficient or excess plant nutrients, and control erosion to the extent that these functions are applicable to the operation.

The producer must use preventive practices to manage crop pests, weeds, and diseases, including but not limited to crop rotation, soil and crop nutrient management, sanitation measures, and cultural practices that enhance crop health. Such cultural practices include the selection of plant species and varieties with regard to suitability to site-specific conditions and resistance to prevalent pests, weeds, and diseases. Mechanical and biological methods that do not entail application of synthetic substances may be used as needed to control pest, weed, and disease problems that may occur. Pest control practices include augmentation or introduction of pest predators or parasites; development of habitat for natural enemies; and nonsynthetic controls such as lures, traps, and repellents. Weed management practices include mulching with fully biodegradable materials; mowing; livestock grazing; hand weeding and mechanical cultivation; flame, heat, or electrical techniques; and plastic or other synthetic mulches, provided that they are removed from the field at the end of the growing or harvest season. Disease problems may be controlled through management practices which suppress the spread of disease organisms and the application of nonsynthetic biological, botanical, or mineral inputs. When these practices are insufficient to prevent or control crop pests, weeds, and diseases, a biological or botanical substance or a synthetic substance that is allowed on the National List may be used provided that the conditions for using the substance are documented in the organic system plan. The producer must

not use lumber treated with arsenate or other prohibited materials for new installations or replacement purposes that comes into contact with soil or livestock.

A wild crop that is to be sold, labeled, or represented as "100 percent organic," "organic," or "made with organic (specified ingredients or food group(s))" must be harvested from a designated area that has had no prohibited substances applied to it for a period of 3 years immediately preceding the harvest of the wild crop. The wild crop must also be harvested in a manner that ensures such harvesting or gathering will not be destructive to the environment and will sustain the growth and production of the wild crop.

Livestock Production

Any livestock product to be sold, labeled, or represented as organic must be maintained under continuous organic management from the last third of gestation or hatching with three exceptions. Poultry or edible poultry products must be from animals that have been under continuous organic management beginning no later than the second day of life. Milk or milk products must be from animals that have been under continuous organic management beginning no later than 1 year prior to the production of such products, except for the conversion of an entire, distinct herd to organic production. For the first 9 months of the year of conversion, the producer may provide the herd with a minimum of 80-percent feed that is either organic or produced from land included in the organic system plan and managed in compliance with organic crop requirements. During the final 3 months of the year of conversion, the producer must provide the herd feed in compliance with section 205.237. Once the herd has been converted to organic production, all dairy animals shall be under organic management from the last third of gestation. Livestock used as breeder stock may be brought from a nonorganic operation into an organic operation at any time, provided that, if such livestock are gestating and the offspring are to be organically raised from birth, the breeder stock must be brought into the organic operation prior to the last third of gestation.

Should an animal be brought into an organic operation pursuant to this section and subsequently moved to a nonorganic operation, neither the animal nor any products derived from it may be sold, labeled, or represented as organic. Breeder or dairy stock that has not been under continuous organic management from the last third of

gestation may not be sold, labeled, or represented as organic slaughter stock. The producer of an organic livestock operation must maintain records sufficient to preserve the identity of all organically managed livestock and all edible and nonedible organic livestock products produced on his or her operation.

Except for nonsynthetic substances and synthetic substances included on the National List that may be used as feed supplements and additives, the total feed ration for livestock managed in an organic operation must be composed of agricultural products, including pasture and forage, that are organically produced. Any portion of the feed ration that is handled must comply with organic handling requirements. The producer must not use animal drugs, including hormones, to promote growth in an animal or provide feed supplements or additives in amounts above those needed for adequate growth and health maintenance for the species at its specific stage of life. The producer must not feed animals under organic management plastic pellets for roughage or formulas containing urea or manure. The feeding of mammalian and poultry slaughter by-products to mammals or poultry is prohibited. The producer must not supply animal feed, feed additives, or feed supplements in violation of the Federal Food, Drug, and Cosmetic Act.

The producer of an organic livestock operation must establish and maintain preventive animal health care practices. The producer must select species and types of livestock with regard to suitability for site-specific conditions and resistance to prevalent diseases and parasites. The producer must provide a feed ration including vitamins, minerals, protein, and/or amino acids, fatty acids, energy sources, and, for ruminants, fiber. The producer must establish appropriate housing, pasture conditions, and sanitation practices to minimize the occurrence and spread of diseases and parasites. Animals in an organic livestock operation must be maintained under conditions which provide for exercise, freedom of movement, and reduction of stress appropriate to the species. Additionally, all physical alterations performed on animals in an organic livestock operation must be conducted to promote the animals' welfare and in a manner that minimizes stress and pain.

The producer of an organic livestock operation must administer vaccines and other veterinary biologics as needed to protect the well-being of animals in his or her care. When preventive practices

and veterinary biologics are inadequate to prevent sickness, the producer may administer medications included on the National List of synthetic substances allowed for use in livestock operations. The producer may not administer synthetic parasiticides to breeder stock during the last third of gestation or during lactation if the progeny is to be sold, labeled, or represented as organically produced. After administering synthetic parasiticides to dairy stock, the producer must observe a 90-day withdrawal period before selling the milk or milk products produced from the treated animal as organically produced. Every use of a synthetic medication or parasiticide must be incorporated into the livestock operation's organic system plan subject to approval by the certifying agent.

The producer of an organic livestock operation must not treat an animal in that operation with antibiotics, any synthetic substance not included on the National List of synthetic substances allowed for use in livestock production, or any substance that contains a nonsynthetic substance included on the National List of nonsynthetic substances prohibited for use in organic livestock production. The producer must not administer any animal drug, other than vaccinations, in the absence of illness. The use of hormones for growth promotion is prohibited in organic livestock production, as is the use of synthetic parasiticides on a routine basis. The producer must not administer synthetic parasiticides to slaughter stock or administer any animal drug in violation of the Federal Food, Drug, and Cosmetic Act. The producer must not withhold medical treatment from a sick animal to maintain its organic status. All appropriate medications and treatments must be used to restore an animal to health when methods acceptable to organic production standards fail. Livestock that are treated with prohibited materials must be clearly identified and shall not be sold, labeled, or represented as organic.

A livestock producer must document in his or her organic system plan the preventative measures he or she has in place to deter illness, the allowed practices he or she will employ if illness occurs, and his or her protocol for determining when a sick animal must receive a prohibited animal drug. These standards will not allow an organic system plan that envisions an acceptable level of chronic illness or proposes to deal with disease by sending infected animals to slaughter. The organic system plan must reflect a proactive approach to health management, drawing upon allowable

practices and materials. Animals with conditions that do not respond to this approach must be treated appropriately and diverted to nonorganic markets.

The producer of an organic livestock operation must establish and maintain livestock living conditions for the animals under his or her care which accommodate the health and natural behavior of the livestock. The producer must provide access to the outdoors, shade, shelter, exercise areas, fresh air, and direct sunlight suitable to the species, its stage of production, the climate, and the environment. This requirement includes access to pasture for ruminant animals. The producer must also provide appropriate clean, dry bedding, and, if the bedding is typically consumed by the species, it must comply with applicable organic feed requirements. The producer must provide shelter designed to allow for the natural maintenance, comfort level, and opportunity to exercise appropriate to the species. The shelter must also provide the temperature level, ventilation, and air circulation suitable to the species and reduce the potential for livestock injury. The producer may provide temporary confinement of an animal because of inclement weather; the animal's stage of production; conditions under which the health, safety, or well-being of the animal could be jeopardized; or risk to soil or water quality. The producer of an organic livestock operation is required to manage manure in a manner that does not contribute to contamination of crops, soil, or water by plant nutrients, heavy metals, or pathogenic organisms and optimizes nutrient recycling.

Handling

Mechanical or biological methods can be used to process an agricultural product intended to be sold, labeled, or represented as "100 percent organic," "organic," or "made with organic ingredients" for the purpose of retarding spoilage or otherwise preparing the agricultural product for market. Processed multiingredient products labeled "100 percent organic," may only use wholly organic ingredients, pursuant to paragraph (a) of section 205.301. Nonagricultural substances that are allowed for use on the National List and nonorganically produced agricultural products may be used in or on "organic" and "made with * * *" products pursuant to paragraphs (b) and (c) of section 205.301, respectively. Documentation of commercial availability of each substance to be used as a nonorganic ingredient in products labeled "organic" must be listed in the

organic handling system plan in accordance with section 205.201.

Handlers are prohibited from using: (1) Ionizing radiation for the treatment or processing of foods; (2) ingredients produced using excluded methods; or (3) volatile synthetic solvents in or on a processed product or any ingredient which is sold, labeled, or represented as organic. The prohibition on ionizing radiation for the treatment or processing of foods is discussed under Applicability, section 205.105. This rule does not prohibit an organic handling operation from using Food and Drug Administration (FDA)-approved X-rays for inspecting packaged foods for foreign objects that may be inadvertently commingled in the packaged product.

The two paragraphs on excluded methods and ionizing radiation in section 205.270(c) of the proposed rule are replaced with new paragraph (c)(1) which cross-references those practices under paragraphs (e) and (f) of section 205.105. New section 205.105 clearly specifies that ionizing radiation and excluded methods are two practices that handlers must not use in producing organic agricultural products and ingredients. The prohibition on the use of volatile synthetic solvents, also included under paragraph (c) of section 205.270 does not apply to nonorganic ingredients in "made with * * *" products.

The practice standard for facility pest management under section 205.271 requires the producer or handler operating a facility to use management practices to control and prevent pest infestations. Prevention practices in paragraph (a) include removing pest habitats, food sources, and breeding areas; preventing access to handling facilities; and controlling environmental factors, such as temperature, light, humidity, atmosphere, and air circulation, to prevent pest reproduction. Permitted pest control methods in paragraph (b) include mechanical or physical controls, such as traps, light, or sound. Lures and repellents using nonsynthetic substances may be used as pest controls. Lures and repellents with synthetic substances that are allowed on the National List also may be used. Prevention and control practices in paragraphs (a) and (b) may be used concurrently.

If the practices in paragraphs (a) and (b) are not effective, amended paragraph (c) provides that handlers may then use a nonsynthetic or synthetic substance consistent with National List. If the measures and substances provided under paragraphs (a), (b), and (c) are not

effective, synthetic substances not on the National List may be used to control pest infestations. Under new paragraph (d), the handler and the operation's certifying agent, prior to using such a substance, must agree on the substance to be used to control the pest, measures to be taken to prevent contact with organically produced product, and ingredients that may be in the handling facility.

This rule recognizes that certain local, State, and Federal laws or regulations may require intervention with prohibited substances before or at the same time substances allowed in paragraphs (b) and (c) are used. To the extent that this occurs, this rule permits the handler to follow such laws and regulations to market a product as organically handled, provided that the product does not come into contact with the pest control substance used.

The extent of pest infestation cannot be foreseen when an organic plan is submitted by the certified operation and approved by the certifying agent. A handler who uses any nonsynthetic or synthetic substance to control facility pests must update its organic handling system plan to address all measures taken or intended to be taken to prevent contact between the substance and any organically produced ingredient or finished product.

Section 205.272 provides additional practice standards that must be followed by an organic handling operation to prevent the commingling of organic and nonorganic products and to protect organic products from contact with prohibited substances. An organic handling operation must not use packaging materials and storage containers or bins that contain a synthetic fungicide, preservative, or fumigant in handling an organic product. The operation also must not use or reuse any storage bin or container that was previously in contact with any prohibited substance unless the reusable bin or container has been thoroughly cleaned and poses no risk of prohibited materials contacting the organic product.

Temporary Variances

This subpart establishes conditions under which certified organic operations may receive temporary variances from the production and handling provisions of this subpart. The Administrator may establish temporary variances due to: (1) Natural disasters declared by the Secretary; (2) unavoidable business interruption caused by natural catastrophes such as drought, wind, fire, flood, excessive moisture, hail, tornado, or earthquake;

or (3) to conduct research on organic production and handling techniques or inputs. An SOP's governing State official or a certifying agent may recommend that the Administrator establish a temporary variance for various reasons including an unavoidable business interruption. The Administrator will determine how long a temporary variance will be in effect at the time it is established, subject to such extension as the Administrator deems necessary. Temporary variances may not be issued to allow use of any practice, material, or procedure which is prohibited under section 205.105.

The proposed rule inadvertently omitted the SOP's governing State official as having authority to recommend a temporary variance to the Administrator. We have added that authority in paragraph (b) of section 205.290.

Upon notification by the Administrator that a temporary variance has been established, the certifying agent must inform each production and handling operation it certifies that may be affected by the temporary variance. For example, if a drought causes a severe shortage of organically produced hay, a dairy operation may be permitted to substitute some nonorganic hay for a portion of the herd's diet to prevent liquidation of the herd. The producer must keep records showing the source and amount of the nonorganic hay used and the timeframe needed to restore the total feed ration to organic sources. The certifying agent may require that the next organic plan include contingency measures to avoid the need to resort to nonorganic feed in case of a future shortage.

General—Changes Based on Comments

This subpart differs from the proposal in several respects as follows:

(1) *Maintain or Improve Provision for Production Operations Only.* A number of commenters questioned whether the requirement in the proposed rule that an operation must "maintain or improve the natural resources of the operation, including soil and water quality" applied to handling as well as production operations. They stated that handling operations are not integrated into natural systems the way that production systems are. As a result, these commenters were uncertain how handlers could fulfill the "maintain or improve" requirement.

The "maintain or improve" requirement addresses the impact of a production operation on the natural resource base that sustains it and, as such, does not apply to handling operations. We have modified the final

rule in section 205.200 by limiting the "maintain or improve" requirement to production practices.

(2) *Management Practices and Physical Barriers to Prevent Commingling.* Many commenters, including numerous certifying agents, stated that the proposed provisions for an organic system plan were not adequate for the task of certifying an operation that produces both organic and nonorganic products. The commenters requested that the final rule incorporate the provisions established in the OFPA for certifying these split operations. These provisions include separate recordkeeping for the organic and nonorganic operations and the implementation of protective practices to prevent the commingling of product and the unintentional contact of organic product with prohibited substances. We have amended the provisions for an organic system plan in section 205.201(a)(5) to require greater accountability regarding the segregation of organic and nonorganic products in a split operation. The changes we made incorporate language from the OFPA ("physical facilities, management practices") to provide clear criteria for producers, handlers and certifying agents to agree upon an organic system plan that protects the integrity of organic product.

(3) *Commercial Availability.* The proposed rule required that a raw or processed agricultural product sold, labeled, or represented as organic must contain not less than 95 percent organically produced raw or processed agricultural product. Additionally, section 205.606 of the proposed rule allowed any nonorganically produced agricultural product to be used in the 5 percent nonorganic component of an agricultural product sold, labeled, or represented as organic. Many commenters objected to these provisions and recommended that nonorganically produced agricultural products should only be allowed in an organic product when the organically produced form was not commercially available. Commenters stated that allowing nonorganically produced agricultural products within the 5 percent would significantly weaken demand for many organically produced commodities, especially herbs and spices. These commenters stated that herbs and spices often constitute less than 5 percent of the ingredients in a raw or processed agricultural product and that handlers producing an organic product would instinctively seek out the less expensive nonorganic variety. They also indicated that the 5 percent component is an important market for many products

produced from organically produced livestock, such as milk derivatives and meat by-products, that are not typically marketed directly to consumers. Commenters stated that the preponderance of current certification programs use the commercial availability criterion when determining whether a nonorganically produced agricultural product may be used within the 5 percent component. Commenters cited the National Organic Standards Board's (NOSB) recommendation that organic agricultural products be used in this 5 percent component unless they are commercially unavailable and requested that the final rule incorporate the criteria for determining commercial availability that accompanied that NOSB recommendation.

We agree with commenters that a preference for organically produced agricultural commodities, when commercially available, can benefit organic producers, handlers, and consumers in a variety of ways. We believe that the commercial availability requirement may allow consumers to have confidence that processed products labeled as "organic" contain the highest feasible percentage of organic ingredients. Some producers may benefit from any market incentive to supply organically produced minor ingredients that handlers need for their processed products. We recognize that the provision does impose an additional requirement on handlers who must ascertain whether the agricultural ingredients they use are commercially available in organic form. The NOSB recommended that the final rule contain a commercial availability provision based upon the guidelines developed by the American Organic Standards project of the Organic Trade Association. For these reasons, we have amended the final rule to require that an agricultural commodity used as an ingredient in a raw or processed product labeled as organic must be organic when the ingredient is commercially available in an organic form.

While recognizing the potential benefits of applying the commercial availability standard to all agricultural ingredients in a processed product, we are concerned that enforcing this provision could impose an excessive burden on handlers. Although many commenters stated that some existing certifying agents apply a commercial availability standard, we do not have complete information on the criteria used by these certifying agents, and we are unsure whether a consensus exists on criteria for commercial availability within the organic community. Additionally, we are concerned that,

unless the standard is clearly articulated and consistently interpreted and enforced, it will not be effective. Disagreement among certifying agents regarding when and under what circumstances an ingredient is commercially available would undermine our intent to create an equitable and enforceable standard.

AMS is soliciting additional comment and information on a number of issues concerning the development of standards for the commercial availability of organically produced agricultural commodities used in processed products labeled as "organic." On the basis of these comments and information and additional recommendations that the NOSB may develop, AMS will develop a commercial availability standard for use in implementing the final rule. AMS intends to develop the commercial availability standard and incorporate it within the final rule prior to the commencement of certification activities by accredited certifying agents. This approach will provide organic handlers and certifying agents the standard necessary to incorporate the consideration of commercial availability of ingredients in an organic system plan at the time that the USDA organic standard comes into use. Specifically, AMS requests comments and information addressing the following questions:

What factors, such as quantity, quality, consistency of supply, and expense of different sources of an ingredient, should be factored into the consideration of commercial availability? What relative importance should each of these factors possess, and are there circumstances under which the relative importance can change?

What activities and documentation are sufficient to demonstrate that a handler has taken appropriate and adequate measures to ascertain whether an ingredient is commercially available?

How can AMS ensure the greatest possible degree of consistency in the application of the commercial availability standard among multiple certifying agents?

Could potentially adverse effects of a commercial availability standard, such as uncertainty over the cost and availability of essential ingredients, impact or impede the development of markets for organically processed products?

What economic and administrative burdens are imposed by the commercial availability standards found in existing organic certification programs?

How would producers benefit from market incentives to increase use of organic ingredients that result from a commercial availability standard?

Would lack of a commercial availability standard provide a disincentive for handlers of products labeled "organic" to seek out additional organic minor ingredients? What impacts could this have on producers of minor ingredients?

AMS welcomes any new or unpublished research results or information that exists concerning a commercial availability standard. AMS specifically invites comment from establishments which currently operate using commercial availability or a comparable provision in the conduct of their business. AMS will receive comment on this issue until 90 days after publication of the final rule.

(4) *Conservation of Biodiversity.* Many commenters recommended amending the definition of organic production to include the requirement that an organic production system must promote or enhance biological diversity (biodiversity). Commenters stated that the definitions for organic production developed by the NOSB and the Codex Commission include this requirement. We agree with these commenters and have amended the definition of organic production to require that a producer must conserve biodiversity on his or her operation. The use of "conserve" establishes that the producer must initiate practices to support biodiversity and avoid, to the extent practicable, any activities that would diminish it. Compliance with the requirement to conserve biodiversity requires that a producer incorporate practices in his or her organic system plan that are beneficial to biodiversity on his or her operation.

General—Changes Requested But Not Made

This subpart retains from the proposed rule regulations on which we received comments as follows:

Organic Plan Excessively Restrictive. One organic inspector was concerned that the requirements of the organic system plan were too prescriptive and would create an excessive paper work burden for producers and handlers. The commenter stated that the excessive specificity of certain requirements (composition and source of every substance used), combined with the ambiguity of others (soil and tissue testing required but with no mention of the frequency), would confuse the working relationship between a producer or handler and his or her certifying agent. The commenter was

concerned that strict adherence to the specifications in the organic system plan would compromise the ability of producers and handlers to run their businesses. While agreeing that flexibility in the development of the organic system plan was valuable, the commenter stated that producers and handlers, not the certifying agent, must retain the primary managerial role for their operation. Other commenters maintained that the organic system plan requirements were too ambiguous and would inhibit certifying agents' efforts to review necessary information. For example, a trade association commented that the absence of specific recordkeeping requirements for livestock feed materials, medications, and health care activities would impair compliance monitoring.

The provisions for an organic system plan were one of the most significantly revised components of the proposed rule, and, with minor changes related to split operations, we have retained them in the final rule. These provisions provide ample discretion for producers, handlers, and certifying agents to perform their duties while recognizing that mutual consent is a prerequisite for them to meet their responsibilities. The organic system plan enables producers and handlers to propose and certifying agents to approve site and operation-specific practices that fulfill all applicable program requirements. Producers and handlers retain the authority to manage their operations as they deem necessary, but any actions they undertake that modify their organic system plan must be approved by the certifying agent. With regard to recordkeeping, certifying agents are authorized to require the additional information, such as the livestock records mentioned in the comment, that they deem necessary to evaluate compliance with the regulations.

One certifying agent stated that the requirement to maintain or improve the natural resources of the operation was worthy in principle but unreasonable to achieve. This commenter stated that the long-term consequences of an organic system plan could not be foreseen and recommended requiring that producers "must endeavor" to maintain or improve the operation's natural resources. We have not changed this requirement because the vast majority of commenters supported an organic system plan that mandated the "maintain or improve" principle. A good working relationship between the producer and his or her certifying agent, including the annual inspection and accompanying revisions to the organic

system plan, can rectify the unforeseen and unfavorable conditions that arise.

Crop Production—Changes Based on Comments

This subpart differs from the proposal in several respects as follows:

(1) *Crop nutrient management.* The fundamental requirement of the soil fertility and crop nutrient management practice standard, that tillage, cultivation, and nutrient management practices maintain or improve the physical, chemical, and biological condition of the soil and minimize erosion, remains unaltered. The proposed rule required that a producer budget crop nutrients by properly utilizing manure or other animal and plant materials, mined substances of low or high solubility, and allowed synthetic amendments. Many commenters disagreed with using the term, "budget," which they considered too limiting to characterize nutrient management in organic systems. These commenters recommended that the practice standard instead emphasize the diverse practices used in organic systems to cycle nutrients over extended periods of time.

We agree with these commenters and have amended the final rule to require that producers manage crop nutrients and soil fertility through the use of crop rotations and cover crops in addition to plant and animal materials. Additionally, we clarified that producers may manage crop nutrients and soil fertility by applying mined substances if they are used in compliance with the conditions established in the National List. Finally, we removed the word, "waste," from our description of animal and plant materials in the proposed rule to emphasize the importance of these resources in organic soil fertility management.

(2) *Compost Practice Standard.* The proposed rule required that a composted material used on an organic operation must be produced at a facility in compliance with the Natural Resource Conservation Service (NRCS) practice standard. While many commenters agreed with the need for greater oversight of the feedstocks and procedures used to produce compost, most stated that the NRCS practice standard would not be suitable for this purpose. Commenters stated that the requirements in the NRCS practice standard were not designed for organic operations and would prohibit many established, effective composting systems currently used by organic producers. For example, adoption of the NRCS practice standard would prevent

producers from using nonfarm wastes as compost feedstocks. Materials such as food processing by-products and leaves from curbside collection programs have long been used with beneficial results.

Commenters also stated that the minimum acceptable requirements for the design, construction, and operation of a composting facility contained in the practice standard were appropriate for a voluntary cost share program but were excessive as a compliance requirement for organic certification. Commenters questioned whether producers could justify the investment of time and resources needed to comply with the multiple design and operation criteria specified in the NRCS practice standard.

We agree with commenters who stated that, given the diversity of composting systems covered by a national organic standard, requiring full compliance with the NRCS practice standard would be overly prescriptive. We maintain, however, that implementation of the OFPA requires a rigorous, quantitative standard for the production of compost. The OFPA contains significant restrictions on applying raw manure that are reflected in the soil fertility and crop nutrient management practice standard. These restrictions pertain to raw manure and do not apply once fresh animal materials are transformed into a composted material. An organic producer using a composted material containing manure must comply with the nutrient cycling and soil and water conservation provisions in his or her organic system plan but is not constrained by the restrictions that apply to raw manure. Therefore, producers intending to apply soil amendments will require clear and verifiable criteria to differentiate raw manure from composted material. We developed the requirements in the final rule for producing an allowed composted material by integrating standards used by the Environmental Protection Agency (EPA) and USDA's Natural Resources Conservation Service (NRCS). The requirements for the carbon-to-nitrogen (C:N) ratio for composting materials are the same as that found in the NRCS practice standard for a composting facility. The time and temperature requirements for in-vessel, static aerated pile, and windrow composting systems are consistent with that EPA regulates under 40 CFR Part 503 for the production of Class A sewage sludge. Additionally, AMS reviewed these compost production requirements with USDA's Agricultural Research Service (ARS).

The conditions in the final rule for producing an allowed composted material begin with the selection of appropriate feedstocks. The producer's first responsibility is to identify the source of the feedstocks used in the composting system. This requirement ensures that only allowed plant and animal materials are included in the composting process, that they are not contaminated with prohibited materials, and that they are incorporated in quantities suitable to the design of the composting system. Certifying agents will exercise considerable discretion for evaluating the appropriateness of potential feedstock materials and may require testing for prohibited substances before allowing their use. For example, a certifying agent could require a producer to monitor off-farm inputs such as leaves collected through a municipal curbside program or organic wastes from a food processing facility. Monitoring may be necessary to protect against contamination from residues of prohibited substances, such as motor oil or heavy metals, or gross inert materials such as glass shards that can enter the organic waste stream.

The final rule further requires that the producer adhere to quantitative criteria when combining and managing the plant and animal materials that are being composted. When combining feedstocks to initiate the process, producers must establish a C:N ratio of between 25:1 and 40:1. This range allows for very diverse combinations of feedstock materials while ensuring that, when properly managed, the composting process will yield high quality material. While some commenters maintained that specifying any C:N ratio in the final rule would be too restrictive, it would be far more problematic not to establish a range. The 25:1 to 40:1 range ensures that producers will establish appropriate conditions under which the additional requirements in this practice standard, most notably the time and temperature criteria, can be achieved with minimal producer oversight. Composting operations using a C:N ratio lower than 25:1 require increasingly intensive management as the ratio drops due to the risk of putrefaction. Operations in excess of the 40:1 range may achieve the minimum temperature but are likely to drop off quickly and result in a finished material that is inadequately mature and deficient in nitrogen. The producer is not required to perform a physical analysis of each feedstock component if he or she can demonstrate that an estimated value is reliable. For example, estimates of the carbon and nitrogen

content in specific manures and plant materials are generally recognized. Other feedstocks of consistent quality may be tested once and assumed to approximate that value.

The producer must develop in his or her organic system plan the management strategies and monitoring techniques to be used in his or her composting system. To produce an allowed composted material, the producer must use an in-vessel, static aerated pile, or windrow composting system. Producers using an in-vessel or static aerated pile system must document that the composting process achieved a temperature between 131°F and 170°F and maintained that level for a minimum of 3 days. Producers using a windrow composting system must document that the composting process achieved a temperature between 131°F and 170°F and maintained that level for a minimum of 15 days. Compost produced using a windrow system must be turned five times during the process. These time and temperature requirements are designed to minimize the risk from human pathogens contained in the feedstocks, degrade plant pathogens and weed seeds, and ensure that the plant nutrients are sufficiently stabilized for land application.

The final rule does not contain provisions for the use of materials commonly referred to as "compost teas." A compost tea is produced by combining composted plant and animal materials with water and a concentrated nutrient source such as molasses. The moisture and nutrient source contribute to a bloom in the microbial population in the compost, which is then applied in liquid form as a crop pest or disease control agent. The microbial composition of compost teas are difficult to ascertain and control and we are concerned that applying compost teas could impose a risk to human health. Regulation of compost teas was not addressed in the proposed rule. The National Organic Program (NOP) will request additional input from the NOSB and the agricultural research community before deciding whether these materials should be prohibited in organic production or whether restrictions on their use are appropriate.

In addition to managing crop nutrients with raw manure and composted plant and animal materials, a producer may use uncomposted plant materials. These are materials derived exclusively from plant sources that a producer manages in a manner that makes them suitable for application in a cropping system. For example, plant materials that are degraded and

stabilized through a vermicomposting process may be used as a soil fertility and crop nutrient amendment.

(3) *Mined Substances of High Solubility.* The proposed rule treated mined substances of high solubility as a single category of soil amendment and allowed their use where warranted by soil and crop tissue testing. Many commenters objected to the general allowance for this category of substances and were particularly disappointed that the NOSB annotations on two such materials, sodium (Chilean) nitrate and potassium chloride, were not included. Commenters cited the potential detrimental effects of these highly soluble and saline substances on soil quality and stated that several international organic certification programs severely prescribe or prohibit their use. One certifying agent recommended that natural substances of high solubility and salinity be handled comparably to similar synthetic materials such as liquid fish products and humic acids that appear on the National List, complete with their original NOSB annotations.

At its June 2000 meeting, the NOSB recommended that the NOP delete general references to mined substances of high solubility from the final rule, and incorporate the NOSB's specific annotations for materials of this nature. We have adopted this recommendation by retaining a place for mined substances of high solubility in the soil fertility and crop nutrient management practice standard but restricting their use to the conditions established for the material as specified on the National List of prohibited natural substances. Under this approach, mined substances of high solubility are prohibited unless used in accordance with the annotation recommended by the NOSB and added by the Secretary to the National List. We deleted the provision from the proposed rule that use of the substance be "justified by soil or crop tissue analysis." The final rule contains two materials—sodium nitrate and potassium chloride—that may be used in organic crop production with the annotations developed by the NOSB.

While "mined substances of high solubility" is not a discrete, recognized category such as crop nutrients, the proposed rule mentioned sodium nitrate, potassium chloride, potassium nitrate (niter), langbeinite (sulfate of potash magnesia), and potassium sulfate in this context. Based on the recommendation of the NOSB, the final rule would prohibit use of these materials, unless the NOSB developed recommendations on conditions for their use and the Secretary added them

to the National List. The NOP would welcome further guidance from the NOSB on these materials.

(4) *Burning crop residues.* The proposed rule prohibited burning as a means of crop disposal, except for burning prunings from perennial crops to suppress the spread of disease. Many commenters supported the principle behind the prohibition but maintained that the proposed language was too restrictive and would preclude certain beneficial agronomic practices. Several producers stated that the proposed rule would prevent them from collecting and burning residues from diseased annual crops, which they felt was an effective and beneficial practice. Other producers cited their use of prescriptive burning as a management practice for certain native or wild crops. As evidenced by the allowance for burning to suppress disease with perennial crops, the proposed rule was not designed to preclude the selective use of fire in organic production. We agree with the commenters that a more flexible allowance for the practice is warranted, and we have amended the provision to allow burning of annual and perennial crop residues for the suppression of disease and to stimulate seed germination. Producers must establish their need and procedures for burning in their organic system plan, and the practice cannot be used solely to remove crop debris from fields.

(5) *Requirement for Organic Seed in Sprout Production.* The proposed rule allowed nonorganically produced seeds for all purposes, including sprout production, when the certifying agent concurred with the producer that organically produced seeds were not commercially available. While commenters predominately supported this approach with seed used for planting, they were virtually unanimous in stating that it is never appropriate to allow nonorganically produced and handled seeds in organic sprout production. Commenters cited the NOSB's June 1994 recommendation that seed used for the production of edible sprouts shall be organically produced and stated that existing certification standards do not provide an exemption based on commercial availability. We agree with these commenters and have modified the final rule to require that organic seed must be used for the production of edible sprouts.

(6) *Mitigating the Effects of a Biological, Botanical, or Synthetic Substance.* The proposed rule required that producers who used a biological or botanical substance or an allowed synthetic substance to control crop pests, weeds, or disease evaluate and

mitigate the effects of repetitive use of the same or similar substances. While agreeing that pest resistance and shifts in pest populations were important considerations, commenters stated that managing these issues was beyond the ability of individual operations. Commenters recommended that the NOP develop principles and practices for managing pest resistance and shifts in pest types that would apply to all production operations. We agree with these comments and have deleted the requirement to evaluate and mitigate the effects of using the same or similar crop pest, weed, or disease control substances. The final rule requires that producers document the use of such substances in their organic systems plans, subject to the approval of their certifying agent.

(7) *Prohibition on Use of Treated Lumber.* The proposed rule did not specifically address the use of lumber that had been treated with a prohibited substance, such as arsenic, in organic production. Citing the explicit prohibition on these substances in existing organic standards, many commenters felt that treated lumber should be excluded in the final rule. Commenters also cited the NOSB's recommendation to prohibit the use of lumber treated with a prohibited substance for new construction and replacement purposes effective upon publication of the final rule. We have included a modified version of the NOSB's recommendation within the crop pest, weed, and disease management practice standard. This provision prohibits the use of lumber treated with arsenate or other prohibited materials for new installations or replacement purposes in contact with an organic production site. We included this modification to clarify that the prohibition applies to lumber used in direct contact with organically produced and handled crops and livestock and does not include uses, such as lumber for fence posts or building materials, that are isolated from production. The prohibition applies to lumber used in crop production, such as the frames of a planting bed, and for raising livestock, such as the boards used to build a farrowing house.

(8) *Greater Rigor in the Wild Harvest Production Organic System Plan.* A number of commenters stated that the wild-crop harvesting practice standard was insufficiently descriptive and that the proposed rule failed to apply the same oversight to wild harvest operations as it did to those producing crops and livestock. Some commenters maintained that the proposed rule did

not require a wild harvest producer to operate under an approved organic system plan. These commenters proposed specific items, including maps of the production area that should be required in a wild harvest operation's organic system plan. One commenter recommended that the definition for "wild crop" be modified to allow the harvest of plants from aquatic environments.

We amended the practice standard for wild-crop harvesting to express the compliance requirements more clearly. Wild-crop producers must comply with the same organic system plan requirements and conditions, as applicable to their operation, as their counterparts who produce crops and livestock. Wild harvest operations are production systems, and they must satisfy the general requirement that all practices included in their organic system plan must maintain or improve the natural resources of the operation, including soil and water quality. We modified the practice standard to emphasize that wild harvest production is linked to a designated site and expect that a certifying agent would incorporate mapping and boundary conditions into the organic system plan requirements. Finally, we changed the definition of "wild crop" to specify that harvest takes place from a "site" instead of "from land," thereby allowing for aquatic plant certification.

Crop Production—Changes Requested But Not Made

This subpart retains from the proposed rule regulations on which we received comments as follows:

(1) *Application of Raw Manure.* The soil fertility and crop nutrient management practice standard in the proposed rule permitted the application of raw manure to crops not intended for human consumption and established restrictions for applying it to crops used for human food. For human food crops, the proposed rule required a 120-day interval between application and harvest of crops whose edible portion had direct contact with the soil or soil particles, and a 90-day interval for crops that did not. These provisions reflected the recommendations developed by the NOSB at its June 1999 meeting. The practice standard also required that raw manure must be applied in a manner that did not contribute to the contamination of crops, soil, or water by plant nutrients, pathogenic organisms, heavy metals, or residues of prohibited substances.

The majority of commenters supported the provisions for applying raw manure. Some commenters stated

that the provisions effectively balanced the benefits of applying raw manure to the soil with the environmental and human health risks associated with its use. These commenters stated that the lengthy intervals between application and harvest would not impose an unreasonable or unfeasible burden on organic producers. The NOSB strongly supported the provisions in the proposed rule, emphasizing that raw manure contributed significant benefits to soil nutrient, structure, and biological activity that other soil fertility practices and materials do not provide. Other commenters stated that the provisions were consistent with the requirements in existing organic standards and added that the restrictions were justifiable because they reflected responsible management practices.

For differing reasons, a number of commenters disagreed with the proposed provisions. Some commenters cited the human health risks associated with pathogenic organisms found in raw manure and stated that the proposed intervals between application and harvest were not adequately protective. These commenters recommended that the NOP conduct more extensive risk assessment procedures before determining what, if any, intervals between application and harvest would adequately protect human health. Some of these commenters identified the risk assessment methodology and pathogen treatment procedures governing the production and use of sewage sludge as the most suitable precedent for guiding the additional work required in this area. Conversely, a number of commenters stated that the provisions in the proposed rule were excessive because they exceeded the minimum 60-day interval between application and harvest established in the OFPA. Many of these commenters recommended eliminating the distinction between crops that come into contact with soil or soil particles and those that don't and applying a uniform 60-day interval between harvest and application for any crop to which raw manure had been applied. Some commenters stated that the 120-day interval severely limited the flexibility of producers who operated in regions such as the Northeast where the growing season lasted only slightly longer. Other commenters maintained that the practice standard did not address specific practices, such as applying raw manure to frozen fields, that they maintained should be expressly prohibited.

The responsibility to use raw manure in a manner that is protective of human health applies to all producers, whether organic or not, who apply such

materials. We acknowledge the commenters who noted that the OFPA cites food safety concerns relative to manure use and, therefore, that food safety considerations should be reflected in the practice standard for applying raw manure in the final rule. Some of the commenters favored more extensive risk assessment procedures or lengthening the interval between application and harvest. We have not, however, changed the provisions for applying raw manure.

Although public health officials and others have identified the use of raw manure as a potential food safety concern, at the present time, there is no science-based, agreed-upon standard for regulating the use of raw manure in crop production. The standard in this rule is not a public health standard. The determination of food safety demands a complex risk assessment methodology, involving extensive research, peer review, and field testing for validation of results. The only comparable undertaking in Federal rulemaking has been EPA's development of treatment and application standards for sewage sludge, an undertaking that required years of dedicated effort. The NOP does not have a comparable capacity with which to undertake a comprehensive risk assessment of the safety of applying raw manure to human food crops. To delegate the authority to determine what constitutes safe application of raw manure to certifying agents would be even more problematic. A certifying agent cannot be responsible for establishing a Federal food safety standard. Therefore, the standard in this rule is a reflection of AMS' view and of the public comments that this standard is reasonable and consistent with current organic industry practices and NOSB recommendations for organic food crop production. Should additional research or Federal regulation regarding food safety requirements for applying raw manure emerge, AMS will ensure that organic production practice standards are revised to reflect the most up-to-date food safety standard.

Neither the identification of food safety as a consideration in the OFPA nor the inclusion of this practice standard in the final rule should be construed to suggest that organically produced agricultural products are any safer than nonorganically produced ones. USDA has consistently stated that certification is a process claim, not a product claim, and, as such, cannot be used to differentiate organic from nonorganic commodities with regard to food safety. National organic standards for manure use cannot be used to establish a food safety standard for

certified commodities in the absence of as uniform Federal regulation to ensure the safety of all human food crops to which raw manure has been applied. The OFPA was designed to certify a process for informational marketing purposes.

Neither have we changed the practice standard in response to comments that the requirement in the final rule should not exceed the 60-day interval contained in the OFPA. The OFPA clearly establishes that the interval must be no less than 60 days and does not preclude a longer standard. The NOSB has strongly supported the proposed 90- and 120-day intervals, and the vast majority of commenters indicated that these provisions would be feasible for virtually all organic cropping systems. The requirement in the practice standard that raw manure must be applied in a manner that does not contribute to the contamination of crops, soil, or water by plant nutrients, pathogenic organisms, heavy metals, or residues of prohibited substances provides certifying agents the discretion to prohibit specific practices that would not be in compliance. With this discretion, a certifying agent could prohibit practices, such as applying manure to frozen ground or too close to water resources, that many commenters stated were not appropriate for organic production.

(2) *No Prohibition on Manure from Nonorganic Operations.* The proposed rule identified animal and plant waste materials as important components in soil fertility and crop nutrient management without providing criteria for distinguishing allowed and prohibited sources. A large number of commenters objected to this provision and stated that manure from nonorganic sources may contain residues from prohibited substances, including animal medications. These commenters maintained that some of these residues, such as antibiotics, may remain active for extended intervals, and others, such as heavy metals, could accumulate on the organic operation. Commenters stated that if either or both conditions prevailed, the integrity of the organic operation would be jeopardized. Many producers and certifying agents emphasized that the proposed rule conflicted with the Codex guidelines that prohibit the use of manure from factory farms. These commenters were concerned that failure to restrict the use of manure from nonorganic operations would put their products at a competitive disadvantage, particularly in European markets. When raising this issue, most commenters requested that the final rule either prohibit the use of

manure from factory farms or state that certifying agents could regulate the practice by requiring residue testing and restrictions on application.

We have not changed the provisions for using manure from nonorganic operations in the final rule. In many discussions on the subject throughout the years, the NOSB has never recommended that manure from nonorganic farms be prohibited. Existing organic certification standards routinely permit the use of manure from nonorganic operations with appropriate oversight, and the final rule incorporates a similar approach. Under the final rule, a certifying agent can require residue testing when there is reasonable concern that manure, either raw or as a component of compost, contains sufficient quantities of prohibited materials to violate the organic integrity of the operation. Providing certifying agents the discretion to require screening for prohibited materials will minimize the risk of introducing contaminants while maintaining the ecologically important practice of recycling organic material from nonorganic operations. Additionally, the final rule requires that producers apply manure and compost in a manner that maintains or improves the soil and water quality of their operation. This provision provides an additional safeguard that certifying agents may use to ensure that the application of any form of manure protects the natural resources of the operation.

(3) *Rotating a Field in and out of Organic Production.* Some commenters stated that a producer should not be allowed to rotate fields on their operation in and out of organic production. These commenters were concerned that producers could apply prohibited substances that persisted for many years, such as soil fumigants, and begin harvesting organically produced crops after 3 years. They stated that, without a prohibition on the rotation of fields in this manner, organic producers could effectively use a prohibited substance on their operation.

We have not amended the final rule to prohibit the rotation of a field on an operation in and out of organic production. The statutory prohibition on the application of a prohibited substance is 3 years, and this requirement is contained in section 205.202(b). This prohibition restricts the application of a prohibited substance, not its residual activity. If AMS receives evidence that the rotation of fields in this manner threatens to compromise organic production, the NOP and NOSB will collaborate on developing standards to remedy it.

(4) *Use of Seed Treatments on the National List.* The seed and planting stock practice standard in the proposed rule generated a very diverse array of responses that, while largely favorable, highlighted a potentially disruptive impact on organic producers. The practice standard favored organic seed and planting stock over nonorganically produced but untreated varieties and nonorganically produced, untreated seed and planting stock over nonorganically produced seeds and planting stock treated with an allowed synthetic substance. Producers could use the less preferable seed or planting stock variety if they demonstrated to their certifying agent that an equivalent variety in the preferred form was not commercially available. Most commenters endorsed the principle of requiring organic seed and planting stock and agreed that the proposed provisions were a workable approach to enforcement. They stated that the provisions created an incentive for seed and planting stock providers to develop supplies for organic markets, yet enabled producers who made a good faith effort but failed to locate seed or planting stock in the preferred form the ability to continue producing organically. Most commenters indicated that this approach would support the existing market for organic seed and planting stock while fostering its continued development.

A number of commenters, however, stated that the seed and planting stock practice standard was unreasonable and unworkable and would adversely affect organic producers. These effects would include significantly reduced planting options due to the nonavailability of seed in any allowed form and higher seed costs, which represent a significant percentage of the total production cost for some commodities. These commenters maintained that the three categories of seed and planting stock allowed in the order of preference could not reliably provide producers with many commercial varieties currently being planted. They pointed out that there were no synthetic seed treatments on the National List in the proposed rule, thereby eliminating the use of treated seed in organic production. Commenters stated that producers often rely upon seed and planting stock varieties that are uniquely well adapted for their growing conditions or marketing requirements and that these particular varieties would very often not be available in untreated form. These commenters concluded that the proposed practice standard would compel many producers to abandon

many tried and true varieties of seed and planting stock and perhaps phase out organic production entirely. One commenter maintained that the proposed rule's stated intention of using the practice standard to stimulate production of organic seed and planting stock was not within the purpose of the OFPA.

We have not changed the seed and planting stock practice standard in response to these commenters because the prohibition on using synthetic materials not on the National List is a requirement of the OFPA. The final rule cannot allow producers to use synthetic seed treatments that have not been reviewed, favorably recommended by the NOSB, and added to the National List by the Secretary. The practice standard creates incentives for producers to seek out seed and planting stock inputs that are the most compatible with organic production, yet includes allowances when preferred forms are not commercially available. While no seed treatments are included on the National List in the final rule, individuals may petition the NOSB for review of such substances. Additionally, the practice standard creates an incentive for seed and planting stock producers and suppliers to develop natural treatments suitable for organic systems that would not need to appear on the National List. The objectives of spurring production of organically grown seed and promoting research in natural seed treatments are compatible with the OFPA's purpose of facilitating commerce in organically produced and processed food. We designed the practice standard to pursue these objectives while preventing the disruption that an ironclad requirement for organically produced seed and planting stock may have caused.

(5) *Practice Standard for Maple Syrup.* Many commenters stated that the proposed rule lacked production and handling standards for operations that produce maple syrup. Commenters stated that maple syrup production is a significant enterprise for many organic producers and that the absence of a practice standard in the final rule would adversely affect existing markets for organic products. Many commenters recommended that the final rule incorporate the maple syrup practice standard from an existing certification program or the American Organic Standards.

We have not included a practice standard for the production and handling of maple syrup because the final rule contains sufficient provisions for the certification of these types of operations. After reviewing existing

practice standards for maple syrup, we determined that the standards in the final rule for crop production, handling operations, and allowed and prohibited materials on the National List provided comparable guidance.

Crop Production—Clarifications

Clarification is given on the following issues raised by commenters:

(1) *Applicability of Crop Rotation Requirement to all Operations.* One State program commented that the crop rotation practice standard in the proposed rule was unreasonable for producers who operated in regions where limited rainfall and irrigation resources or unique soil conditions made cover cropping impractical. This commenter stated that certain dryland cropping systems, such as *aloe vera* production, function as “semi-perennial” systems that do not include rotations, yet fulfill the objectives of the crop rotation practice standard. A certifying agent expressed a similar concern by suggesting that the crop rotation practice standard be changed by adding “may include, but is not limited to” prior to the list of allowed management practices. This commenter felt that the “may include” clause afforded individual growers greater discretion by acknowledging that not every allowed management practice would be applicable to all operations.

We have retained the language from the proposed rule because it already provides the flexibility to develop site-specific crop rotation practices requested by these commenters. The regulation as originally written includes the “but not limited to” clause that allows producers to include alternative management practices in their organic system plan. Additionally, the regulation states that the producer must implement a crop rotation that provides the required functions “that are applicable to the operation.” This further establishes that the crop rotation component of an organic system plan must be considered within the context of site-specific environmental conditions including climate, hydrology, soil conditions, and the crops being produced. The final rule requires implementation of a crop rotation, but the producer and certifying agent will determine the specific crops and the frequency and sequencing of their use in that rotation. Crop rotations must fulfill the requirements of this practice standard—to maintain or improve soil organic matter content, provide for pest management, manage deficient or excess plant nutrients, and control erosion—and are not obligated to use any specific management

practice. We structured this and other practice standards, as well as the requirements of the organic system plan, to enable producers and certifying agents to develop organic system plans adapted to natural variation in environmental conditions and production systems.

(2) *Excluding Annual Seedlings from Planting Stock.* The proposed rule allowed a producer to use nonorganically produced seeds and planting stock if organically produced equivalent varieties were not commercially available. Several commenters, including the NOSB, were concerned that the definition of planting stock as “any plant or plant tissue, including rhizomes, shoots, leaf or stem cuttings, roots, or tubers, used in plant production or propagation” was sufficiently broad to be applied to annual seedlings. While many commenters, including the NOSB, supported the commercial availability exemption in the case of seeds and planting stock, they objected to extending it to annual seedlings. The proposed rule did not intend to include annual seedling within the definition of planting stock and included a separate definition of “annual seedling” as “a plant grown from seed that will complete its life cycle or produce a harvestable crop yield within the same crop year or season in which it is planted.” The proposed rule addressed annual seedlings as a distinct category within the seed and planting stock practice standard. There was no allowance for using nonorganically produced annual seedlings based on commercial availability, and such seedlings can only be used when a temporary variance has been issued due to a catastrophic business interruption. The growth of markets for organically produced annual seedlings, unlike those for seeds and planting stock, obviates the need for the commercial availability provision. We have retained this approach in the final rule.

Livestock Production—Changes Based on Comments

This subpart differs from the proposal in several respects as follows:

(1) *Whole Herd Conversion.* The proposed rule required that livestock receive 1 year of continuous organic management prior to the milk or milk products they produce being labeled as organic. Based on the feed provisions in that proposal, producers would be required to provide a 100-percent organic feed ration (exclusive of National List substances allowed as feed supplements and additives) for that entire year. Many producers,

consumers, State certification programs, and certifying agents commented that the full year organic feed requirement created an insurmountable barrier for small and medium-size dairy operations wishing to convert to organic production. They maintained that the added expense of a full year, 100-percent organic feed requirement was economically prohibitive. These commenters stated that “new entry” or “whole herd” conversion provisions in existing certification standards have been instrumental in enabling established nonorganic dairies to make the transition to organic production. Commenters stated that these provisions typically allow producers to provide livestock 80-percent organic or self-raised feed for the first 9 months of a herd’s transition, before requiring 100-percent organic feed for the final 3 months. Some commenters stated that many current organic dairies had capitalized on this whole herd conversion provision and that the consistent growth in demand for organic milk and milk products reflected consumer acceptance of the principle.

At its June 2000 meeting, the NOSB reiterated its prior endorsement of the conversion principle for operations that jointly convert dairy herds and the land on which they are raised. The NOSB recommended allowing a producer managing an entire, distinct herd to provide 80-percent organic or self-raised feed during the first 9 months of the final year of conversion, and 100-percent organic feed for the final 3 months. The recommendation further required that dairy animals brought onto an organic dairy must be organically raised from the last third of gestation, except that feed produced on land managed under an organic system plan could be fed to young stock up to 12 months prior to milk production.

While the preponderance of comments supported the whole herd conversion provision, a significant number of individuals, certifying agents, and State certification programs opposed it. Some commenters felt that requiring less than 1 full year of 100-percent organic feed would not satisfy consumer expectations for an organically managed dairy. Other commenters stated that the whole herd conversion merely favored one segment of organic producers over another. They maintained that the full year, 100-percent organic feed requirement would stimulate markets for organically produced hay and grain, thereby rewarding good row crop rotation. One certifying agent was concerned that the conversion provision would create a permanent exemption and that split

operation dairies could use it repeatedly to bring nonorganic animals into the organic operation.

The final rule contains a provision for whole herd conversion that closely resembles those found in the NOSB recommendation and the existing certification standards. The final rule requires that an entire, distinct dairy herd must be under organic management for 1 year prior to the production of organic milk. During the first 9 months of that year, the producer must provide a feed ration containing a minimum of 80-percent organic feed or feed that is raised from land included in the organic system plan and managed in compliance with organic crop requirements. The balance of the feed ration may be nonorganically produced, but it must not include prohibited substances including antibiotics or hormones. The producer must provide the herd 100-percent organic feed for the final 3 months before the production of organic milk. The producer must comply with the provisions in the livestock health and living conditions practice standard during the entire year of conversion. After the dairy operation has been certified, animals brought on to the operation must be organically raised from the last third of gestation. We did not incorporate the NOSB's recommendation to provide young stock with nonorganic feed up to 12 months prior to the production of certified milk. By creating an ongoing allowance for using nonorganic feed on a certified operation, this provision would have undermined the principle that a whole herd conversion is a distinct, one-time event.

We anticipate that the provisions added to the final rule will address the concerns of commenters who objected to the conversion principle. Consumers have embraced milk and milk products from dairies certified under private whole herd conversion provisions essentially identical to that in the final rule. While the conversion provision may temporarily reduce demand for organic feed materials, it encourages producers to develop their own supplies of organic feed. The conversion provision also rewards producers for raising their own replacement animals while still allowing for the introduction of animals from off the farm that were organically raised from the last third of gestation. This should protect existing markets for organically raised heifers while not discriminating against closed herd operations. Finally, the conversion provision cannot be used routinely to bring nonorganically raised animals into an organic operation. It is a one-time opportunity for producers working with

a certifying agent to implement a conversion strategy for an established, discrete dairy herd in conjunction with the land resources that sustain it.

(2) *Organic Management for Livestock from the Last Third of Gestation.* The proposed rule required that organically managed breeder and dairy stock sold, labeled, or represented as organic slaughter stock must be under continuous organic management from birth. Many commenters stated that this requirement was an inappropriate relaxation of most existing organic standards, which require organic management for all slaughter stock from the last third of gestation. These commenters cited the NOSB's 1994 recommendation that all slaughter stock must be the progeny of breeder stock under organic management from the last third of gestation or longer. Commenters also recommended extending the organic management provision to cover the last third of gestation to make it consistent with the requirements in section 205.236(a)(4) for the organically raised offspring of breeder stock. We agree with the argument presented by commenters and have changed the final rule to require that breeder or dairy stock be organically raised from the last third of gestation to be sold as organic slaughter stock.

(3) *Conversion Period for Nonedible Livestock Products.* The proposed rule required that livestock must be under continuous organic management for a period not less than 1 year before the nonedible products produced from them could be sold as organic. Several commenters questioned the basis for creating different origin of livestock requirements based on whether the operation intended to produce edible or nonedible products. These commenters stated that the OFPA does not sanction such a distinction, nor is it contained in existing certification standards. They questioned why the proposed rule created such a provision in the absence of a favorable NOSB recommendation. We agree that the creation of a separate origin of livestock requirement for animals intended to provide nonedible products could be confusing. We have changed this provision in the final rule to require that nonedible products be produced from livestock that have been organically managed from the last third of gestation.

(4) *Provisions for Feed Supplements and Feed Additives.* The proposed rule provided that nonagricultural products and synthetic substances included on the National List could be used as feed additives and supplements. Many commenters stated that allowing nonagricultural products and synthetic

substances as feed supplements contradicted the definition for "feed supplement" found in the proposed rule. That definition stipulated that a feed supplement must, itself, be a feed material, and the definition for "feed" in the proposed rule precluded using nonagricultural products and synthetic substances. These commenters requested that either the definition of "feed supplement" be changed to make it consistent with the allowance for nonagricultural products and synthetic substances or else that the term be dropped from the final rule. The Food and Drug Administration (FDA) recommended modifying the definitions for "feed additive" and "feed supplement" and further specifying the components required in a feed ration under the livestock health care practice standard.

We amended the definition in the final rule to state that a feed supplement is "a combination of feed nutrients added to livestock feed to improve the nutritional balance or performance of the total ration." We retained the second component of the proposed definition, which described how a feed supplement could be offered to livestock. We amended the definition of "feed additive" to "a substance added to feed in micro quantities to fulfill a specific nutritional need; i.e., essential nutrients in the form of amino acids, vitamins, and minerals." The definitions for "feed supplement" and "feed additive" in the proposed rule were originally recommended by the NOSB. While our intent in the proposed rule was to codify as fully as possible the recommendations of the NOSB, we agree with commenters that the proposed definitions were incompatible with the overall provisions for livestock feed. The definitions in the final rule are consistent with the NOSB's objective to create clear distinctions between feed, feed supplements, and feed additives while clarifying the role for each within an organic livestock ration. We also incorporated FDA's recommendation to include protein and/or amino acids, fatty acids, energy sources, and fiber for ruminants as required elements of a feed ration in the livestock health care practice standard. These additions make the livestock health care practice standard more consistent with the National Research Council's Committee on Animal Nutrition's Nutrient Requirement series, which we cited in the proposed rule as the basis for feed requirements.

Many commenters addressed provisions in the proposed rule to allow or prohibit specific materials and categories of materials used in livestock

feed. Among these, some commenters questioned whether enzymes were defined as a feed additive and, therefore, allowed. One certifying agent requested guidance on the status of supplementing livestock feed with amino acids. At its October 1999 meeting, the NOSB discussed the Technical Advisory Panel (TAP) reviews on the use of enzymes and amino acids in livestock feed. The NOSB determined that natural sources of enzymes exist and that their use should be allowed in organic production. Their discussion of natural sources of enzymes concluded that enzymes derived from edible, nontoxic plants and nonpathogenic bacteria or fungi that had not been genetically engineered should be allowed as a nonorganic feed additive. The NOSB did not take a position on amino acids during this meeting but indicated that it would revisit the subject in the near future. Based on these recommendations, the final rule allows the use of natural enzymes but not amino acids as nonorganic feed additives. The NOSB's recommendation that natural sources of enzymes existed and were compatible with organic livestock production supports allowing them without adding them to the National List. Some commenters discussed the animal welfare and environmental benefits associated with providing amino acids in livestock feed and supported allowing them. However, without a recommendation from the NOSB that amino acids are natural or should be added to the National List as a synthetic, the final rule does not allow their use.

Commenters questioned whether nonsynthetic but nonagricultural substances, such as ground oyster shells and diatomaceous earth, would be allowed in agricultural feed. In 1994, the NOSB recommended that natural feed additives can be from any source, provided that the additive is not classified as a prohibited natural on the National List. We agree with this recommendation and have amended the final rule to allow such materials as feed additives and supplements. The only additional constraint on these materials is that every feed, feed additive, and feed supplement be used in compliance with the Federal Food, Drug, and Cosmetic Act, as stated in section 205.237(b)(6).

The NOSB recommended that ruminants maintained under temporary confinement must have access to dry, unchopped hay. Although this position was an NOSB recommendation and not part of the proposed rule, several commenters responded to it. Most of

these commenters stated that the language was too restrictive and could preclude the use of many suitable forage products. One dairy producer stated that the requirement would not be practical for operations that mix hay with other feed components. We agree that the NOSB's proposed language is too prescriptive and have not included it in the final rule.

(5) *Provisions for Confinement.* The proposed rule established the health, nutritional, and behavioral needs of the particular species and breed of animal as the primary considerations for determining livestock living conditions. The proposed rule also identified essential components of the practice standard, including access to shade, shelter, exercise areas, fresh air, and direct sunlight, while stating that species-specific guidelines would be developed in conjunction with future NOSB recommendations and public comment. Finally, the proposed rule outlined the conditions pertaining to animal welfare and environmental protection under which producers could temporarily confine livestock.

While supportive of the underlying principles of this practice standard, the vast majority of commenters stated that the actual provisions suffered from a lack of clarity and specificity. Many commenters were concerned that the proposed rule did not adequately ensure access to the outdoors for all animals. While supportive of the access to pasture requirement for ruminant production, commenters stated that the final rule needed a clear definition of pasture to make the provision meaningful. Conversely, some commenters supported the less prescriptive approach adopted in the proposed rule. The NOSB added considerably to its earlier recommendations on livestock living conditions during its June 2000 meeting.

Many commenters stated that the criteria identified as required elements in the provisions for livestock living conditions did not specifically include access to the outdoors. One commenter stated that the requirement that animals receive direct sunlight could be interpreted to simply require windows in livestock confinement facilities. Commenters were virtually unanimous that, except for the limited exceptions for temporary confinement, all animals of all species must be afforded access to the outdoors. Commenters also maintained that the outdoor area must accommodate natural livestock behavior, such as dust wallows for poultry and, in the case of ruminants, provide substantial nutrition. Many commenters specifically opposed dry

lots as an allowable outdoor environment. The NOSB recommended that the final rule state that all livestock shall have access to the outdoors. As a result of these comments, we have revised the final rule to establish that access to the outdoors is a required element for all organically raised livestock.

We further amended the final rule to include a definition of "pasture." The definition of "pasture" we included emphasizes that livestock producers must manage their land to provide nutritional benefit to grazing animals while maintaining or improving the soil, water, and vegetative resources of the operation. The producer must establish and maintain forage species-appropriate for the nutritional requirements of the species using the pasture.

Numerous commenters requested clarification on species-specific living conditions, such as the use of cages for poultry and confinement systems for veal production. The use of continuous confinement systems including cages for poultry and veal production is incompatible with the requirement that organically raised livestock receive access to the outdoors and the ability to engage in physical activity appropriate to their needs. There will be times when producers must temporarily confine livestock under their care, but these instances must be supported by the exemptions to the outdoor access requirement included in the final rule. Other commenters requested additional guidance on whether confinement for the purpose of finishing slaughter stock would be allowed, and, if so, how long that confinement could last. Commenters who supported an allowance for finishing most often recommended that, in the case of cattle, confinement should not exceed 90 days. The final rule does not include a specific length of time that cattle or other species may be confined prior to slaughter. We will seek additional input from the NOSB and public comment before developing such standards.

Several commenters questioned whether a Federal, State, or local regulation that required confinement would supersede the requirement for outdoor access. These commenters were aware of county ordinances that prohibited free ranging livestock production to protect water quality. Organic operations must comply with all Federal, State, and local regulations. At the same time, to sell, label, or represent an agricultural commodity as "100 percent organic," "organic," or "made with * * *" the producer or handler must comply with all the applicable requirements set forth in this

regulation. Federal, State, or local regulations that prohibit a required practice or require a prohibited one will essentially preclude organic certification of the affected commodity within that jurisdiction.

(6) *Prohibition on Parasiticides During Lactation.* The proposed rule provided that breeder stock could receive synthetic parasiticides included on the National List, provided that the treatment occurred prior to the last third of gestation for progeny that were to be organically managed. Many commenters supported this principle but were concerned that the wording would allow producers to administer parasiticides to lactating breeder stock while the offspring were still nursing. These commenters felt that such an allowance violated the intent of the provision because offspring could be exposed to systemic parasiticides or their residues through their mother's milk. The NOSB recommended a prohibition on using allowed synthetic parasiticides during lactation for progeny that are organically managed. We agree with these commenters and have modified the final rule to prohibit the treatment of organically managed breeder stock with allowed synthetic parasiticides during the last third of gestation or lactation.

Livestock Production—Changes Requested But Not Made

This subpart retains from the proposed rule regulations on which we received comments as follows:

(1) *Prohibition on Factory Farms.* Many commenters requested that the final rule prohibit the certification of "factory farms." These commenters stated that factory farms are dependent upon practices and materials that are inconsistent with or expressly prohibited in the OFPA. The final rule does not contain such a prohibition because commenters did not provide a clear, enforceable definition of "factory farm" for use in the final rule. All organic operations, regardless of their size or other characteristics, must develop and adhere to an approved organic system plan that complies with these regulations in order to be certified.

(2) *Nonorganic Feed Protocol.* The proposed rule required that, except for nonagricultural products and synthetic substances included on the National List, a producer must provide livestock with a total feed ration composed of agricultural feed products, including pasture and forage, that is organically produced and, if applicable, handled. It also included provisions for temporary variances that, under very limited circumstances and with the approval of

the certifying agent and the Administrator, would provide an exemption from specific production and handling standards. The preamble of the proposed rule described an emergency resulting in the unavailability of organic agricultural feed products as an example of a situation in which a temporary variance could be issued. Many commenters recommended that the final rule require a producer who received a temporary variance for a feed emergency to follow the order of preference for noncertified organic feed developed by the NOSB. This order of preference requires a producer to procure agricultural feed products from sources that are as close to complying with the standards for organic certification as possible. Commenters stated that adherence to the order of preference would most closely conform with the expectation of consumers that organically raised livestock received organic feed and would create an incentive for livestock feed producers to pursue certification.

We have not included the NOSB's feed emergency order of preference in the final rule because it would be too prescriptive and difficult to enforce during an emergency. Receiving a temporary variance categorically exempts a producer from the provision for which it was issued, although that producer may not substitute any practice, material, or procedure that is otherwise prohibited, although that producer may not substitute any practice, material, or procedure that is otherwise prohibited under section 205.105. Additionally, certified organic feed is far more available in terms of quantity and affordability than when the NOSB developed its order of preference in 1994. We anticipate that producers whose original supply of organic agricultural feed products is interrupted will be able to fill the shortfall through the marketplace.

(3) *Prohibition on Physical Alterations.* The proposed rule required that producers perform physical alterations as needed to promote animal welfare and in a manner that minimizes pain and stress. This provision was one component of the health care practice standard that required producers to establish and maintain preventive livestock health care practices. We stated in the preamble that there was insufficient consensus from previous public comment to designate specific physical alterations as allowed or prohibited and envisioned working with producers, certifying agents, and consumers to achieve that goal. We requested comment on techniques to measure animal stress that could be

used to evaluate whether specific physical alterations were consistent with the conditions established in the proposed rule.

We received significant numbers of comments both opposing and supporting the provision in the proposed rule for performing physical alterations. Many commenters opposed any allowance for physical alterations and argued that such practices are cruel and debilitating to animals. These commenters maintained that modifications in breed selection, stocking densities, and the configuration of living conditions could achieve results similar to physical alterations without harming the animal. They stated that by adapting their production systems to promote the physical and psychological welfare of animals, producers could obviate the need for physical alterations. In particular, commenters cited physical alterations to the beaks and feet of poultry as unnecessary due to the availability of alternative production systems. Many commenters expressed concern that the allowance for physical alterations would facilitate the certification of large confinement operations. Commenters also stated that performing physical alterations was inconsistent with Codex guidelines and objected to the allowance before full public deliberation on the subject through the NOSB process.

A large number of commenters stated that, if reasonable guidelines could be established, the allowance for physical alterations would be a beneficial, and even necessary, condition for organic livestock production. These commenters maintained that producers engage in physical alterations for the overall welfare of the flock or herd and that the pain and stress of performing them must be weighed against the pain and stress of not doing so. For example, these commenters cited the traumatic effect of cannibalism on poultry flocks that had not undergone beak trimming or the injuries caused by animals whose horns had not been removed. Many of these commenters stated that producers could reduce but not eliminate the need for physical alterations through alternative production practices such as breed selection and stocking densities. The NOSB supported the provision as written in the proposed rule, stating that it met the animal welfare requirements while allowing practices necessary for good animal husbandry. We have retained the proposed provision for physical alterations without taking any further position on whether specific practices are allowed or prohibited. We did not receive substantial new

guidance on techniques to measure stress in animals due to physical alterations and have made no revisions in that regard. The final rule establishes that, when appropriately performed and within the context of an overall management system, specific physical alterations are allowed. It also mandates that, as an element of a preventative health care program, physical alterations must benefit the ultimate physical and psychological welfare of the affected animal.

(4) *Withdrawal for Synthetic Parasiticides in Lactating Livestock.* The proposed rule required a 90-day withdrawal period before milk and milk products produced from livestock treated with an allowed synthetic parasiticide could be labeled as organic. Referencing the statement in the preamble to the proposed rule that the 90-day withdrawal period was attributable to "consumer expectations of organically raised animals," a dairy producer commented that the provision ignored animal welfare and farm economic sustainability considerations. The commenter considered the 90-day withdrawal period capricious and problematic since, for bovine dairy operations, it would compel producers to either shorten an animal's natural drying off period, or lose 30 days of organic milk production. The commenter stated that the optimal extended withdrawal period for this situation would be 60 days since this is the approximate duration of a dairy cow's natural dry period. Under this approach, livestock requiring treatment could receive an allowed synthetic parasiticide at the time of drying off, thus allowing the withdrawal period to coincide with the natural 60-day period when the livestock were not lactating. Livestock could complete the withdrawal period prior to the birth of their offspring in approximately 60 days, at which time the mother's milk could again be sold as organic. The commenter maintained that the 60-day period would satisfy consumer expectation for an extended withdrawal period after treatment with an allowed synthetic parasiticide without imposing an unnecessary constraint on the producer.

We have retained the 90-day withdrawal period in the final rule. The provisions in the final rule for treating livestock with an allowed synthetic parasiticide reflect the 90-day withdrawal period recommended by the NOSB at its October 1999 meeting. The NOSB has the authority to reconsider this issue and propose an alternative annotation for the Secretary's consideration.

(5) *Delineation of Space Requirements for Animal Confinement.* The proposed rule did not establish space requirements for livestock living conditions but stated that a producer must accommodate the health and natural behavior of animals under his or her care. Some commenters stated their preference for space requirements because they are more uniform and enforceable. These commenters stated that some existing certification standards include space requirements in standards for livestock living conditions and that Codex guidelines support this approach. While not disagreeing that space requirements could be an effective certification tool for organic livestock production systems, we have not incorporated any such provisions in the final rule. We anticipate that additional NOSB recommendations and public comment will be necessary for the development of space requirements. At its June 2000 meeting, the NOSB agreed that it would be premature to include space requirements in the final rule.

(6) *Access to pasture versus pasture-based.* Commenters stated that the proposed rule's requirement that ruminants receive "access to pasture" did not sufficiently characterize the relationship that should exist between ruminants and the land they graze. Many of these commenters recommended that the final rule require that ruminant production be "pasture-based." Many commenters stated that the final rule needed a more explicit description of the relationship between livestock and grazing land. The NOSB shared this perspective and recommended that the final rule require that ruminant production systems be "pasture-based." In contrast, an organic dairy producer maintained that a uniform, prescriptive definition of pasture would not be appropriate in a final rule. This commenter stated that the diversity of growing seasons, environmental variables, and forage and grass species could not be captured in a single definition and that certifying agents should define pasture on a case-by-case basis. This commenter also disagreed with the "pasture-based" requirement, stating that pasture should be only one of several components of balanced livestock nutrition. Singling out pasture as the foundation for ruminant management would distort this balance and deprive other producers of the revenue and rotation benefits they generate by growing livestock feed.

We retained the "access to pasture" requirement because the term, "pasture-based," has not been sufficiently defined to use for implementing the

final rule. The final rule does include a definition for pasture, and retention of the "access to pasture" provision provides producers and certifying agents with a verifiable and enforceable standard. The NOP will work with the NOSB to develop additional guidance for managing ruminant production operations.

(7) *Stage of Production.* The proposed rule contained provisions for temporary confinement, during which time livestock would not receive access to the outdoors. Many commenters were concerned that the stage-of-production justification for temporary confinement could be used to deny animals access to the outdoors during naturally occurring life stages, including lactation. Commenters overwhelmingly opposed such an allowance and stated that the stage of production exemption should be narrowly applied. One commenter stated that a dairy operation, for example, might have seven or eight distinct age groups of animals, with each group requiring distinct living conditions. Under these circumstances, the commenter maintained that a producer should be allowed to temporarily house one of these age groups indoors to maximize use of the whole farm and the available pasture. At its June 2000 meeting, the NOSB stated that the allowance for temporary confinement should be restricted to short-term events such as birthing of newborn or finish feeding for slaughter stock and should specifically exclude lactating dairy animals.

We have not changed the provision in the final rule for the stage-of-production allowance in response to these comments. The NOSB has supported the principle of a stage-of-production allowance but has not provided sufficient guidance for determining, on a species-specific basis, what conditions would warrant such an allowance. Without a clearer foundation for evaluating practices, we have not identified any specific examples of practices that would or would not warrant a stage-of-production allowance. We will continue to explore with the NOSB specific conditions under which certain species could be temporarily confined to enhance their well-being.

In the final rule, temporary confinement refers to the period during which livestock are denied access to the outdoors. The length of temporary confinement will vary according to the conditions on which it is based, such as the duration of inclement weather. The conditions for implementing temporary confinement for livestock do not minimize the producer's ability to

restrain livestock in the performance of necessary production practices. For example, it is allowable for a producer to restrain livestock during the actual milking process or under similar circumstances, such as the administration of medication, when the safety and welfare of the livestock and producer are involved.

Handling—Changes Based on Comments

The following changes are made based on comments received.

(1) *Commercial Availability.* A large number of commenters, including organic handlers and certifying agents, stated that “commercial availability” must be included as a requirement for the 5 percent of nonorganic ingredients that are used in products labeled “organic.”

We agree and have added a commercial availability requirement as part of a handler’s organic system plan under section 205.201 of this subpart. Up to 5 percent (less water and salt) of a product labeled “organic,” may be nonorganic agricultural ingredients. However, handlers must document that organic forms of the nonorganic ingredients are not commercially available before using the nonorganic ingredients.

(2) *Prohibited Practices.* Commenters were unclear about the extent of the prohibition on use of excluded methods and ionizing radiation. To make that prohibition clear, we have moved the handling prohibitions in proposed rule sections 205.270 (c) to 205.105, Applicability, subpart B. Paragraphs (c)(1) and (c)(2) which listed excluded methods and ionizing radiation in the proposed rule are combined into paragraph (c)(1) that cross-references new section 205.105.

(3) *Use of Predator Pests and Parasites.* Paragraph (b)(1) of section 205.271 proposed that predator pests and parasites may be used to control pests in handling facilities. Under FDA’s Good Manufacturing Practice, 21 CFR part section 110.35(c), it states that “No pests shall be allowed in any area of a food plant.” Some commenters believed use of predator pests in handling facilities is prohibited by the FDA regulation. Other commenters stated that predator pests could be used in certain handling facilities under the FDA regulation. One commenter claimed that the FDA regulation in 21 CFR part 110.19 allows exemptions for certain establishments that only harvest, store, or distribute raw agricultural product. Another commenter suggested that use of predator pests should be

allowed when FDA does not prohibit their use.

We do not intend to be inconsistent with the FDA requirement and, thus, have removed proposed paragraph (b)(1) of section 205.271. Use of predator pests in various organic handling and storage areas is subject to FDA’s Good Manufacturing Practice. Paragraphs (b)(2) and (b)(3) are redesignated.

(4) *Use of Synthetic Pheromone Lures.* Proposed paragraph (b)(3) provided for use of nonsynthetic lures and repellent. A few handlers and certifying agents commented that nearly all pheromone lures use synthetic substances. Because pheromone lures do not come into contact with products in a handling facility, commenters argued that such lures should be allowed, provided that the synthetic substance used is on the National List.

We agree and have added “synthetic substances” to redesignated paragraph (b)(2) for use in lures and repellents. The synthetic substances used must be consistent with the National List.

(5) *Restrict Initial Use of Synthetics to National List Substances.* Paragraph (c) in the proposed rule provided for use of any synthetic substance to prevent or control pests. Several handlers and certifying agents stated that use of nonsynthetic and synthetic substances should initially be limited first to substances which are allowed on the National List. This would mean that substances not allowed for use on the National List could not be used initially to control or prevent pest infestations.

We agree with these comments. Use of allowed substance before use of other substances is a fundamental principle of organic agriculture. Therefore, if preferred practices under paragraphs (a) and (b) are not successful in preventing or controlling pest infestations, handlers may then use, under amended paragraph (c), only nonsynthetic or synthetic substances which are allowed for use on the National List.

We have removed the proviso that applications of a pest control substance must be consistent with the product’s label instructions. This requirement is readily understood and does not need to be explicitly stated in the regulations.

Because paragraph (c) now provides for use only of allowed National List substances, a new paragraph (d) is added to allow for use of other synthetic substances, including synthetic substances not on the National List, to prevent or control pest infestations.

These substances may be used only if the practices in paragraphs (a), (b), and (c) are ineffective. Before the substance is used, the handler and the operation’s certifying agent must agree on the

synthetic substance to be used and the measures to be taken to prevent contact of the substance with organic products and ingredients in the facility. We expect that this communication can be accomplished with telephone calls or by electronic means.

This regulation does not preempt Federal, State, or local health and sanitation requirements. We recognize that inspectors who monitor compliance with those regulations may require immediate intervention and use of synthetic substances, not on the National List, before or at the same time as the methods specified in paragraphs (b) and (c). Therefore, to make this clear, we have added a new paragraph (f). To ensure that the use of the substances does not destroy a product’s organic integrity, we are requiring that the handler take appropriate measures to prevent contact of the product with the pest control substance used.

(6) *Preventing Contact with Prohibited Substances.* Commenters recommended that, if prohibited substances are applied by fogging or fumigation, the organic product and packaging material must be required to be completely removed from the facility and reentry of the product or packaging be delayed for a period three times longer than that specified on the pesticide label. Commenters believed removal and reentry should be mandatory, regardless of the organic product or container.

We understand the commenters’ concerns. However, their recommendations are not appropriate for all pest infestations. We believe that measures needed to be taken to prevent contact with a synthetic substance must be determined on a case-by-case basis by the handler and certifying agent. As stated earlier, new paragraph (d) of section 205.271 requires a handler and certifying agent to agree on control and prevention measures prior to application of a synthetic substance. We believe that such an agreement will help safeguard a product’s organic integrity. Use of a synthetic substance in fogging or fumigation should be based on, among other things, location of the pest relative to the organic products in the facility; the extent of the pest infestation; the substance and application method to be used; the state of the organically produced product or ingredient (raw, unpackaged bulk, canned, or otherwise sealed); and health and sanitation requirements of local, State, and Federal authorities.

Paragraph (e) is changed to clarify that an operation’s organic handling plan must be updated to document all measures taken to prevent contact between synthetic pest control

substances and organically produced products and ingredients.

(7) *Repetitive Use of Pest Control Measures.* One commenter suggested a change in the paragraph (e) requirement that handlers' organic plans must include "an evaluation of the effects of repetitive use" of pest prevention and control materials. The commenter believed that the requirement was excessive and beyond what should be expected of handlers. The commenter indicated that handlers' organic plans should address the "techniques that will be used to minimize" the negative effects of repetitive use of pest control materials.

We agree that "an evaluation of the effects of repetitive use" is more than what is reasonable to expect of handlers in their organic plans. We do not agree, however, that an organic plan should be required to address the "techniques" used to minimize the effects of repetitive use of pest control materials. However, we believe that handlers should update their organic handling plans to account for the use of pest control or prevention substances, particularly if the substances are prohibited substances. The update should include a description of the application methods used and the measures taken to prevent contact between the substance used and the organic product. We have added these requirements in redesignated paragraph (e). Proposed paragraph (e) of section 205.271 is removed.

Handling—Changes Requested But Not Made

(1) *Exceptions to Handling Processes.* A commenter stated that many herbal products are extracted from organically produced herbs but that the extraction of those products "can employ significantly different methods than those used in the manufacture of more traditional foods." To be labeled as "organic" ingredients, substances such as herbs, spices, flavorings, colorings, and other similar substances, must be derived from a certified organic source and be extracted without the use of prohibited substances.

(2) *Allowed Synthetics Used in Packaging Materials and Storage Containers.* A State department of agriculture commented that section 205.272(b)(1) prohibits use of synthetic fungicides, preservatives, or fumigants in packaging materials and storage containers or bins. The comment stated that it is inconsistent to permit use of allowed substances as ingredients in processed products but prohibit their use as a preservative or fumigant in the packaging materials and storage

containers and bins. The commenter suggested that paragraph (b)(1) be amended to permit use of National List-allowed substances in section 205.605, particularly carbon dioxide and ozone, in packaging materials and storage containers or bins.

We understand the commenter's concern. However, section 6510(a)(5) of the Act specifically prohibits use of any packaging materials, storage containers, or bins that contain synthetic fungicides, preservatives, or fumigants.

(3) *Additional Measures to Prevent Product Contamination.* A few commenters suggested changing paragraph (e) of section 205.271 to require that handlers' organic handling plans specify measures that would be taken to prevent contact between a pest control substance and "packaging materials." This would be in addition to measures preventing contamination of "any ingredient or finished product" in the handling facility.

We understand the commenters' objective. However, for the reasons stated earlier in regard to commenters' request that mandatory removal of product during pest control treatment be required, we believe that such a requirement should not be mandatory for all packaging materials. Measures to prevent contamination of packaging material should be left to the handler and certifying agent to specify in the handling plan.

Handling—Clarifications

Clarification is given on the following issues raised by commenters.

(1) *Use of Nonorganic Ingredients in Processed Products.* We have corrected paragraph (c) of section 205.270 to clarify what must not be used in or on organically produced ingredients and nonorganically produced ingredients used in processed organic products. The prohibition on use of ionizing radiation, excluded methods, and volatile synthetic solvents applies to all organically produced ingredients. The 5 percent of nonorganic ingredients in products labeled "organic," also are subject to the three prohibited practices. The nonorganic ingredients in products labeled "made with organic ingredients" must not be produced using ionizing radiation or excluded methods but may be produced using volatile synthetic solvents. The nonorganic ingredients in products containing less than 70 percent organically produced ingredients may be produced and processed using ionizing radiation, excluded methods, and synthetic solvents.

(2) *Water Quality Used in Processing.* A handler questioned whether public

drinking water containing approved levels of chlorine, pursuant to the Safe Drinking Water Act, is acceptable for use in processing products labeled "100 percent organic." Water meeting the Safe Drinking Water Act may be used in processing any organically produced products.

Temporary Variances—Changes Based on Comments

Additional Causes for Issuing Temporary Variance. A few State department of agriculture commenters suggested that "drought" should be added to the regulatory text as a natural disaster warranting a temporary variance from regulations.

We agree and have added drought to the regulatory text in paragraph (a)(2) of section 205.290. We have also added "hail" as a natural disaster warranting a temporary variance. Both drought and hail were mentioned in the preamble of the proposed rule but were unintentionally left out of the regulatory text.

Temporary Variances—Changes Requested But Not Made

Allowance of Temporary Variances. A few commenters suggested that SOP's governing State officials should be able to authorize temporary variances due to local natural disasters which may occur in a State. We do not agree that with these comments. For consistency of application, we believe that only the Administrator should have the authority to grant a temporary variance. Citing local conditions, an SOP's governing State official and certifying agents may recommend a temporary variance to the Administrator. We are committed to providing quick responses to such recommendations.

Subpart D—Labels, Labeling, and Market Information

The Act provides that a person may sell or label an agricultural product as organically produced only if the product has been produced and handled in accordance with provisions of the Act and these regulations. This subpart sets forth labeling requirements for organic agricultural products and products with organic ingredients based on their percentage of organic composition. For each labeling category, this subpart establishes what organic terms and references can and cannot be displayed on a product package's principal display panel (pdp), information panel, ingredient statement, and on other package panels. Labeling requirements also are established for organically produced livestock feed, for containers used in shipping and storing organic

product, and for denoting organic bulk products in market information which is displayed or disseminated at the point of retail sale. Restrictions on labeling organic product produced by exempt operations are established. Finally, this subpart provides for a USDA seal and regulations for display of the USDA seal and the seals, logos, or other identifying marks of certifying agents.

The intent of these sections is to ensure that organically produced agricultural products and ingredients are consistently labeled to aid consumers in selection of organic products and to prevent labeling abuses. These provisions cover the labeling of a product as organic and are not intended to supersede other labeling requirements specified in other Federal labeling regulations. The Food and Drug Administration (FDA) regulates the placement of information on food product packages in 21 CFR parts 1 and 101. USDA's Food Safety and Inspection Service's (FSIS) Federal Meat Inspection Act, Poultry Products Inspection Act, and Egg Products Inspection Act have implementing regulations in 9 CFR part 317 which must be followed in the labeling of meat, poultry, and egg products. The Federal Trade Commission (FTC) regulations under the Fair Packaging and Labeling Act (FLPA) in 16 CFR part 500 and the Alcohol Tobacco and Firearms (ATF) regulations under the Federal Alcohol Administration Act (FAA) in 27 CFR parts 4, 5, and 7, also must be followed, as applicable to the nature of the product. The labeling requirements specified in this subpart must be implemented in a manner so that they do not conflict with the labeling requirements of these and other Federal labeling requirements.

While this regulation does not require labeling of an organic product as organic, we assume that producers and handlers choose to label their organic products and display the USDA seal to the extent allowed in these regulations. They do this to improve the marketability of their organic product.

Under the National Organic Program (NOP), the assembly, packaging, and labeling of multiingredient organic products are considered handling activities. The certification of handling operations is covered in subpart C of this regulation. No claims, statements, or marks using the term, "organic," or display of certification seals, other than as provided in this regulation, may be used. Based on comments received, several important labeling changes from the proposed rule are made in this final rule. (1) The term, "organic," cannot be used in an agricultural product name if

it modifies an ingredient that is not organically produced (e.g., "organic chocolate ice cream" when the chocolate flavoring is not organically produced). (2) The 5 percent or less of nonorganic ingredients in products labeled "organic" must be determined not "commercially available" in organic form. (3) Display of a product's organic percentage is changed from required to optional for "organic" and "made with * * *" products. (4) The minimum organic content for "made with * * *" products is increased from 50 percent to 70 percent. (5) In addition to listing individual ingredients, the "made with * * *" label may identify a food group on the label ("made with organic fruit"). (6) A new section is added to provide labeling of livestock feed that is organically produced. (7) Finally, a revised design for the USDA seal is established. In addition to these changes, we have made a few changes in the regulatory text for clarity and consistency purposes. These do not change the intent of the regulation.

Once a handler makes a decision to market a product as organic or containing organic ingredients, the handler is required to follow the provisions in this subpart regarding use, display, and location of organic claims and certification seals. Handlers who produce and label organic ingredients and/or assemble multiingredient products composed of 70 percent or more organic ingredients must be certified as an organic handling operation. Handlers of products of less than 70 percent organic ingredients do not have to be certified unless the handler actually produces one or more of the organic ingredients used in the product. Repackers who purchase certified organic product from other entities for repackaging and labeling must be certified as an organic operation. Entities which simply relabel an organic product package are subject to recordkeeping requirements which show proof that the product purchased prior to relabeling was, indeed, organically produced and handled. Distributors which receive and transport labeled product to market are not subject to certification or any labeling requirements of this regulation.

Many commenters appealed for "transition" or "conversion" labeling. This issue is discussed under Applicability in subpart B. Transition labeling is not provided for in the Act or the proposed rule and is not provided for in this regulation.

Description of Regulations

General Requirements

The general labeling principle employed in this regulation is that labeling or identification of the organic nature of a product increases as the organic content of the product increases. In other words, the higher the organic content of a product, the more prominently its organic nature can be displayed. This is consistent with provisions of the Act which establish the three percentage categories for organic content and basic labeling requirements in those categories.

Section 205.300 specifies the general use of the term, "organic," on product labels and market information. Paragraph (a) establishes that the term, "organic," may be used only on labels and in market information as a modifier of agricultural products and ingredients that have been certified as produced and handled in accordance with these regulations. The term, "organic," cannot be used on a product label or in market information for any purpose other than to modify or identify the product or ingredient in the product that is organically produced and handled. Food products and ingredients that are not organically produced and handled cannot be modified, described, or identified with the term, "organic," on any package panel or in market information in any way that implies the product is organically produced.

Section 6519(b) of the Act provides the Secretary with the authority to review use of the term, "organic," in agricultural product names and the names of companies that produce agricultural products. While we believe that the term, "organic," in a brand name context does not inherently imply an organic production or handling claim and, thus, does not inherently constitute a false or misleading statement, we intend to monitor the use of the term in the context of the entire label. We will consult with the FTC and FDA regarding product and company names that may misrepresent the nature of the product and take action on a case-by-case basis.

Categories of Organic Content

Section 205.301 establishes the organic content requirements for different labeling provisions specified under this program. The type of labeling and market information that can be used and its placement on different panels of consumer packages and in market information is based on the percentage of organic ingredients in the product. The percentage must reflect the actual weight or fluid volume (excluding water

and salt) of the organic ingredients in the product. Four categories of organic content are established: 100 percent organic; 95 percent or more organic; 70 to 95 percent organic; and less than 70 percent organic.

100 Percent Organic

For labeling and market information purposes, this regulation allows a "100 percent organic" label on: (1) agricultural products that are composed of a single ingredient such as raw, organically produced fruits and vegetables and (2) products composed of two or more organically produced ingredients, provided that the individual ingredients are, themselves, wholly organic and produced without any nonorganic ingredients or additives. Only processing aids which are, themselves, organically produced, may be used in the production of products labeled "100 percent organic." With the exception of the description phrase "100 percent" on the pdp, the labeling requirements for "100 percent organic" products are the same as requirements for 95 percent organic products specified in section 205.303.

Organic

Products labeled or represented as "organic" must contain, by weight (excluding water and salt), at least 95 percent organically produced raw or processed agricultural product. The organic ingredients must be produced using production and handling practices pursuant to subpart C. Up to 5 percent of the ingredients may be nonagricultural substances (consistent with the National List) and, if not commercially available in organic form pursuant to section 205.201, nonorganic agricultural products and ingredients in minor amounts (hereinafter referred to as minor ingredients) (spices, flavors, colorings, oils, vitamins, minerals, accessory nutrients, incidental food additives). The nonorganic ingredients must not be produced using excluded methods, sewage sludge, or ionizing radiation.

Made with Organic Ingredients

For labeling and market information purposes, the third category of agricultural products are multiingredient products containing by weight or fluid volume (excluding water and salt) between 70 and 95 percent organic agricultural ingredients. The organic ingredients must be produced in accordance with subpart C and subpart G. Such products may be labeled or represented as "made with organic (specified ingredients or food group(s))." By "specified," we mean the

name of the agricultural product(s) or food group(s) forming the organic ingredient(s). Up to three organically produced ingredients or food groups may be named in the phrase.

If one or more food groups are specified in the phrase, all ingredients in the product which belong to the food group(s) identified on the label must be organically produced. For the purposes of this labeling, the following food groups may be identified as organically produced on a food package label: beans, fish, fruits, grains, herbs, meats, nuts, oils, poultry, seeds, spices, sweeteners, and vegetables. In addition, processed milk products (butter, cheese, yogurt, milk, sour creams, etc.) also may be identified as a "milk products" food group. For instance, a vegetable soup made with 85 percent organically produced and handled potatoes, tomatoes, peppers, celery, and onions may be labeled "soup made with organic potatoes, tomatoes, and peppers" or, alternatively, "soup made with organic vegetables." In the latter example, the soup may not contain nonorganic vegetables. For the purposes of this labeling provision, tomatoes are classified, accordingly to food use, as a vegetable.

To qualify for this organic labeling, the nonorganic agricultural ingredients must be produced and handled without use of the first three prohibited practices specified in paragraph (f) of section 205.301, but may be produced or handled using practices prohibited in paragraphs (f)(4) through (f)(7).

Because of the length of the labeling phrase "made with organic (specified ingredients or food group(s))," such products are referred to in this preamble as "made with * * *" products. The labeling requirements for "made with * * *" products are specified in section 205.304.

Product With Less Than 70 Percent Organic Ingredients

The final labeling category covers multiingredient products with less than 70 percent organic ingredients (by weight or fluid volume, excluding water and salt). The organic ingredients must be produced in accordance with subparts C and G. The remaining nonorganic ingredients may be produced, handled, and assembled without regard to these regulations (using prohibited substances and prohibited production and handling practices). Organic labeling of these products is limited to the information panel only as provided in section 205.305.

Products that fail to meet the requirements for one labeling category

may be eligible for a lower labeling category. For example, if a product contains wholly organic ingredients but the product formulation requires a processing aid or less than 5 percent of a minor ingredient that does not exist in organic form, the product cannot be labeled "100 percent organic" and must be labeled as "organic." If a multiingredient product is 95 percent or more organic but contains a prohibited substance in the remaining 5 percent, the product cannot be labeled as "organic," because of the presence of the prohibited substance, but may be labeled as a "made with * * *" product. Further, a handler who produces a "100 percent organic" or "organic" product but chooses not to be certified under this program may only display the organic percentage on the information panel and label the ingredients as "organic" on the ingredient statement. The handler must comply with recordkeeping requirements in subpart E.

Livestock Feed

All agricultural ingredients used in raw and processed livestock feed that is labeled as "100 percent organic" and "organic" must be organically produced and handled in accordance with the requirements of these regulations. The difference between the two labels is that feed labeled as "100 percent organic" must be composed only of organically produced agricultural ingredients and may not contain nonorganic feed additives or supplements. The agricultural portion of livestock feed labeled as "organic" must contain only organically produced raw and processed agricultural ingredients and may contain feed additives and supplements in conformance with the requirements of section 205.237. Additionally, labeling of livestock feed containers must follow State livestock feed labeling laws.

Prohibited Practices

The labeling of whole products or ingredients as organic is prohibited if those products or ingredients are produced using any of the following production or handling practices: (1) Ingredients or processing aids produced using excluded methods; (2) ingredients that have been produced using applications of sewage sludge; (3) ingredients that have been processed with ionizing radiation; (4) synthetic substances not on the National List; (5) sulfites, nitrates, or nitrites added to or used in processing of an organic product in addition to those substances occurring naturally in a commodity (except the use of sulfites in the

production of wine); (6) use of the phrase, "organic when available," or similar statement on labels or in market information when referring to products composed of nonorganic ingredients used in place of specified organic ingredients; and (7) labeling as

"organic" any product containing both organic and nonorganic forms of an ingredient specified as "organic" on the label.

These seven prohibitions apply to the four labeling categories of products and are not individually repeated as

prohibited practices in the following sections. Table 1, Prohibited Production and Handling Practices for Organic Labeling, shows how use of the seven prohibited practices affects the labeling of organically produced products and ingredients used in those products.

TABLE 1.—PROHIBITED PRODUCTION AND HANDLING PRACTICES FOR LABELING CATEGORIES

Organic and use label	Use excluded methods	Use sewage sludge	Use ionizing radiation	Use substances not on National List	Contain added sulfites, nitrates, nitrites	Use non-organic ingredients and label "when available"	Use both organic and nonorganic forms of same ingredient
"100 percent organic": Single/multiingredients completely organic.	NO	NO	NO	NO	NO	NO	NO
"Organic":							
Organic ingredients (95% or more).	NO	NO	NO	NO	NO	NO	NO
Nonorganic ingredients (5% or less).	NO	NO	NO	NO	NO	NO	NO
"Made with organic ingredients":							
Organic ingredients (70–95%).	NO	NO	NO	NO	NO—except wine.	NO	NO
Nonorganic ingredients (30% or less).	NO	NO	NO	OK	OK	NA*	NA*
Less-than 70% organic ingredients:							
Organic ingredients (30% or less).	NO	NO	NO	NO	NO—except wine.	NO	NO
Nonorganic ingredients (70% or more).	OK	OK	OK	OK	OK	NA*	NA*

* Not applicable, provided that the nonorganic ingredient is not labeled as "organic" on the ingredient statement and is not counted in the calculation of the product's organic percentage.

Calculating the Percentage of Organic Ingredients

Section 205.302 specifies procedures for calculating the percentage, by weight or fluid volume, of organically produced ingredients in an agricultural product labeled or represented as "organic." The calculation is made by the handler at the time the finished product is assembled.

The organic percentage of liquid products and liquid ingredients is determined based on the fluid volume of the product and ingredients (excluding water and salt). When a product is identified on the pdp or the information panel as being reconstituted with water from a concentrate, the organic content is calculated on the basis of a single-strength concentration.

For products that contain organically produced dry and liquid ingredients, the percentage of total organic ingredients is based on the combined weight of the dry organic ingredient(s) and the weight of the liquid organic ingredient(s) (excluding water and salt). For example, a product may be made using organically produced vegetable oils or grain oils or contain organic

liquid flavoring extracts in addition to other organic and nonorganic ingredients. In such cases, the weight of the liquid organic oils or flavoring extracts, less any added water and salt, would be added to other solid organic ingredients in the product, and their combined weight would be the basis for calculating the percentage of organic ingredients.

At the discretion of the handler, the total percentage of all organic ingredients in a food product may be displayed on any package panel of the product with the phrase, "contains X percent organic ingredients," or a similar phrase. If the total percentage is a fraction, it must be rounded down to the nearest whole number. The percentage of each organic ingredient is not required to be displayed in the ingredient statement.

A certified operation that produces organic product may contract with another operation to repackage and/or relabel the product in consumer packages. In such cases, the repacker or relabeler may use information provided by the certified operation to determine the percentage of organic ingredients and properly label the organic product

package consistent with the requirements of this subpart.

Labeling "100 Percent Organic" and "Organic" Products

Section 205.303 includes optional, required, and prohibited practices for labeling agricultural products that are "100 percent organic" or "organic." Products that are composed of wholly organic ingredients may be identified with the label statement, "100 percent organic," on any package panel. Products composed of between 95 and 100 percent organic ingredients may be identified with the label statement "organic" on any package panel, and the handler must identify each organic ingredient in the ingredient statement.

The handler may display the following information on the pdp, the information panel, and any other part of the package and in market information representing the product: (1) The term, "100 percent organic" or "organic," as applicable to the content of the product; and (2) for products labeled "organic," the percentage of organic ingredients in the product. The size of the percentage statement must not exceed one-half the size of the largest type size on the panel

on which the statement is displayed. It also must appear in its entirety in the same type size, style, and color without highlighting; (3) the USDA seal; and (4) the seal, logo, or other identifying mark of the certifying agent (hereafter referred to as "seal or logo") which certified the handler of the finished product. The seals or logos of other certifying agents which certified organic raw materials or organic ingredients used in the product also may be displayed, at the discretion of the finished product handler. If multiple organic ingredients are identified on the ingredient statement, the handler of the finished product that combined the various organic ingredients must maintain documentation, pursuant to subpart B of this regulation.

While certifying agent identifications can appear on the package with the USDA seal, they may not appear larger than the USDA seal on the package. There is no restriction on the size of the USDA seal as it may appear on any panel of a packaged product, provided that display of the Seal conforms with the labeling requirements of FDA and FSIS.

If a product is labeled as "100 percent organic" the ingredients may be identified with the term, "organic," but will not have to be so labeled because it is assumed from the 100 percent label that all ingredients are organic. For 95 percent-plus products, each organically produced ingredient listed in the ingredient statement must be identified with the term, "organic," or an asterisk or other mark to indicate that the ingredient is organically produced. Water and salt cannot be identified as "organic" in the ingredient statement.

The handler of these products also must display on the information panel the name of the certifying agent which certified the handling operation that produced the finished product. The handler may include the business address, Internet address, or telephone number of the certifying agent. This information must be placed below or otherwise near the manufacturer or distributor's name.

Labeling Products "Made With Organic (specified ingredients or food group(s))"

With regard to agricultural products "made with * * *"—those products containing between 70 and 95 percent organic ingredients—this rule establishes, in section 205.304, the following optional, required, and prohibited labeling practices.

Under optional practices, the "made with * * *" statement is used to identify the organically produced ingredients in the product. The

statement may be placed on the pdp and other panels of the package. The same statement can also be used in market information representing the product. However, the following restrictions are placed on the statement: (1) The statement may list up to three ingredients or food group commodities that are in the product; (2) the individually specified ingredients and all ingredients in a labeled food group must be organically produced and must be identified as "organic" in the ingredient statement on the package's information panel; (3) the statement cannot appear in print that is larger than one half (50 percent) of the size of the largest print or type appearing on the pdp; and (4) the statement and optional display of the product's organic percentage must appear in their entirety in the same type size, style, and color without highlighting.

The following food groups can be specified in the "made with" labeling statement: fish, fruits, grains, herbs, meats, nuts, oils, poultry, seeds, spices, sweeteners, and vegetables. In addition, organically produced and processed butter, cheeses, yogurt, milk, sour cream, etc., may be identified as a "milk products" food group. For the purposes of this labeling, tomatoes are considered as vegetables, based on their use in a product. As noted immediately above, all of a product's ingredients that are in the specified food group(s) must be organically produced.

Display of the "made with * * *" statement on other panels must be similarly consistent with the size of print used on those panels. These restrictions are in accordance with FDA labeling requirements and similar to the recommendations of the National Organic Standards Board (NOSB). This provision helps assure that the "made with * * *" statement is not displayed in such a manner as to misrepresent the actual organic composition of the product.

The USDA seal may not be displayed on the pdp of products labeled "made with organic ingredients." However, at the handler's option and consistent with any contract agreement between the organic producer or handler and the certifying agent, the certifying agent's seal or logo may be displayed on the pdp and other package panels.

Packages of "made with * * *" products may display on the pdp, information panel, or any package panel, the total percentage of organic ingredients in the product. Any organically produced ingredient, including any ingredient that is a member of a food group listed on the "made with * * *" statement, must be

identified in the ingredient statement with the term, "organic." Alternatively, an asterisk or other mark may be placed beside each organically produced ingredient in the ingredients statement with an explanation that the mark indicates the ingredient is organically produced.

The name of the certifying agent which certified the handler of the finished product must be displayed below or otherwise near the manufacturer or distributor's name. The statement may include the phrase, "Certified organic by * * *" or "Ingredients certified as organically produced by * * *" to help distinguish the certifying agent from the manufacturer or distributor. The handler may include the business address, Internet address, or telephone number of the certifying agent which certified the handler of the finished product.

If the percentage of organic ingredients in the product is displayed, the handler who affixes the label to the product package is responsible for determining the percentage. The handler may use information provided by the certified operation in determining the percentage. As part of the certifying agent's annual certification of the handler, the certifier must verify the calculation and labeling of packages.

Labeling Products With Less Than 70 Percent Organic Ingredients

Section 205.305 covers the final labeling category of packaged multiingredient agricultural products containing less than 70 percent organic ingredients.

Handlers of "less than 70 percent" multiingredient products, who choose to declare the organic nature of their product, may do so only in the ingredient statement by identifying the organically produced ingredients with the term, "organic," or with an asterisk or other mark. If the handler identifies the ingredients that are organically produced, the handler also may declare the percentage of organic content in the product. The percentage may only be placed on the information panel so that it can be viewed in relation to the ingredient statement.

Processed products composed of less than 70 percent organic content cannot display the USDA seal or any certifying agent's organic certification seal or logo anywhere on the product package or in market information.

Handlers of such products are subject to this regulation in the following ways. Those handlers who only purchase organic and nonorganic ingredients and

assemble a finished product of less than 70 percent organic content do not have to be certified as organic handlers. However, they are responsible for appropriate handling and storage of the organic ingredients (section 205.101(a)(3)) and for maintaining records verifying the organic

certification of the ingredients used in the product (section 205.101(c)). To the extent that the packaging process includes affixing the label to finished product package, those handlers are responsible for meeting the labeling requirements of this subpart. The nonorganic ingredients may be

produced, handled, and assembled without regard to the requirements of this part.

Table 2, *Labeling Consumer Product Packages*, provides a summary of the required and prohibited labeling practices for the four labeling categories.

TABLE 2.—LABELING CONSUMER PRODUCT PACKAGES

Labeling category	Principal display panel	Information panel	Ingredient statement	Other package panels
"100 percent Organic" (Entirely organic; whole, raw or processed product).	"100 percent organic" (optional). USDA seal and certifying agent seal(s) (optional).	"100% organic" (optional). Certifying agent name (required); business/Internet address, tele. No. (optional).	If multiingredient product, identify each ingredient as "organic" (optional).	"100 percent organic" (optional). USDA seal and certifying agent seal(s) (optional).
"Organic" (95% or more organic ingredients).	"Organic" (plus product name) (optional). "X% organic" (optional). USDA seal and certifying agent seal(s) (optional).	"X% organic" (optional) Certifying agent name (required); business/Internet address, tele. No. (optional).	Identify organic ingredients as "organic" (required if other organic labeling is shown).	"X% organic" (optional). USDA seal and certifying agent seal(s) (optional).
"Made with Organic Ingredients" (70 to 95% organic ingredients).	"made with organic (ingredients or food group(s))" (optional). "X% organic" (optional) Certifying agent seal of final product handler (optional). <i>Prohibited: USDA seal</i>	"X% organic ingredients" (optional). Certifying agent name (required); business/Internet address, tele. No. (optional). <i>Prohibited: USDA seal</i>	Identify organic ingredients as "organic" (required if other organic labeling is shown).	"made with organic (ingredients or food group(s))" (optional). "X% organic" (optional). Certifying agent seal of final product handler (optional). <i>Prohibited: USDA seal.</i>
Less-than 70% organic ingredients.	<i>Prohibited: Any reference to organic content of product.</i> <i>Prohibited: USDA seal & certifying agent seal.</i>	"X% organic" (optional) <i>Prohibited: USDA seal & certifying agent seal.</i>	Identify organic ingredients as "organic" (optional) (required if % organic is displayed).	<i>Prohibited: USDA seal & certifying agent seal.</i>

Misrepresentation in Labeling of Organic Products. The labeling requirements of this final rule are intended to assure that the term, "organic," and other similar terms or phrases are not used on a product package or in marketing information in a way that misleads consumers as to the contents of the package. Thus, we intend to monitor the use of the term, "organic," and other similar terms and phrases. If terms or phrases are used on product packages to represent "organic" when the products are not produced to the requirements of this regulation, we will proceed to restrict their use.

Handlers may not qualify or modify the term, "organic," using adjectives such as, "pure" or "healthy," e.g., "pure organic beef" or "healthy organic celery." The term, "organic," is used in labeling to indicate a certified system of agricultural production and handling. Terms such as "pure," "healthy," and other similar adjectives attribute hygienic, compositional, or nutritional characteristics to products. Use of such adjectives may misrepresent products produced under the organic system of agriculture as having special qualities as a result of being produced under the organic system. Furthermore, use of

such adjectives would incorrectly imply that products labeled in this manner are different from other organic products that are not so labeled.

Moreover, "pure," "healthy," and other similar terms are regulated by FDA and FSIS. These terms may be used only in accordance with the labeling requirements of FDA and FSIS. The prohibition on use of these terms to modify "organic" does not otherwise preclude their use in other labeling statements as long as such statements are in accordance with other applicable regulations. Representations made in market information for organic products are also subject to the requirements and restrictions of other Federal statutes and applicable regulations, including the Federal Trade Commission Act, 15 U.S.C. 45 *et seq.*

Labeling Organically Produced Livestock Feed Products

New section 205.306 is added to provide for labeling of the two categories of livestock feed that are organically produced under this regulation. Feed labeled "100 percent organic" may contain only organically produced agricultural product. Such feed must not contain feed additives,

supplements, or synthetic substances. Feed labeled "organic" must contain only organically produced agricultural products and may contain feed additives and supplements in accordance with section 205.237, Livestock Feed, and section 205.603 of the National List. This rule does not limit the percentage of such additives and supplements in organic feed products, which may be required under various State laws.

Livestock feed labeled "100 percent organic" and "organic" may, at the handler's option, display the USDA seal and the seal or logo of the certifying agent. The organic ingredients listed on the ingredient statement may be identified with the word, "organic," or other reference mark. The name of the certifying agent must be displayed on the information panel. The business address, Internet address, and other contact information for the certifying agent may be displayed. These are the only labeling options to indicate that livestock feed that is organically produced.

Labeling of Products Shipped in International Markets

Domestically produced organic products intended for export may be labeled to meet the requirements of the country of destination or any labeling requirements specified by a particular foreign buyer. For instance, a product label may require a statement that the product has been certified to, or meets, certain European Union (EU) organic standards. Such factual statements regarding the organic nature of the product are permitted. However, those packages must be exported and cannot be sold in the United States with such a statement on the label because the statement indicates certification to standards other than are required under this program. As a safeguard for this requirement, we require that shipping containers and bills of lading for such exported products display the statement, "for export only," in bold letters. Handlers also are expected to maintain records, such as bills of lading and U.S. Customs Service documentation, showing export of the products. Only products which have been certified and labeled in accordance with the requirements of the NOP may be shipped to international markets without marking the shipping containers "for export only."

Organically produced products imported into the United States must be labeled in accordance with the requirements of this subpart. Labeling and market representation of the product cannot imply that the product is also certified to other organic standards or requirements that differ from this national program.

Labeling Nonretail Containers

Section 205.307 provides for labeling nonretail containers used to ship or store raw or processed organic agricultural products that are labeled "100 percent organic," "organic," and "made with organic * * *". Labeling nonretail containers as containing organically produced product should provide for easy identification of the product to help prevent commingling with nonorganic product or handling of the product which would destroy the organic nature of the product (fumigation, etc.). These labeling provisions are not intended for shipping or storage containers that also are used in displays at the point of retail sale. Retail containers must meet labeling provisions specified in section 205.307.

Containers used only for shipping and storage of any organic product labeled as containing 70 percent or more organic content may, at the handler's

discretion, display the following information: (1) The name and contact information of the certifying agent which certified the handler of the finished product; (2) the term, "organic," modifying the product name; (3) any special handling instructions that must be followed to maintain the organic integrity of the product; and (4) the USDA seal and the appropriate certifying agent seal. This information is available to handlers if they believe display of the information helps ensure special handling or storage practices which are consistent with organic practices.

Containers used for shipping and storage of organic product must display a production lot number if such a number is used in the processing and handling of the product. Much of this information may overlap information that the handler normally affixes to shipping and storage containers or information that is required under other Federal labeling regulations. There are no restrictions on size or display of the term, "organic," or the certifying agent seal unless required by other Federal or State statutes.

Labeling Products at the Point of Retail Sale

Section 205.308 applies to organically produced "100 percent organic" and "organic" products that are not packaged prior to sale and are presented in a manner which allows the consumer to select the quantity of the product purchased.

The terms, "100 percent organic" and "organic," as applicable, may be used to modify the name of the product in retail displays, labeling, and market information. The ingredient statement of a product labeled "organic" displayed at retail sale must identify the organic ingredients. If the product is prepared in a certified facility, the retail materials may also display the USDA seal and the seal or logo of the certifying agent. If shown, the certifying agent seal must not be larger than the USDA seal.

Section 205.309 addresses "made with * * *" products that are not packaged prior to sale and are presented in a manner which allows the consumer to select the quantity of the product purchased. These products include, but are not limited to, multiingredient products containing between 70 and 95 percent organic ingredients. The "made with * * *" label may be used to modify the name of the product in retail displays, labeling, and market information. Up to three organic ingredients or food groups may be identified in the statement. If such statement is declared in market

information at the point of retail sale, the ingredient statement and market information must identify the organic ingredients. Retail display and market information of bulk products cannot display the USDA seal but may, if the product is prepared in a certified facility, display the seal or logo of the certifying agent which certified the finished product. The certifying agent's seal or logo may be displayed at the option of the retail food establishment.

Products containing less than 70 percent organic ingredients may not be identified as organic or containing organic ingredients at retail sale. The USDA seal and any certifying agent seal or logo may not be displayed for such products.

Labeling Products Produced in Exempt or Excluded Operations

Section 205.310 provides limited organic labeling provisions for organic product produced or handled on exempt and excluded operations. Such operations would include retail food establishments, certain manufacturing facilities, and production and handling operations with annual organic sales of less than \$5,000. These operations are discussed more thoroughly in subpart B, Applicability.

Any such operation that is exempt or excluded from certification or which chooses not to be certified may not label its organically produced products in a way which indicates that the operation has been certified as organic. Exempt producers may market whole, raw organic product directly to consumers, for example, at a farmers market or roadside stand as "organic apples" or "organic tomatoes." Exempt producers may market their products to retail food establishments for resale to consumers. However, no terms may be used which indicate that such products are "certified" as organic. Finally, exempt organic producers cannot sell their product to a handler for use as an ingredient or for processing into an ingredient that is labeled as organic on the information panel.

These provisions are truth in labeling provisions because display of a certification seal indicates that the product has been certified. We believe this requirement helps differentiate between certified and uncertified products and helps maintain the integrity of certified products while providing organic labeling opportunities for exempt and excluded operations.

USDA Organic Seal

This final rule establishes a USDA seal that can be placed on consumer packages, displayed at retail food

establishments, and used in market information to show that certified organic products have been produced and handled in accordance with these regulations. The USDA seal can only be used to identify raw and processed products that are certified as organically produced. It cannot be used for products labeled as "made with organic ingredients" (70 to 95 percent organic ingredients) or on products with less than 70 percent organic ingredients.

The USDA seal is composed of an outer circle around two interior half circles with an overlay of the words "USDA Organic." When used, the USDA seal must be the same form and design as shown in figure 1 of section 205.311 of this regulation. The USDA seal must be printed legibly and conspicuously. On consumer packages, retail displays, and labeling and market information, the USDA seal should be printed on a white background in earth tones with a brown outer circle and separate interior half circles of white (upper) and green (lower). The term, "USDA," must appear in green on the white half circle. The term, "organic," must appear in white on the green half circle. The handler may print the USDA seal in black and white, using black in the place of green and brown. Size permitting, the green (or black) lower half circle may have four light lines running from left to right and disappearing at the right horizon, to resemble a cultivated field. The choice between these two color schemes is left to the discretion of the producer, handler, or retail food establishment.

Labeling—Changes Based on Comments

The following changes are made based on comments received.

(1) *Use of "Organic" in Product Names.* The NOSB, State organic program (SOP) managers, certifying agents, and a large number of individual commenters strongly recommended that USDA prohibit use of the term, "organic," to modify an ingredient in a product name if the ingredient, itself, is not produced organically. The examples offered were "organic chocolate ice cream" and "organic cherry sweets" in which the ice cream and candy are at least 95 percent organic but the chocolate and cherry flavoring is not organically produced.

We agree with commenters that such product names can be misleading and would be a violation of section 205.300(a). In the examples, the word, "organic," precedes the words, "chocolate" and "cherry," and clearly implies that those ingredients are organically produced. The chocolate and cherry flavorings must be

organically produced to be used in this way. If the product is at least 95 percent organically produced but the flavoring is nonorganic, the word sequence must be reversed or the word, "flavored," must be added to the name; e.g., "chocolate organic ice cream" or "chocolate flavored organic ice cream." A sentence has been added to section 205.300(a) to specify that the term, "organic," may not be used in a product name to identify an ingredient that is not organically produced.

A similar comment was received asking how a single product with two separately wrapped components can be labeled if one of the components is organically produced and the other is not. The commenter's example was a carrot and dip snack pack in which the carrots are organically produced and the dip is a conventional product. Another example is ready-to-eat tossed green salad in which the salad greens are organically produced but the separately pouched salad dressing is a nonorganic component of the product.

Such products also must be labeled in accordance with section 205.300(a). It would be misleading to label the snack pack "organic carrots and dip" or "organic green salad and ranch dressing," if the dip and ranch dressing are not produced with organic ingredients. The salad may be labeled "organic green salad with ranch dressing."

Section 6519(b) of the Act provides the Secretary with the authority to take action against misuse of the term, "organic." USDA will monitor use of the term, "organic," in product names and will restrict use of the term in names that are determined to be deliberately misleading to consumers. Such determinations must be made on a case-by-cases basis.

(2) *Labeling Livestock Feed.* In the definition of "agricultural product," the Act includes product marketed for "livestock consumption." This means that NOP regulations have applicability to livestock feed production. The Association of American Feed Control Officials (AAFCO) and a few States departments of agriculture commented that the proposed provisions conflict with widely followed standards for livestock feed labeling. AAFCO's "Model Bill and Regulation" standards are incorporated in many State feed laws. The commenters claimed that the requirement to identify organic ingredients in the ingredient statement conflicts with feed regulations which prohibit reference to an ingredient's "quality or grade." They also claimed that the percentage of organic content requirement is a quantitative claim that

must be verified by independent sources (e.g., sources other than the certifying agent). The commenters suggested that a provision be added to address labeling of commercial livestock feed.

We have added new paragraph (e) of section 205.301 which provides for two kinds of feed that can be labeled as "organic." The first is feed that contains only organically produced agricultural ingredients and contains no added nutrients or supplements. The second organic feed category also must contain only organically produced agricultural ingredients but may contain feed additives and supplements that are needed to meet the nutritional and health needs of the livestock for which the feed is intended. Feed labeled as "organic" must conform with the requirements of section 205.237, Livestock feed. That section provides that feed additives and supplements produced in conformity with section 205.603 of the National List may be used. The NOP requires that livestock under organic management must only be fed organically produced agricultural ingredients.

We also have added new section 205.306 to address commenters' labeling concerns. The new section provides for optional display of a feed's organic percentage and optional identification of the feed ingredients that are organically produced. The labeling requirements are not intended to supersede the general feed labeling requirements established in the FFDCA and those found under various State laws. Handling processes, feed formulations and recordkeeping must be sufficient to meet the requirements of applicable State regulations.

We believe the provisions in new paragraph (e) of section 205.301 on feed content and new section 205.306 on labeling will allow livestock feed producers to produce and label organic livestock feed that is in accordance with these regulations and State requirements.

(3) *Organic Processing Aids.* Several industry leaders and SOP managers questioned whether the proposed rule intended to exclude the use of certified organic processing aids in the creation of "100 percent organic" products. Commenters pointed out that a handler should be able to use organically produced processing aids to create products that are labeled as "100 percent organic." The processing aid can be a by-product of an organic agricultural product; e.g., a filter made of rice hulls from organically produced rice. AMS concurs. Accordingly, a change is made in paragraph (f)(4) of section 205.301 to provide for use of

organically produced processing aids in products labeled "100 percent organic."

To help clarify this and correct an incomplete reference in the proposed rule preamble, we have changed the column heading of the fourth prohibited practice in the preamble table 1.

(4) *Content of "100 Percent Organic Products."* Certifying agents and several industry commenters called attention to the regulatory text of section 205.301(a) describing 100 percent organic products. They argued that the proposed rule would allow products with one or more 95 percent-plus "organic" ingredients to be combined as components and have the resulting product be labeled as "100 percent organic."

We did not intend to allow any ingredient that is less than 100 percent organic to be used in a product labeled "100 percent organic." To leave no doubt as to the nature of any product labeled "100 percent organic," we have changed the wording of paragraph (a) of section 205.301 to clarify that a multiingredient "100 percent organic" product must be comprised entirely of 100 percent organic ingredients.

(5) *Labeling of Organic Percentage.* We received many comments requesting clearer display of a product's percentage of organic content. Most suggested that any product containing less than 100 percent organic ingredients should be required to display the organic percentage on the pdp. They argued that display of the organic percentage on the front of the package would enable consumers to more easily determine organic content, compare competing products, and make better purchase decisions. The NOSB did not recommend display of organic percentage on the pdp for all products containing organic ingredients.

We also received several comments from handlers concerned that the required display of a product's organic percentage can be a burden on handlers. They stated that, to save packaging and printing costs, handlers order bulk quantities of printed packages, labels, and other printed marketing materials. When printed in advance of a growing season and harvest, the handler may not be able to assemble a product that is exactly consistent with the preprinted labeling information, particularly the percentage of organic content. One commenter representing a commodity association opposed the required percentage labeling because the association believes consumers will not understand any organic claim if a percentage of less than 100 percent is displayed.

We believe that display of the percentage of organic content is important product information that can be very helpful to consumers in their purchase decisions. We also believe that the opportunity to display the percentage content of organically produced ingredients can be a positive factor in encouraging handlers to use more organic ingredients in their multiingredient products. At the same time, we understand the financial commitment involved in preprinting bulk quantities of packages and labels well in advance of harvests, which determine availability of needed ingredients.

This final rule implements changes in sections 205.303 and 205.304 for products labeled "organic" and "made with organic ingredients." The requirement to display the percentage of organic content on the information panel is removed. That requirement is replaced with optional labeling of the product's organic percentage on the pdp or any other package panels. This will allow those handlers to display the percentage of their product's organically produced contents on the pdp where it will be most immediately visible to consumers. Handlers who cannot, with certainty, display their product's organic percentage or who choose not to display the percentage, are not required to do so.

This revised labeling provision also removes the requirement in section 205.305 that products with less than 70 percent organic content display the product's organic percentage on the information panel. Under this final rule, that percentage labeling is optional but is still restricted to the information panel. The percentage of a less than 70 percent organic product may not be displayed on the pdp and may not be displayed if the organic ingredients are not identified in the ingredient statement.

(6) *Designation of Organically Produced Ingredients.* A certifying agent suggested that identification of organic ingredients in ingredient statements should be allowed to be made with an asterisk or similar mark, with the asterisk defined on the information panel. The commenter stated that the repetitive use of the word, "organic," may cause space problems on some small packages and that use of a mark is a common industry practice. We agree with the comment and have changed sections 205.303(b)(1), 205.304(b)(1), and 205.305(a)(i) of the regulatory text accordingly. Thus, organic ingredients may be identified in the ingredient statement with either the term, "organic," or an asterisk or other mark,

provided that the asterisk or other mark is defined on the information panel adjacent to the ingredient statement.

(7) *Minimum Organic Percentage for Labeling.* In the proposed rule's preamble, we asked for public comment on whether the 50 percent minimum organic content for pdp labeling should be increased. The 50 percent minimum content was established in section 6505(c) of the Act. However, the Act also provides the Secretary with the authority to require such other terms and conditions as are necessary to implement the program. Thus, the minimum organic content level for pdp labeling could be changed if the change would further the purposes of the Act.

Comments to the first (1997) proposal and to the revised proposed rule suggested that the minimum organic content for labeling purposes should be increased. All comments received, including comments from certifying agents, a leading organic association, the EU and other international commenters recommended that the minimum organic content to qualify for pdp labeling should be raised to 70 percent, which is the EU's minimum. All comments stated that the increase is necessary to make the NOP standards consistent with international organic standards. Commenters also pointed to advances in organic production and processing technologies and to increases in the availability of organically produced products and processed ingredients. These factors should make it easier for handlers to assemble food products with higher organic content.

We concur with the comments. We view this as a tightening of labeling requirements in that pdp labeling now requires a higher percentage of organic ingredients and makes the U.S. standard consistent with international norms.

In the proposed rule's preamble, we also asked for specific public comment on whether a minimum percentage of total product content should be required for any single organic ingredient that is included in the pdp statement "made with organic (specified ingredients)." No commenters responded to this question. Therefore, no required minimum percentage for a single organic ingredient in "made with * * *" products is established.

(8) *"Made With Organic (Specified Food Groups)."* Several industry organizations suggested that, as an alternative to listing up to three organic ingredients in the "made with * * *" label, the rule should also allow for identification of food "groups" or "classes" of food in the "made with" label. Commenters suggested, for instance, that a soup (with 70 percent or

more organic ingredients, less water and salt) containing organically produced potatoes, carrots, and onions may be labeled as "soup made with organic potatoes, carrots, and onions" or, alternatively, "soup made with organic vegetables."

We agree that this label option offers handlers of such multiingredient products with more flexibility in their labeling. All ingredients in the identified food group must be organically produced and must be identified in the ingredient statement as "organic." In the above example, if soup also contains conventionally produced cauliflower, only "soup made with organic potatoes, carrots, and onions" can be displayed.

We also believe that some parameters must be established as to what are considered as food groups or classes of food. For the purposes of this regulation, products from the following food groups may be labeled as "organic" in a "made with * * *" label: beans, fruits, grains, herbs, meats, nuts, oils, poultry, seeds, spices, and vegetables. In addition, organically produced and processed butter, cheeses, yogurt, milk, sour cream, etc. may be combined in a product and identified as "organic milk products." Organically produced and processed sugar cane, sugar beets, corn syrup, maple syrup, etc. may be used in a product and identified as "organic sweeteners."

Finally, to be consistent with the "made with * * *" labeling for individual ingredients, up to three food groups can be identified in the "made with * * *" statement. Section 205.304 is changed accordingly.

(9) *Labeling Products from Exempt and Excluded Operations.* A change is made in redesignated section 205.310 which provides for labeling of organic products produced by exempt and excluded operations. SOP managers and an organic handler pointed out that the preamble suggested restrictions on labeling that would prevent exempt and excluded operations from identifying their products as "organic." After review of the proposed rule, we have revised redesignated section 205.310 to more clearly specify labeling opportunities for exempt operations. The regulatory text more clearly states that such operations may not label or represent their organic products as being "certified" as organic and that such exempt and excluded operations must comply with applicable production and handling provisions of subpart C. Labeling must be consistent with the four labeling categories based on the product's organic content.

A State organic advisory board recommended that proposed section 205.309 be revised to apply to exempt and excluded operations which choose to be certified under this program. We do not believe it is necessary to provide separate regulatory text for exempt and excluded operations that are certified. An exempt operation is not precluded from organic certification, if qualified.

(10) *Redesigned USDA Seal.* Leading industry members, certifying agents, SOP managers, and many individual commenters opposed the proposed wording and design of the USDA seal. Comments generally stated the following points: (1) The proposed Seal wording indicates that USDA is the certifying agent rather than accredited certifiers; (2) international Organization for Standardization (ISO) Guide 61 prohibits government bodies from acting or appearing as certifying agents; and (3) The shield or badge design indicates a certification of product "quality" and assurance of safety which is inconsistent with the NOP's claim to be a certification of "process" only. Commenters suggested several alternative seal statements, including: "Certified Organic—USDA Accredited," "Certified Organic—USDA Approved," "USDA Certified Organic Production," "Meets USDA Organic Production Requirements."

Based on comments received, we are implementing a revised USDA seal which is shown in the regulatory text under section 301.311. It is a circular design with the words, "USDA Organic." The color scheme is a white background, brown outer circle, white and green inner semicircles, and green and white words. A black and white color scheme also may be used if preferred by the handler.

Some commenters suggested changing the shape of the USDA seal to a circle or triangle which, they state, is more in keeping with recognized recycling and sustainability logos. We did not choose a triangle design because processors have commented that triangle designs may cause tears in shrink wrap coverings at the points of the triangle.

Labeling—Changes Requested But Not Made

(1) *"Organic" in Company Names.* Many commenters stated that the term, "organic," must not be used as part of a company name if the company does not market organically produced foods. They are concerned that the term in a company name would incorrectly imply that the product, itself, is organically produced.

While we understand commenter concerns, we do not know the extent of

the problem. We do not believe those concerns require such a prohibition in the regulations at this time. These regulations may not be the best mechanism to address the issue. Section 6519(b) of the Act provides the Secretary with the authority to take action against misuse of the term, "organic." USDA will monitor use of the term, "organic," in company names and will work with the FTC to take action against such misuse of the term. These determinations must be made on a case-by-case basis. The proposed rule did not specifically address this issue. We have added a sentence to paragraph (a) of section 205.300 to this effect.

(2) *The "100 Percent Organic" Label.* A large number of commenters opposed the "100 percent organic" label for different reasons. A few claimed that the label is not authorized under the Act. Several commenters suggested that consumers will not understand the difference between multiingredient products labeled "100 percent organic" and "organic." Others raised the concern that the "100 percent organic" phrase to modify raw, fresh fruits and vegetables in produce sections and farmers markets may be confusing to consumers.

Regarding the first comment, the term is not specifically provided for in the Act. However, the Secretary has the authority under section 6506(a)(11) to require other terms and conditions as may be necessary to develop a national organic program. When a product is wholly organic, pursuant to the production and handling requirements of the NOP, we believe the handler should have the option to differentiate it from products which, by necessity, are less than 100 percent organic. We believe the label meets the purposes of the Act.

Regarding consumer confusion, we believe consumers will understand the difference between the two kinds of organic products and will make their organic purchases accordingly.

Regarding the labeling of raw, fresh product as "100 percent organic," organically produced products can be labeled to a lower labeling category. Raw, fresh fruits and vegetables which qualify for a "100 percent organic" label may be labeled simply as "organic," if the producer or retail operator believes that label is best for marketing purposes.

(3) *Explain Why Product Is Not 100 Percent Organic.* A large number of commenters also suggested any "product that is less than 100 percent organic should carry that information on the main display panel * * *" By "that information," we assume the commenters are referring to the reasons

why a product cannot be certified as "100 percent organic."

AMS believes such a labeling requirement is impractical. Products may fail to qualify for a "100 percent organic" label for very technical, or little understood, reasons. Contemporary food processing often uses ingredients, processing technologies, and product formulations that are complicated, technical, and probably not of interest to the general organic consumer. Such information is not required on nonorganically produced products for the simple reason that it is not considered useful to consumers. Explanations of the different processing technologies used in food products would be cumbersome and would interfere with other product labeling.

We believe the optional display of the organic percentage and required identification of organic ingredients on the information panel provides sufficient information for consumers to make purchase decisions. Other descriptive information regarding processing substances and procedures may, of course, be provided at the handler's option and placed in accordance with other Federal labeling requirements.

(4) *Check the Appropriate Organic Category.* One commenter suggested that packages of organically produced product display a small box listing the four organic label categories and a check mark beside the category which fits the product.

We understand the simplicity and comparative nature of such a standardized organic label that allows easy comparison of similar products. However, we believe that the optional display of the product's organic percentage and required identification of organic ingredients will be more helpful to consumers and makes the grid box redundant.

(5) *Nonorganic Ingredients in Organic Products.* A large number of comments were received on the composition and use of nonorganic ingredients in products labeled "made with * * *" and on conventional products with less than 50 (now 70) percent organic ingredients. Several industry commenters suggested that nonorganic ingredients in "made with * * *" products must be "natural" (nonsynthetic agricultural substances) and not be artificially produced. Commenters argued that all ingredients in "made with * * *" and less than 70 percent products should be produced in accordance with the prohibited practices under sections 205.105 and 205.301(f). A significant number of

commenters opposed identification of organic ingredients in what they called "natural food" products.

First, we do not agree that the nonorganic ingredients in "made with * * *" products must be restricted to only "natural" products. Such restrictions on the composition of nonorganic ingredients would significantly reduce handlers' options in producing those products and, thus, reduce consumers' options in purchasing products with organic ingredients.

Regarding prohibited practices, this rule implements the strong industry and consumer demand that the prohibited practices found under section 205.105 (excluded methods, irradiation, and sewage sludge) not be used in nonorganic ingredients in "made with * * *" products. However, we do not believe that restrictions on use of the other prohibited practices, found in section 205.301(f), would further the purposes of the Act. Application of all prohibited practices on the nonorganic ingredients in the "made with * * *" and less-than 70 percent organic products would essentially require that those products be organically produced. The Act allows for products that are not wholly organic. We believe the "made with * * *" label and the labeling restrictions on the less-than 70 percent organic products clearly states to consumers that only some of the ingredients in those products are organically produced.

If accepted, these comments would unnecessarily restrict a handler's ability to truthfully represent and market a conventionally produced agricultural product with some organic ingredients. A handler should not be prohibited from making a truthful claim about some ingredients in a less than 70 percent organic product.

(6) *Alternative "Made With * * *" Labels.* A few SOP managers commented that the phrase, "made with * * *," is confusing. They stated that many processed foods contain at least 50 percent organic ingredients but do not make an organic claim on the pdp. They believe the label would be less confusing if it stated a minimum organic percentage rather than identifying the organic ingredients. They suggest the labeling category be changed to "contains at least 50 percent organic ingredients (or, as revised in this rule, "contains at least 70 percent organic ingredients").

We disagree. Identification of up to three organically produced ingredients or food groups on the pdp gives consumers useful, specific information about the product's organic ingredients.

This label, combined with the optional display of the percentage content on the pdp and required identification of organic ingredients, should provide enough information for consumers to make good decisions.

A few commenters contended that the statement "made with organic (specified ingredients)" is unclear and "open ended" and that consumers may assume the entire product is organically produced. The "made with * * *" labeling claim refers only to the organic ingredients and not to the whole product. We do not believe that consumers will be confused by the label.

(7) *Use of Other Terms as Synonymous for "Organic".* A few commenters representing international organic standards suggested that use of the terms, "biologic" and "ecologic," which are synonymous with "organic" in other countries, should be allowed under the NOP. Commenters claimed these terms are approved by Codex and their inclusion in this regulation would facilitate international trade and equivalency agreements.

These terms were addressed in the proposed rule and are not accepted. Under the NOP, these terms may be used as eco-labels on a product package but may not be used in place of the term, "organic." Although such terms may be considered synonymous with "organic" in other countries, they are not widely used or understood in this country. We believe their use as synonymous for "organic" would only lend to consumer confusion. Regarding the Codex labeling standard, we point out that Codex also provides that terms commonly used in a country may be used in place of "biologic" and "ecologic." Thus, the use of "organic" in the United States is consistent with Codex standards.

With regard to the commenters' claim that the alternate labels would facilitate international trade, this regulation allows alternative labeling of products which are being shipped to international markets. Thus, a certified organic operation in the United States may produce a product to meet contracted organic requirements of a foreign buyer, label the product as "biologic" or "ecologic" on the pdp consistent with the market preferences of the receiving country, and ship the product to the foreign buyer.

Other terms were suggested by commenters as alternatives to the term, "organic," including "grown by age-old, natural methods," "grown without chemical input," and "residue Free." These phrases may be consumer friendly but clearly do not convey the

extensive and complex nature of contemporary organic agriculture. These phrases may be used as additional, eco-labels, provided they are truthful labeling statements. They are not permitted as replacements for the term, "organic."

(8) *Reconstituted Organic Concentrates*. A certifying agent objected to paragraph (a)(2) of section 205.302, which allows labeling of an organically produced concentrate ingredient which is reconstituted with water during assembly of the processed product. The commenter claimed that this provision gives consumers the message that reconstituted juice is equivalent to fresh juice when, the commenter claims, it is not the same.

AMS disagrees. This labeling is consistent with current industry practices. The Act does not prohibit such labeling of concentrates. We believe it is in the interest of the program to allow labeling of organically produced concentrates, provided that the process to produce the concentrate and the reconstitution process is consistent with organic principles and the National List.

(9) *Calculating Reconstituted Versus Dehydrated Weight*. Several comments were received regarding specific problems encountered in the calculation of the percentage of organic content as provided under section 295.302. A handler claimed the reconstituted weight of an organically produced spice should be counted in the percentage calculation rather than the dehydrated weight of the spice used in the formulation. A similar comment was received from a food cooperative suggesting that, if an organically produced concentrate (in powdered form) is added to the same organically produced ingredient in its organic liquid form (not from concentrate), then the product's organic percentage should be calculated based on the concentrate's single-strength reconstituted weight plus the weight of the natural organic liquid.

AMS disagrees with these comments. This regulation provides for an ingredient's weight to be calculated, excluding added water and salt. If an organically produced spice is added to a product in its natural form, the weight of the spice is calculated. If the spice ingredient is in dehydrated, powdered form when added in the product formulation, the dehydrated weight of the spice must be the basis for its percentage of content calculation. If an organically produced dehydrated spice is reconstituted with water prior to product assembly, the spice must still be calculated at its dehydrated weight

because percentage calculations are based on the ingredient weight, excluding water and salt. It would be misleading to calculate the weight of the concentrate ingredient in its reconstituted form.

Likewise, if a powdered ingredient is added to the same organically produced ingredient in its natural, liquid form, the weight of the powdered ingredient must be used. Using the reconstituted weight of the powdered ingredient would increase the percentage of the ingredient above the actual weight of the ingredient in the product. We believe that if the comment were accepted, the handler would be able to use less natural organic liquid than the organic percentage and ingredient statement indicates.

(10) *Calculate Organic Percentage in Tenths of a Percent*. A trade organization suggested that the organic percentage be rounded to tenths of one percent to accommodate products that may contain a minor ingredient or additive that comprises less than 1 percent of the product. The example provided was Vitamin D in milk. The comment suggested that it is misleading to consumers to suggest that 1 percent of a milk product is nonorganic when the Vitamin D additive may be comprise only a few tenths of one percent of the product.

AMS disagrees. Rounding down the percentage to a whole number is sufficient for consumer information and does not misrepresent the product's organic content. A handler may add a qualifying statement regarding the minor ingredient's weight in relation to the whole product weight.

(11) *Verifying Calculations*. A State department of agriculture comment suggested that the paragraph (c) of section 205.302 be revised slightly to provide that percentage calculations must be verified "to the satisfaction" of the certifying agent. The commenter believes that the suggested language allows the handler the flexibility to determine the number calculations that need to be checked in order to verify that the organic percentage calculation is correct.

We do not believe the suggested change is necessary. We assume that any use of a certifying agent's seal on a product means that the certifying agent has checked and approves of the method of calculating the product's organic percentage. If the calculations are not to the certifying agent's satisfaction, the agent would not certify the handling process.

While we appreciate the point made by the commenter, we do not believe the suggested change means what the

commenter intends. Paragraph (c) of section 205.302 does not specify the number and methods of calculations that need to be carried out by a certifying agent because that will depend on the handling process being certified and the ingredients in the product. We leave that to the discretion of the certifying agent. Also, the basis for a product's organic percentage calculation should be clarified in the organic plan. It is assumed that the certifying agent will either be satisfied that the methodology for calculating organic percentage is correct or the methodology will be changed.

(12) *Labeling Nonretail Shipping Containers*. A few State departments of agriculture commented that shipping and storage containers with organic products should be required to be labeled as containing organic product. Other commenters recommended that shipping containers be required to display the name of the grower and the certifying agent. They cite these requirements as current industry practice.

This regulation does not require organic labeling on shipping and storage containers because those containers are not used in the marketplace. The only information required by the NOP is the production lot number of the product, if a lot number exists for the particular product. Product content and shipper information may be displayed, as required by other Federal or State regulations or at the discretion of the handler. Proper identification of the organic nature of a product with special instructions for shipment or storage could prevent exposure to prohibited substances that would lead to subsequent loss of the shipment as an organic product.

(13) *Disclaimers on Organic Products*. Several commenters complained that consumers are misled by the organic labeling and the NOP. They claimed that when science-based technologies (genetic engineering, irradiation, chlorination, etc.) are not used on products, the food is less safe than conventionally produced foods. Some of the commenters suggested that a disclaimer regarding food safety and nutritional value be required on packages with organic labeling.

AMS disagrees. The USDA seal indicates only that the product has been certified to a certain production and/or handling "process" or "system." The seal does not convey a message of food safety or more nutritional value. The NOP prohibitions on use of excluded methods, ionizing radiation, sewage sludge, and some substances and materials are not intended to imply that

conventionally produced products made by those methods or containing those prohibited substances are less safe or nutritious than organically produced products. We do not believe that organic food packages or labeling should carry disclaimers of what the USDA seal or a certifying agent's seal does not represent. Other Federal and State seals and marketing claims are placed on consumer products, including food products, without disclaimers regarding those seals and claims. A disclaimer displayed in relation to USDA seal or a certifying agent's seal would confuse consumers. Finally, disclaimer statements also would present space problems on small product packages.

Labeling—Clarifications

Clarification is given on the following issues raised by commenters:

(1) *Certification Is to an Organic Process, Not Organic Product.* Several commenters suggested that the final rule more clearly state that the NOP provides for certification of an organic process or system of agriculture and not certification of products, themselves, as "organic." They stated that the phrase "* * * contain or be created using * * *" in paragraphs (a), (b), and (c) of section 205.301 implies certification of the product's content and not to the processed-based, organic system of agriculture.

We agree and have revised the wording in those paragraphs to clarify that such products must be organically produced in accordance with organic production and handling requirement of this regulation.

(2) *Phasing Out Use of Old Labels and Packages.* Citing FDA regulations, the NOSB, certifying agents, and some State agencies suggested a minimum 18-month period for handlers to use up their current supplies of packages and labels before complying with the new labeling requirements.

This rule provides for an interim period of 18 months between publication of the final rule and the implementation date of the program. Publication of this final rule serves notice to certified producers and handlers that they should begin planning for phasing out use of labels that are not in accordance with these requirements.

The implementation process is discussed in Applicability, subpart B. An organic operation will automatically be certified under this program when its certifying agent is accredited by AMS. At that time, the operation may begin following these labeling requirements but may not display the new USDA seal until the implementation date. AMS

assumes that certifying agents and their client certified operations will maintain frequent contact as to the status of the agent's application for accreditation so that the certified operation may schedule the phasing out of old labels and purchase of new labels and packages. AMS expects to accredit all currently operating certifying agents by the implementation date of this regulation. Stick-on labels to comply with the new requirements are acceptable.

Newly established organic operations certified for the first time must immediately begin using labels in accordance with this program.

(3) *Labeling of Products With Minor Ingredients.* Several commenters questioned how the minor ingredients (spices, flavors, colorings, preservatives, oils, vitamins, minerals, accessory nutrients, processing aids, and incidental food additives) needed for formulation or processing of many multiingredient products will be treated under the "100 percent organic" and "organic" labeling categories. Because minor ingredients may not exist or are difficult to obtain in organic form, their use in a product can affect the labeling of the product, even though the percentage of the ingredient is extremely small compared to the rest of the product's ingredients.

Minor ingredients and processing aids must be treated as any other ingredient or substance which is used as an ingredient in or in the processing of an organically produced product. To be added as an ingredient or used in the processing of a product labeled "100 percent organic," a minor ingredient must be extracted from a certified organic source without the use of chemicals or solvents. To be added as an ingredient or used in the processing of a product labeled "organic," a minor ingredient must be from an organic agricultural source, if commercially available. If not commercially available, the ingredient must be an agricultural product or a substance consistent with the National List.

(4) *Reusing Containers.* A commenter complained that small producers should not be subjected to costly packaging and labeling requirements when their products are sold directly to the public at farmers markets and roadside stands. The commenter requested that small producers be able to reuse retail boxes and labels. The commenter did not specify which labeling provisions presented burdensome costs on small entities.

We agree that costs for exempt operations, indeed all organic operations, should be kept to a

minimum. NOP does not prohibit reuse of containers provided their labeling does not misrepresent product and does not allow organic product to come into contact with prohibited substances from the container's previous contents.

(5) *Clarifying Prohibited Labeling Practices.* Commenters identified a few inconsistencies between the preamble and regulatory text regarding the seven prohibited production and processing practices now specified in section 205.301(f). We have made the following changes to clarify the intent of the regulation.

A commenter correctly pointed out that the regulatory text of paragraph (f) incorrectly refers only to ingredients that cannot be produced using the seven prohibited production and handling practices listed in the paragraph. That text is not consistent with the preamble, which correctly states that whole products, as well as ingredients, labeled as "organic" cannot be produced or processed using the seven prohibited practices. The term, "whole products," is added to the introductory sentence of new section 205.301(f).

A few commenters pointed out that all seven practices are prohibited in the production of nonorganic ingredients used in products labeled as "organic." The second sentence of proposed paragraph (b) of section 205.301 (products labeled "organic") incorrectly listed only the first three prohibited practices. A phrase is added to the introductory sentence of new paragraph (f) to specify that the 5 percent or less of nonorganic ingredients in products labeled as "organic" may not be produced or handled using any of the seven prohibited practices.

Finally, with the addition of the commercial availability requirement in section 205.201, a conforming change is needed in section 205.301(f)(6) regarding use of nonorganic ingredients when organically produced ingredients are available.

(6) *Consistency with State Labeling Requirements.* One State organic association commented that the State's law requires identification of the certifying agent if the term, "certified organic," appears on the label. The comment was not clear about where on the package the certifier must be identified; e.g., with the "certified organic" term on the pdp or anywhere on the package. The commenter did not specifically suggest changing the labeling provisions to include the certifying agent on the pdp.

This regulation allows a handler the option of displaying the certifying agent's seal or logo on the pdp for products with 70 percent or more

organically produced ingredients. This regulation also requires identification of the certifying agent on the information panel of all products containing 70 percent or more organically produced ingredients. The identification must include an address or contact information and be placed adjacent to identification of the manufacturer, required by FDA. We believe these provisions are sufficient to meet the State's labeling requirements. The NOP will be available to consult with States regarding alternative labeling required to be used in the State.

(7) *Clarifying Labeling of Products in Other Than Packaged Form.* We have modified sections 205.308 and 205.309 to clarify that products in other than packaged form at the point of retail sale that are prepared by an exempt or excluded operation may be labeled as "100 percent organic," "organic," or "made with * * *" as appropriate. Consistent with the general restrictions on the labeling of products from such operations, which are found in section 205.310, such products may not display the USDA seal or any certifying agent's seal or other identifying mark or otherwise be represented as a certified organic product.

Subpart E—Certification

This subpart sets forth the requirements for a national program to certify production and handling operations as certified organic production or handling operations. This certification process will be carried out by accredited certifying agents.

Description of Regulations

General Requirements

Production and handling operations seeking to receive or maintain organic certification must comply with the Act and applicable organic production and handling regulations. Such operations must establish, implement, and annually update an organic production or handling system plan that is submitted to an accredited certifying agent. They must permit on-site inspections by the certifying agent with complete access to the production or handling operation, including noncertified production and handling areas, structures, and offices.

As discussed in subpart B, certified operations must maintain records concerning the production and handling of agricultural products that are sold, labeled, or represented as "100 percent organic," "organic," or "made with organic (specified ingredients or food group(s))" sufficient to demonstrate compliance with the Act and

regulations. Records applicable to the organic operation must be maintained for not less than 5 years beyond their creation. Authorized representatives of the Secretary, the applicable State organic program's (SOP) governing State official, and the certifying agent must be allowed access to the operation's records during normal business hours. Access to the operation's records will be for the purpose of reviewing and copying the records to determine compliance with the Act and regulations.

Certified operations are required to immediately notify the certifying agent concerning any application, including drift, of a prohibited substance to any field, production unit, site, facility, livestock, or product that is part of the organic operation. They must also immediately notify the certifying agent concerning any change in a certified operation or any portion of a certified operation that may affect its compliance with the Act and regulations.

Certification Process

To obtain certification, a producer or handler must submit an application for certification to an accredited certifying agent. The application must contain descriptive information about the applicant's business, an organic production and handling system plan, information concerning any previous business applications for certification, and any other information necessary to determine compliance with the Act.

Applicants for certification and certified operations must submit the applicable fees charged by the certifying agent. An applicant may withdraw its application at anytime. An applicant who withdraws its application will be liable for the costs of services provided up to the time of withdrawal of the application.

The certifying agent will decide whether to accept the applicant's application for certification. A certifying agent must accept all production and handling applications that fall within its area(s) of accreditation and certify all qualified applicants to the extent of its administrative capacity to do so. In other words, a certifying agent may decline to accept an application for certification when the certifying agent is not accredited for the area to be certified or when the certifying agent lacks the resources to perform the certification. However, the certifying agent may not decline to accept an application on the basis of race, color, national origin, gender, religion, age, disability, political beliefs, sexual orientation, or marital or family status.

Upon acceptance of an application for certification, a certifying agent will review the application to ensure completeness and to determine whether the applicant appears to comply or may be able to comply with the applicable production or handling regulations. As part of its review, the certifying agent will verify that an applicant has submitted documentation to support the correction of any noncompliances identified in a previously received notification of noncompliance or denial of certification. We anticipate that at a future date the certifying agent will also review any available U.S. Department of Agriculture (USDA) data on production and handling operations for information concerning the applicant.

We anticipate using data collected from certifying agents to establish and maintain a password-protected Internet database only available to accredited certifying agents and USDA. This database would include data on production and handling operations issued a notification of noncompliance, noncompliance correction, denial of certification, certification, proposed suspension or revocation of certification, and suspension or revocation of certification. Certifying agents would use this Internet database during their review of an application for certification. This data will not be available to the general public because much of the data would involve ongoing compliance issues inappropriate for release prior to a final determination.

After a complete review of the application, which shall be conducted within a reasonable time, the certifying agent will communicate its findings to the applicant. If the review of the application reveals that the applicant may be in compliance with the applicable production or handling regulations, the certifying agent will schedule an on-site inspection of the applicant's operation to determine whether the applicant qualifies for certification. The initial on-site inspection must be conducted within a reasonable time following a determination that the applicant appears to comply or may be able to comply with the requirements for certification. The initial inspection may be delayed for up to 6 months to comply with the requirement that the inspection be conducted when the land, facilities, and activities that demonstrate compliance or capacity to comply can be observed.

The certifying agent will conduct an initial on-site inspection of each production unit, facility, and site that produces or handles organic products and that is included in the applicant's

operation. As a benchmark, certifying agents should follow auditing guidelines prescribed by the International Organization for Standardization Guide 10011-1, "Guidelines for auditing quality systems—Part 1: Auditing" (ISO Guide 10011-1).¹ The certifying agent will use the on-site inspection in determining whether to approve the request for certification and to verify the operation's compliance or capability to comply with the Act and regulations. Certifying agents will conduct on-site inspections when an authorized representative of the operation who is knowledgeable about the operation is present. An on-site inspection must also be conducted when land, facilities, and activities that demonstrate the operation's compliance with or capability to comply with the applicable production or handling regulations can be observed.

The on-site inspection must verify that the information provided to the certifying agent accurately reflects the practices used or to be used by the applicant or certified operation and that prohibited substances have not been and are not being applied to the operation. Certifying agents may use the collection and testing of soil; water; waste; plant tissue; and plant, animal, and processed products samples as tools in accomplishing this verification.

The inspector will conduct an exit interview with an authorized representative of the operation who is knowledgeable about the inspected operation to confirm the accuracy and completeness of inspection observations and information gathered during the on-site inspection. The main purpose of this exit interview is to present the inspection observations to those in charge of the firm in such a manner so as to ensure they clearly understand the results of the inspection. The firm is not required to volunteer any information during the exit interview but would be required to respond to questions or requests for additional information. The inspector will raise and discuss during the exit interview any known issues of concern, taking into account their perceived significance. As a general rule, the inspector will not make recommendations for improvements to

the operation during the exit interview. However, the certifying agent will have the discretion to decide the extent to which an inspector may discuss any compliance issue. At the time of the inspection, the inspector shall provide the operation's authorized representative with a receipt for any samples taken by the inspector. There shall be no charge to the inspector for the samples taken.

The certifying agent shall, within a reasonable time, provide the inspected operation with a copy of the on-site inspection report, as approved by the certifying agent, for any on-site inspection performed and provide the operation with a copy of the test results for any samples taken by an inspector.

Notification of Approval

A certifying agent will review the on-site inspection report, the results of any analyses for substances, and any additional information provided by the applicant within a reasonable time after completion of the initial on-site inspection. The certifying agent will grant certification upon making two determinations: (1) that the applicant's operation, including its organic system plan and all procedures and activities, is in compliance with the Act and regulations and (2) that the applicant is able to conduct operations in accordance with its organic systems plan.

Upon determining the applicant's compliance and ability to comply, the agent will grant certification and issue a "certificate of organic operation." The certification may include requirements for the correction of minor noncompliances within a specified time period as a condition of continued certification. A certificate of organic operation will specify the name and address of the certified operation; the effective date of certification; the categories of organic operation, including crops, wild crops, livestock, or processed products produced by the certified operation; and the name, address, and telephone number of the certifying agent. Once certified, a production or handling operation's organic certification continues in effect until surrendered by the organic operation or suspended or revoked by the certifying agent, the SOP's governing State official, or the Administrator.

Denial of Certification

Should the certifying agent determine that the applicant is not able to comply or is not in compliance with the Act, the certifying agent will issue a written notification of noncompliance to the applicant. The notification of

noncompliance will describe each noncompliance, the facts on which the notification is based, and the date by which rebuttal or correction of each noncompliance must be made. Applicants who receive a notification of noncompliance may correct the noncompliances and submit, by the date specified, a description of correction and supporting documentation to the certifying agent. As an alternative, the applicant may submit a new application to another certifying agent, along with the notification of noncompliance and a description of correction of the noncompliances and supporting documentation. Applicants may also submit, by the date specified, written information to the issuing certifying agent to rebut the noncompliance described in the notification of noncompliance. When a noncompliance cannot be corrected, a notification of noncompliance and a "notification of denial of certification" may be combined in one notification.

The certifying agent will evaluate the applicant's corrective actions taken and supporting documentation submitted or the written rebuttal. If necessary, the certifying agent will conduct a followup on-site inspection of the applicant's operation. When the corrective action or rebuttal is sufficient for the applicant to qualify for certification, the certifying agent will approve certification. When the corrective action or rebuttal is not sufficient for the applicant to qualify for certification, the certifying agent will issue the applicant a written notice of denial of certification. The certifying agent will also issue a written notice of denial of certification when an applicant fails to respond to the notification of noncompliance. The notice of denial of certification will state the reasons for denial and the applicant's right to reapply for certification, request mediation, or file an appeal.

An applicant who has received a notification of noncompliance or notice of denial of certification may apply for certification again at any time with any certifying agent. When the applicant submits a new application to a different certifying agent, the application must include, when available, a copy of the notification of noncompliance or notice of denial of certification. The application must also include a description of the actions taken, with supporting documentation, to correct the noncompliances noted in the notification of noncompliance. When a certifying agent receives such an application, the certifying agent will treat the application as a new

¹ ISO Guide 10011-1 is available for viewing at USDA-AMS, Transportation and Marketing Programs, Room 2945-South Building, 14th and Independence Ave., SW, Washington, DC, from 9:00 a.m. to 4:00 p.m., Monday through Friday (except official Federal holidays). A copy may be obtained from the American National Standards Institute, 11 West 42d Street, New York, NY 10036; Website: www.ansi.org; E-mail: ansionline@ansi.org; Telephone: 212-642-4900; Facsimile: 212-398-0023.

application and begin a new application process.

A certifying agent has limited authority to deny certification without first issuing a notification of noncompliance. This authority may be exercised when the certifying agent has reason to believe that an applicant for certification has willfully made a false statement or otherwise purposefully misrepresented its operation or its compliance with the requirements for certification.

Continuation of Certification

Each year, the certified operation must update its organic production or handling system plan and submit the updated information to the certifying agent and pay the certification fees to continue certification. The updated organic system plan must include a summary statement, supported by documentation, detailing deviations from, changes to, modifications to, or other amendments to the previous year's organic system plan. The updated organic system plan must also include additions to or deletions from the previous year's organic system plan, intended to be undertaken in the coming year. The certified operation must update the descriptive information about its business and other information as deemed necessary by the certifying agent to determine compliance with the Act and regulations. The certified operation must also provide an update on the correction of minor noncompliances previously identified by the certifying agent as requiring correction for continued certification.

Following receipt of the certified operation's updated information, the certifying agent will, within a reasonable time, arrange and conduct an on-site inspection of the certified operation. When it is impossible for the certifying agent to conduct the annual on-site inspection following receipt of the certified operation's annual update of information, the certifying agent may allow continuation of certification and issue an updated certificate of organic operation on the basis of the information submitted and the most recent on-site inspection conducted during the previous 12 months. However, the annual on-site inspection must be conducted within the first 6 months following the certified operation's scheduled date of annual update. As a benchmark, certifying agents should follow auditing guidelines prescribed by ISO Guide 10011-1. Upon completion of the inspection and a review of updated information, the certifying agent will determine whether the operation

continues to comply with the Act and regulations. If the certifying agent determines that the operation is in compliance, certification will continue. If any of the information specified on the certificate of organic operation has changed, the certifying agent will issue an updated certificate of organic operation. If the certifying agent finds that the operation is not complying with the Act and regulations, a written notification of noncompliance will be issued as described in section 205.662.

In addition to annual inspections, a certifying agent may conduct additional on-site inspections of certified operations that produce or handle organic products to determine compliance with the Act and regulations. The Administrator or SOP's governing State official may also require that additional inspections be performed by the certifying agent to determine compliance with the Act and regulations. Additional inspections may be announced or unannounced and would be conducted, as necessary, to obtain information needed to determine compliance with identified requirements.

Such on-site inspections would likely be precipitated by reasons to believe that the certified operation was operating in violation of one or more requirements of the Act or these regulations. The policies and procedures regarding additional inspections, including how the costs of such inspections are handled, would be the responsibility of each certifying agent. Misuse of such authority would be subject to review by USDA during its evaluation of a certifying agent for reaccreditation and at other times in response to complaints. Certified production and handling operations can file complaints with USDA at any time should they believe a certifying agent abuses its authority to perform additional inspections.

Certification After Suspension or Revocation of Certifying Agent's Accreditation

When the Administrator revokes or suspends a certifying agent's accreditation, affected certified operations will need to make application for certification with another accredited certifying agent. The certification of the production or handling operation remains in effect during this transfer of the certification. The certified production or handling operation may seek certification by any qualified certifying agent accredited by the Administrator. To minimize the burden of obtaining the new certification, the Administrator will

oversee transfer of the original certifying agent's file on the certified operation to the operation's new certifying agent.

Upon initiation of suspension or revocation of a certifying agent's accreditation or upon suspension or revocation of a certifying agent's accreditation, the Administrator may initiate proceedings to suspend or revoke the certification of operations certified by the certifying agent. The Administrator's decision to suspend or revoke a producer's or handler's certification in light of the loss of its certifying agent's accreditation would be made on a case-by-case basis. Actions such as fraud, bribery, or collusion by the certifying agent, which cause the Administrator to believe that the certifying agent's clients do not meet the standards of the Act or these regulations, might require the immediate initiation of procedures to suspend or revoke certification from some or all of its client base. Removal of accreditation, regardless of the reason, in no way affects the appeals rights of the certifying agent's clients. Further, a certified operation's certification will remain in effect pending the final resolution of any proceeding to suspend or revoke its certification.

A private-entity certifying agent must furnish reasonable security for the purpose of protecting the rights of operations certified by such certifying agent. This security is to ensure the performance of the certifying agent's contractual obligations. As noted elsewhere in this rule, the specific amount and type of security that must be furnished by a private certifying agent will be the subject of future rulemaking by USDA. We anticipate that the amount of the security will be tied to the number of clients served by the certifying agent and the anticipated costs of certification that may be incurred by its clients in the event that the certifying agent's accreditation is suspended or revoked. We anticipate that the security may be in the form of cash, surety bonds, or other financial instrument (such as a letter of credit) administered in a manner comparable to cash or surety bonds held under the Perishable Agricultural Commodities Act.

Certification—Changes Based on Comments

This subpart differs from the proposal in several respects as follows:

(1) *Access to Production and Handling Operation.* We have amended section 205.400(c) by changing “noncertified areas and structures” to “noncertified production and handling

areas, structures, and offices.” A commenter requested that section 205.400(c) be amended to allow for access to farm-related structures only. The commenter believes that the requirements of section 205.400(c) could be interpreted as giving inspectors access to residential property. We agree with the commenter that residential privacy should be maintained. However, if a certified operation conducts business from or stores records at a residential property, the certified operation will be considered to be maintaining an office at the residential property. The records in such office shall be made accessible for review and copying. Accordingly, we have amended section 205.400(c) to further clarify which areas and structures are to be made accessible during an on-site inspection.

(2) *Application for Certification.* We have amended the first paragraph of section 205.401 by replacing the word, “request,” each time it occurred with the word, “application.” A commenter recommended that we amend the first paragraph of section 205.401 by replacing the word, “request,” with “application.” We have accepted the commenter’s recommendation because the amendment makes the language in the first paragraph consistent with the title and the requirements of the section.

(3) *Verification of Correction of Noncompliances.* To make section 205.402(a)(3) consistent with section 205.401(c) we have amended the language in section 205.402(a)(3) to require that the certifying agent verify that an applicant who previously applied to another certifying agent and received a notification of denial of certification has submitted documentation to support the correction of any noncompliances identified in the notification of denial of certification. A commenter recommended that section 205.402(a)(3) be amended by inserting “or denial of certification” after the phrase, “notification of noncompliance.” We have accepted the commenter’s recommended amendment because it is consistent with the requirements of section 205.401(c). Section 205.401(c) requires an applicant for certification to include the name(s) of any organic certifying agent(s) to which application has previously been made, the year(s) of application, and the outcome of the application(s) submission. The applicant is also required to include, when available, a copy of any notification of noncompliance or denial of certification issued to the applicant for certification. The words, “when available,” have been added to this requirement in this final

rule to satisfy concerns regarding the status of applicants who cannot find or no longer have a copy of any notification of noncompliance or denial of certification previously received. We see no down side to relaxing this requirement since the applicant must still comply with each of the other provisions in section 205.401(c), including the requirement that the applicant include a description of the actions taken to correct the noncompliances noted in any notification of noncompliance or denial of certification, including evidence of such correction. Further, the certifying agent will be using USDA’s database of certification actions during its review of an application for certification.

(4) *Timely Communication to the Applicant.* We have amended section 205.402(b), by requiring at paragraph (b)(1) that the certifying agent, within a reasonable time, review the application materials received and communicate its findings to the applicant. A commenter requested that we amend section 205.402(b) which required a certifying agent to communicate to the applicant its findings on the review of application materials submitted by the applicant. Specifically, the commenter requested that section 205.402(b) be amended by adding to the end thereof, “in a timely manner so as to prevent the avoidable tillage of native habitat that had been identified in the application as lands for organic production.”

We concur that certification decisions should be timely. There are many reasons (e.g., financial and contractual) for why certification must be timely. It would be impractical, however, to attempt to address all of the reasons for timely certification in these regulations. We have, therefore, amended section 205.402(b) as noted above. This amendment is consistent with the requirement in section 205.402(a) that the certifying agent, upon acceptance of an application for certification, review the application for completeness, determine by a review of the application materials whether the applicant appears to comply or may be able to comply with the requirements for certification, and schedule an on-site inspection. The “upon acceptance” requirement necessitates that the certifying agent review the application for certification and provide feedback to the applicant in a timely manner.

(5) *On-site Inspections.* We have amended section 205.403(a)(1) by specifying that the initial and annual on-site inspections of each production unit, facility, and site in an operation applies to those units, facilities, and sites that produce or handle organic

products. A commenter recommended that section 205.403(a)(1) be amended to specify that on-site inspections of each production unit, facility, and site will include just those that produce or handle organic products. The commenter stated that this change was necessary because some retail corporations choose to certify all store locations regardless of whether the location sells organic products. The commenter went on to say that, if a location does not stock any organic products, the certifying agent should have the discretion to modify the inspection requirement.

We have excluded all retail food establishments from certification. The exclusion is found in section 205.101(b)(2). Accordingly, the commenter’s recommendation is not applicable to retail food establishments. We have, however, made the recommended amendment to section 205.403(a)(1) because of its potential applicability to other operations which may apply for certification.

(6) *Scheduling Initial On-site Inspection.* We have amended section 205.403(b) to provide that the initial inspection may be delayed for up to 6 months to comply with the requirement that the inspection be conducted when the land, facilities, and activities that demonstrate compliance or capacity to comply with the organic production and handling requirements can be observed. We received a comment stating that if an application is received in January for a crop that will be planted in May, it would be necessary to delay the inspection until late May or June to observe the crop in the field. The commenter went on to say that the alternative would be to conduct the initial inspection before the crop is planted, in order to meet the “within a reasonable time” requirement, and then conduct a reinspection during the growing season. The commenter recommended amending section 205.403(b) to allow the certifying agent to delay the initial on-site inspection until the land, facilities, and activities that demonstrate compliance or capacity to comply can be observed.

We have accepted the recommendation because there may be situations where a later on-site inspection will prove mutually beneficial to the certifying agent and the operation to be inspected. However, certifying agents are reminded that the operation may be certified following a demonstration that the operation is able to comply with the organic production and handling requirements found in subpart C of these regulations. Accordingly, certifying agents should

not unnecessarily delay the certification of an organic production or handling operation by insisting that the inspection only be performed when the operation can demonstrate its actual compliance with the organic production and handling requirements. Applicants who believe that the certifying agent is abusing its authority to delay the on-site inspection may file a complaint with the Administrator.

We have also amended the second sentence in section 205.403(b) by inserting the word, "all," and removing both references to "applicant" to clarify that the provision applies to all on-site inspections.

(7) *Exit Interview.* We have amended section 205.403(d) by requiring that the inspector conduct an exit interview with "an authorized representative of the operation who is knowledgeable about the inspected operation" rather than "an authorized representative of the inspected operation" as required in the proposed rule. This amendment is consistent with the requirement in section 205.403(b) that an on-site inspection be conducted when an authorized representative of the operation who is knowledgeable about the operation is present.

A commenter requested that we define "authorized representative." Another commenter recommended changing the term, "authorized representative," to "responsible executive." Our amendment of section 205.403(d) responds to both of these comments by clarifying the qualifications of an authorized representative.

A third commenter stated that an exit interview is not a practical requirement and that an initial interview is often preferred. The commenter stressed that verification that the inspector has correctly understood what is presented is ongoing. This commenter also expressed the belief that there may be times when it may not be appropriate for the inspector to address issues of concern and that such issues may be best left to the certifying agent. The commenter recommended that the requirement for an exit interview be deleted or presented as an option. Another commenter suggested that issues of concern are often identified and discussed with the operation's representative during the course of the inspection. This commenter believes that it is unnecessarily confrontational to require an exit interview during which these issues of concern are repeated. This commenter recommended replacing the required exit interview with a communications provision that would require the

inspector to discuss the need for any additional information as well as any issues of concern. The recommended provision would also authorize the certifying agent to provide the applicant with a summary of the inspector's areas of concern.

While we agree that the language in section 205.403(d) needed clarification, we do not agree that the exit interview is impractical or unnecessarily confrontational. The exit interview is intended to give the inspector an opportunity to confirm the accuracy and completeness of inspection observations and information gathered during the on-site inspection, to request any additional information necessary to establish eligibility for certification, and to raise and discuss any known issues of concern. Issues of concern that may involve compliance issues will be handled as authorized by the certifying agent. The exit interview is also intended to give the inspected operation's authorized representative general information concerning the inspector's observations. Such exit interviews are required under ISO Guide 10011-1. Accordingly, requiring exit interviews is consistent with ISO standards and our expectation, as stated earlier in this preamble, that certifying agents benchmark their on-site inspection procedures to ISO Guide 10011-1.

(8) *On-site Inspection Documentation.* We have amended section 205.402(b) by adding the requirements that the certifying agent: (1) provide the applicant with a copy of the on-site inspection report, as approved by the certifying agent, for any on-site inspection performed and (2) provide the applicant with a copy of the test results for any samples taken by an inspector. We have also amended section 205.403 by adding a new paragraph (e) that requires the inspector, at the time of the inspection, to provide the operation's authorized representative with a receipt for any samples taken by the inspector. This new paragraph also addresses the requirement that the certifying agent provide the operation inspected with a copy of the inspection report and any test results. Having the certifying agent issue the on-site inspection report to the operation inspected is consistent with ISO Guide 65, section 11(b).

Several commenters recommended that section 205.403 be amended to require that the inspector issue a copy of the on-site inspection report to the operation at the exit interview. They also recommended that the inspector be required to provide the operation with a receipt for samples collected for

testing. The commenters, further, recommended that the certifying agent be required to provide the operation with a written report on the results of the testing performed on the samples taken. A commenter also recommended that the operation be paid for any samples taken. One of the commenters recommended that section 205.403 be amended by adding protocol for an exit interview.

We concur that the applicant for certification and certified operations should be provided with a copy of the on-site inspection report, a receipt for samples taken, and a copy of the test results for samples taken. Accordingly, we have amended sections 205.402(b) and 205.403 as noted above.

The protocol for an exit interview will be set forth in the certifying agent's procedures to be used to evaluate certification applicants, make certification decisions, and issue certification certificates. The NOP is available to respond to questions and to assist certifying agents in the development of these procedures which are required under section 205.504(b)(1). Accordingly, AMS is not amending the section to include a protocol for exit interviews. AMS is also not including a requirement that the certifying agent pay the applicant for samples taken, since such charges would just be charged back to the applicant as a cost for processing the applicant's application for certification.

(9) *Granting Certification.* We have amended the last sentence of section 205.404(a) by removing the word, "restrictions," and replacing it with "requirements for the correction of minor noncompliances within a specified time period." A commenter suggested that the last sentence of section 205.404(a) be amended to read: "The approval may include restrictions or requirements as a condition of continued certification, which includes a time line for fulfilling the requirement." Another commenter requested that we define "restrictions." This commenter also recommended amending section 205.404(a) to clarify the meaning of "restrictions" and to require corrective action by the operator within a specific time period. We agree with the commenters that the last sentence of section 205.404(a) was in need of further clarification. We also agree that it is appropriate for the regulations to require that the requirements for correction include a specified time period within which the corrections must be made. Accordingly, we amended section 205.404(a) as noted above. The certifying agent will make the determination of whether a violation

of the Act and regulations is minor. Minor noncompliances are those infractions that, by themselves, do not preclude the certification or continued certification of an otherwise qualified organic producer or handler. The certifying agent would be free to modify the time period for correction should it believe it to be appropriate.

We have also made editorial changes to section 205.404(a) consistent with suggestions we received on section 205.506. In the title to section 205.404 we have replaced "Approval of" with "Granting." In section 205.404(a) we have replaced "approve" with "grant" and "approval" with "certification." This change makes the language in section 205.404 consistent with ISO Guide 65, section 4.6, which addresses the granting of certification.

(10) *Payment of Fees.* We have amended the introductory statement within section 205.406(a) by adding the requirement that, to continue certification, a certified operation annually pay the certifying agent's certification fees. A commenter recommended amending section 205.404(c) by adding a sentence providing that a certified operation's failure to pay the certifying agent's certification fees may be a cause for suspension or revocation of certification. We agree that the issue of payment of fees should be addressed but not in section 205.404(c), which deals with the duration of a certified operation's certification. We believe the issue of payment of certification fees is more appropriately addressed in section 205.406, which deals with continuation of certification. Accordingly, we have amended section 205.406(a) to require payment of the certifying agent's fees as a condition of continued certification. This addition would allow a certifying agent to initiate suspension or revocation proceedings against any operation that fails to pay the required fees. The certifying agent is not required to initiate suspension or revocation proceedings for failure to pay the fees. In fact, the certifying agent is encouraged to use one or more of the legal debt collection alternatives available to it.

(11) *Denial of Certification.* We have amended section 205.405 to include noncompliance and resolution provisions originally included by cross-reference to section 205.662(a). We have made this amendment in response to a comment that these regulations do not provide an opportunity for a hearing upon denial of certification. We disagree with the commenter's assessment but have amended section 205.405(a) to eliminate confusion that may result

from the cross-reference to section 205.662(a). We have determined that section 205.662(a) may cause confusion for certification applicants because the section does not specifically address applicants.

As amended, section 205.405(a) required a written notification of noncompliance that describes each noncompliance, the facts on which the noncompliance is based, and the date by which the applicant must rebut or correct each noncompliance and submit supporting documentation of each such correction when correction is possible. Section 205.405(b) lists the options available to the applicant, including the options of correcting the noncompliance or submitting written information to rebut the noncompliance. Successful correction or rebuttal will result in an approval of certification. When the corrective action or rebuttal is not sufficient for the applicant to qualify for certification, the certifying agent will issue a written notice of denial of certification. This notice will state the reason(s) for denial and the applicant's right to request mediation in accordance with section 205.663 or to file an appeal in accordance with section 205.681.

(12) *Rebuttal of a Noncompliance.* We have amended section 205.405(b)(3) to clarify that rebuttal of a noncompliance shall be submitted to the certifying agent that issued the notification of noncompliance. We made this amendment in response to a commenter's question about who has authority to evaluate a written rebuttal.

(13) *Correction of Minor Noncompliances.* We have amended section 205.406(a) by adding a new paragraph (3) which requires the certified operation to include with its annual reporting an update on the correction of minor noncompliances previously identified by the certifying agent as requiring correction for continued certification. A commenter recommended adding at 205.406(a) a requirement that the certified operation address any restrictions that have been applied to its certification under 205.404(a). We agree with the commenter that the annual reporting by the certified operation should include an update addressing the certified operation's compliance with the certifying agent's requirements for the correction of minor noncompliances. Accordingly, we amended section 205.406(a) as noted above and redesignated paragraph (3) as paragraph (4). The certifying agent will make the determination of whether a violation of the Act and regulations is minor. Minor noncompliances are those infractions that, by themselves, do not preclude the

certification or continued certification of an otherwise qualified organic producer or handler.

(14) *Scheduling Annual On-site Inspections.* We have amended section 205.406(b) to provide that, when it is impossible for the certifying agent to conduct the annual on-site inspection following receipt of the certified operation's annual update of information, the certifying agent may allow continuation of certification and issue an updated certificate of organic operation on the basis of the information submitted and the most recent on-site inspection conducted during the previous 12 months. The annual on-site inspection, required by section 205.403, must, however, be conducted within the first 6 months following the certified operation's scheduled date of annual update.

A commenter expressed the belief that the requirement for an on-site inspection after receipt of the certified operation's annual update of information would have required that all annual on-site inspections be performed at the same time of the year. The commenter went on to express the belief that, to avoid inspecting certified operations twice a year, certifying agents would have to schedule the annual update to occur during the growing season in order to comply with the requirement for timing inspections when normal production activities can be observed. The commenter stated that certifying agents should be given more flexibility for scheduling inspections and conducting their certification programs according to management procedures best suited to their agency. The commenter recommended amending section 205.406(b) by adding to the end thereof: "or base the decision regarding eligibility for renewal on an on-site inspection conducted during the previous 12 months."

We agree with the commenter that certifying agents should be given more flexibility for scheduling on-site inspections so as to best meet the management needs of the certifying agent. Accordingly, we have amended section 205.406(b) to allow continuation of certification and issuance of an updated certificate of organic operation on the basis of the information submitted and the most recent on-site inspection conducted during the previous 12 months. This option will be available to the certifying agent when renewal is scheduled for a time when it is impossible to conduct the annual on-site inspection following receipt of the annual update and at a time when land, facilities, and activities that demonstrate the operation's compliance or capability

to comply can be observed. This change does not affect the requirement in section 205.403(a)(1) that the certifying agent conduct an annual on-site inspection of each certified operation. Further, the annual on-site inspection must be conducted within the first 6 months following the certified operation's scheduled date of annual update.

Certification—Changes Requested But Not Made

This subpart retains from the proposed rule regulations on which we received comments as follows:

(1) *Number of On-site Inspections.* A commenter recommended that section 205.403(a)(1) be amended by adding a requirement that production operations be under active organic management for the last year of the 3-year land conversion period and that two on-site inspections be performed prior to organic certification.

Section 205.403(a)(1) provides that the certifying agent must conduct an initial on-site inspection of each production unit, facility, and site that produces or handles organic products and that is included in an operation for which certification is requested. The requirement does not preclude a certifying agent from conducting additional on-site inspections, if necessary, to establish the applicant's eligibility for certification. The Act requires a 3-year period immediately preceding harvest, during which the production operation must be free from the application of prohibited substances. The Act does not, however, require that land be under active organic management during this period, and we do not believe such a requirement in these regulations is necessary. Such a requirement, for example, would necessitate some process for verifying that an operation is under active organic management, which would, in effect, require a certification-type decision a year before certification is granted and the operation can begin to label products as certified organic. Accordingly, we disagree with the commenter's recommendation that an operation be under active organic management for the last year of the 3-year land conversion and that two on-site inspections be required.

(2) *Unannounced Inspections.* A commenter recommended that section 205.403(a)(2)(iii) be amended to require additional unannounced inspections either by defining the circumstances under which the inspections should be undertaken or by setting a minimum percentage of unannounced inspections. The commenter claimed that 5 percent

is a common percentage adopted by certifying agents around the world.

Section 205.403 requires an initial on-site inspection, annual on-site inspection, and additional on-site inspections to determine compliance with the Act and regulations, to verify that information provided reflects actual practices, and to verify, through testing if necessary, that prohibited substances are not used by the operation. Because of the widely disparate nature of certified operations, we believe the certifying agent is in the best position to determine the need for additional on-site inspections. Accordingly, we have rejected the commenter's request that the regulations require additional unannounced visits either by defining the circumstances under which these should be undertaken or by setting a minimum percentage.

(3) *Timeliness of Certifying Agent Review Information.* A commenter requested that section 205.404(a) be amended to specify a timeframe of 60 days rather than "Within a reasonable time" as the time by which the certifying agent must review the on-site inspection report, the results of any analyses for substances, and any additional information requested from or supplied by the applicant.

Section 205.404(a) requires the certifying agent, within a reasonable time after completion of the initial on-site inspection, to review the on-site inspection report, the results of any analyses for substances conducted, and any additional information requested from or supplied by the applicant. Section 205.504(b)(1) requires the certifying agent to submit a copy of the procedures to be used to evaluate certification applicants, make certification decisions, and issue certification certificates. Such procedures and the certifying agent's performance in making timely certification decisions will be subject to review during accreditation and reaccreditation of the certifying agent. Certifying agents are expected to make timely decisions regarding whether to certify an applicant and whether a certified operation is in compliance with the Act and regulations. Applicants with complaints regarding timeliness of service could forward their complaints to the Administrator. Accordingly, timely service will be in the best interest of certifying agents since such complaints could have an impact on their reaccreditation or continued accreditation. Further, our original position is consistent with those commenters requesting flexibility in determining what constitutes reasonable time. Accordingly, we have

not amended section 205.404(a) as requested.

(4) *Categories of Organic Operation.* We received a variety of comments regarding the requirement that the certifying agent issue a certificate of organic operation which specifies the categories of organic operation, including crops, wild crops, livestock, or processed products produced by the certified operation. One commenter recommended that section 205.404(b)(3) be amended, with regard to processing, to only require a processing category to be specified on the certificate, such as food processing or feed processing. The commenter stated that it should not be necessary to list every product on the certificate. Specifically, the commenter recommended amending section 205.404(b)(3) by inserting the words, "general categories of," immediately in front of the word, "processed." Another commenter recommended amending section 205.404(b)(3) to require the identity of specific crops and the specific processing operations certified. Still another commenter requested that section 205.404(b) be amended by adding a new paragraph requiring that the certificate include the number of livestock of each species produced on the certified operation. This same commenter also recommended the addition of a new paragraph requiring that the certificate identify the specific location of each certified organic field and handling operation. We also received support for section 205.404(b)(3) as written. This commenter does not support the addition of information regarding the number of livestock or the location of fields.

We disagree with the suggestion that the certificate list every crop, wild crop, livestock, or processed product produced by the certified operation. We believe that listing categories of organic operation is sufficient. This does not, however, prevent the certifying agent, in cooperation with the certified operation, from listing specific crops, livestock, or processed products on the certificate. Such information could always be listed on the certificate when requested by the certified operation. We also disagree with the commenter who requested that certifying agents display the number of livestock of each species produced by the certified operation and the specific location of each certified organic field and handling operation. We do not believe it is necessary to list the quantity of product to be produced or handled at a certified operation, nor do we believe it is necessary to list the location of a certified operation's fields or facilities. Such information may,

however, be listed on the certificate upon the written request of the certified operation. By requiring the name, address, and telephone number of the certifying agent, the certificate would provide interested persons with a contact for obtaining releasable information concerning the certified operation. Further, the certifying agent is the first line of compliance under this program and, as such, is the person to whom all questions and concerns should be addressed about certified operations.

(5) *Annual Renewal of Certification.* Numerous commenters requested that section 205.404(b)(2) be amended to provide for the placement of an expiration date on the certificate of organic operation. The commenters want yearly expiration of certification and yearly expiration of the certificate of organic operation. Commenters also requested that section 205.404(c) be amended to provide that once certified, a production or handling operation's organic certification continues in effect until the expiration date on the certificate, until surrendered by the organic operation, or until suspended or revoked by the certifying agent, the SOP's governing State official, or the Administrator. Some commenters recommended the addition of a new paragraph 205.406(e) that would provide for automatic suspension of a certification if the certified operation did not provide the information required in paragraph 205.406(a) by the expiration date to be placed on the certificate of organic operation.

We disagree with the commenters who have requested annual renewal of certification and that the certified operation's certification and its certificate of organic operation expire annually. We prefer continuous certification due to the very real possibility that the renewal process might not always be completed before expiration of the certification period. Expiration of the certification period would result in termination of the operation's certification. Even a short period of interruption in an operation's organic status could have severe economic ramifications. Further, we believe that a regular schedule of expiration of certification is unnecessary inasmuch as all certified operations are required to annually update their organic system plan and submit any changes to their certifying agent. More importantly, unlike accreditation, where the Act provides for expiration and renewal, the Act does not provide for an expiration or renewal of certification. Therefore, it is also our position that once granted certification

the production or handling operation retains that certification until voluntarily surrendered or removed, following due process, for violation of the Act or these regulations.

(6) *Denial of Certification.* A commenter recommended that section 205.405(e) be amended to place a time restriction on reapplication for certification after denial of certification. The commenter suggested a 3-year period. We disagree with this recommendation because the reasons for denial include a wide range of noncompliances. The ability to correct noncompliances will vary as will the time needed to correct the noncompliances.

(7) *Production and Handling Operation Certification Following Suspension or Revocation of Certifying Agent Accreditation.* A few commenters requested amendment of section 205.406 through the addition of a new paragraph (f). Specifically, the commenters requested provisions that would provide for USDA notification of certified operations regarding the suspension or revocation of their certifying agent's accreditation. Some of these commenters requested that the provisions also allow the affected certified operation to use current market labels for a maximum period of 12 months, provided the certified operation made application for certification with another USDA-accredited certifying agent within 3 months of being notified of their certifying agent's suspension or revocation of accreditation. Another commenter requested that the new paragraph provide that the affected certified operation will continue to operate as if certified by the USDA and will be allowed to use current market labels for a maximum period of 12 months. The commenter stated that this amendment would provide the certified operation with the time needed to obtain recertification by an accredited certifying agent and to prepare new labels.

We disagree with the recommendations. USDA does not perform organic certification activities under any circumstance, including upon surrender, suspension, or revocation of an accredited certifying agent's accreditation. Operations certified by a certifying agent that surrenders or loses its USDA accreditation will be notified by USDA and given an opportunity to immediately begin seeking certification by the USDA-accredited certifying agent of their choice. Certified operations shall not affix the seal or other representation of a certifying agent to any product that they produce after the

certifying agent has surrendered or had its accreditation revoked. The certified operation may use the USDA organic seal. In the case of suspension of the certifying agent, the reasons for the suspension and the terms of the suspension will determine whether the certifying agent's certified operations will have to seek recertification or stop affixing the certifying agent's seal or other representation to their products. USDA will announce the suspension or revocation of a certifying agent's accreditation, and the announcement will address the status of operations certified by the certifying agent.

Certification—Clarifications

Clarification is given on the following issues raised by commenters as follows:

(1) *Recordkeeping.* A commenter stated that most computerized recordkeeping systems used at retail and wholesale are set up to save the data for a maximum of 2 years; adding 3 additional years to that requirement would be extremely costly as systems modifications and additional hardware and support would be required to meet the mandate. The commenter suggested that since food product is generally sold and consumed within a matter of months (if not weeks), shortening this requirement to 2 years should meet the goal for tracking of any product through the distribution system. This commenter was referring to the requirement in section 205.400(d) that records be maintained for not less than 5 years beyond their creation.

Section 205.103 requires that a certified operation maintain records; that the records be adapted to the particular business that the certified operation is conducting, fully disclose all activities and transactions of the certified operation in sufficient detail as to be readily understood and audited, be maintained for not less than 5 years beyond their creation, and be sufficient to demonstrate compliance with the Act and the regulations in this part; and that the certified operation must make such records available for inspection and copying during normal business hours by authorized representatives of the Secretary, the applicable SOP's governing State official, and the certifying agent. The requirements do not state in what form (i.e., paper, electronic, film) that the records must be maintained. Therefore, in answer to the commenter's concern, database records more than 2 years old could be stored in any form, including on an electronic storage device, which would permit retrieval upon request.

(2) *Application Fees.* A commenter recommended that section 205.401 be

amended by adding a new paragraph (e) which would require an applicant for certification to include, along with the other required application information, the application fees required by the certifying agent.

The requested language is unnecessary because section 205.400(e) requires submission of the applicable fees charged by the certifying agent as a general requirement for certification.

(3) *Applicant Identification.* In reference to section 205.401(c) a commenter stated that an applicant that is a corporation could easily change the name of the corporation in order to avoid having to report applications submitted and denied under the previous name. The commenter went on to state that there must be a database available to certifying agents that includes names and location addresses of operations that have received a notification of noncompliance, denial of certification, or a suspension or revocation of certification.

Section 205.401(b) requires the applicant to include in its application the name of the person completing the application; the applicant's business name, address, and telephone number; and, when the applicant is a corporation, the name, address, and telephone number of the person authorized to act on the applicant's behalf.

As we stated in the preamble to the proposed rule, we anticipate using the data collected under section 205.501(a)(15) to establish and maintain two Internet databases. The first Internet database would be accessible to the general public and would include the names and other appropriate data on certified organic production and handling operations. The second Internet database would be password protected and only available to accredited certifying agents and USDA. This second database would include data on production and handling operations issued a notification of noncompliance, noncompliance correction, denial of certification, certification, proposed suspension or revocation of certification, and suspension or revocation of certification. Certifying agents would use the second Internet database during their review of an application for certification.

(4) *Withdrawal of Application.* Several commenters expressed the belief that allowing an applicant to voluntarily withdraw its application will be used as a tool to avoid denial of certification. They expressed concern that voluntary withdrawal before denial of certification will allow the applicant to make

application with a different certifying agent with a clean record. These commenters were responding to the provision in section 205.402(e) which allows an applicant for certification to withdraw its application at any time.

We continue to believe that operations should not be unnecessarily stigmatized because they applied for certification before the operation was ready to meet all requirements for certification. While some operations may use voluntary withdrawal as a means to avoid the issuance of a notification of noncompliance or a notice of denial of certification, this should not adversely affect the National Organic Program (NOP) because all certifying agents are responsible for using qualified personnel in the certification process and for ensuring an applicant's eligibility for certification. Further, all applicants for certification are required under section 205.401(c) to include in their application the name(s) of any organic certifying agent(s) to which application has previously been made, the year(s) of application, and the outcome of the application(s) submission.

(5) *On-site Inspections.* Section 205.403(a)(2)(ii) provides that the Administrator or SOP's governing State official may require that additional inspections be performed by the certifying agent for the purpose of determining compliance with the Act and the regulations in this part. In commenting on this provision, a commenter asked, "Who is running this program: State or Federal officials?"

This is a national organic program administered by the Agricultural Marketing Service of the United States Department of Agriculture. States may administer their own organic program. However, all SOP's are subject to USDA approval. The National Organic Standards and a State's organic standards under a USDA-approved SOP are the National Organic Standards for that State. The State, under USDA's approval of the SOP, has enforcement responsibilities for the Federal and State components of the organic program within the State.

(6) *Verification of Information.* A commenter stated that section 205.403(c) is insufficiently comprehensive. The commenter stated that organic inspection is assessment of a process evaluated against comprehensive standards and, as such, it requires specific rules to provide confidence in the quality of the inspection. The commenter recommended amending section 205.403(c) by including requirements on minimum verification methods.

Section 205.403(c) identifies what must be verified during the on-site inspection. The details on how the verification will be accomplished will be set forth in the certifying agent's procedures to be used to evaluate certification applicants, make certification decisions, and issue certification certificates and the certifying agent's procedures for reviewing and investigating certified operation compliance with the Act and regulations. The NOP is available to respond to questions and to assist certifying agents in complying with the on-site inspection requirements, including those for the verification of information.

(7) *Notifying Customers of Change in Certification Status.* A commenter stated that the regulations do not indicate when a certified organic producer must stop using the organic seal or whether they must notify customers of their denial of certification. The commenter recommended amending section 205.405 to include a provision for notifying customers of a certified operation's change in certification status.

Any producer or handler who plans to sell, label, or represent its product as "100 percent organic," "organic," or "made with * * *" must be certified unless exempted under the small operation exemption under section 205.101(a)(1) or not regulated under the NOP (i.e., a producer of dog food). Only certified operations may represent themselves as certified. Operations denied certification may not represent their products as "100 percent organic," "organic," or "made with * * *". Operations that have had their certification suspended or revoked will be subject to the terms and conditions of their suspension or revocation relative to the labeling of product produced prior to the suspension or revocation. No product produced by an operation after suspension or revocation of certification may be sold, labeled, or represented as "100 percent organic," "organic," or "made with * * *".

Buyers of organic product can request to see the producer's or handler's certificate of organic operation. Operations that have lost their organic status will be unable to obtain an updated certificate. Buyers with questions regarding an operation's organic status may also contact the certifying agent identified on a certificate of organic operation. Further, as previously noted, we anticipate using the data collected under section 205.501(a)(15) to establish and maintain an Internet database accessible to the general public that will include the

names and other appropriate data on certified organic production and handling operations.

(8) *Continuation of Certification.* A few commenters recommended amending section 205.406 to include a safety net for producers who are certified by a certifying agent that does not become accredited by USDA. They stated that the rule must clearly state that a certified organic producer will have the full 18-month implementation period starting from the effective date of the final rule to get recertified if their certifying agent is not accredited. One of the commenters stated that because the NOP anticipates that the accreditation process will require 12 months, producers will, in effect, have 6 months to be certified by a new certifying agent should the producer's certifying agent not be accredited.

Certification under the NOP will become mandatory 18 months after the effective date of the final rule. Applications for accreditation will be processed on a first-come, first-served basis. Accreditations will be announced approximately 12 months after the effective date of the final rule for those qualified certifying agents who apply within the first 6 months following the effective date and for any other applicants that AMS determines eligible. Certifying agents will begin the process of certifying organic production and handling operations to the national standards upon receipt of their USDA accreditation. All production and handling operations certified by an accredited certifying agent will be considered certified to the national standards until the certified operation's anniversary date of certification. This phase-in period will only be available to those certified operations certified by a certifying agent that receives its accreditation within 18 months from the effective date of the final rule. We anticipate that certifying agents and production and handling operations will move as quickly as possible to begin operating under the national organic standards. Operations certified by a certifying agent, which fails to apply for or fails to meet the requirements for USDA accreditation under the NOP, must seek and receive certification by a USDA-accredited certifying agent before they can sell, label, or represent their products as organic, effective 18 months after the effective date of the final rule.

Subpart F—Accreditation of Certifying Agents

This subpart sets forth the requirements for a national program to accredit State and private entities as

certifying agents to certify domestic or foreign organic production or handling operations. This subpart also provides that USDA will accept a foreign certifying agent's accreditation to certify organic production or handling operations if: (1) USDA determines, upon the request of a foreign government, that the standards under which the foreign government authority accredited the foreign certifying agent meet the requirements of this part; or (2) the foreign governmental authority that accredited the certifying agent acted under an equivalency agreement negotiated between the United States Government and the foreign government.

This National Organic Program (NOP) accreditation process will facilitate national and international acceptance of U.S. organically produced agricultural commodities. The accreditation requirements in these regulations will, upon announcement of the first group of accredited certifying agents, replace the voluntary fee-for-service organic assessment program, established by AMS under the Agricultural Marketing Act of 1946. That assessment program verifies that State and private organic certifying agents comply with the requirements prescribed under the International Organization for Standardization/International Electrotechnical Commission Guide 65, "General Requirements for Bodies Operating Product Certification Systems" (ISO Guide 65).² ISO Guide 65 provides the general requirements that a certifying agent would need to meet to be recognized as competent and reliable. That assessment program was originally established to enable organic certifying agents in the absence of a U.S. national organic program to comply with European Union (EU) requirements beginning on June 30, 1999. That assessment program verifies that State and private organic certifying agents are operating third-party certification systems in a consistent and reliable manner, thereby facilitating uninterrupted exports of U.S. organic agricultural commodities to the EU. ISO Guide 65 was used as a benchmark in developing the accreditation program described in this final rule. Certifying agents accredited under the NOP that

² ISO/IEC Guide 65 is available for viewing at USDA-AMS, Transportation and Marketing Programs, Room 2945-South Building, 14th and Independence Ave., SW., Washington, DC, from 9:00 a.m. to 4:00 p.m., Monday through Friday (except official Federal holidays). A copy may be obtained from the American National Standards Institute, 11 West 42d Street, New York, NY 10036; Website: www.ansi.org; E-mail: ansionline@ansi.org; Telephone: 212-642-4900; Facsimile: 212-398-0023.

maintain compliance with the Act and these regulations will meet or exceed the requirements of ISO Guide 65; therefore, the organic assessment program is no longer needed.

Participation in the NOP does not preclude the accredited certifying agent from conducting other business operations, including the certification of agricultural products, practices, and procedures to standards that do not make an organic claim. An accredited certifying agent may not, however, engage in any business operations or activities which would involve the agent in a violation of or in a conflict of interest under the NOP.

Description of Regulations

The Administrator will accredit qualified domestic and foreign applicants in the areas of crops, livestock, wild crops, or handling or any combination thereof to certify domestic or foreign production or handling operations as certified organic operations. Qualified applicants will be accredited for 5 years.

Application Process

Certifying agents will apply to the Administrator for accreditation to certify production or handling operations operating under the NOP. The certifying agent's application must include basic business information, must identify each area of operation for which accreditation is requested and the estimated number of each type of operation to be certified annually, and must include a list of each State or foreign country where it currently certifies production or handling operations and where it intends to certify such operations. Certifying agents must also submit personnel, administrative, conflict of interest, current certification, and other documents and information to demonstrate their expertise in organic production or handling techniques, their ability to comply with and implement the organic certification program, and their ability to comply with the requirements for accreditation. Certifying agents planning to certify production or handling operations within a State with an approved State organic program (SOP) must demonstrate their ability to comply with the requirements of the SOP.

The administrative information submitted by the applicant must include copies of its procedures for certifying operations, for ensuring compliance of its certified operations with the Act and regulations, for complying with recordkeeping requirements, and for making information available to the

public about certified operations. The procedures for certifying operations encompass the processes used by the certifying agent to evaluate applicants, make certification decisions, issue certification certificates, and maintain the confidentiality of any business information submitted by the certified operation. The procedures for ensuring compliance of the certified operations will include the methods used to review and investigate certified operations, for sampling and residue testing, and to report violations.

The personnel information submitted with the application must demonstrate that the applicant uses a sufficient number of adequately trained personnel to comply with and implement the organic certification program. The certifying agent will also have to provide evidence that its responsibly connected persons, employees, and contractors with inspection, analysis, and decision-making responsibilities have sufficient expertise in organic production or handling techniques to successfully perform the duties assigned. They must also show that all persons who review applications for certification perform on-site inspections, review certification documents, evaluate qualifications for certification, make recommendations concerning certification, or make certification decisions and that all parties responsibly connected to the certifying agent have revealed existing or potential conflicts of interest.

Applicants who currently certify production or handling operations must also submit a list of the production and handling operations currently certified by them. For each area in which the applicant requests accreditation, the applicant should furnish copies of inspection reports and certification evaluation documents for at least three operations. If the applicant underwent any other accrediting process in the year previous to the application, the applicant should also submit the results of the process.

Certifying agents are prohibited from giving advice or providing consultancy services to certification applicants or certified operations for overcoming identified barriers to certification. This requirement does not apply to voluntary education programs available to the general public and sponsored by the certifying agent.

The Administrator will provide oversight of the fees to ensure that the schedule of fees filed with the Administrator is applied uniformly and in a nondiscriminatory manner. The Administrator may inform a certifying agent that its fees appear to be

unreasonable and require that the certifying agent justify the fees. The Administrator will investigate the level of fees charged by an accredited certifying agent upon receipt of a valid complaint or under compelling circumstances warranting such an investigation.

Statement of Agreement

Upon receipt of the certifying agent's application for accreditation, the Administrator will send a statement of agreement to the person responsible for the certifying agent's day-to-day operations for signature. The statement of agreement affirms that, if granted accreditation as a certifying agent under this subpart, the applicant will carry out the provisions of the Act and the regulations in this part. Accreditation will not be approved until this statement is signed and returned to the Administrator.

The statement of agreement will include the applicant's agreement to accept the certification decisions made by another certifying agent accredited or accepted by USDA pursuant to section 205.500 and the applicant's agreement to refrain from making false or misleading claims about its accreditation status, the USDA accreditation program, or the nature or qualities of products labeled as organically produced. Further, the statement will include the applicant's agreement to pay and submit the fees charged by AMS and to comply with, implement, and carry out any other terms and conditions determined by the Administrator to be necessary. Applicants are also required to affirm through this statement of agreement that they will: (1) conduct an annual performance evaluation of all persons who review applications for certification, perform on-site inspections, review certification documents, evaluate qualifications for certification, make recommendations concerning certification, or make certification decisions and implement measures to correct any deficiencies in certification services; and (2) have an annual program review conducted of their certification activities by their staff, an outside auditor, or a consultant who has expertise to conduct such reviews and implement measures to correct any noncompliances with the Act and the regulations in this part that are identified in the evaluation.

A private entity certifying agent must additionally agree to hold the Secretary harmless for any failure on the agent's part to carry out the provisions of the Act and regulations. A private entity certifying agent's statement will also

include an agreement to furnish reasonable security for the purpose of protecting the rights of operations certified by such certifying agent. Such security will be in an amount and according to such terms as the Administrator may by regulation prescribe. A private entity certifying agent must agree to transfer all records or copies of records concerning its certification activities to the Administrator if it dissolves or loses its accreditation. This requirement for the transfer of records does not apply to a merger, sale, or other transfer of ownership of a certifying agent. A private entity certifying agent must also agree to make such records available to any applicable SOP's governing State official.

Granting Accreditation

Upon receiving all the required information, including the statement of agreement, and the required fee, the Administrator will determine if the applicant meets the requirements for accreditation. The Administrator's determination will be based on a review of the information submitted and, if necessary, a review of the information obtained from a site evaluation. The Administrator will notify the applicant of the granting of accreditation in writing. The notice of accreditation will state the area(s) for which accreditation is given, the effective date of the accreditation, any terms or conditions for the correction of minor noncompliances, and, for a private-entity certifying agent, the amount and type of security that must be established.

Certifying agents who apply for accreditation and do not meet the requirements for accreditation will be provided with a notification of noncompliance which will describe each noncompliance, the facts on which the notification is based, and the date by which the applicant must rebut or correct each noncompliance and submit supporting documentation of each such correction when correction is possible. If the applicant is successful in its rebuttal or provides acceptable evidence demonstrating correction of the noncompliances, the NOP Program Manager will send the applicant a written notification of noncompliance resolution and proceed with further processing of the application. If the applicant fails to correct the noncompliances, fails to report the corrections by the date specified in the notification of noncompliance, fails to file a rebuttal by the date specified in the notification of noncompliance, or is unsuccessful in its rebuttal, the Program

Manager will issue a written notification of accreditation denial to the applicant. An applicant who has received written notification of accreditation denial may apply for accreditation again at any time or file an appeal of the denial of accreditation with the Administrator by the date specified in the notification of accreditation denial.

Once accredited, a certifying agent may establish a seal, logo, or other identifying mark to be used by certified production and handling operations. However, the certifying agent may not require use of its seal, logo, or other identifying mark on any product sold, labeled, or represented as organically produced as a condition of certification. The certifying agent also may not require compliance with any production or handling practices other than those provided for in the Act and regulations as a condition for use of its identifying mark. However, certifying agents certifying production or handling operations within a State with more restrictive requirements, approved by the Administrator, shall require compliance with such requirements as a condition of use of their identifying mark by such operations.

Site Evaluations

One or more representatives of the Administrator will perform site evaluations for each certifying agent in order to examine the certifying agent's operations and to evaluate compliance with the Act and regulations. Site evaluations will include an on-site review of the certifying agent's certification procedures, decisions, facilities, administrative and management systems, and production or handling operations certified by the certifying agent. A site evaluation of an accreditation applicant will be conducted before or within a reasonable time after issuance of the applicant's notification of accreditation. Certifying agents will be billed for each site evaluation conducted in association with an initial accreditation, amendments to an accreditation, and renewals of accreditation. Certifying agents will not be billed by USDA for USDA-initiated site evaluations conducted to determine compliance with the Act and regulations.

As noted above, a certifying agent may be accredited prior to a site evaluation. If the Program Manager finds, following the site evaluation, that an accredited certifying agent is not in compliance with the Act or regulations, the Program Manager will issue the certifying agent a written notification of noncompliance. If the certifying agent fails to correct the noncompliances,

report the corrections by the date specified in the notification of noncompliance, or file a rebuttal by the date specified in the notification of noncompliance, the Administrator will begin proceedings to suspend or revoke the accreditation. A certifying agent that has had its accreditation suspended may at any time, unless otherwise stated in the notification of suspension, submit a request to the Secretary for reinstatement of its accreditation. The request must be accompanied by evidence demonstrating correction of each noncompliance and corrective actions taken to comply with and remain in compliance with the Act and regulations. A certifying agent whose accreditation is revoked will be ineligible for accreditation for a period of not less than 3 years following the date of such determination.

Peer Review Panels

The Administrator shall establish a peer review panel pursuant to the Federal Advisory Committee Act (FACA) (5 U.S.C. App. 2 *et seq.*). The peer review panel shall be composed of not fewer than three members who shall annually evaluate the NOP's adherence to the accreditation procedures in subpart F of these regulations and ISO/IEC Guide 61,³ General requirements for assessment and accreditation of certification/registration bodies, and the NOP's accreditation decisions. This will be accomplished through the review of: (1) accreditation procedures, (2) document review and site evaluation reports, and (3) accreditation decision documents or documentation. The peer review panel shall report its finding, in writing, to the NOP Program Manager.

Continuing Accreditation

An accredited certifying agent must submit annually to the Administrator, on or before the anniversary date of the issuance of the notification of accreditation, the following reports and fees: (1) A complete and accurate update of its business information, including its fees, and information evidencing its expertise in organic production or handling and its ability to comply with these regulations; (2) information supporting any changes requested in the areas of accreditation; (3) a description

of measures implemented in the previous year and any measures to be implemented in the coming year to satisfy any terms and conditions specified in the most recent notification of accreditation or notice of renewal of accreditation; (4) the results of the most recent performance evaluations and annual program review and a description of adjustments to the certifying agent's operation and procedures implemented or to be implemented in response to the performance evaluations and program review; and (5) the required AMS fees.

Certifying agents will keep the Administrator informed of their certification activities by providing the Administrator with a copy of: (1) Any notice of denial of certification, notification of noncompliance, notification of noncompliance correction, notification of proposed suspension or revocation, and notification of suspension or revocation issued simultaneously with its issuance and (2) a list, on January 2 of each year, including the name, address, and telephone number of each operation granted certification during the preceding year.

One or more site evaluations will occur during the 5-year period of accreditation to determine whether an accredited certifying agent is complying with the Act and regulations. USDA will establish an accredited certifying agent compliance monitoring program, which will involve no less than one randomly selected site evaluation of each certifying agent during its 5-year period of accreditation. Larger and more diverse operations, operations with clients marketing their products internationally, and operations with a history of problems should expect more frequent site evaluations by USDA. Operations with clients marketing their products internationally will be annually site evaluated to meet the ISO-Guide 61 requirement for periodic surveillance of accredited certifying agents. USDA may also conduct site evaluations during investigations of alleged or suspected violations of the Act or regulations and in followup to such investigations. Such investigations will generally be the result of complaints filed with the Administrator alleging violations by the certifying agent. Compliance site evaluations may be announced or unannounced at the discretion of the Administrator. Certifying agents will not be billed by USDA for USDA-initiated site evaluations conducted to determine compliance with the Act and regulations.

³ ISO/IEC Guide 61 is available for viewing at USDA-AMS, Transportation and Marketing Programs, Room 2945-South Building, 14th and Independence Ave., SW., Washington, DC, from 9:00 a.m. to 4:00 p.m., Monday through Friday (except official Federal holidays). A copy may be obtained from the American National Standards Institute, 11 West 42d Street, New York, NY 10036; Website: www.ansi.org; E-mail: ansionline@ansi.org; Telephone: 212-642-4900; Facsimile: 212-398-0023.

An accredited certifying agent must provide sufficient information to persons seeking certification to enable them to comply with the applicable requirements of the Act and these regulations. The certifying agent must maintain strict confidentiality with respect to its clients and not disclose to third parties (with the exception of the Secretary or the applicable SOP's governing State official or their authorized representatives) any business-related information concerning any client obtained while implementing these regulations except as authorized by regulation. A certifying agent must make the following information available to the public: (1) Certification certificates issued during the current and 3 preceding calendar years; (2) a list of producers and handlers whose operations it has certified, including for each the name of the operation, type(s) of operation, products produced, and the effective date of the certification, during the current and 3 preceding calendar years; and (3) the results of laboratory analyses for residues of pesticides and other prohibited substances conducted during the current and 3 preceding calendar years. A certifying agent may make other business information available to the public if permitted in writing by the producer or handler. This information will be made available to the public at the public's expense.

An accredited certifying agent must maintain records according to the following schedule: (1) Records obtained from applicants for certification and certified operations must be maintained for not less than 5 years beyond their receipt; (2) records created by the certifying agent regarding applicants for certification and certified operations must be maintained for not less than 10 years beyond their creation; and (3) records created or received by the certifying agent pursuant to the accreditation requirements, excluding any records covered by the 10-year requirement, must be maintained for not less than 5 years beyond their creation or receipt. Examples of records obtained from applicants for certification and certified operations include organic production system plans, organic handling system plans, application documents, and any documents submitted to the certifying agent by the applicant/certified operation. Examples of records created by the certifying agent regarding applicants for certification and certified operations include certification certificates, notices of denial of certification, notification of noncompliance, notification of

noncompliance correction, notification of proposed suspension or revocation, notification of suspension or revocation, correspondence with applicants and certified operations, on-site inspection reports, documents concerning residue testing, and internal working papers and memorandums concerning applicants and certified operations. Examples of records created or received by the certifying agent pursuant to the accreditation requirements include operations manuals; policies and procedures documents (personnel, administrative); training records; annual performance evaluations and supporting documents; conflict of interest disclosure reports and supporting documents; annual program review working papers, memorandums, letters, and reports; fee schedules; annual reports of operations granted certification; application materials submitted to the NOP; correspondence received from and sent to USDA; and annual reports to the Administrator.

The certifying agent must make all records available for inspection and copying during normal business hours by authorized representatives of the Secretary and the applicable SOP's governing State official. In the event that the certifying agent dissolves or loses its accreditation, it must transfer to the Administrator and make available to any applicable SOP's governing State official all records or copies of records concerning its certification activities. This requirement for the transfer of records does not apply to a merger, sale, or other transfer of ownership of a certifying agent.

Certifying agents are also required to prevent conflicts of interest and to require the completion of an annual conflict of interest disclosure report by all persons who review applications for certification, perform on-site inspections, review certification documents, evaluate qualifications for certification, make recommendations concerning certification, or make certification decisions and all parties responsibly connected to the certifying agent. Coverage of the conflict of interest provisions extends to immediate family members of persons required to complete an annual conflict of interest disclosure report. A certifying agent may not certify a production or handling operation if the certifying agent or a responsibly connected party of such certifying agent has or has held a commercial interest in the production or handling operation, including an immediate family interest or the provision of consulting services, within the 12-month period prior to the application for certification. A certifying

agent may certify a production or handling operation if any employee, inspector, contractor, or other personnel of the certifying agent has or has held a commercial interest, including an immediate family interest or the provision of consulting services, within the 12-month period prior to the application for certification. However, such persons must be excluded from work, discussions, and decisions in all stages of the certification process and the monitoring of the entity in which they have or have held a commercial interest. The acceptance of payment, gifts, or favors of any kind, other than prescribed fees, from any business inspected is prohibited. However, a certifying agent that is a not-for-profit organization with an Internal Revenue Code tax exemption or, in the case of a foreign certifying agent, a comparable recognition of not-for-profit status from its government, may accept voluntary labor from certified operations. Certifying agents are also prohibited from giving advice or providing consultancy services to certification applicants or certified operations for overcoming identified barriers to certification. To further ensure against conflict of interest, the certifying agent must ensure that the decision to certify an operation is made by a person different from the person who conducted the on-site inspection.

The certifying agent must reconsider a certified operation's application for certification when the certifying agent determines, within 12 months of certifying the operation, that a person participating in the certification process and covered under section 205.501(c)(11)(ii) has or had a conflict of interest involving the applicant. If necessary, the certifying agent must perform a new on-site inspection. All costs associated with a reconsideration of an application, including onsite inspection costs, shall be borne by the certifying agent. When it is determined that, at the time of certification, a conflict of interest existed between the applicant and a person covered under section 205.501(c)(11)(i), the certifying agent must refer the certified operation to a different accredited certifying agent for recertification. The certifying agent must also reimburse the operation for the cost of the recertification.

No accredited certifying agent may exclude from participation in or deny the benefits of the NOP to any person due to discrimination because of race, color, national origin, gender, religion, age, disability, political beliefs, sexual orientation, or marital or family status. Accredited certifying agents must accept all production and handling

applications that fall within their areas of accreditation and certify all qualified applicants, to the extent of their administrative capacity to do so, without regard to size or membership in any association or group.

Renewal of Accreditation

To avoid a lapse in accreditation, certifying agents must apply for renewal of accreditation at least 6 months prior to the fifth anniversary of issuance of the notification of accreditation and each subsequent renewal of accreditation. The Administrator will send the certifying agent a notice of pending expiration of accreditation approximately 1 year prior to the scheduled date of expiration. The accreditation of certifying agents who make timely application for renewal of accreditation will not expire during the renewal process. The accreditation of certifying agents who fail to make timely application for renewal of accreditation will expire as scheduled unless renewed prior to the scheduled expiration date. Certifying agents with an expired accreditation must not perform certification activities under the Act and these regulations.

Following receipt of the certifying agent's annual report and fees and the results of a site evaluation, the Administrator will determine whether the certifying agent remains in compliance with the Act and regulations and should have its accreditation renewed. Upon a determination that the certifying agent is in compliance with the Act and regulations, the Administrator will issue a notice of renewal of accreditation. The notice of renewal will specify any terms and conditions that must be addressed by the certifying agent and the time within which those terms and conditions must be satisfied. Renewal of accreditation will be for 5 years. Upon a determination that the certifying agent is not in compliance with the Act and regulations, the Administrator will initiate proceedings to suspend or revoke the certifying agent's accreditation. Any certifying agent subject to a proceeding to suspend or revoke its accreditation may continue to perform certification activities pending resolution of the proceedings to suspend or revoke the accreditation.

Amending Accreditation

An accredited certifying agent may request amendment to its accreditation at any time. The application for amendment must be sent to the Administrator and must contain information applicable to the requested change in accreditation, a complete and

accurate update of the certifying agent's application information and evidence of expertise and ability, and the applicable fees.

Accreditation—Changes Based on Comments

This subpart differs from the proposal in several respects as follows:

(1) *Advice and Consultancy Services.* We have amended section 205.501(a)(11)(iv) to clarify that certifying agents are to prevent conflicts of interest by not giving advice or providing consultancy services to applicants for certification and certified operations for overcoming identified barriers to certification. This amendment has been made in response to a commenter who stated that the provisions of section 205.501(a)(11)(iv), as proposed, seemed to preclude the providing of advice and educational workshops and training programs. It was not our intent to prevent certifying agents from sponsoring in-house publications, conferences, workshops, informational meetings, and field days for which participation is voluntary and open to the general public. The provisions as originally proposed and as amended are intended to prohibit certifying agents from telling applicants and certified operations how to overcome barriers to certification identified by the certifying agent. It would be a conflict of interest for a certifying agent to tell an operation how to comply inasmuch as the certifying agents impartiality and objectivity will be lost should the advice or consultancy prove ineffective in resolving the noncompliance. The provisions of section 205.501(a)(11)(iv) are consistent with ISO Guide 61.

To further clarify this issue, we have also amended section 205.501(a)(16) by adding "for certification activities" after the word, "charges."

(2) *Conflicts of Interest—Persons Covered.* We have amended section 205.501(a)(11)(v) to limit the completion of annual conflict of interest disclosure reports to all persons who review applications for certification, perform on-site inspections, review certification documents, evaluate qualifications for certification, make recommendations concerning certification, or make certification decisions and all parties responsibly connected to the certifying agent. A commenter recommended amending section 205.501(a)(11)(v) to have it apply to all persons with direct oversight of or participation in the certification program rather than all persons identified in section 205.504(a)(2). Section 205.504(a)(2) includes all personnel to be used in the

certification operation, including administrative staff, certification inspectors, members of any certification review and evaluation committees, contractors, and all parties responsibly connected to the certifying agent. We have decided that completion of annual conflict of interest disclosure reports by persons not involved in the certification process or responsibly connected to the certifying agent is unnecessary. As amended, section 205.501(a)(11)(v) includes all persons with the opportunity to influence the outcome of a decision on whether to certify a specific production or handling operation. Completed conflict of interest disclosure reports will be used by certifying agents to identify persons with interests in applicants for certification and certified operations that may affect the impartiality of such persons.

(3) *Reporting Certifications Granted.* We have amended section 205.501(a)(15)(ii) (formerly section 205.501(a)(14)(ii)) by replacing "a quarterly calendar basis" with "January 2 of each year." A commenter stated that the requirement that certifying agents report certifications that they have granted on a quarterly basis to the Administrator is burdensome. The commenter requested that section 205.501(a)(14)(ii) be amended to require a midyear or end-year reporting. Section 205.501(a)(15)(ii) now requires the certifying agent to submit a list, on January 2 of each year, including the name, address, and telephone number of each operation granted certification during the preceding year. Certifying agents can fulfill this requirement by providing an up-to-date copy of the list of producers and handlers required to be made available to the public by section 205.504(b)(5)(ii).

(4) *Notification of Inspector.* We have added a new section 205.501(a)(18) requiring the certifying agent to provide the inspector, prior to each on-site inspection, with previous on-site inspection reports and to notify the inspector of the certifying agent's decision relative to granting or denying certification to the applicant site inspected by the inspector. Such notification must identify any requirements for the correction of minor noncompliances. We have made this addition because we agree with the commenter that such information should be provided to the inspector and because the requirements are consistent with ISO Guide 61.

(5) *Acceptance of Applications.* We have added a new section 205.501(a)(19) requiring the certifying agent to accept all production or handling applications

for certification that fall within the certifying agent's areas of accreditation and to certify all qualified applicants, to the extent of their administrative capacity to do so, without regard to size or membership in any association or group. We have made this addition because we agree with the many commenters who requested that certifying agents be required to certify all qualified applicants. We recognize, however, that there may be times when the certifying agent's workload or the size of its client base might make it necessary for the certifying agent to decline acceptance of an application for certification within its area of accreditation. This is why we have included the proviso, "to the extent of their administrative capacity to do so." We have included "without regard to size or membership in any association or group" to address commenter concerns about discrimination in the providing of certification services. This addition is consistent with ISO Guide 61.

(6) *Ability to Comply with SOP.* We have added a new section 205.501(a)(20) requiring the certifying agent to demonstrate its ability to comply with an SOP, to certify organic production or handling operations within the State. This change, as pointed out by a State commenter, is necessary to clarify that a certifying agent must be able to comply with an SOP to certify production or handling operations within that State.

(7) *Performance Evaluation.* We have amended section 205.501(a)(6) by replacing "appraisal" with "evaluation" and expanding the coverage from inspectors to persons who review applications for certification, perform on-site inspections, review certification documents, evaluate qualifications for certification, make recommendations concerning certification, or make certification decisions. Corresponding amendments have also been made to section 205.510(a)(4). Further, we have amended section 205.501(a)(6) to clarify that the deficiencies to be corrected are deficiencies in certification services. We changed "appraisal" to "evaluation" at the request of a State commenter who pointed out that State inspectors generally perform other duties in addition to the inspection of organic production or handling operations. We concur that this change will help differentiate between the State's employee performance appraisal for all duties as a State employee and the evaluation of certification services provided under the NOP. Expanding the coverage from inspectors to all persons involved in the certification process

makes the regulation consistent with ISO Guide 61. Sections 205.505(a)(3) and 205.510(a)(4) have been amended to make their language consistent with the changes to section 205.501(a)(6).

(8) *Annual Program Evaluation.* We have amended section 205.501(a)(7) by replacing "evaluation" with "review" and by replacing "evaluations" with "reviews." A commenter suggested amending section 205.501(a)(7) by replacing the requirement of an annual program evaluation with an annual review of program activities. We agree that "review" is a more appropriate term than "evaluate" since to review is to examine, report, and correct while evaluate is more in the nature of assessing value. We have not, however, accepted that portion of the commenter's suggestion which would have removed the reference to the review being conducted by the certifying agent's staff, an outside auditor, or a consultant who has the expertise to conduct such reviews. We have not accepted this suggestion because the comment would have limited the review to being conducted by the certifying agent with no requirement that the certifying agent be qualified to conduct the review. Another commenter wanted to change the requirement to an annual assessment of the quality of the inspection system. We have not accepted this suggestion because it can be interpreted as narrowing the scope of the review from the full certification program to just the inspection component of the certification program. This commenter would also have limited the review to being conducted by the certifying agent with no requirement that the certifying agent be qualified to conduct the review. We believe that narrowing the scope of the review would be inconsistent with ISO Guide 65. It is also inconsistent with our intent that the entire certification program be reviewed annually. We also received a comment stating that it is a violation of ISO Guide 65 to have staff perform an internal review. We disagree with this commenter. ISO Guide 65 provides that the certification body shall conduct periodic internal audits covering all procedures in a planned and systematic manner. Sections 205.505(a)(4) and 205.510(a)(4) have been amended to make their language consistent with the changes to section 205.501(a)(7).

(9) *Certification Decision.* We have added a new section 205.501(a)(11)(vi) that requires the certifying agent to ensure that the decision to certify an operation is made by a person different from the person who carried out the on-

site inspection. Commenters requested that this provision be added to the requirement that certifying agents prevent conflicts of interest. We concur with the request because it clearly separates the act of inspecting an organic operation from the act of granting certification. This addition is also consistent with ISO Guide 65, section 4.2(f), which requires that the certification body ensure that each decision on certification is taken by a person different from those who carried out the evaluation.

(10) *Determination of Conflict of Interest.* We have added a new section 205.501(a)(12) addressing situations where a conflict of interest present at the time of certification is identified after certification. Several commenters requested the addition of a provision that, if a conflict of interest is identified within 12 months of certification, the certifying agent must reconsider the application and may reinspect the operation if necessary. We agree with the commenters that the issue of conflicts of interest present at the time of certification but identified after certification need to be addressed in the regulations. Accordingly, we have provided that an entity accredited as a certifying agent must reconsider a certified operation's application for certification and, if necessary, perform a new on-site inspection when it is determined, within 12 months of certifying the operation, that any person participating in the certification process and covered under section 205.501(a)(11)(ii) has or had a conflict of interest involving the applicant. Because the certifying agent is responsible for preventing conflicts of interest, all costs associated with a reconsideration of application, including onsite inspection costs, must be borne by the certifying agent. Further, a certifying agent must refer a certified operation to a different accredited certifying agent for recertification when it is determined that any person covered under section 205.501(a)(11)(i) at the time of certification of the applicant had a conflict of interest involving the applicant. Because the certifying agent is responsible for preventing conflicts of interest, the certifying agent must reimburse the operation for the cost of the recertification. Sections 205.501(a)(12) through 205.501(a)(17) have been redesignated as sections 205.501(a)(13) through 205.501(a)(18), respectively.

(11) *Financial Security.* We published an advanced notice of proposed rulemaking and request for comments regarding financial security in the

August 9, 2000, issue of the **Federal Register**. We issued a news release announcing the **Federal Register** publication on August 9, 2000. Numerous commenters expressed concern about reasonable security relative to its amount and impact on small certifying agents. A few commenters requested a definition for reasonable security. Others stated that the formula for determining the amount of security should be published in the **Federal Register**. The March 13, 2000, NOP proposed rule stated that the amount and terms of reasonable financial security would be the subject of additional rulemaking. The August 9, 2000, advanced notice of proposed rulemaking solicited comments on all aspects of reasonable security and protection of the rights of program participants. We requested comments from any interested parties, including producers and handlers of organic agricultural products, certifying agents, importers and exporters, the international community, and any other person or group. Six questions were provided to facilitate public comment on the advanced notice of proposed rulemaking. Comments addressing other relevant issues were also invited. The questions posed in the advanced notice of proposed rulemaking were:

(a) From what risks or events might a customer of a private certifying agent require reasonable security?

(b) What are the financial instrument(s) that could provide the reasonable security to protect customers from these events?

(c) What dollar amounts of security would give reasonable protection to a customer of a private certifying agent?

(d) What are the financial costs to private certifiers, especially small certifiers, of providing reasonable security?

(e) Do the risks or events provided in response to question #1 necessarily require financial compensation?

(f) Are there situations in which reasonable security is not needed?

Following analysis of the comments received, we will publish a proposed rule on reasonable security in the **Federal Register**. The public will again be invited to submit comments. The proposed rule will include the proposed regulation, an explanation of the decision-making process, an analysis of the costs and benefits, the effects on small businesses, and an estimate of the paperwork burden imposed by the regulation.

(12) *Use of Identifying Mark*. We have amended section 205.501(b)(2) to clarify that all certifying agents (private and State) certifying production or handling

operations within a State with more restrictive requirements, approved by the Secretary, shall require compliance with such requirements as a condition of use of their identifying mark by such operations. Numerous commenters stated that they wanted USDA to permit higher production standards by private certifying agents. See also item 17 under Accreditation—Changes Requested But Not Made. This amendment is intended to further clarify our position that no certifying agent (State or private) may establish or require compliance with its own organic standards. It is an SOP, not a State certifying agent, that receives approval from the Secretary for more restrictive requirements. See also item 7 under Accreditation—Clarifications.

(13) *Transfer of Records*. To address the issues of a merger, sale, or other transfer of ownership, we have added the following to the end of section 205.501(c)(3); “*Provided*, That, such transfer shall not apply to a merger, sale, or other transfer of ownership of a certifying agent.” Commenters suggested amending section 205.501(c)(3) to provide for the transfer of records accumulated from the time of accreditation to the Administrator or his or her designee, another accredited certifying agent, or an SOP’s governing State official in a State where such official exists. It was also stated that this section needs to take into account a certifying agent’s decision to merge or transfer accounts to another certifying agent in the case of loss of accreditation. Under the NOP, should a certifying agent dissolve or lose its accreditation, its certified operations will be free to seek certification with the accredited certifying agent of their choice. Accordingly, it would be inappropriate to automatically transfer an operation’s records to another certifying agent as requested by the commenters. However, in analyzing the comments, we realized that a provision was needed for a merger, sale, or other transfer of ownership of a certifying agent; thus, the amendment to section 205.501(c)(3). Section 205.505(b)(3) has been amended to make its language consistent with the changes to section 205.501(c)(3).

(14) *Fees for Information*. We have amended section 205.504(b)(5) by inserting “including any fees to be assessed” after the word, “used.” This change is made in response to the question of whether fees may be charged for making information available to the public. It is our intent that certifying agents may charge reasonable fees for document search time, duplication, and, when applicable, review costs. We anticipate that review costs will most likely be incurred when the information

requested is located within documents which may contain confidential business information.

(15) *Information Available to the Public*. We have amended section 205.504(b)(5)(ii) by adding products produced to the information to be released to the public. This addition responds in an alternate way to commenters who wanted the information included on certificates of organic operation. That request was denied; see item 4, Changes Requested But Not Made, under subpart E, Certification. This addition is consistent with ISO Guide 61.

(16) *Equivalency of Certification Decisions and Statement of Agreement*. We have amended sections 205.501(a)(12) (redesignated as 205.501(a)(13)) and 205.505(a)(1) by deleting the words, “USDA accredited” and “as equivalent to its own,” and adding to the end thereof: “accredited or accepted by USDA pursuant to section 205.500.” We have made this amendment to clarify that the provision applies to certification decisions by domestic certifying agents as well as foreign certifying agents accredited or accepted by USDA pursuant to section 205.500.

There were many comments in support of section 205.501(a)(12) as written. However some did not agree that certifying agents should have to recognize another agent’s decision as equivalent to their own. These commenters want to maintain the right and ability not to use their seal on a product that does not meet their standards. The most strongly voiced comment stated: “delete section 205.501(a)(12) and section 205.505(a)(1). The requirements constitute a “taking” in violation of the Fifth Amendment and are unnecessary to accomplish the goal of establishing a consistent standard and facilitating trade.”

We do not concur with the commenters who want to change sections 205.501(a)(12) and 205.505(a)(1). We also do not agree with the comment that sections 205.501(a)(12) and 205.505(a)(1) constitute a taking in violation of the Fifth Amendment and are unnecessary to accomplish the goal of establishing a consistent standard and facilitating trade. We believe that, to accomplish the goal of establishing a consistent standard and to facilitate trade, it is vital that an accredited certifying agent accept the certification decisions made by another certifying agent accredited or accepted by USDA pursuant to section 205.500. All domestic organic production and handling operations, unless exempted or excluded under

section 205.101, must be certified to these national standards and, when applicable, any State standards approved by the Secretary. All domestic certified operations must be certified by a certifying agent accredited by the Administrator. No USDA-accredited certifying agent, domestic or foreign, may establish or require compliance with its own organic standards. Certifying agents are not required to have an identifying mark for use under the NOP. However, if a certifying agent is going to use an identifying mark under the NOP, the use of such mark must be voluntary and available to all of the certifying agent's clients certified under the NOP. Accordingly, we have not changed the requirement that a certifying agent accept the certification decisions made by another USDA-accredited certifying agent. We have, however, as noted above, amended both sections to require that USDA-accredited certifying agents accept the certification decisions made by another certifying agent accredited or accepted by USDA pursuant to section 205.500.

(17) *Granting Accreditation.* We have made editorial changes to section 205.506 consistent with the suggestion that we replace "approval of accreditation" with "granting of accreditation." In the title to section 205.506, we have replaced "Approval of" with "Granting." In section 205.506(a), we have replaced "approved" with "granted," and in section 205.506(b), we have replaced "approval" with "the granting." We have made these change because, under the NOP, we grant accreditation rather than approve accreditation.

(18) *Correction of Minor Noncompliances.* We have added a new section 205.506(b)(3) providing that the notification granting accreditation will state any terms and conditions for the correction of minor noncompliances. Commenters requested the addition of language to section 205.506(b) which would clarify that the Administrator may accredit with required corrective actions for minor noncompliances. In the proposed rule, we addressed accreditation subject to the correction of minor noncompliances at section 205.510(a)(3). We agree with commenters that, for the purposes of clarity, this issue should also be addressed in section 205.506 on the granting of accreditation. Accordingly, we have added new section 205.506(b)(3) as noted above. We have also retained the provisions of section 205.510(a)(3), which requires certifying agents to annually report on actions taken to satisfy any terms and conditions addressed in the most recent

notification of accreditation or notice of renewal of accreditation. Section 205.506(b)(3) has been redesignated as section 205.506(b)(4).

(19) *Denial of Accreditation.* We have amended section 205.507 to include noncompliance and resolution provisions originally included by cross-reference to section 205.665(a). This cross-reference created confusion for commenters, regarding section 205.665's applicability to applicants for accreditation because the section does not specifically address applicants. Rather than specifically identifying applicants within section 205.665, we believe the issue is best clarified by addressing noncompliance and resolution within section 205.507. As amended, section 205.507 now states in paragraph (a) that the written notification of noncompliance must describe each noncompliance, the facts on which the notification is based, and the date by which the applicant must rebut or correct each noncompliance and submit supporting documentation of each such correction when correction is possible. This rewrite of paragraph (a) also enabled us to eliminate paragraph (b) since its provisions are addressed in amended paragraph (a). The section also provides, at new paragraph (b), that when each noncompliance has been resolved, the Program Manager will send the applicant a written notification of noncompliance resolution and proceed with further processing of the application. We have also clarified the applicant's appeal rights by adding "or appeal the denial of accreditation in accordance with section 205.681 by the date specified in the notification of accreditation denial" to the end of paragraph (c).

(20) *Reinstatement of Accreditation.* We have amended section 205.507(d) by removing the requirement that a certifying agent that has had its accreditation suspended reapply for accreditation in accordance with section 205.502. In its place, we provide that the certifying agent may request reinstatement of its accreditation. Such request may be submitted at any time unless otherwise stated in the notification of suspension. Amended section 205.507(d) also provides that the certifying agent's request must be accompanied by evidence demonstrating correction of each noncompliance and corrective actions taken to comply with and remain in compliance with the Act and the regulations in this part. We have made this change because unlike revocation, suspension does not terminate a certifying agent's accreditation. Accordingly, requiring a new

application for accreditation is unnecessary and burdensome on the certifying agent. This change is consistent with changes to sections 205.662(f) and 205.665(g)(1), which were made based on comments received on section 205.662(f).

(21) *Ineligible for accreditation.* We have amended section 205.507(d) by deleting "private entity" from the third sentence. The amended sentence provides that "A certifying agent whose accreditation is revoked will be ineligible for accreditation for a period of not less than 3 years following the date of such determination." Several commenters recommended deletion of "private entity" so that private certifying agents would be regulated on an equivalent basis with State certifying agents. It is our intent to regulate private and State certifying agents on an equivalent basis. Accordingly, we made the recommended change.

(22) *Peer Review.* We have amended section 205.509. As amended, the section requires that the Administrator establish a peer review panel pursuant to FACA (5 U.S.C. App. 2 *et seq.*). The peer review panel will be composed of not less than 3 members who will annually evaluate the NOP's adherence to the accreditation procedures in subpart F of these regulations and ISO/IEC Guide 61, General requirements for assessment and accreditation of certification/registration bodies, and the NOP's accreditation decisions. This will be accomplished through the review of accreditation procedures, document review and site evaluation reports, and accreditation decision documents and documentation. The peer review panel will report its finding, in writing, to the NOP's Program Manager. We developed this approach to peer review as a means of addressing the suggestions of the commenters and the need for administration of an effective and timely accreditation program.

Many commenters wanted the opening language in the first sentence of section 205.509 changed from "The Administrator may" to the "The Administrator shall" establish a peer review panel to assist in evaluating applicants for accreditation, amendment to an accreditation, and renewal of accreditation as certifying agents. One of the most frequent comments, including a comment by the NOSB, was that peer reviewers should be compensated for their time and expenses. Many commenters believe also that the peer review process should be collaborative. Some commenters who wanted this change recognized that a collaborative process where confidential information was shared could run into problems

because FACA (P.L. 92–463, 5 U.S.C. App.) meetings are open to the public. They advised creating a FACA panel but restricting public access during discussion of confidential business information based on 5 U.S.C. Section 522b(c)(4) of the Government in the Sunshine Act.

As requested, amended section 205.509 requires the formation of a peer review panel. Also as requested, peer reviewers, who will serve as a FACA committee, will be reimbursed for their travel and per diem expenses. The reviewers will also work collaboratively. We have not, however, provided for collaborative review of each applicant for accreditation by the peer review panel because of the administrative burden that an outside collaborative review process would place on the NOP. Currently, there are 36 private and 13 State certifying agencies. It is, therefore, likely that USDA will receive approximately 50 applications for accreditation the first year of the program. Given the need to make accreditation decisions in a timely, organized fashion, it would be infeasible to convene a panel of peers for each applicant for accreditation prior to rendering a decision on accreditation. However, as noted above, we have provided that a peer review panel will annually evaluate the NOP's adherence to the accreditation procedures in subpart F of these regulations and ISO/IEC Guide 61, General requirements for assessment and accreditation of certification/registration bodies, and validate the NOP's accreditation decisions.

We have also amended current section 205.510(c)(3) by removing the reference to reports submitted by a peer review panel to make that section consistent with the rewrite of section 205.509.

(23) *Expiration of accreditation.* We have added a new section 205.510(c)(1) which provides that the Administrator shall send the accredited certifying agent a notice of pending expiration of accreditation approximately 1 year prior to the scheduled date of expiration. A commenter suggested USDA notification of certifying agents at least 1 year prior to the scheduled expiration of accreditation. We have made the suggested change because we believe notification about 1 year prior to expiration will facilitate the timely receipt of applications for renewal. We have redesignated sections 205.510(c)(1) and 205.510(c)(2) as 205.510(c)(2) and 205.510(c)(3), respectively.

(24) *Amendments to Accreditation.* We have added a new section 205.510(f) to provide that an amendment to an

accreditation may be requested at any time. The application for amendment must be sent to the Administrator and must contain information applicable to the requested change in accreditation. The application for amendment must also contain a complete and accurate update of the information submitted in accordance with section 205.503, Applicant information; and section 205.504, Evidence of expertise and ability. The applicant must also submit the applicable fees required in section 205.640. We have added this new section because we agree with the commenter who expressed concern that the regulations were not clear regarding amendments to accreditation. This addition is consistent with section 205.510(a)(2) which allows certifying agents to request amendment of their accreditation as part of their annual report to the Administrator.

Accreditation—Changes Requested But Not Made

This subpart retains from the proposed rule, regulations on which we received comments as follows:

(1) *Accreditation by USDA.* A commenter stated that ISO/IEC Guide 61 specifies, but the proposed rule did not specify, the requirements for USDA to assess and accredit certifying agents. The commenter questioned USDA's acceptance internationally as a competent accreditation body. A few commenters requested that USDA provide certifying agents with assurance of international trade acceptance of the USDA's accreditation program prior to implementation of the final rule. We do not believe that it is necessary to include in these regulations detailed procedures by which USDA will operate its accreditation program. USDA has developed its accreditation and certification programs with the intent that they meet or exceed international guidelines. Every country will make its own decision regarding acceptance of this accreditation program. Accordingly, while we do not anticipate problems with acceptance of our accreditation program, we cannot provide assurance against problems as requested by the commenters.

(2) *Equivalency at the European Community (EC) Level.* A commenter requested confirmation that an equivalency agreement would be negotiated at the EC level since the EC legislation provides for the basic rules while accreditation of certifying agents is a task for each member state. Another commenter pointed out that because Switzerland has the same regulations as the EC, equivalency would have to be done in close coordination with the EC.

The commenter went on to say that according to Swiss and European practice, not only the organic product, but also the bodies involved will be mutually accepted. This commenter also stated that, due to Swiss import provisions, brokers must be subject to a certain control. Equivalency will be negotiated between the United States and the foreign government authority seeking the equivalency agreement.

(3) *Period of Accreditation.* It was suggested that accreditation should be for a 4-year period with full reevaluation occurring once every 4 years and annual surveillance visits in the intervening years. We do not concur with changing the period of accreditation from 5 years to 4 years as suggested. The 5-year period that we have provided that accreditation is consistent with the Act, which provides that accreditation shall be for a period of not to exceed 5 years. The commenter claims that the international norm is for full reevaluations to take place once every 4 years with annual surveillance visits in the intervening years. ISO Guide 61, section 3.5.1, provides that the accreditation body shall have an established documented program, consistent with the accreditation granted, for carrying out periodic surveillance and reassessment at sufficiently close intervals to verify that its accredited body continues to comply with the accreditation requirements. We believe that accreditation for 5 years is a reasonable period of time. Further, we believe that a 5-year period of accreditation is consistent with ISO Guide 61 inasmuch as we require an annual evaluation of the certification program; annual review of persons associated with the certification process, including inspectors; annual reporting with a complete and accurate update of information required for accreditation; and one or more site evaluations during the period of accreditation in addition to the initial site evaluation for the period of accreditation. Accordingly, we have not made the recommended change.

(4) *Accreditation by Private-Sector Accreditation Bodies.* Numerous commenters wanted language added to section 205.500(c) that would allow private sector accreditation bodies to accredit foreign certifying agents. For example, several commenters suggested adding a provision reading as follows: "The foreign certifying agent is accredited by a private accreditation body recognized by the USDA as defined by an equivalency agreement negotiated between the USDA and the accreditation body." Commenters also wanted us to amend section 205.502(a)

to recognize accreditation by private accreditation programs.

USDA is the accrediting body for all accreditations under the NOP. USDA will not recognize nongovernmental accrediting bodies. USDA will recognize foreign certifying agents accredited by a foreign government authority when USDA determines that the foreign government's standards meet the requirements of the NOP or when an equivalency agreement has been negotiated between the United States and a foreign government.

(5) *Requirements for Accreditation.* Some commenters requested more specificity in the requirements for accreditation. For example, one recommended that section 205.501(a)(1) should include the requirement that inspectors demonstrate completion of a specified training program or internship or ongoing education and/or licensing. Another commenter wanted baseline criteria for denying an application due to expertise. Still others wanted a definition for (1) "experience and training pertaining to organic/sustainable agricultural methods and their implementation on farm or in processing facilities," (2) "trained certifying agent personnel," and (3) "reasonable time." Finally, one wanted recordkeeping and evaluative parameters. AMS does not believe that it is necessary to present the requirements for accreditation to the extent of detail requested by the commenters. The intent is to provide flexibility to the certifying agents such that they can tailor their policies and procedures to the nature and scope of their operation. The NOP is available to respond to questions and to assist certifying agents in complying with the requirements for accreditation.

(6) *Volunteer Board Members.* Some commenters suggested amending section 205.501(a)(5) to include a reference to committees and to expand "sufficient expertise" to "sufficient balance of interests and expertise." The commenters proposed the amendment to create a firewall between those persons involved in decision making and the volunteer board members. However, the purpose of section 205.501(a)(5) is to ensure that the persons used by the certifying agent to assume inspection, analysis, and decision-making responsibilities have sufficient expertise in organic production or handling techniques to successfully perform the duties assigned. Therefore, we have not made the suggested changes. Conflict of interest guidelines are found at section 205.501(a)(11).

(7) *Confidentiality.* A commenter stated that Texas law prevents the Texas Department of Agriculture from guaranteeing confidentiality to its clients. Accordingly, the commenter requested that section 205.501(a)(10) be amended by adding to the end thereof: "or as required by State statutes." We have not made the suggested change because the Act requires that the certifying agent maintain strict confidentiality with respect to its clients under the NOP and not disclose any business-related information concerning such client obtained while implementing the Act. To be accredited under the NOP, certifying agents must fully comply with the requirements of the Act and these regulations. Further, no SOP will be approved which does not comply with the NOP.

(8) *Certifying Agent Fees.* Several commenters requested that the regulations prohibit royalty formulas (i.e., fees from every certified sale) for certifying agent fees. It is not our intent to regulate how a certifying agent sets its fees beyond their being reasonable and nondiscriminatory.

(9) *Conflicts of Interest.* We received numerous comments stating that section 205.501(a)(11)(i) was too restrictive and unnecessary due to the provisions of section 205.501(a)(11)(ii) to prevent conflicts of interest. Some argued that these conflict of interest provisions are beyond ISO requirements and place an undue burden on membership based certifying agents and the entities they serve. They requested a conflict of interest policy enabling membership-based certification organizations to continue operating. A commenter suggested that section 205.501(a)(11) be amended to require that a certifying agent's board members sign an affidavit listing potential conflicts of interest, identify issues where an organization decision might help them personally, and exclude themselves from decision-making that would assist them personally. This commenter proposed the amendment for the purpose of creating a firewall between those persons involved in certification decision-making and the volunteer board members.

We do not believe that the conflict of interest provisions are too restrictive. These provisions are very similar to conflict of interest provisions under other USDA programs involving public-private partnerships (e.g., grain inspection). The certifying agent and its responsibly connected parties, including volunteer board members, hold positions of influence over the certifying agent's employees and persons with whom the certifying agent

contracts for such services as inspection, sampling, and residue testing. Therefore, we continue to believe that avoiding such conflicts of interest is necessary to maintain the integrity of the organic certification process.

(10) *Conflicts of Interest and Prohibition on Certification.* A commenter requested that we include an "or" between sections 205.501(a)(11)(i) and 205.501(a)(11)(ii). We have not made the recommended change because both sections must be complied with; they are not mutually exclusive. Section 205.501(a)(11)(i) prohibits the certification of an applicant when the certifying agent or a responsibly connected party of such certifying agent has or has held a commercial interest in the applicant for certification, including an immediate family interest or the provision of consulting services, within the 12-month period prior to the application for certification. When the certifying agent and its responsibly connected persons are free of any conflict of interest involving the applicant for certification, the applicant may be certified if qualified. However, section 205.501(a)(11)(ii) requires the certifying agent to exclude any person (employees and contractors who do not meet the definition of responsibly connected), including contractors, with conflicts of interest from work, discussions, and decisions in all stages of the certification process and the monitoring of certified production or handling operations for all entities in which such person has or has held a commercial interest, including an immediate family interest or the provision of consulting services, within the 12-month period prior to the application for certification.

(11) *Gifts and Contributions.* Commenters recommended that section 205.501(a)(11)(iii) be amended to allow not-for-profit organizations to accept gifts and contributions from certified operations for those programs not directly related to the certifying agent's organic certification activities. They also wanted it clarified that not-for-profit organizations can accept voluntary labor from certified operations for those programs not directly related to the certifying agent's organic certification activities. We have not made the requested changes. First, the acceptance of gifts and contributions would constitute a conflict of interest and would be contrary to ISO Guide 61. Certifying agents must have the financial stability and resources to perform their certification duties without relying on gifts and contributions from those they serve.

Second, we have not added the requested provision on voluntary labor because section 205.501(a)(11)(iii) already addresses the acceptance of voluntary labor by not-for-profit organizations from certified operations.

(12) *Conflicts of Interest—*

Determination Period. Commenters wanted to increase the conflict determination period from 12 months to 24 months. Some also wanted the period to extend for 2 years after, with the exception of those who have left the employ of the certifying agent or are no longer under contract with the certifying agent.

We disagree with the recommendations calling for a longer precertification conflict of interest prohibition period. We continue to believe that 12 months is a sufficient period to ensure that any previous commercial interest would not create a conflict of interest situation for two reasons. First, this time period is consistent with similar provisions governing conflicts of interest for government employees. Second, section 205.501(a)(11)(v) requires the completion of an annual conflict of interest disclosure report by all personnel designated to be used in the certification operation, including administrative staff, certification inspectors, members of any certification review and program evaluation committees, contractors, and all parties responsibly connected to the certification operation. This requirement will assist certifying agents in complying with the requirements to prevent conflicts of interest. We also continue to believe that a longer prohibition period would have the effect of severely curtailing most certifying agents' ability to comply with the Act's requirement that they employ persons with sufficient expertise to implement the applicable certification program. Accordingly, we have not made the recommended change.

The change recommended by the commenters who requested that the conflict of interest determination period extend for 2 years after certification is unnecessary. Certifying agents and their responsibly connected parties, employees, inspectors, contractors, and other personnel are prohibited from engaging in activities or associations at any time during their affiliation with the certifying agent which would result in a conflict of interest. While associated with the certifying agent, all employees, inspectors, contractors, and other personnel are expected to disclose to the certifying agent any offer of employment they have received and not immediately refused. They are also expected to

disclose any employment they are seeking and any arrangement they have concerning future employment with an applicant for certification or a certified operation. The certifying agent would then have to exclude that person from work, discussions, and decisions in all stages of the certification or monitoring of the operation making the employment offer. If a certifying agent or a responsibly connected party of the certifying agent has received and not immediately refused an offer of employment, is seeking employment, or has an arrangement concerning future employment with an applicant for certification, the certifying agent may not accept or process the application. Further, certifying agents and responsibly connected parties may not seek employment or have an arrangement concerning future employment with an operation certified by the certifying agent while associated with that certifying agent. Certifying agents and responsibly connected parties must sever their association with the certifying agent when such person does not immediately refuse an offer of employment from a certified operation. Accordingly, we have decided not to include a postcertification prohibition period in this final rule.

(13) *False and Misleading Claims.* A commenter asked who will determine what is a misleading claim about the nature or qualities of products labeled as organically produced. This same commenter recommended amending section 205.501(a)(13) by removing the prohibition against making false or misleading claims about the nature or qualities of products labeled as organically produced.

We disagree with this recommendation. Claims regarding accreditation status, the USDA accreditation program for certifying agents, and the nature and quality of products labeled as organically produced all fall under the authority of the Act. Accordingly, USDA will determine what is a misleading claim. We believe that the requirements are needed to prevent the dissemination of inaccurate or misleading information to consumers about organically produced products. We further believe that the change suggested by the commenter would undermine the goal of a uniform NOP by allowing certifying agents to make claims that would state or imply that organic products produced by operations that they certify are superior to those of operations certified by other certifying agents. These requirements would not prohibit certifying agents from sharing factual information with consumers, farmers, processors, and

other interested parties regarding verifiable attributes of organic food and organic production systems. Accordingly, we have not made the recommended change to what is now section 205.501(a)(14).

(14) *Certifying Agent Compliance With Terms and Conditions Deemed Necessary.* A commenter recommended that we remove section 205.501(a)(17). This section requires that certifying agents comply with and implement other terms and conditions deemed necessary by the Secretary. This requirement is consistent with section 6515(d)(2) of the Act, which requires a certifying agent to enter into an agreement with the Secretary under which such agent shall agree to such other terms and conditions as the Secretary determines appropriate. Accordingly, we have not accepted the commenter's recommendation. This requirement is located at current section 205.501(a)(21).

(15) *Limitations on the Use of Certifying Agent's Marks.* Numerous commenters stated that they wanted USDA to permit higher production standards by private certifying agents. A common argument for allowing higher standards was that practitioners must be allowed to "raise the bar" through superior ecological on-farm practices or pursuit of other social and ecological goals. Some commenters recommended that the language in section 205.501(b)(2) be replaced with provisions that would allow certifying agents to issue licensing agreements with contract specifications that clearly establish conditions for use of the certifying agent's identifying mark.

We believe the positions advocated by the commenters are inconsistent with section 6501(2) of the Act, which provides that a stated purpose of the Act is to assure consumers that organically produced products meet a consistent national standard. We believe that, to accomplish the goal of establishing a consistent standard and to facilitate trade, it is vital that an accredited certifying agent accept the certification decisions made by another certifying agent accredited or accepted by USDA pursuant to section 205.500. All organic production and handling operations, unless exempted or excluded under section 205.101 or not regulated under the NOP (i.e., a producer of dog food), must be certified to these national standards and, when applicable, any State standards approved by the Secretary. All certified operations must be certified by a certifying agent accredited by the Administrator. No accredited certifying agent may establish or require compliance with its

own organic standards. Accredited certifying agents may establish other standards outside of the NOP. They may not, however, refer to them as organic standards nor require that applicants for certification under the NOP or operations certified under the NOP comply with such standards as a requirement for certification under the NOP. Use of the certifying agent's identifying mark must be voluntary and available to all of its clients certified under the NOP. However, a certifying agent may withdraw a certified operation's authority to use its identifying mark during a compliance process. The certifying agent, however, accepts full liability for any such action.

The national standards implemented by this final rule can be amended as needed to establish more restrictive national standards. Anyone may request that a provision of these regulations be amended by submitting a request to the NOP Program Manager or the Chairperson of the NOSB. Requests for amendments submitted to the NOP Program Manager will be forwarded to the NOSB for its consideration. The NOSB will consider the requested amendments and make its recommendations to the Administrator. When appropriate, the NOP will conduct rulemaking on the recommended amendment. Such rulemaking will include an opportunity for public comment.

(16) *Evidence of Expertise and Ability.* A commenter stated that section 205.504, which addresses the documentation necessary to establish evidence of expertise and abilities, requires too much paperwork. We believe the amount of paperwork is appropriate for the task at hand, verifying a certifying agent's expertise in and eligibility for accreditation to certify organic production and handling operations to the NOP. We further believe that the level of paperwork is necessary to meet international guidelines for determining whether an applicant is qualified for accreditation as a certifying agent.

(17) *Procedures for Making Information Available to the Public.* Comments on section 205.504(b)(5) were mixed. Some commenters felt that the proposal fell short of the OFPA requirement to "Provide for public access to certification documents and lab analysis." Others thought that too much confidential information would be released.

The Act requires public access, at section 2107(a)(9), to certification documents and laboratory analyses pertaining to certification. Accordingly, we disagree with those commenters who

requested that such documents not be released to the public. We also disagree with the commenters who contend that the requirement for public disclosure falls short of what is required by the Act. Section 205.504(b)(5) meets the requirements of the Act by requiring the release of those documents cited in section 2107(a)(9) of the Act. The section also authorizes the release of other business information as authorized in writing by the producer or handler.

(18) *Accreditation Prior to Site Evaluation.* Numerous commenters recommended that we require site visits prior to accreditation. Some commenters cited ISO Guide 61, section 2.3.1, in their arguments for site visits prior to accreditation. ISO Guide 61, section 2.3.1., provides that the decision on whether to accredit a body shall be made on the basis of the information gathered during the accreditation process and any other relevant information. Section 3.3.2 of ISO Guide 61 provides that the accreditation body shall witness fully the on-site activities of one or more assessments or audits conducted by an applicant body before an initial accreditation is granted.

We do not concur with the commenters. These regulations provide for assessment of the applicant's qualifications and capabilities through a rigorous review of the application and supporting documentation. Following this review, an initial site evaluation shall be conducted before or within a reasonable period of time after issuance of the applicant's "notification of accreditation." In cases where the document review raises concerns regarding the applicant's qualifications and capabilities and the Administrator deems it necessary, a preapproval site evaluation will be conducted. We have further provided that a site evaluation shall be conducted after application for renewal of accreditation but prior to renewal of accreditation.

Our purpose in allowing for initial accreditation prior to a site evaluation is to facilitate implementation of the NOP and to provide a means for newly established certifying agents to obtain a client base to demonstrate that they can meet the requirements of the NOP regulations. We believe this is consistent with the intent of ISO Guide 61, section 2.3.1. and fits within its "and any other relevant information" provision. Accordingly, we restate our position that accreditation approval without a site evaluation is appropriate, necessary in the case of established certifying agents that may need to make adjustments in their operations to comply with the NOP regulations, and

necessary in the case of newly established certifying agents who will have to obtain a client base to demonstrate beyond the paperwork that they can meet the requirements of the NOP regulations.

(19) *Ineligibility After Revocation of Accreditation.* Section 205.507(d) provides that a certifying agent whose accreditation is revoked will be ineligible for accreditation for a period of not less than 3 years following the date of such determination. A commenter stated that the 3-year period of ineligibility is overly long and effectively puts the certifying agent out of business. The commenter suggested that a 6- to 12-month period might be reasonable. We have not accepted the suggested 6- to 12-month ineligibility period because the Act requires a period of ineligibility of not less than 3 years following revocation of accreditation.

(20) *Qualifications of the Site Evaluator.* A commenter recommended amending section 205.508(a) to indicate the required qualifications of the site evaluator. We have not accepted the recommendation. We do not believe that it is necessary to specify the required qualifications of site evaluators in these regulations. All USDA employees who will perform site evaluations under the NOP are quality systems auditors trained in accordance with internationally recognized protocols.

(21) *Complaint Process.* A commenter recommended that section 205.510 include a complaint process for complaints by certified operations regarding the performance of a certifying agent or inspector. The commenter also recommended that section 205.510 include a complaint process for the public should they feel that a certifying agent is not in compliance.

We do not believe that it is necessary to include a complaint process in the regulations. All interested parties are free to file a complaint with an accredited certifying agent, SOP's governing State official, or the Administrator at any time. We will provide guidance to accredited certifying agents and SOP's governing State officials regarding the type of information to gather when receiving a complaint. SOP's governing State officials will include in their request for approval of their SOP information on their collection of complaint information. Certifying agents will include details regarding the collection of complaint information and the investigation of complaints involving certified operations in their procedures for reviewing and investigating certified operation compliance (section

205.504(b)(2)). This will include maintaining records of complaints and remedial actions relative to certification as well as documentation of followup actions. Further, certifying agents will include details regarding the collection of complaint information and the investigation of complaints involving inspectors and other personnel employed by or contracted by the certifying agents in their policies and procedures for training, evaluating, and supervising personnel (section 205.504(a)(1)).

(22) *Recordkeeping by Certifying Agents.* A commenter stated that the 10-year recordkeeping requirement of section 205.510(b)(2) for records created by the certifying agent regarding applicants for certification and certified operations is excessive. The commenter recommended a 5-year retention period. We have not accepted the recommended 5-year records retention period for records created by the certifying agent regarding applicants for certification and certified operations because the Act requires the retention of such records for 10 years.

(23) *Reaccreditation.* A commenter recommended that section 205.510(c)(1) be amended to require reaccreditation every 3 years. We have provided that accreditation will be for a period of 5 years. This is consistent with the Act which provides that accreditation shall be for a period of not to exceed 5 years. The commenter believes that a 5-year period is not consistent with ISO Guide 61, section 3.5.1, which provides that the accreditation body shall have an established documented program, consistent with the accreditation granted, for carrying out periodic surveillance and reassessment at sufficiently close intervals to verify that its accredited body continues to comply with the accreditation requirements. We believe that accreditation for 5 years is a reasonable period of time. Further, we believe that a 5-year period of accreditation is consistent with ISO Guide 61 inasmuch as we require an annual evaluation of the certification program; annual review of persons associated with the certification process, including inspectors; annual reporting with a complete and accurate update of information required for accreditation; and one or more site evaluations during the period of accreditation in addition to the initial site evaluation for the period of accreditation. Accordingly, we have not made the recommended change. This requirement is located at current section 205.510(c)(2).

(24) *Notice of Renewal of Accreditation.* A commenter recommended that section 205.510(d) be

amended to include a timeframe within which the Administrator must notify an applicant of its renewal of accreditation. We believe that a mandated timeframe for notifying the applicant of renewal of accreditation is inappropriate. We plan to process all applications for renewal of accreditation in the order in which they are received, to confirm the receipt of each application, and to establish a dialog with the applicant upon confirmation of receipt of an application for renewal of accreditation. The length of the renewal process will depend in large part on the nature of the operation seeking renewal of accreditation. To minimize the chances that an accreditation will expire during the renewal process, we have: (1) provided that the Administrator shall send the accredited certifying agent a notice of pending expiration of accreditation approximately 1 year before the date of expiration of the certifying agent's accreditation, (2) required that an application for renewal of accreditation must be received at least 6 months prior to expiration of the certifying agent's accreditation, and (3) provided that the accreditation of a certifying agent who makes timely application for renewal of accreditation will not expire during the renewal process. Accordingly, we have not made the recommended amendment.

Accreditation—Clarifications

Clarification is given on the following issues raised by commenters as follows:

(1) *Accreditation of Foreign Certifying Agents.* A commenter suggested that section 205.500 be amended to provide that if there is a government system operating in a foreign country then the government is the appropriate pathway for that country to apply for accreditation.

USDA will accept an application for accreditation to perform certification activities under the NOP from any private entity or governmental entity certifying agent and accredit such applicant upon proof of qualification for accreditation. USDA will provide for USDA accreditation of certifying agents and acceptance of a foreign government's accreditation of certifying agent within the same country. This maximizes opportunity for certifying agents without the potential for confusion and overlap in documentation. Further, we believe these requirements facilitate world trade.

(2) *State Approval of Product From Foreign Countries.* A commenter stated that any product making claims of organic agricultural ingredients to be sold in California shall fall under the

jurisdiction of the California Organic Program for enforcement, inspection, and certification direction. The commenter further stated that, should any foreign certifying agents be accepted, they too shall be subject to the sovereign rights of the State of California to protect and enforce the laws of the State of California and to protect agricultural claims in this State.

Any organic program administered by a State will have to be approved by the Secretary. Approval of an SOP will be contingent upon the State's agreeing to accept the certification decisions made by certifying agents accredited or accepted by USDA pursuant to section 205.500.

(3) *Equivalency.* A commenter stated that USDA should declare in section 205.500 that there are no alternative methods of production that meet the Congressional purpose "to assure consumers that organically produced products meet a consistent standard." The commenter went on to state that, if USDA proceeds with equivalency then the regulations should be amended to provide for: (1) No importing until final determination, (2) no final determination until Federal Register publication and public comment, (3) audit of foreign agency and production sites, and (4) revocation of accreditation for violations. The commenter also recommended that foreign certifying agents be reviewed with the same frequency as State certifying agents.

We disagree that there are no alternative methods of production that assure consumers that organically produced products meet a consistent standard. Accordingly, we will negotiate equivalency agreements with foreign governments. A final equivalency agreement will be required before affected product may be imported into the United States and sold, labeled, or represented as organic. Equivalency agreements will be announced to the public through a notice in the **Federal Register** and a news release. Site evaluations are a possibility. Foreign certifying agents that receive USDA accreditation, rather than recognition through their government, will have to fully comply with the NOP and will be treated the same as domestic accredited certifying agents.

(4) *Evaluation of Equivalency.* Commenters asked how equivalency would be evaluated and recommended basing equivalency, not on a check of formalities, but on the finding of substantive equivalence and equivalent effectiveness of certifying systems.

The negotiation of an equivalency agreement will involve meetings between representatives of the foreign

government seeking equivalency and representatives of USDA's Agricultural Marketing Service and Foreign Agricultural Service. Support will be provided by the Office of the U.S. Trade Representative. The process will also include the review of documents and possibly one or more site evaluations. Equivalency agreements will be announced to the public through a notice in the **Federal Register** and a news release.

(5) *Treatment of Certifying Agents Operating in More Than One Country.* A few commenters requested that we amend section 205.500(c) by adding a provision to clarify the issue of how the international activities of foreign or domestic certifying agents will be treated when they operate in more than one country.

We believe that the requested provision is unnecessary. Certifying agents, domestic and foreign, accredited under the NOP will be expected to comply fully with the requirements of the NOP regardless of where they operate. The only exception would be when they operate in a country in which the Secretary has negotiated an equivalency agreement.

(6) *Accreditation of Foreign Certifying Agents.* A commenter requested that we amend section 205.500(c) to exempt foreign applicants from having to be accredited certifying agents in USDA's program if the exporting country's national organic program meets international standards; e.g., Codex guidelines.

We have provided for USDA accreditation of qualified foreign certifying agents upon application. We have also provided that USDA will accept a foreign certifying agent's accreditation to certify organic production or handling operations if it determines, upon the request of a foreign government, that the standards under which the foreign government authority accredited the foreign certifying agent meet the requirements of this part. We have further provided that USDA will accept a foreign certifying agent's accreditation to certify organic production or handling operations if the foreign government authority that accredited the foreign certifying agent acted under an equivalency agreement negotiated between the United States and the foreign government. These recognitions of foreign government programs, however, do not extend to international standards such as Codex guidelines. In either case, we are recognizing the ability of a foreign government's program to meet U.S. standards, not some other international standard.

(7) *States with an Organic Statute.* A commenter stated that a State with an organic statute or regulations that does not certify organic producers or organic handlers should not have to be accredited.

The NOP requires the Secretary's approval of SOP's whether or not the State has a State certifying agent. A State may have an SOP but not have a State certifying agent. In this case the SOP must be approved by the Secretary. A State may have a State certifying agent but no SOP. In this case, the State certifying agent must apply for and receive accreditation to certify organic production or handling operations. Finally, a State may have an SOP and a State certifying agent. In this case, the SOP must be approved by the Secretary, and the State certifying agent must apply for and receive accreditation to certify organic production or handling operations.

(8) *Nondiscriminatory Services.* A commenter wanted the addition of a provision in section 205.501(a) requiring certifying agents to provide nondiscriminatory services. We have not included the suggested addition in this final rule because the provision already exists in section 205.501(d).

(9) *Release of Information.* A few commenters requested that we amend section 205.501(a)(10) to include a general exclusion allowing the release of any information with the client's permission. We have not included the suggested addition in this final rule because section 205.504(b)(5)(iv) already addresses the allowed release of other business information as permitted in writing by the producer or handler.

(10) *Use of the Term, "Certified Organic."* In commenting on section 205.501(b)(1), a commenter stated that if the term, "certified organic," is included on a label, it must state by whom, according to Maine State law. We do not believe that the requirements of section 205.501(b)(1) would preclude a certified operation from complying with a State law requiring identification of the certifying agent on a product sold, labeled, or represented as "certified organic." Further, these regulations do not require a certified operation to use the word, "certified," on its label.

(11) *Holding the Secretary Harmless.* In commenting on the requirements of section 205.501(c)(1), a commenter stated that certifying agents are responsible for representing USDA but seem to have no recourse. Another commenter asked, what happens if a certifying agent is found in violation of the Act but the violation was due to information or direction that came from USDA?

Under the NOP, accredited certifying agents are required to comply with and carry out the requirements of the Act and these regulations. If they fail to do so, they are responsible for their actions or failures to act. This would not be true if the action or failure to act was at the direction of the Secretary.

(12) *Self-evaluation of Ability to Comply.* A commenter requested that section 205.504 be amended to provide clarity on the baseline requirements that would allow a certifying agent to conduct a self-evaluation to determine its ability to comply. The commenter stated that there should be some type of baseline acceptance of expertise and ability. The commenter wants details regarding the "training" or "experience" requirements necessary to qualify for accreditation. This commenter also stated that criteria for inspector and reviewer training should be added and enlarged.

We do not believe that it is necessary to present the requirements for accreditation to the extent of detail requested by the commenter. The intent is to provide flexibility to the certifying agents such that they can tailor their policies and procedures to the nature and scope of their operation. The NOP is available to respond to questions and to assist certifying agents in complying with the requirements for accreditation.

(13) *Evidence of Expertise and Ability.* Commenters stated that important elements of ISO Guide 65 are missing from section 205.504. They cite the maintenance of a complaints register and a register of precedents and provisions for subcontracting and a documents control policy or a document register.

Certifying agents grant certification, deny certification, and take enforcement action against a certified operation's certification. Certifying agents are required to maintain records applicable to all such actions and to report such actions to the Administrator. Certifying agents may contract with qualified individuals for the performance of services such as inspection, sampling, and residue testing. Certifying agents are required to submit personnel information (employed and contracted) and administrative policies and procedures to the Administrator. All such documents must be updated annually. The regulations also require the maintenance of records according to specified retention periods. All of these factors will be considered in granting or denying accreditation. We believe these requirements meet or exceed the ISO Guide 65 guidelines.

(14) *Personnel Evidence of Expertise.* A commenter inquired about the

frequency at which the personnel information, required by section 205.504(a) and used to establish evidence of expertise and ability, is to be updated. Section 205.510 requires that the certifying agent annually submit a complete and accurate update of the information required in section 205.504.

(15) *Responsibly Connected.* A commenter stated that the term, "responsibly connected," as used in section 205.504(a)(2) is a broad sweep. The commenter believes the term would include everyone they do business with.

Section 205.504(a)(2) requires the certifying agent to provide the name and position description of all personnel to be used in the certification operation. The section assists the certifying agent in meeting the requirement by identifying categories of persons covered by the requirement including persons responsibly connected to the certifying agent. Responsibly connected does not include everyone that the certifying agent does business with. Responsibly connected is defined in the Definitions subpart of this final rule as "any person who is a partner, officer, director, holder, manager, or owner of 10 percent or more of the voting stock of an applicant or a recipient of certification or accreditation." This definition has not changed.

(16) *Independent Third-Party Inspectors.* A commenter recommended amending section 205.504(a)(3)(I) to provide for the use of independent third-party inspectors. We believe that this recommended amendment is unnecessary since nothing in these regulations precludes a certifying agent from contracting with independent third parties for inspection services.

(17) *Response to Accreditation Applicant.* A commenter requested that section 205.506(a)(3) be amended to provide a timeframe within which the Administrator has to respond to the accreditation application. While section 205.506(a)(3) identifies the information to be reviewed by the Administrator prior to the granting of accreditation, we assume the commenter is seeking a specific time limit by which the Administrator will acknowledge receipt of an application for accreditation. In the alternative, the commenter may have been seeking a specific time limit by which the Administrator must grant or deny accreditation. We believe that a regulation-mandated timeframe for notifying the applicant of receipt of an application or for granting or denying accreditation is unnecessary. We plan to process all applications in the order in which they are received, to confirm the receipt of each application upon receipt, and to establish a dialog with the

applicant upon confirmation of receipt of an application for accreditation. We will work with each applicant to complete the accreditation process as expeditiously as possible. A firm timeframe, however, cannot be set for granting or denying accreditation due to the anticipated uniqueness of each applicant and its application for accreditation.

(18) *Duration of Accreditation and Certification.* A commenter asked, "How can certification be essentially in perpetuity and accreditation have a time restraint?" The commenter's question does not indicate a preference for certification or accreditation longevity. The commenter correctly points out that certification and accreditation, both of which must be updated annually, are granted for different time periods. The Act limits the period of accreditation to 5 years but does not establish a limit to the period of certification. We believe the requirement that the certified operation submit an annual update of its organic plan negates the need for a certification expiration date.

(19) *Denial of Accreditation.* In commenting on section 205.507, a commenter stated that the regulations need to address what happens to a certifying agent's clients when the certifying agent fails to qualify for accreditation on its first attempt.

Section 205.507(c) provides that an applicant who has received written notification of accreditation denial may apply for accreditation again at any time in accordance with section 205.502. Upon implementation of the certification requirements of the NOP, production and handling operations planning to sell, label, or represent their products as organic must be certified by a USDA-accredited certifying agent before selling, labeling, or representing their products as organic. If a producer's or handler's choice of certifying agents does not receive USDA accreditation, the producer or handler must seek and receive certification under the NOP from a USDA-accredited certifying agent before selling, labeling, or representing their products as organic. Producers and handlers not so certified may not sell, label, or represent their products as organic. Any producer or handler who violates this requirement will be subject to prosecution under section 2120 of the Act.

(20) *Loss of Accreditation After Initial Site Visit.* Commenting on section 205.508(b), a commenter stated the belief that accreditation before a site visit may cause problems if the certifying agent does not meet the requirements and, subsequently, loses its accreditation. We believe the

problems will be no greater than will occur at any other time when it becomes necessary to revoke a certifying agent's accreditation, including when it becomes necessary to initiate proceedings to suspend or revoke the certification of one or more of the certifying agent's certified operations. However, just because revocation of a certifying agent's accreditation may be justified, it may not be necessary to suspend or revoke the certification of one or more of its clients. An operation certified by a certifying agent that has lost its accreditation must make application with a new certifying agent if it is going to continue to sell, label, or represent its products as organic.

(21) *Prohibition on Certification After Expiration of Accreditation.* A commenter stated that, "USDA should allow certifying agents to apply the same provisions to expiration of certification of a certified operation." The provision referenced by the commenter is the section 205.510(c)(1) (current section 205.510(c)(2)) requirement that certifying agents with an expired accreditation must not perform certification activities under the Act and these regulations. We have not accepted the commenter's request that the same prohibition be applied to production and handling operations with an expired certification because certification does not expire.

(22) *Expiration of Accreditation.* Many commenters requested that we amend section 205.510(c)(1) to require annual reports and "minivisits." The commenters cited ISO Guide 61, section 3.5.1. We do not believe that annual "minivisits" are necessary to meet the requirements of ISO Guide 61 or to assure compliance with the NOP. One or more site evaluations will be conducted during the period of accreditation. The certifying agent's annual report will be used as a determining factor in whether to conduct a site evaluation. A request for amendment to a certifying agent's area of accreditation will also result in a site evaluation. This requirement is located at current section 205.510(c)(2).

(23) *Update and Review of Inspector Lists.* In commenting on section 205.510(c)(1) (current section 205.510(c)(2)) several commenters stated that updating and review of inspector lists must occur more frequently than every 5 years. They cited ISO Guide 61, section 3.5.1.

Section 205.510(a)(1) requires that the certifying agent annually update the information required in section 205.504. This includes the inspector information required by paragraphs 205.504(a)(2) and 205.504(a)(3)(i).

Subpart G—Administrative**The National List of Allowed and Prohibited Substances****Description of Regulations***General Requirements*

This subpart contains criteria for determining which substances and ingredients are allowed or prohibited in products to be sold, labeled, or represented as “organic” or “made with organic (specified ingredients or food group(s)).” It establishes the National List of Allowed and Prohibited Substances (National List) and identifies specific substances which may or may not be used in organic production and handling operations. Sections 6504, 6510, 6517, and 6518 of the Organic Foods Production Act (OFPA) of 1990 provide the Secretary with the authority to develop the National List. The contents of the National List are based upon a Proposed National List, with annotations, as recommended to the Secretary by the National Organic Standards Board (NOSB). The NOSB is established by the OFPA to advise the Secretary on all aspects of the National Organic Program (NOP). The OFPA prohibits synthetic substances in the production and handling of organically produced agricultural products unless such synthetic substances are placed on the National List.

Substances appearing on the National List are designated using the following classifications:

1. Synthetic substances allowed for use in organic crop production
2. Nonsynthetic substances prohibited for use in organic crop production
3. Synthetic substances allowed for use in organic livestock production
4. Nonsynthetic substances prohibited for use in organic livestock production
5. Nonagricultural (nonorganic) substances allowed as ingredients in or on processed products labeled as “organic” or “made with organic (specified ingredients or food group(s))”
6. Nonorganically produced agricultural products allowed as ingredients in or on processed products labeled as organic” or “made with organic (specified ingredients or food group(s))”

This subpart also outlines procedures through which an individual may petition the Secretary to evaluate substances for developing proposed National List amendments and deletions.

The NOSB is responsible for making the recommendation of whether a substance is suitable for use in organic production and handling. The OFPA allows the NOSB to develop substance

recommendations and annotations and forward to the Secretary a Proposed National List and any subsequent proposed amendments. We have made every effort to ensure the National List in this final rule corresponds to the recommendations on allowed and prohibited substances made by the NOSB. In developing their recommendations, the NOSB evaluates synthetic substances for the National List utilizing the criteria stipulated by the Act. Additionally, criteria for evaluating synthetic processing ingredients have been implemented by the NOSB. These criteria are an interpretation and application of the general evaluation criteria for synthetic substances contained in the OFPA that the NOSB will apply to processing aids and adjuvants. The NOSB adopted these criteria as internal guidelines for evaluating processing aids and adjuvants. The adopted criteria do not supersede the criteria contained in the OFPA or replace the Food and Drug Administration’s (FDA) regulations related to food additives and generally recognized as safe (GRAS) substances. The NOSB has also provided recommendations for the use of synthetic inert ingredients in formulated pesticide products used as production inputs in organic crop or livestock operations. The Environmental Protection Agency (EPA) regulates and maintains the EPA Lists of Inert ingredients used for pesticide. In this final rule, EPA Inerts List 1 and 2 are prohibited, EPA List 3 is also prohibited unless specifically recommended as allowed by the NOSB, and EPA List 4 Inerts are allowed unless specifically prohibited.

In this final rule, only EPA List 4 Inerts are allowed as ingredients in formulated pesticide products used in organic crop and livestock production. The allowance for EPA List 4 Inerts only applies to pesticide formulations. Synthetic ingredients in any formulated products used as organic production inputs, including pesticides, fertilizers, animal drugs, and feeds, must be included on the National List. As sanctioned by OFPA, synthetic substances can be used in organic production and handling as long as they appear on the National List. The organic industry should clearly understand that NOSB evaluation of the wide variety of inert ingredients and other nonactive substances will require considerable coordination between the NOP, the NOSB, and industry. Materials review can be anticipated as one of the NOSB’s primary activities during NOP implementation. Considering the critical

nature of this task, the organic industry should make a collaborative effort to prioritize for NOSB review those substances that are essential to organic production and handling. The development and maintenance of the National List has been and will be designed to allow the use of a minimal number of synthetic substances that are acceptable to the organic industry and meet the OFPA criteria.

We expect the maintenance of the National List to be a dynamic process. We anticipate that decisions on substance petitions for the inclusion on or deletion from the National List will be made on an annual basis. Any person seeking a change in the National List should request a copy of the petition procedures that were published in the **Federal Register** (65 Fed Reg 43259–43261) on July 13, 2000, from the NOP. The National List petition process contact information is: Program Manager, National Organic Program, USDA/AMS/TMP/NOP, Room 2945–S, Ag Stop 0268, P.O. Box 96456, Washington, DC 20090–6456 or visit the NOP website: www.ams.usda.gov/nop. Substances petitioned for inclusion on the National List will be reviewed by the NOSB, which will forward a recommendation to the Secretary. Any amendments to the National List will require rulemaking and must be published for comment in the **Federal Register**.

Nothing in this subpart alters the authority of other Federal agencies to regulate substances appearing on the National List. FDA issues regulations for the safe use of substances in food production and processing. USDA’s Food Safety and Inspection Service (FSIS) has the authority to determine efficacy and suitability regarding the production and processing of meat, poultry, and egg products. FDA and FSIS restrictions on use or combinations of food additives or GRAS substances take precedence over the approved and prohibited uses specified in this final rule. In other words, any combinations of substances in food processing not already addressed in FDA and FSIS regulations must be approved by FDA and FSIS prior to use. FDA and FSIS regulations can be amended from time to time under their rulemaking procedures, and conditions of safe use of food additives and GRAS substances can be revised by the amendment. It is important that certified organic producers and handlers of both crop and livestock products consult with FDA regulations in 21 CFR parts 170 through 199 and FSIS regulations in this regard. All feeds, feed ingredients, and additives for feeds used in the

production of livestock in an organic operation must comply with the Federal Food, Drug, and Cosmetic Act (FFDCA). Animal feed labeling requirements are published in 21 CFR Part 501, and new animal drug requirements and a listing of approved animal drugs are published in 21 CFR parts 510–558. Food (feed) additive requirements, a list of approved food (feed) additives generally recognized as safe substances, substances affirmed as GRAS, and substances prohibited from use in animal food or feed are published in 21 CFR parts 570–571, 21 CFR part 573, 21 CFR part 582, 21 CFR part 584, and 21 CFR part 589, respectively. Furthermore, the Food and Drug Administration has worked closely with the Association of American Feed Control Officials (AAFCO) and recognizes the list of additives and feedstuffs published in the AAFCO Official Publication, which is updated annually.

Under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), EPA regulates the use of all pesticide products, including those that may be approved for use in the NOP. In registering a pesticide under FIFRA, EPA approves the uses of each pesticide product. It is a violation of FIFRA to use a registered product in a manner inconsistent with its labeling. The fact that a substance is on the National List does not authorize use or a pesticide product for that use if the pesticide product label does not include that use. If the National List and the pesticide labeling conflict, the pesticide labeling takes precedence and may prohibit a practice allowed on the National List.

National List—Changes Based On Comments

This subpart differs from the proposal in several respects as follows:

(1) *Comprehensive Prohibition on Excluded Methods.* Many commenters supported a comprehensive prohibition on the use of excluded methods in organic production and handling. These commenters stated that the proposed language on excluded methods could have allowed some uses since the general prohibition described in section 205.301 of the proposed rule could be interpreted as applying only to multiingredient products. In order to provide a comprehensive prohibition on the use of excluded methods, we incorporated a new provision within section 205.105. A more comprehensive discussion of this issue is found in subpart B, Applicability.

(2) *Substance Evaluation Criteria for the National List.* Commenters stated that the final rule should include in the

regulation text the evaluation criteria utilized by the NOSB for the development of substance recommendations. We agree, and we have inserted the substance evaluation criteria developed by the NOSB for processing ingredients and cited the criteria within the Act (7 U.S.C. 6518(m)) for crops and livestock production as new provisions for section 205.600, which is now entitled “Evaluation criteria for allowed and prohibited substances, methods, and ingredients.”

(3) *Substances Approved for Inclusion on the National List.* Commenters stated that the National List did not contain all of the substances recommended by the NOSB for inclusion on the National List of Allowed and Prohibited Substances. We agree and have added the following substances consistent with the most recent NOSB recommendations:

Crop Production

Lime sulfur as a plant disease control substance

Elemental sulfur as a plant or soil amendment

Copper as a plant or soil micronutrient

Streptomycin sulfate as plant disease control substances with the annotation “for fire blight control in apples and pears only”

Terramycin (oxytetracycline calcium complex) as a plant disease control substance with the annotation “for fire blight control only”

Magnesium sulfate as a plant or soil amendment with the annotation “allowed with a documented soil deficiency”

Ethylene as a plant growth regulator, with the annotation “for regulation of pineapple flowering”

We have added sodium nitrate and potassium chloride to the National List as nonsynthetic substances prohibited for use in crop production unless used in accordance with the substance annotations. Sodium nitrate is prohibited unless use is restricted to no more than 20 percent of the crop’s total nitrogen requirement. Potassium chloride is prohibited unless derived from a mined source and applied in a manner that minimizes chloride accumulation in the soil. These additions are discussed further in item 3 under Changes Based on Comments, subpart C.

Livestock Production

Oxytocin with the annotation “for use in postparturition therapeutic applications”

EPA List 4 inert ingredients as synthetic inert ingredients for use with nonsynthetic substances or synthetic

substances allowed in organic livestock production.

Several commenters recommended that the final rule should specify which nonsynthetic substances are prohibited for use in livestock production. These commenters stated that the proposed rule prohibited six such substances for use in crop production and maintained that an analogous list for livestock operations would be beneficial. Of the six nonsynthetic substances in the proposed rule prohibited for use in crop production, four were based on NOSB recommendations (strychnine, tobacco dust, sodium fluoaluminate (mined), and ash from burning manure) and two were based on statutory provisions in the OFPA (arsenic and lead salts). After reviewing these substances and the NOSB recommendations, we determined that the prohibition for one, strychnine, also applies to livestock production. Individuals may petition the NOSB to have additional nonsynthetic substances prohibited for use in organic crop and livestock production.

Organic Handling (Processing)

Tribasic calcium phosphate

Nonsynthetic colors

Flavors, with the annotation

“nonsynthetic sources only and must not be produced using synthetic solvents and carrier systems or any artificial preservatives”

Nonsynthetic waxes, carnauba wax, wood resin

Cornstarch (native), gums, kelp, lecithin and pectin were moved from section 205.605 to section 205.606

(4) *Substance Removed from the National List.* Commenters stated that certain substances on the National List in the proposed rule had not been recommended by the NOSB. We agree with the comment that the NOSB did not recommend that magnesium should be allowed as a plant or soil micronutrient and have removed it from the National List.

(5) *Changes in Substance Annotations on the National List.* Commenters stated that certain annotations in the proposed rule did not capture the precise recommendations of the NOSB. We agree and have amended the annotations within the National List as follows:

The annotation for hydrated lime as a plant disease control substance now states, “must be used in a manner that minimizes accumulation of copper in the soil.”

The annotation for horticultural oils as an insecticide substance and as a plant disease control substance now

states, "Narrow range oils as dormant, suffocating, and summer oils."

The annotation for hydrated lime in livestock production now states, "not permitted for soil application or to cauterize physical alterations or deodorize animal wastes."

The annotation for the allowed synthetic parasiticide Ivermectin has been modified to state that the substance may not be used during the lactation period of breeding stock.

The annotation for trace minerals and vitamins allowed as feed additives has been modified and now states, "used for enrichment or fortification when FDA approved."

The annotation for magnesium sulfate in organic handling now states, "nonsynthetic sources only."

The annotation for EPA List 4 Inerts allowed in crop and livestock production has been modified to state, " * * * for use with nonsynthetic substances or synthetic substances listed in this section * * *"

(6) *Sulfur Dioxide for Organic Wines.* Many commenters recommended that this final rule should allow for the use of sulfur dioxide in wine labeled "made with organic grapes." They argued that sulfur dioxide is necessary in organic wine production and that prohibiting its use would have a negative impact on organic grape production and wineries that produce wine labeled "made with organic grapes." The prohibition on the use of sulfur dioxide in the proposed rule was based upon the requirement in the Act that prohibited the addition of sulfites to organically produced foods. However, a change in the Act now allows the use of sulfites in wine labeled as "made with organic grapes." Therefore, we have added sulfur dioxide to the National List with the annotation, "for use only in wine labeled "made with organic grapes." Provided, That, total sulfite concentration does not exceed 100 ppm." The label for the wine must indicate the presence of sulfites. This addition to the National List is also in agreement with the NOSB recommendation for allowing the use of sulfur dioxide in producing wine to be labeled as "made with organic grapes."

National List—Changes Requested But Not Made

This subpart retains from the proposed rule regulations on which we received comments as follows:

(1) *Restructuring the National List.* Commenters requested a restructuring of the National List to improve its clarity and ease of use. Some of the commenters asked for minor changes involving the wording of section titles. Other commenters were opposed to the

categories used in the National List because the categories are not in compliance with the Act. In its June 2000 meeting, the NOSB asked the NOP to review a proposal from a research institute proposing that processing materials for the National List be categorized according to industry standards. This proposal recommended including new sections for substances used in "made with * * *" and substances used in the 5-percent nonorganic portion of "organic" multiingredient products. We agree that the present structure of the National List may not have optimum clarity and ease of use. However, extensive restructuring of the National List without additional NOSB consideration and public discussion would be a significant variation from the policy that established the National List for this final rule. The NOP will work with the NOSB and the public to refine the National list consistent with industry norms and public expectations.

(2) *Use of EPA List 4 Inerts.* The proposed rule allowed EPA List 4 Inerts to be used as synthetic inert ingredients with allowed synthetic active ingredients in crop production. Some commenters stated that certain substances among the EPA List 4 inerts should not be allowed in organic production. Some commenters went further and recommended that the allowance for synthetic inert ingredients should be limited to the subset of materials that the EPA designates as List 4A. We do not agree with these commenters and have retained the allowance for all inerts included on EPA List 4. List 4 inerts are classified by EPA as those of "minimal concern" and, after continuing consultation with EPA, we believe there is no justification for a further restriction to List 4A. If commenters believe that a particular List 4 inert should not be allowed in formulated products used in organic production, they can petition the NOSB to have that substance prohibited.

(3) *Removing Vaccines from the National List.* Some commenters asserted that vaccines should not be included on the National List because the NOSB had never favorably recommended their use in livestock production. However, the OFPA authorizes the use of vaccines, and in 1995, the NOSB recommended allowing their use. The NOSB stated that use of vaccines may be necessary to ensure the health of the animal and to remain in compliance with Federal, State, or regional regulations. We agree with the NOSB's recommendation and have retained vaccines as an allowed substance in livestock medication.

(4) *Adding Amino Acids to the National List.* Some commenters recommended that amino acids should be added to the National List as allowed synthetic substances for livestock production. We have not added amino acids to the National List because the NOSB has not recommended that they should be allowed. This subject is discussed further in item 4, Livestock—Changes Based on Comments, subpart C.

(5) *Creating a Category for Prohibited Nonsynthetic Seed Treatments.* A commenter stated that the National List of nonsynthetic substances prohibited for use in crop production should include provisions for seed treated with a nonsynthetic substance. This commenter stated that the final rule should acknowledge that a nonsynthetic seed treatment could be prohibited on the National List. We do not believe it is necessary to include a separate category for seed treatments under the prohibited nonsynthetic section of the National List. An individual may petition the NOSB to have a particular nonsynthetic seed treatments placed on the prohibited list without creating a new category for seed treatments.

(6) *Creating a Category for Treated Seed and Toxins Derived from Bacteria.* Commenters stated that the National List of synthetic substances allowed in crop production should include categories for treated seed and toxins derived from bacteria. These commenters stated that these categories are sanctioned by the OFPA, and failure to consider them would place a significant burden on organic producers. We believe it is unnecessary to include these categories on the National List. Specific substances from these categories could be incorporated in existing categories that reflect their function, such as plant disease control or insecticide. An individual may submit petitions to the NOSB to have specific substances from these categories considered for inclusion on the National List.

(7) *Remove Categories for Feed Supplements.* A commenter stated that it was inappropriate for the National List of synthetic substances allowed in livestock production to contain categories for feed supplements and feed additives because they are not authorized in the OFPA. We disagree with this commenter because the identification of categories on the National List does not mean that all substances within that category are allowed. The categories help to clarify which types of materials may be included on the National List. The substances included under the categories of feed supplements and feed

additives were recommended by the NOSB and added to the National List with the Secretary's approval.

(8) *Neurotoxic Substances on the National List.* Many commenters requested that the NOP remove particular substances from section 205.605 of the National List. They stated these substances were sources of neurotoxic compounds that negatively effect human health. The substances cited were yeast (autolysate and brewers), carrageenan, and enzymes. Moreover, these commenters argued against including on the National List some amino acids or their derivatives which the commenters claim have neurotoxic side effects. These commenters requested that amino acids should be prohibited from the National List due to the possibility that neurotoxic substances could be utilized for either organic agricultural production or handling.

We do not agree with the requests of the commenters and we have not made the requested changes. There are no amino acids currently on the National List; therefore, synthetic sources of amino acids are prohibited. Unless recommended for use by the NOSB, synthetic amino acids will not be included on the National List. The NOP has established a petition process for substances to be evaluated for inclusion on or removal from the National List of Allowed and Prohibited Substances in organic production and handling. Anyone seeking to have a particular substance removed from the National List may file a substance petition to amend the National List.

(9) *EPA List 4 Inerts for Organic Processing.* A few commenters recommended that substances in EPA List 4 inerts that are allowed for use in crop production also be allowed for use as processing materials. We do not agree, and we have not included EPA List 4 Inerts on the National List for organic handling. Inerts listed on EPA List 4 have been evaluated and approved for use in pesticide formulations, not for use as processing materials. Inerts that are included on EPA List 4 would have to be further evaluated to determine whether such materials meet the criteria for inclusion on the National List.

(10) *Modifying Annotations of Organic Processing Substances.* One commenter requested that the Department modify the annotation for phosphoric acid to include its use as a processing aid. We have not made the suggested change. Any change in the annotation of a substance can only occur through an NOSB recommendation. Individuals or groups

can use the petition process to submit substance petitions to the NOSB for the evaluation to be included on or removed from the National List.

(11) *Nutritional Supplementation of Organic Foods.* Some commenters asserted that 21 CFR 104.20 is not an adequate stand-alone reference for nutritional supplementation of organic foods. As a result, these commenters recommended that the final rule include as additional cites 21 CFR 101.9(c)(8) for FDA-regulated foods and 9 CFR 317.30(c), 318.409(c)(8) for foods regulated by FSIS to support 21 CFR 104.20. We did not implement the suggested changes of the commenters. Section 205.605(b)(20) in the proposed rule allowed the use of synthetic nutrient vitamins and minerals to be used in accordance with 21 CFR 104.20, Nutritional Quality Guidelines For Foods, as ingredients in processed products to be sold as "organic" or "made with * * *." The commenters recommended cites, 21 CFR 101.9(c)(8) for FDA-regulated foods and 9 CFR 317.30(c); section 318.409(c)(8) did not provide provisions for nutritional supplementation of foods. Instead, these suggested cites were particularly aimed toward: (1) The declaration of nutrition information on the label and in labeling of a food; (2) labeling, marking devices, and containers; (3) entry into official establishments; and (4) reinspection and preparation of products. The NOP, in consultation with FDA, considers 21 CFR 104.20 to be the most appropriate reference regarding nutritional supplementation for organic foods.

(12) *National List Petition Process as Part of the Final Rule.*

Commenters have requested that the National List Petition Process, approved by the NOSB at its June 2000 meeting (and published in the **Federal Register** on July 13, 2000), be included in the final rule. We do not agree with the commenters, and we have retained the National List Petition Process regulation language from the proposed rule. We have separated the specific petition process from the regulation to provide for maximum flexibility to change and clarify the petition process to accommodate new considerations developed during the NOP implementation. If this process were part of this final rule, updates to the petition process would require notice and comment rulemaking. Any changes in the National List that may be a result of the petition process, however, would require notice and comment rulemaking.

(13) *Nonapproved Substance Amendments to the National List.* Commenters also requested to have

many substances that are not on the National List and that have not been recommended by the NOSB for use in organic production and handling be added to the National List. We do not agree. Amendments to the National List must be petitioned for NOSB consideration, must have an NOSB recommendation, and must be published for public comment in the **Federal Register**.

National List—Clarifications

Clarification is given on the following issues raised by commenters as follows:

(1) *Inerts Use in Botanical or Microbial Pesticides.* Commenters expressed concern that the prohibition on the use of EPA List 3 inerts would prevent organic producers from using certain botanical or microbial formulated products that are currently allowed under some certification programs. These commenters requested that the NOP and the NOSB expedite the evaluation of List 3 inerts used in nonsynthetic formulated products to prevent the loss of certain formulated products. The prohibition of List 3 inerts was based on the recommendation of the NOSB to add only those substances from List 4 to the National List. The NOSB also recommended that individual inert substances included on List 3 could be petitioned for addition to the National List. The NOP has requested that the NOSB identify for expedited review those List 3 inerts that are most important in formulated products used in organic production. Individuals may petition to have these inerts considered for inclusion on the National List. Additionally, the NOP will work with the EPA and the registrants of formulated products to expedite review of List 3 inerts currently included in formulated products used in organic production. Unless List 3 inerts are moved to List 4 or individually added to the National List, they are prohibited for use in organic production.

(2) *Prohibiting Ash, Grit, and Screenings Derived from Sewage Sludge.* Many commenters recommended that the ash, grit, and screenings derived from the production of sewage sludge should be added to the National List as nonsynthetic materials prohibited for use in crop production. While the use of sewage sludge, including ash, grit, and screenings, is prohibited in organic production, we did not add them to the National List as prohibited nonsynthetic substances. This subject is discussed further under subpart A, Definitions—Changes Requested But Not Made.

(3) *Allowed Uses for Pheromones.* Some commenters were concerned that

the annotation for using pheromones as "insect attractants" was too limiting and would not include uses such as mating disruption, trapping, and monitoring. The annotation for pheromones does not preclude any use for a pheromone that is otherwise allowed by Federal, State, or local regulation.

(4) *Nonagricultural Products as Livestock Feed Ingredients.* Some commenters questioned whether nonsynthetic, nonagricultural substances such as fishmeal and crushed oyster shell needed to be added to the National List to be used in livestock feed. Nonsynthetic substances do not have to appear on the National List and may be used in organic livestock feed, provided that they are used in compliance with the FFDCA. This subject is discussed further under item 4, Livestock—Changes Based on Comments, subpart C.

(5) *Chlorine Disinfectant Limit Annotation for Organic Production and Handling.* Some commenters requested clarification on the annotation for using chlorine materials as an allowed synthetic substance in crop and handling operations. The annotation in the proposed rule, which has been retained in the final rule, stated that "residual chlorine levels in the water shall not exceed the maximum residual disinfectant limit under the Safe Water Drinking Act." With this annotation, the residual chlorine levels at the point where the waste water stream leaves the production or handling operation must meet limits under the Safe Drinking Water Act.

(6) *Tobacco Use in Organic Production.* One commenter questioned whether forms of tobacco other than tobacco dust, such as water extracts or smoke, were prohibited nonsynthetic substances. The technical advisory panel (TAP) review on which the NOSB based its recommendation to prohibit tobacco dust identified nicotine sulfate as the active ingredient. Therefore, any substance containing nicotine sulfate as an active ingredient is prohibited in crop production.

(7) *Nonsynthetic Agricultural Processing Aids on the National List.* A commenter requested clarification from the NOP on whether processing aids (e.g., defoaming agents), which are nonsynthetic and nonorganic agricultural substances (e.g., soybean oil), must appear on the National List when used in processing. In the regulation, a nonsynthetic and nonorganic agricultural product, such as soybean oil, used as a processing aid does not have to appear on the National List. Such products are included in the provision in section 205.606 that

nonorganically produced agricultural products may be used in accordance with any applicable restrictions when the substance is not commercially available in organic form.

(8) *Transparency of the National List Petition Process.* Some commenters stated the petition process for amending the National List appears to have limited public access and should be more transparent. These commenters advocate that any amendments to the National List should be subject to notice and comment. They also requested clarity on how petitions are prioritized and reviewed and the timeframes for review. Additionally, these commenters asked the NOP to expedite the review of materials for the National List. On July 13, 2000, AMS published in the **Federal Register** (Vol. 65, 43259–43261) guidelines for submitting petitions for the evaluations of substances for the addition to or removal from the National List. In this notice, the NOP stated that most petition information is available for public inspection with the exception of information considered to be "confidential business information." The notice also specified that any changes to the National List must be published in the **Federal Register** for public comment. The published petition notice has also provided an indication to the industry about the urgency of the need for substance review and that the industry should provide pertinent information to the NOSB to expedite the review of materials not on the National List.

State Organic Programs

The Act provides that each State may implement an organic program for agricultural products that have been produced and handled within the State, using organic methods that meet the requirements of the Act and these regulations. The Act further provides that a State organic program (SOP) may contain more restrictive requirements for organic products produced and handled within the State than are contained in the National Organic Program (NOP). All SOP's and subsequent amendments thereto must be approved by the Secretary.

A State may have an SOP but not have a State certifying agent. A State may have a State certifying agent but no SOP. Finally, a State may have an SOP and a State certifying agent. In all cases, the SOP's must be approved by the Secretary. In all cases, the State certifying agent must apply for and receive accreditation to certify organic production or handling operations pursuant to subpart F.

In States with an approved SOP, the SOP's governing State official is responsible for administering a compliance program for enforcement of the NOP and any more restrictive requirements contained in the SOP. The SOP governing State officials may review and investigate complaints of noncompliance involving organic production or handling operations operating within their State and, when appropriate, initiate suspension or revocation of certification. The SOP governing State officials may also review and investigate complaints of noncompliance involving accredited certifying agents operating within their State. They must report the findings of any review and investigation of a certifying agent to the NOP Program Manager along with any recommendations for appropriate action. States that do not have an SOP will not be responsible for compliance under the NOP, except that an accredited State certifying agent operating within such State will have compliance responsibilities under the NOP as a condition of its accreditation.

The sections covering SOP's, beginning with section 205.620, establish: (1) The requirements for an SOP and amending such a program and (2) the process for approval of an SOP and amendments to the SOP's. Review and approval of an SOP will occur not less than once during each 5-year period. Review related to compliance matters may occur at any time.

Description of Regulations

State Organic Program Requirements

A State may establish an SOP for production and handling operations within the State that produces and handles organic agricultural products. The SOP and supporting documentation must demonstrate that the SOP meets the requirements for organic programs specified in the Act.

An SOP may contain more restrictive requirements governing the production and handling of organic products within the State. Such requirements must be based on environmental conditions or specific production or handling practices particular to the State or region of the United States, which necessitates the more restrictive requirement. More restrictive requirements must be justified and shown to be consistent with and to further the purposes of the Act and the regulations in this part. Requirements necessitated by an environmental condition that is limited to a specific geographic area of the State should only be required of organic production and

handling operations operating within the applicable geographic area. If approved by the Secretary, the more restrictive requirements will become the NOP regulations for organic producers and handlers in the State or applicable geographical area of the State. All USDA-accredited certifying agents planning to operate within a State with an SOP will be required to demonstrate their ability to comply with the SOP's more restrictive requirements.

No provision of an SOP shall discriminate against organic agricultural products produced by production or handling operations certified by certifying agents accredited or accepted by USDA pursuant to section 205.500. Specifically, an SOP may not discriminate against agricultural commodities organically produced in other States in accordance with the Act and the regulations in this part. Further, an SOP may not discriminate against agricultural commodities organically produced by production or handling operations certified by foreign certifying agents operating under: (1) Standards determined by USDA to meet the requirements of this part or (2) an equivalency agreement negotiated between the United States and a foreign government.

To receive approval of its SOP, a State must assume enforcement obligations in the State for the requirements of this part and any more restrictive requirements included in the SOP and approved by the Secretary. Specifically, the State must ensure compliance with the Act, the regulations in this part, and the provisions of the SOP by certified production and handling operations operating within the State. The SOP must include compliance and appeals procedures equivalent to those provided for under the NOP.

An SOP and any amendments thereto must be approved by the Secretary prior to implementation by the State.

State Organic Program Approval Process

An SOP and subsequent amendments thereto must be submitted to the Secretary by the SOP's governing State official for approval prior to implementation. A request for approval of an SOP must contain supporting materials that include statutory authorities, program descriptions, documentation of environmental or ecological conditions or specific production and handling practices particular to the State which necessitate more restrictive requirements than the requirements of this part, and other information as may be required by the Secretary. A request for amendment of

an approved SOP must contain supporting materials that include an explanation and documentation of the environmental or ecological conditions or specific production practices particular to the State or region, which necessitate the proposed amendment. Supporting material also must explain how the proposed amendment furthers and is consistent with the purposes of the Act and the regulations in this part.

Each request for approval of an SOP or amendment to an SOP and its supporting materials and documentation will be reviewed for compliance with the Act and these regulations. Within 6 months of receiving the request for approval, the Secretary will notify the SOP's governing State official of approval or disapproval. A disapproval will include the reasons for disapproval. A State receiving a notice of disapproval of its SOP or amendment to its SOP may submit a revised SOP or amendment to its SOP at any time.

Review of State Organic Programs

SOP's will be reviewed at least once every 5 years by the Secretary as required by section 6507(c)(1) of the Act. The Secretary will notify the SOP's governing State official of approval or disapproval of the program within 6 months after initiation of the review.

State Organic Programs—Changes Based on Comments

This portion of subpart G differs from the proposal in several respects as follows:

(1) *Publication of SOP's and Consideration of Public Comments.* Some commenters assert that the USDA should not publish SOP provisions for public comment in the **Federal Register**. These commenters argued that it is not appropriate for the NOP to have nonresidents commenting on a particular State program as nearly all States have a mechanism to ensure full public participation in their regulation promulgation. They believe the comment process set forth in the proposed rule is a redundant and unacceptable intrusion on State sovereignty.

We will not publish for public comment the provisions of SOP's under review by the Secretary in the **Federal Register**. We have removed the provision from this final rule, described in section 205.621(b), requiring the Secretary to publish in the **Federal Register** for public comment a summary of the SOP and a summary of any amendment to such a program. Alternatively, we will announce which SOP's are being reviewed through the

NOP website. The NOP will issue public information notices that will announce each approved SOP and any approved amendments to an existing State program. The notices will identify the characteristics of the approved State program that warranted the more restrictive organic production or handling requirements. We also will include a summary of the new program on the NOP website.

(2) *NOP Oversight of SOP's.* Several commenters stated that, in the proposed rule, the provisions did not provide a comprehensive description of organic programs operated by States that would be under NOP authority. Some commenters implied that the proposed rule would only include States with organic certification programs, while other commenters inquired whether the sections 205.620 to 205.622 included other SOP activities beyond certification.

To address the commenters' concerns, we have modified the section heading by adding the term, "organic," and removing the term, "certification," from the description and definition of SOP's. We have taken this action to clarify that, while certification is one component of the requirements, it does not define the extent of evaluation of State programs that will be conducted by the NOP. SOP's can choose not to conduct certification activities under their existing organic program. State programs whose provisions fall within the scope of the eleven general provisions described in the Act (7 U.S.C. 6506) will require Departmental review.

States may conduct other kinds of organic programs that will not need review and approval by the NOP. Examples of these other programs may include: organic promotion and research projects, marketing; transition assistance or cost share programs, registration of State organic production and handling operations, registration of certifying agents operating within the State, or a consumer referral program. The NOP will not regulate such State activities. Such programs may not advertise, promote, or otherwise infer that the State's organic products are more organic or better than organic product produced in other States. Such programs and projects would be beyond the scope of this national program and will not be subject to the Secretary's review.

State Organic Programs—Changes Requested But Not Made

(1) *Limitations on SOP More Restrictive Requirements.* Commenters expressed concern that limiting a State's

ability to craft a regulation designated as a more restrictive requirement to environmental conditions or specific production and handling practices would hinder the ongoing development of SOP's. They were concerned that any State legislation modifying the SOP would need to be preapproved by the Secretary.

We have retained the provision limiting the scope of more restrictive requirements States can include in their organic program as described in section 205.620(c). We believe the language contained in the provision is broad enough to facilitate the development of SOP's without hindering development or State program implementation and enforcement. Section 6507(b)(1) of the Act provides that States may establish more restrictive organic certification requirements; paragraph (b)(2) establishes parameters for those requirements. More restrictive SOP requirements must: further the purposes of the Act, be consistent with the Act, not discriminate against other State's agricultural commodities, and be approved by the Secretary before becoming effective. We expect that a State's more restrictive requirements are likely to cover specific organic production or handling practices to address a State's specific environmental conditions. The Secretary will approve State's requests for more restrictive State requirements that are consistent with the purposes of the Act. However, we believe requests from States for more restrictive requirements will be rare. Although SOP's can impose additional requirements, we believe States will be reluctant to put their program participants at a competitive disadvantage when compared to producers and handlers in other States absent compelling environmental conditions or a compelling need for special production and handling practices. While preapproval of State legislation modifying an existing SOP is not required, the NOP envisions a close consultation with States with existing programs to ensure consistency with the final rule.

(2) *SOP Enforcement Obligations.* Some commenters expressed concern about States having adequate resources available to implement enforcement activities that they are obligated to conduct under the NOP. A few of these commenters argue that the enforcement obligation will result in their State programs being discontinued. A few commenters cited a lack of federal funding to support State enforcement obligations and suggested the NOP provide funding for enforcement activities.

The proposed rule indicated that States with organic programs must assume enforcement obligations for this regulation within their State. We have retained this enforcement obligation in section 205.620(d). Many States currently have organic programs with the kind of comprehensive enforcement and compliance mechanisms necessary for implementing any State regulatory program. Assuming those enforcement activities are consistent with the NOP, this final rule adds no additional regulatory burden to the SOP's. The costs associated with the enforcement activities of an approved SOP should be similar to the enforcement costs associated with the existing State program. Additional clarification of SOP enforcement obligations is in the Accreditation, Appeals, and Compliance preamble discussions.

(3) *SOP Evaluation Notification Period.* A few commenters indicated that the SOP review and decision notification period described in section 205.621(b) of the proposed rule could hinder a State's ability to develop or implement an SOP. These commenters cited potential cases in which particular States have requirements for regulatory promulgation that must occur within 6 months under a State legislative session that is held once every 2 years. These commenters suggested the NOP should reduce the notification time to 1 to 3 months.

We disagree with the commenters. In the proposed rule in section 205.621(b), the Secretary is required to notify the SOP's governing State official within 6 months of receipt of submission of documents and information regarding the approval of the SOP. We have retained this time period. We will review SOP applications as quickly as possible and will endeavor to make decisions in less than 6 months whenever possible. However, some SOP's may be very complex and require more review time. The NOP envisions working closely with the States and State officials to ensure a smooth transition to the requirements of this final rule.

State Organic Programs—Clarifications

(1) *Discrimination Against Organic Products.* Several commenters requested the addition of a provision prohibiting an SOP from discriminating against agricultural commodities organically produced in other States. Discrimination by a State against organically produced agricultural products produced in another State is prevented in two ways. First, any organic program administered by a State must meet the requirements for organic

programs specified in the Act and be approved by the Secretary. Finally, a USDA-accredited certifying agent must accept the certification decisions made by another USDA-accredited certifying agent as its own.

(2) *Potential Duplication Between the Accreditation and SOP Review Process.* Some commenters asked about possible duplication between the process for reviewing SOP's and the process of accreditation review. These commenters have asked the NOP to eliminate any duplication that may exist between the two review processes. The NOP will be conducting a review process for SOP's and a separate review process for accrediting State and private certifying agents. The two reviews are different. The SOP review is the evaluation of SOP compliance with the Act and the NOP regulations. If approved, the SOP becomes the NOP standards for the particular State with which all certifying agents operating in that State must comply. Approved SOP's must be in compliance with the Act and the NOP regulations. They cannot have weaker standards than the NOP. States can have more restrictive requirements than the NOP if approved by the Secretary.

The accreditation review is an evaluation of the ability of certifying agents to carry out their responsibilities under the NOP. This review is a measure of the competency of certifying agents to evaluate compliance to national organic standards. Certifying agents will not be unilaterally establishing regulations or standards related to the certification of organic products. They will only provide an assessment of compliance.

Thus, SOP reviews and accreditation reviews are separate evaluations of different procedures. We acknowledge some of the information for the two evaluations may be similar; e.g., compliance procedures. The reviews do not duplicate the same requirements. However, the NOP envisions working with States to ensure documentation is not duplicated.

(3) *Scope of Enforcement by States.* A number of State commenters have requested clarification on the proposed rule provision specifying that approved SOP's must assume enforcement obligations in their State for the requirements of the NOP and any additional requirements approved by the Secretary. These commenters have indicated that they remain uncertain as to what is expected by the term, "enforcement obligation."

Approved SOP's will have to administer and provide enforcement of the requirements of the Act and the

regulations of the NOP. The administrative procedures used by the State in administering the approved SOP should have the same force and effect as the procedures used by AMS in administering this program. This final rule specifies that the requirements for environmental conditions or for special production and handling practices are necessary for establishing more restrictive requirements. These factors establish our position that a State must agree to incurring increased enforcement responsibilities and obligations to be approved as an SOP under the NOP. For instance, a State with an approved organic program will oversee compliance and appeals procedures for certified organic operations in the State. Those procedures must provide due process opportunities such as rebuttal, mediation, and correction procedures. Once approved by the Secretary, the State governing official of the SOP must administer the SOP in a manner that is consistent and equitable for the certified parties involved in compliance actions.

(4) *SOP's That Do not Certify and NOP Oversight.* A few commenters requested that the NOP develop new provisions to include State programs that have organic regulations but do not conduct certification activities. These commenters argue that any SOP that has a regulatory impact on organic producers, regardless of whether or not the program includes certification, be approved by the Secretary.

This regulation, in section 205.620(b), provides for NOP oversight of SOP's that do not conduct certification activities.

(5) *State's Use of Private Certifying Agents.* Some commenters have requested that the NOP provide clarification of the proposed rule sections 205.620 through 205.622 on how these sections will affect States that delegate certification activities to private certifying agents. These commenters asked how the NOP intends to oversee this type of State activity.

The NOP intends to give considerable latitude to States in choosing the most appropriate system or procedures to structure their programs. This may include a State establishing its own certifying agent or relying on private certifying agents. However, States will not be accrediting certifying agents operating in their State. Accreditation of all certifying agents operating in the United States is the responsibility of USDA. Establishment of a single national accreditation program is an essential part of the NOP. As stated elsewhere in this final rule, any accreditation responsibilities of a State's

current organic program will cease with implementation of this program. Pursuant to the Compliance provisions of this subpart, the governing State official charged with compliance oversight under the SOP may investigate and notify the NOP of possible compliance violations on the part of certifying agents operating in the State. However, the State may not pursue compliance actions or remove accreditation of any certifying agent accredited by the Secretary. That authority is the sole responsibility of the Secretary. If more restrictive State requirements are approved by the Secretary, we will review certifying agent qualifications in the State, as provided by section 205.501(a)(20), and determine whether they are able to certify to the approved, more restrictive requirements. Our accreditation responsibilities include oversight of both State and private certifying agents, including any foreign certifying agents that may operate in a State.

Subpart G—Fees

This portion of subpart G sets forth the regulations on fees and other charges to be assessed for accreditation and certification services under the National Organic Program (NOP). These regulations address the kinds of fees and charges to be assessed by the U.S. Department of Agriculture (USDA) for the accreditation of certifying agents, the level of such fees and charges, and the payment of such fees and charges. These regulations also address general requirements to be met by certifying agents in assessing fees and other charges for the certification of producers and handlers as certified organic operations. Finally, these regulations address the Secretary's oversight of a certifying agent's fees and charges for certification services.

Description of Regulation

Fees and Other Charges for Accreditation

Fees and other charges will be assessed and collected from applicants for initial accreditation and accredited certifying agents submitting annual reports or seeking renewal of accreditation. Such fees will be equal as nearly as may be to the cost of the accreditation services rendered under these regulations. Fees-for-service will be based on the time required to render the service provided calculated to the nearest 15-minute period. Activities to be billed on the basis of time used include the review of applications and accompanying documents and information, evaluator travel, the

conduct of on-site evaluations, review of annual reports and updated documents and information, and the preparation of reports and any other documents in connection with the performance of service. The hourly rate will be the same as that charged by the Agricultural Marketing Service (AMS), through its Quality System Certification Program, to certification bodies requesting conformity assessment to the International Organization for Standardization "General Requirements for Bodies Operating Product Certification Systems" (ISO Guide 65).

Applicants for initial accreditation and accredited certifying agents submitting annual reports or seeking renewal of accreditation during the first 18 months following the effective date of subpart F will receive service without incurring an hourly charge for such service.

Applicants for initial accreditation and renewal of accreditation must pay at the time of application, effective 18 months following the effective date of subpart F, a nonrefundable fee of \$500.00. This fee will be applied to the applicant's fees-for-service account.

When service is requested at a place so distant from the evaluator's headquarters that a total of one-half hour or more is required for the evaluator(s) to travel to such a place and back to the headquarters or from a place of prior assignment on circuitous routing requiring a total of one-half hour or more to travel to the next place of assignment on the circuitous routing, the charge for such service will include all applicable travel charges. Travel charges may include a mileage charge administratively determined by USDA, travel tolls, or, when the travel is made by public transportation (including hired vehicles), a fee equal to the actual cost thereof. If the service is provided on a circuitous routing, the travel charges will be prorated among all the applicants and certifying agents furnished the service involved. Travel charges will become effective for all applicants for initial accreditation and accredited certifying agents on the effective date of subpart F. The applicant or certifying agent will not be charged a new mileage rate without notification before the service is rendered.

When service is requested at a place away from the evaluator's headquarters, the fee for such service shall include a per diem charge if the employee(s) performing the service is paid per diem in accordance with existing travel regulations. Per diem charges to applicants and certifying agents will cover the same period of time for which

the evaluator(s) receives per diem reimbursement. The per diem rate will be administratively determined by USDA. Per diem charges shall become effective for all applicants for initial accreditation and accredited certifying agents on the effective date of subpart F. The applicant or certifying agent will not be charged a new per diem rate without notification before the service is rendered.

When costs, other than fees-for-service, travel charges, and per diem charges, are associated with providing the services, the applicant or certifying agent will be charged for these costs. Such costs include but are not limited to equipment rental, photocopying, delivery, facsimile, telephone, or translation charges incurred in association with accreditation services. The amount of the costs charged will be determined administratively by USDA. Such costs will become effective for all applicants for initial accreditation and accredited certifying agents on the effective date of subpart F.

Payment of Fees and Other Charges

Applicants for initial accreditation and renewal of accreditation must remit the nonrefundable fee along with their application. Remittance must be made payable to the Agricultural Marketing Service, USDA, and mailed to: Program Manager, USDA-AMS-TMP-NOP, Room 2945-South Building, P.O. Box 96456, Washington, DC 20090-6456 or such other address as required by the Program Manager. All other payments for fees and other charges must be received by the due date shown on the bill for collection, made payable to the Agricultural Marketing Service, USDA, and mailed to the address provided on the bill for collection. The Administrator will assess interest, penalties, and administrative costs on debts not paid by the due date shown on a bill for collection and collect delinquent debts or refer such debts to the Department of Justice for litigation.

Fees and Other Charges for Certification

Fees charged by a certifying agent must be reasonable, and a certifying agent may charge applicants for certification and certified production and handling operations only those fees and charges that it has filed with the Administrator. The certifying agent must provide each applicant with an estimate of the total cost of certification and an estimate of the annual cost of updating the certification. The certifying agent may require applicants for certification to pay at the time of application a nonrefundable fee that must be applied to the applicant's fees-

for-service account. A certifying agent may set the nonrefundable portion of certification fees; however, the nonrefundable portion of certification fees must be explained in the fee schedule submitted to the Administrator. The fee schedule must explain what fee amounts are nonrefundable and at what stage during the certification process the respective fees become nonrefundable. The certifying agent must provide all persons inquiring about the application process with a copy of its fee schedule.

Fees—Changes Based on Comments

This subpart differs from the proposal in the following respects:

Nonrefundable Portion of Certification Fees. Commenters were not satisfied with the provision in section 205.642 that stated, "The certifying agent may require applicants for certification to pay at the time of application a nonrefundable fee of no more than \$250.00, which shall be applied to the applicant's fee for service account." Some commenters believed we were requiring the certifying agents to bill fees for inspection services separately. One State agency expressed a concern that we were placing a limit on the initial fee the certifying agent could collect. As a result, the State agency commented that by not being allowed to collect the full certification fee at the time of application, the certifying agent, in effect, would be extending credit to the applicant. Commenters reported that some State agencies are prevented by statute from extending credit and are required to collect all fees at the time of application. Several commenters stated that the amount of \$250.00 was too low and would not cover the costs the certifying agents could incur during the certification process. One organization noted that we should consider prorating the amount of the fee to be refunded when an applicant for certification withdraws before the completion of the certification process. The organization recommended that the amount of the prorated fee should be based on how far along in the certification process the applicant had progressed before withdrawal. Another commenter believed it was inappropriate for USDA to set any fees for private certification programs and that the fees should be market driven.

It was not our intent to limit the initial amount that certifying agents could collect from the applicant for certification. Our intent was to limit the portion of the fee that would be nonrefundable in order to reduce the potential liability for the small

producer/handler who may need to withdraw prematurely from the certification process. However, we acknowledge that this provision could be misinterpreted. We also realize that certifying agents may incur initial costs during the preliminary stage of the certification process that may be more or less than the \$250.00 application rate proposed. As a result, we have removed the provision that stated certifying agents could collect a nonrefundable fee of not more than \$250.00 at the time of application from applicants for certification.

Certifying agents may set the nonrefundable portion of their certification fees. However, the nonrefundable portion of their certification fees must be explained in the fee schedule submitted to the Administrator. The fee schedule must explain what fee amounts are nonrefundable and at what stage during the certification process the respective fees become nonrefundable. Certifying agents will also provide all persons inquiring about the application process with a copy of its fee schedule.

Fees—Changes Requested But Not Made

This subpart retains from the proposed rule regulations on which we received comments as follows:

(1) *Farm Subsidy/Transition Program.* Many commenters asked that USDA subsidize or develop a cost-share program for small farmers/producers who are certified or who are in transition to organic farming. Some commenters wanted these costs to be fully subsidized; a few commenters suggested that USDA pay for any extra site visit costs; and many others wanted USDA to pay premium prices to farmers for their products during the period of transition to organic production. In addition, many commenters argued that USDA should fully fund certification costs. Finally, many commenters suggested that the USDA should provide additional financial support to the organic industry because the industry is relatively young and composed of a large number of small, low-resource businesses.

We have considered the commenters requests but have not made the suggested changes. The NOP under AMS is primarily a user-fee-based Federal program. Section 2107(a)(10) of the Organic Food Production Act of 1990 (OFPA) requires that the NOP provide for the collection of reasonable fees from producers, certifying agents, and handlers who participate in activities to certify, produce, or handle agricultural products as organically produced. Therefore, under the

statutory authority of OFPA, it is outside of the scope of the NOP to provide for the subsidization of producers, handlers, and certifying agents as desired by some commenters. We have, however, established provisions in this part that we believe will minimize the economic impact of the NOP on producers, handlers, and certifying agents.

(2) *Small Farmer Exemption Versus Lower Certification Fees.* Many commenters suggested that certification fees be lowered or based on a sliding scale rather than instituting an exemption from certification for small farmers and handlers.

We have not accepted the commenters' suggestion. We cannot remove the small farmer exemption because section 2106(d) of the Act requires that small farmers be provided an exemption from organic certification if they sell no more than \$5,000 annually in value of agricultural products. Also, certification fees cannot be lowered by USDA because NOP under AMS is primarily a user-fee-based Federal agency. It is not our goal or objective to make a profit on our accreditation activities. However, our fees associated with the accreditation process are targeted toward recovering costs incurred during the accreditation process. Commenters expressed a concern that the accreditation fees charged by USDA would have an impact on the certification fees prescribed by certifying agents to operations seeking organic certification. We understand the commenters' concern that accreditation fees charged to certifying agents will most likely be calculated into the fees that certifiers charge their clients. However, we believe that our provision to waive the hourly service charges for accreditation during the first 18 months of implementation of the NOP should help reduce accreditation costs of the certifying agent and should, therefore, result lower certification fee charged by certifying agents. As provided by the Act and the regulations in this part, fees charged by certifying agents must be reasonable. Also, certifying agents must submit their fee schedule to the Administrator and may only charge those fees and charges filed with the Administrator. In addition, certifiers are required to provide their approved fee schedules to applicants for certification. Therefore, applicants for certification will be able to base their selection of a certifying agent on price if they choose. Moreover, there are no provisions in the regulations that preclude certifying agents from pricing their services on a sliding scale, as long as their fees are consistent and nondiscriminatory and

are approved during the accreditation process.

(3) *Accreditation Fees.* Many industry commenters suggested that we reevaluate our accreditation fee structure. They believe the hourly accreditation rate proposed is unacceptable. Commenters were concerned that high accreditation costs would lead to high certification costs, which would have a greater impact on small operations. Some industry commenters also noted that we should be required to provide a fee schedule such as the certifiers are required to do. They stated that unless USDA provided a fee schedule that included travel costs, they would not be able to accurately budget for these costs. A few commenters wanted USDA to forgo charging travel costs or not charge travel time at the full rate. Several commenters also stated that the hourly rate stated in the proposal is much higher than what the people who actually perform the accreditations will earn. However, a large majority of the commenters favored the 18-month period in which AMS will not charge the hourly accreditation rate to applicants.

As stated in the proposal, the hourly rate will be the same as that of AMS' Quality Systems Certification Program. Due to the fact that AMS' Quality Systems Certification Program publishes one rate that is readily available to the public, it is our belief that it is unnecessary for the NOP to set up a separate fee schedule. The NOP will notify accredited certifying agents and applicants for accreditation of any proposed rate changes and final actions on such rates by AMS. We will also periodically report the status of fees to the National Organic Standards Board.

Those applicants and certifying agents who need accreditation cost estimates, including travel, for budgetary or other reasons may notify the NOP. The NOP staff will provide the applicant with a cost estimate, based on information provided by the applicant. As stated in an earlier response ((2)—Changes Requested But Not Made), the objective of the fee that is charged to accredit certifying agents is not to gain a profit for accreditation activities but to recover costs incurred during the accreditation process. As such, these costs include but are not limited to salaries, benefits, clerical help, equipment, supplies, etc.

Compliance

This portion of subpart G sets forth the enforcement procedures for the National Organic Program (NOP). These procedures describe the compliance responsibilities of the NOP Program Manager, State organic programs' (SOP)

governing State officials, and State and private certifying agents. These provisions also address the rights of certified production and handling operations and accredited certifying agents operating under the NOP. The granting and denial of certification and accreditation are addressed under subparts E and F.

Description of Regulations

The Secretary is required under the Act to review the operations of SOP's, accredited certifying agents, and certified production or handling operations for compliance with the Act and these regulations. The Program Manager of the NOP may carry out compliance proceedings and provide oversight of compliance proceedings on behalf of the Secretary and the Administrator. The Program Manager will initiate proceedings to suspend or revoke a certified operation's certification if a certifying agent or SOP's governing State official fails to take appropriate enforcement action. The Program Manager may also initiate proceedings to suspend or revoke a certified operation's certification if the operation is found to have been erroneously certified by a certifying agent whose accreditation has been suspended or revoked. We anticipate, however, that most investigations, reviews, and analyses of certification noncompliance and initiation of suspension or revocation will be conducted by the certified operation's certifying agent. With regard to certifying agents, the Program Manager will, when appropriate, initiate proceedings to suspend or revoke the accreditation of a certifying agent for noncompliance with the Act and these regulations.

In States with an approved SOP, the SOP's governing State official is responsible for administering a compliance program for enforcement of the NOP/SOP. SOP's governing State officials may review and investigate complaints of noncompliance involving organic production or handling operations operating within their State and, when appropriate, initiate suspension or revocation of certification. SOP's governing State officials may also review and investigate complaints of noncompliance involving accredited certifying agents operating within their State. They must report the findings of any review and investigation of a certifying agent to the Program Manager along with any recommendations for appropriate action.

The compliance provisions of the NOP are consistent with the

requirements of the Administrative Procedure Act (APA) (5 U.S.C. 553–559) in that this program provides for due process including an opportunity for hearing, appeal procedures, written notifications of noncompliance, and opportunities to demonstrate or achieve compliance before any suspension or revocation of organic certification or accreditation is invoked. A compliance action regarding certification carried out under an approved SOP's compliance procedures will have the same force and effect as a certification compliance action carried out under these NOP compliance procedures. The notification process for denying certification and accreditation is laid out in subparts E and F, respectively.

Each notification of noncompliance, rejection of mediation, noncompliance resolution, proposed suspension or revocation, and suspension or revocation issued under these regulations must be sent to the recipient's place of business via a delivery service which provides return receipts. Certified operations and certifying agents must respond to all compliance notifications via a delivery service which provides return receipts.

Noncompliance Procedure for Certified Operations

The Act provides for the enforcement of certification requirements. Statutory oversight of production and handling operations by certifying agents includes review of organic plans, on-site inspections, residue and tissue testing, authority to conduct investigations and initiate suspension or revocation actions, and responsibility to report violations.

Notification of Noncompliance

A written notification of noncompliance will be sent to the certified operation when an inspection, review, or investigation reveals any noncompliance with the Act or these regulations. A noncompliance notification may encompass the entire operation or a portion of the operation. For instance, a violation at one farm may not warrant loss of certification at other farms of the certified operation not affected by the violation. The notification of noncompliance will provide: (1) A description of each condition, action, or item of noncompliance; (2) the facts upon which the notification is based; and (3) the date by which the certified operation must rebut the notification or correct the noncompliance and submit supporting documentation of the correction. A certified operation may continue to sell its product as organic

upon receiving a notification of noncompliance and throughout the compliance proceeding and any appeal procedure which might follow the compliance proceeding unless otherwise notified by a State or Federal government agency.

If a certified operation believes the notification of noncompliance is incorrect or not well-founded, the certified operation may submit a rebuttal to the certifying agent or SOP's governing State official, as applicable, providing supporting data to refute the facts stated in the notification. The opportunity for rebuttal is provided to allow certifying agents and certified operations to informally resolve noncompliance issues. The rebuttal process should be helpful in resolving differences which may be the result of misinterpretation of requirements, misunderstandings, or incomplete information. Alternatively, the certified operation may correct the identified noncompliances and submit proof of such corrections. When the certified operation demonstrates that each noncompliance has been corrected or otherwise resolved, the certifying agent or SOP's governing State official, as applicable, will send the certified operation a written notification of noncompliance resolution.

Proposed Suspension or Revocation of Certification

If the noncompliance is not resolved or is not in the process of being resolved by the date specified in the notification of noncompliance, the certifying agent or SOP's governing State official will send the certified operation a written notification of proposed suspension or revocation of certification for the entire operation or a portion of the operation affected by the noncompliance. The notification will state: (1) The reasons for the proposed suspension or revocation; (2) the proposed effective date of the suspension or revocation; (3) the impact of the suspension or revocation on the certified operation's future eligibility for certification; and (4) that the certified operation has a right to request mediation or to file an appeal. The impact of a proposed suspension or revocation may include the suspension or revocation period or whether the suspension or revocation applies to the entire operation or to a portion or portions of the operation.

If a certifying agent or SOP's governing State official determines that correction of a noncompliance is not possible, the notification of noncompliance and the proposed suspension or revocation of certification may be combined in one notification of

proposed suspension or revocation. The certified operation will have an opportunity to appeal the proposed suspension or revocation.

If a certifying agent or SOP's governing State official has reason to believe that a certified operation has willfully violated the Act or regulations, a notification of proposed suspension or revocation will be sent to the certified operation. The proposed suspension or revocation will be for the entire operation or a portion of the operation. This notification, because it involves a willful violation, will be sent without first issuing a notification of noncompliance.

Mediation

A production or handling operation may request mediation of any dispute regarding denial of certification or proposed suspension or revocation of certification. Mediation is not required prior to filing an appeal but is offered as an option which may resolve the dispute more quickly than the next step, which is filing an appeal. When mediation is requested, it must be requested in writing to the applicable certifying agent. The certifying agent will have the option of accepting or rejecting the request for mediation. If the certifying agent rejects the request for mediation, the certifying agent must provide written notification to the applicant for certification or certified operation. The written notification must advise the applicant for certification or certified operation of the right to request an appeal in accordance with section 205.681. Any such appeal must be requested within 30 days of the date of the written notification of rejection of the request for mediation. If mediation is accepted by the certifying agent, such mediation must be conducted by a qualified mediator mutually agreed upon by the parties to the mediation. If an SOP is in effect, the mediation procedures established in the SOP, as approved by the Secretary, must be followed. The parties to the mediation will have no more than 30 days to reach an agreement following a mediation session. If mediation is unsuccessful, the production or handling operation will have 30 days from termination of mediation to appeal the denial of certification or proposed suspension or revocation in accordance with the appeal procedures in section 205.681.

Any agreement reached during or as a result of the mediation process must be in compliance with the Act and these regulations. The Secretary reserves the right to review any mediated agreement for conformity to the Act and these regulations and to reject any agreement

or provision not in conformance with the Act or these regulations

Suspension or Revocation

The certifying agent or SOP's governing State official will suspend or revoke the certified operation's certification when the operation fails to resolve the issue through rebuttal or mediation, fails to complete needed corrections, or does not file an appeal. The operation will be notified of the suspension or revocation by written notification. The certifying agent or SOP's governing State official must not send a notification of suspension or revocation to a certified operation that has requested mediation or filed an appeal while final resolution of either is pending.

The decision to suspend or revoke certification will be based on the seriousness of the noncompliance. Such decisions must be made on a case-by-case basis. Section 6519 of the Act establishes that willful violations include making a false statement, knowingly affixing a false label, or otherwise violating the purposes of the Act.

In addition to suspension or revocation, a certified operation that knowingly sells or labels a product as organic, except in accordance with the Act, will be subject to a civil penalty of not more than \$10,000 per violation. Further, a certified operation that makes a false statement under the Act to the Secretary, an SOP's governing State official, or a certifying agent will be subject to the provisions of section 1001 of title 18, United States Code.

A certified operation whose certification has been suspended under this section may at any time, unless otherwise stated in the notification of suspension, submit a request to the Secretary for reinstatement of its certification. The request must be accompanied by evidence demonstrating correction of each noncompliance and corrective actions taken to comply with and remain in compliance with the Act and the NOP.

A certified operation or a person responsibly connected with an operation that has had its certification revoked will be ineligible to receive certification for an operation in which such operation or person has an interest for 5 years following the date of revocation. Accordingly, an operation will be ineligible for organic certification if one of its responsibly connected parties, was a responsibly connected party of an operation that had its certification revoked. The Secretary may, when in the best interest of the

certification program, reduce or eliminate the period of ineligibility.

Noncompliance Procedure for Certifying Agents

The Program Manager, on behalf of the Secretary, may initiate a compliance action against an accredited certifying agent who violates the Act or these regulations. Compliance proceedings may be initiated as a result of annual reviews for continuation of accreditation, site evaluations, or investigations initiated in response to complaints of noncompliant activities. Compliance proceedings also may be initiated on recommendation of an SOP's governing State official.

A written notification of noncompliance will be sent by the Program Manager to an accredited certifying agent when an inspection, review, or investigation of such person reveals any noncompliance with the Act or these regulations. A notification of noncompliance will provide a description of each noncompliance found and the facts upon which the notification is based. Additionally, the notification will provide the date by which the certifying agent must rebut or correct each noncompliance described and submit supporting documentation of each correction.

When documentation received by the Program Manager demonstrates that each noncompliance has been resolved, the Program Manager will send the certifying agent a written notification of noncompliance resolution.

If a noncompliance is not resolved by rebuttal or correction, the Program Manager will issue a notification of proposed suspension or revocation of accreditation. The notification will state whether the suspension or revocation will be for the certifying agent's entire accreditation, that portion of the accreditation applicable to a particular field office, or a specific area of accreditation. For instance, if a certifying agent with field offices in different geographic areas is cited for a compliance violation at one field office, the Program Manager could determine that only that portion of the accreditation applicable to the noncompliant field office should be suspended or revoked.

If the Program Manager determines that the noncompliance cannot be immediately or easily corrected, the Program Manager may combine the notification of noncompliance and the proposed suspension or revocation in one notification.

The notification of proposed suspension or revocation of accreditation will state the reasons and

effective date for the proposed suspension or revocation. Such notification will also state the impact of a suspension or revocation on future eligibility for accreditation and the certifying agent's right to file an appeal.

If the Program Manager has reason to believe that a certifying agent has willfully violated the Act or regulations, the Program Manager will issue a notification of proposed suspension or revocation of accreditation. The proposed suspension or revocation may be for the certifying agent's entire accreditation, that portion of the accreditation applicable to a particular field office, or a specified area of accreditation. This notification, because it involves a willful violation, will be sent without first issuing a notification of noncompliance.

The certifying agent may file an appeal of the Program Manager's determination pursuant to section 205.681. If the certifying agent fails to file an appeal of the proposed suspension or revocation, the Program Manager will suspend or revoke the certifying agent's accreditation. The certifying agent will be notified of the suspension or revocation by written notification.

A certifying agent whose accreditation is suspended or revoked must cease all certification activities in each area of accreditation and in each State for which its accreditation is suspended or revoked. Any certifying agent whose accreditation has been suspended or revoked must transfer to the Secretary all records concerning its certification activities that were suspended or revoked. The certifying agent must also make such records available to any applicable SOP's governing State official. The records will be used to determine whether operations certified by the certifying agent may retain their organic certification.

A certifying agent whose accreditation is suspended by the Secretary may at any time, unless otherwise stated in the notification of suspension, submit a request to the Secretary for reinstatement of its accreditation. Such request must be accompanied by evidence demonstrating correction of each noncompliance and actions taken to comply with and remain in compliance with the Act and regulations. A certifying agent whose accreditation is revoked by the Secretary will be ineligible to be accredited as a certifying agent under the Act and regulations for a period of not less than 3 years following the date of revocation.

State Organic Programs' Compliance Procedures

An SOP's governing State official may initiate noncompliance proceedings against certified organic operations operating in the State. Such proceedings may be initiated for failure of a certified operation to meet the production or handling requirements of this part or the State's more restrictive requirements, as approved by the Secretary.

The SOP's governing State official must promptly notify the Program Manager of commencement of noncompliance proceedings initiated against certified operations and forward to the Program Manager a copy of each notice issued. A noncompliance proceeding, brought by an SOP's governing State official against a certified operation may be appealed in accordance with the appeal procedures of the SOP. There will be no subsequent rights of appeal to the Secretary. Final decisions of a State may be appealed to the United States District Court for the district in which such certified operation is located.

An SOP's governing State official may review and investigate complaints of noncompliance with the Act or regulations concerning accreditation of certifying agents operating in the State. When such review or investigation reveals any noncompliance, the SOP's governing State official must send a written report of noncompliance to the Program Manager. The SOP's governing State official's report must provide a description of each noncompliance and the facts upon which the noncompliance is based.

Compliance—Changes Based On Comments

This portion of subpart G differs from the proposal in several respects as follows:

(1) *Written Notifications.* We have added a new paragraph (d) to section 205.660. The preamble to the proposed rule stated that all written notifications sent by certifying agents and SOP's governing State officials, as well as rebuttals, requests for mediation, and notices of correction of noncompliances sent by certified operations, will be sent to the addressee's place of business by a delivery service which provides dated return receipts. The assurance of completed communications and timely compliance procedures was given as the reason for delivery by a service which provides dated return receipts. The addition of paragraph (d) at section 205.660 is one of the actions that we have taken in response to requests from commenters that we further clarify the

compliance process. Paragraph (d) requires that each notification of noncompliance, rejection of mediation, noncompliance resolution, proposed suspension or revocation, and suspension or revocation issued in accordance with sections 205.662, 205.663, and 205.665 and each response to such notification must be sent to the recipient's place of business via a delivery service which provides return receipts. This action will facilitate the effective administration of the compliance process by assuring a verifiable time line on the issuance and receipt of compliance documents and the response given to each such document.

(2) *Determination of Willful.* The preamble statement that "only the Program Manager or governing State official may make the final determination that a violation is willful" was incorrect and inconsistent with the regulatory language in section 205.662(d). Section 205.662(d) provides that, "if a certifying agent or State organic program's governing State official has reason to believe that a certified operation has willfully violated the Act or regulations in this part, the certifying agent or State organic program's governing State official shall send the certified operation a notification of proposed suspension or revocation of certification of the entire operation or a portion of the operation, as applicable to the noncompliance." Accordingly, as recommended by a commenter, the incorrect statement has been deleted from the preamble to this final rule.

(3) *Proposed Suspension or Revocation.* We have amended sections 205.662(c) and 205.665(c) by removing the redundant phrase "or is not adequate to demonstrate that each noncompliance has been corrected" from the first sentence of each section.

(4) *Suspension or Revocation.* We have amended section 205.662(e)(2) by adding "while final resolution of either is pending" to the end thereof. The language of section 205.662(e)(2) now reads: "A certifying agent or State organic program's governing State official must not send a notification of suspension or revocation to a certified operation that has requested mediation pursuant to section 205.663 or filed an appeal pursuant to section 205.681 while final resolution of either is pending." We have made this change because we agree with those commenters who expressed the belief that section 205.662(e)(2) needed to be amended to clarify the duration of the stay on the issuance of a notification of suspension or revocation when

mediation is requested or an appeal is filed. Several commenters stated that section 205.662(e)(2) needed to be amended to clarify that requesting mediation or filing an appeal does not indefinitely stop the suspension or revocation process.

(5) *Eligibility After Suspension or Revocation of Certification.* We have amended section 205.662(f) such that it now parallels section 205.665(g) which addresses suspension and revocation of certifying agents. We have also changed the title of section 205.662(f) from "Ineligibility" to "Eligibility" to parallel section 205.665(g). A few commenters referred to the provisions in section 205.665(g), which addresses eligibility after suspension or revocation of accreditation, and requested clarification of the difference between suspension and revocation of certification. Upon reviewing section 205.662(f), we decided that amendment was needed to clarify the difference between suspension and revocation of certification relative to eligibility for certification. Accordingly, we added a new paragraph (1) which provides that a certified operation whose certification has been suspended under this section may at any time, unless otherwise stated in the notification of suspension, submit a request to the Secretary for reinstatement of its certification. The paragraph also provides that the request must be accompanied by evidence demonstrating correction of each noncompliance and corrective actions taken to comply with and remain in compliance with the Act and the regulations in this part. We also amended what is now paragraph (2) of section 205.662(f) to clarify that the period of ineligibility following revocation of certification is 5 years unless reduced or eliminated by the Secretary.

Further, we have amended section 205.665(g)(1) to clarify that a certifying agent that has had its accreditation suspended may request reinstatement of its accreditation rather than submit a new request for accreditation. The amendment also clarifies that the reinstatement may be requested at any time unless otherwise stated in the notification of suspension. This amendment makes section 205.665(g)(1) similar to new paragraph (1) of section 205.662(f). This amendment is also consistent with commenter desires that the noncompliance procedures for certified operations and accredited certifying agents be similar.

(6) *Penalties for Violations of the Act.* We have amended section 205.662 by adding a new paragraph (g) which incorporates therein the provisions of

paragraphs (a) and (b) of section 2120, 7 U.S.C. 6519, Violations of Title, of the Act. Specifically, paragraph (g) provides that, in addition to suspension or revocation, any certified operation that knowingly sells or labels a product as organic, except in accordance with the Act, shall be subject to a civil penalty of not more than \$10,000 per violation. This paragraph also provides that any certified operation that makes a false statement under the Act to the Secretary, an SOP's governing State official, or a certifying agent shall be subject to the provisions of section 1001 of title 18, United States Code. Commenters requested regulatory language citing section 2120, 7 USC 6519, Violations of Title, of the Act. Commenters also requested a clearer description of enforcement. Specifically, they want provisions describing how USDA will deal with operations that make false claims or do not meet the NOP requirements. Further, numerous commenters expressed concern that there are no penalties in the regulations other than suspension and revocation. The European Community stated that it did not find, in the proposal, requirements for penalties to be applied by certifying agents when irregularities or infringements are found. The European Community went on to say that the European Union requires such penalties.

The Act provides for suspension and revocation of certification and the civil and criminal penalties addressed in 7 U.S.C. 6519. Certified operations are also required through the compliance program set forth in these regulations, to correct all noncompliances with the Act or regulations as a condition of retaining their certification. Furthermore, to get a suspended certification reinstated, an operation must submit a request to the Secretary. The request must be accompanied by evidence demonstrating correction of each noncompliance and corrective actions taken to comply with and remain in compliance with the Act and the regulations in this part. An operation or a person responsibly connected with an operation whose certification has been revoked will be ineligible to receive certification for a period of not more than 5 years.

We believe adding paragraph (g) will help clarify that there are penalties which may be imposed on certified operations that violate the Act and these regulations in addition to suspension or revocation.

The provisions of the Act and these regulations apply to all persons who sell, label, or represent their agricultural product as organic. Accordingly,

persons who falsely sell, label, or represent their product as organic, are subject to the provisions of paragraphs (a) and (b) of section 2120, 7 USC 6519, of the Act. To clarify this, we have added a new paragraph (c) to section 205.100 of the Applicability subpart.

Certifying agents, SOP's governing State officials, and USDA will receive complaints alleging violations of the Act or these regulations. Certifying agents will review all complaints that they receive to determine if the complaint involves one of their clients. If the complaint involves a client of the certifying agent, the agent will handle the complaint in accordance with its procedures for reviewing and investigating certified operation compliance. If the complaint involves a person who is not a client of the certifying agent, the certifying agent will refer the complaint to the SOP's governing State official, when applicable, or, in the absence of an applicable SOP's governing State official, the Administrator. SOP's governing State officials will review all complaints that they receive in accordance with their procedures for reviewing and investigating alleged violations of the NOP and SOP. The SOP's governing State official's review of the complaint could result in referral of the complaint to a certifying agent when the complaint involves a client of the certifying agent, dismissal, or investigation by the SOP's governing State official. SOP's governing State officials will, as appropriate, investigate allegations of violations of the Act by noncertified operations operating within their State. USDA will review all complaints that it receives in accordance with its procedures for reviewing and investigating alleged violations of the NOP. USDA will refer complaints alleging violations of the NOP/SOP to the applicable SOP's governing State official, who may, in turn, refer the complaint to the applicable certifying agent. In States without an approved SOP, USDA will refer complaints to the applicable certifying agent. USDA will, as appropriate, investigate allegations of violations of the Act by noncertified operations operating in States where there is no approved SOP.

(7) *Mediation.* We have amended section 205.663 by providing that a dispute with respect to proposed suspension or revocation of certification may, rather than shall, be mediated. We have also provided that mediation must be requested in writing to the applicable certifying agent. The certifying agent will have the option of accepting or rejecting the request for mediation. If

the certifying agent rejects the request for mediation, the certifying agent must provide written notification to the applicant for certification or certified operation. The written notification must advise the applicant for certification or certified operation of the right to request an appeal within 30 days of the date of the written notification of rejection of the request for mediation. If mediation is accepted by the certifying agent, such mediation must be conducted by a qualified mediator mutually agreed upon by the parties to the mediation.

Several commenters wanted section 205.663 amended to provide that disputes "may," rather than "shall," be mediated. The commenters advocated allowing the certifying agent to determine when mediation is a productive option. Several State commenters wanted to amend the second sentence to read as follows: "If a State organic program is in effect, the mediation procedures established in the State organic program, as approved by the Secretary, will be followed for cases involving the State organic program and its applicants or certified parties." Another commenter wanted to retain the requirement that disputes "shall" be mediated but wanted disputes mediated in accordance with 7 CFR part 11 and section 205.681 of these regulations.

We concur that certifying agents should be authorized to reject a request for mediation, especially when they believe that the noncompliance issue is not conducive to mediation. Accordingly, we amended section 205.663 as noted above. We disagree, however, with the State commenters who want to amend the second sentence. We believe that the recommended change would exclude the clients of private-sector certifying agents operating within the State. USDA approval of an SOP will require that all certified operations operating within the State have the same opportunities for mediation, regardless of whether they are certified by a private or State certifying agent. If an approved SOP provides for mediation, such mediation must be available to all certified operations operating within the State. We also disagree with the commenter who requested that disputes be mediated in accordance with 7 CFR part 11 and section 205.681 of these regulations. First, we believe that States with an approved SOP must be allowed to establish their own mediation program and procedures. Second, the Act and its implementing regulations are subject to the APA for adjudication. The provisions of the APA generally applicable to agency adjudication are not applicable to proceedings under 7

CFR part 11, National Appeals Division Rules of Procedure. Even if 7 CFR part 11 were applicable, it does not address mediation procedures. Mediation is merely addressed in 7 CFR Part 11 as an available dispute resolution method along with its impact on the filing of an appeal.

(8) *Noncompliance Procedure for Certifying Agents.* We have amended section 205.665(a)(3) to clarify that, like certified operations, certifying agents must submit supporting documentation of each correction of a noncompliance identified in a notification of noncompliance. This amendment to section 205.665(a)(3) was made in response to commenter concerns that the noncompliance procedures for certified operations and certifying agents be similar. It had been our intent that certifying agents would have to document their correction of noncompliances and that the noncompliance procedures for certified operations and certifying agents would be similar.

Compliance—Changes Requested But Not Made

This subpart retains from the proposed rule, regulations on which we received comments as follows:

(1) *Funding for Enforcement.* Several commenters stated that USDA should provide funding to the States for the cost of performing enforcement activities. Others asked who should fund investigations and enforcement actions if certifying agents (State and private) are enforcing compliance with a Federal law. Numerous commenters requested information on how enforcement will be funded. The National Organic Standards Board (NOSB) recommended that the NOP examine existing models for capturing enforcement fees such as the State of California's registration program for all growers, handlers, and processors who use the word, "organic," in marketing their products.

We disagree with the commenters who stated that USDA should fund enforcement activities (State and private). Costs for compliance under the NOP will be borne by USDA, States with approved SOP's, and accredited certifying agents. Each of the entities will bear the cost of their own enforcement activities under the NOP. AMS anticipates that States will consider the cost of enforcing their SOP's prior to seeking USDA approval of such programs. We also anticipate that certifying agents will factor the cost of compliance into their certification fee schedules.

We agree that there may be alternatives, such as the State of California's registration program, available to raise funds for enforcing the NOP. We will help identify existing models and potential options that may be available in the future at the Federal, State, or certifying agent level. In the interim, we believe that SOP's should explore funding options at their level and that certifying agents should factor the cost of enforcement into their certification fees structure.

(2) *Stop Sale.* A number of commenters requested that the regulations include the ability to stop sales or recall misbranded or fraudulently produced products. The Act does not authorize the NOP to stop sales or recall misbranded or fraudulently produced product. Accordingly, USDA cannot authorize stop sales or the recall of product. We also believe that the certified operation's right to due process precludes a stop sale or recall prior to full adjudication of the alleged noncompliance. However, the Food and Drug Administration (FDA) and the USDA's Food Safety Inspection Service (FSIS) have stop sale authority that may be used in certain organic noncompliance cases. Further, States may, at their discretion, be able to provide for stop sale or recall of misbranded or fraudulently produced products produced within their State. While the Act does not provide for stop sale or recall, it does provide at 7 U.S.C. 6519 that any person who: (1) knowingly sells or labels a product as organic, except in accordance with the Act, shall be subject to a civil penalty of not more than \$10,000 and (2) makes a false statement under the Act to the Secretary, an SOP's governing State official, or a certifying agent shall be subject to the provisions of section 1001 of title 18, United States Code.

(3) *Notification of Proposed Suspension or Revocation.* A commenter recommended replacing "notification of proposed suspension or revocation" in section 205.662(d) with "notification of suspension or revocation." Certification cannot be suspended or revoked without due process. Accordingly, the issuance of a written notification of proposed suspension or revocation is necessary to provide the certified operation with information regarding the alleged noncompliance(s) and its right to answer the allegations. For this reason we have not accepted the commenter's recommendation.

(4) *Mediation for Certifying Agents.* Several commenters recommended amending section 205.665(c)(4) to provide for mediation between a

certifying agent and the Program Manager when a proposed suspension or revocation is disputed by the certifying agent. We have not accepted the recommendation. USDA uses 7 CFR part 1, Rules of Practice Governing Formal Adjudicatory Proceedings Instituted by the Secretary Under Various Statutes, for adjudicatory proceedings involving the denial, suspension, and revocation of accreditation.

(5) *Revocation of Accreditation.* A commenter stated that revocation of accreditation for 3 years is excessive. The commenter stated that a period of 6 to 12 months might be reasonable. We have not amended section 205.665(g)(2) because the Act requires that the period of revocation for certifying agents, who violate the Act and these regulations, be for not less than 3 years. Suspension is available to the Secretary to address less egregious noncompliances. A certifying agent whose accreditation is suspended may at any time, unless otherwise stated in the notification of suspension, submit a request to the Secretary for reinstatement of its accreditation. The request must be accompanied by evidence demonstrating correction of each noncompliance and corrective actions taken to comply with and remain in compliance with the Act and these regulations.

(6) *Appeals Under SOP's.* Several commenters recommended amending 205.668(b) by adding at the end thereof: "unless the State program's appeals procedures include judicial review through the State District Court." Another commenter wanted 205.668(b) amended by removing "of the State organic certification program. There shall be no subsequent rights of appeal to the Secretary. Final decisions of a State may be appealed to the United States District Court for the district in which such certified operation is located," and inserting in its place "at 7 CFR part 11 and 205.681 of this chapter." We have not accepted the recommendations because the Act at 7 U.S.C. 6520 provides that a final decision of the Secretary may be appealed to the United States District Court for the district in which the person is located. We consider an approved SOP to be the NOP for that State. As such, we consider the SOP's governing State official of such approved SOP to be the equivalent of a representative of the Secretary for the purposes of the appeals procedures under the NOP. Accordingly, the final decision of the SOP's governing State official of an approved SOP is considered the final decision of the Secretary and, as such, is appealable to

the United States District Court for the district in which the person is located, not a State's District Court.

We also disagree with the commenter who wanted all appeals to be made to the National Appeals Division under the provisions at 7 CFR part 11 and section 205.681 of these regulations. First, we believe that States with an approved SOP must be allowed to establish their own appeal procedures. Such procedures would have to comply with the Act, be equivalent to the procedures of USDA, and be approved by the Secretary. Second, as noted elsewhere in this preamble, the Act and its implementing regulations are subject to the APA for adjudication. The provisions of the APA generally applicable to agency adjudication are not applicable to proceedings under 7 CFR part 11.

Compliance—Clarifications

Clarification is given on the following issues raised by commenters:

(1) *Complaints, Investigations, Stop Sales, and Penalties.* Many commenters wanted USDA to spell out the responsibilities and authorities of States, State and private certifying agents, Federal agencies, and citizens to make complaints, investigate violations, halt the sale of products, and impose penalties. Anyone may file a complaint, with USDA, an SOP's governing State official, or certifying agent, alleging violation of the Act or these regulations. Certifying agents, SOP's governing State officials, and USDA will receive, review, and investigate complaints alleging violations of the Act or these regulations as described in item 6 above under Changes Based on Comments. Citizens have no authority under the NOP to investigate complaints alleging violation of the Act or these regulations.

As noted elsewhere in this preamble, the Act does not authorize USDA to stop the sale of product. Accordingly, USDA cannot authorize stop sales by accredited certifying agents. We also believe that the certified operation's right to due process precludes a stop sale prior to full adjudication of the alleged noncompliance. However, FDA and FSIS have stop sale authority that may be used in the event of food safety concerns. Further, States may, at their discretion, be able to provide for stop sale of product produced within their State. Citizens have no authority under the NOP to stop the sale of a product.

The Act and these regulations provide for suspension or revocation of certification by certifying agents, SOP's governing State officials, and the Secretary. Only USDA may suspend or revoke a certifying agent's accreditation.

All proposals to suspend or revoke a certification or accreditation are subject to appeal as provided in section 205.681. The Act provides at 7 U.S.C. 6519 that any person who: (1) knowingly sells or labels a product as organic, except in accordance with the Act, shall be subject to a civil penalty of not more than \$10,000; and (2) makes a false statement under the Act to the Secretary, an SOP's governing State official, or a certifying agent shall be subject to the provisions of section 1001 of title 18, United States Code. Only USDA may bring an action under 7 U.S.C. 6519.

(2) *Certifying Agent's Identifying Mark.* The NOSB reaffirmed its recommendation which would allow private certifying agents to prevent the use of their service mark (seal) upon written notification that: (1) certification by the private certifying agent has been terminated, and (2) the certifying agent has 30 days to appeal the certifying agent's decision to the Secretary of Agriculture. We will neither prohibit nor approve a certifying agent's actions to withdraw a certified operation's authority to use the certifying agent's identifying mark for alleged violations of the Act or regulations. We stand fast in our position that all certified operations are to be given due process prior to the suspension or revocation of their certification. The reader is also reminded that the certifying agent cannot terminate, suspend, or revoke a certification if the certified operation files an appeal with an SOP's governing State official, when applicable, or the Administrator as provided for in the notification of proposed suspension or revocation. The certifying agent accepts full liability for any action brought as a result of the withdrawal of a certified operation's authority to use the certifying agent's identifying mark.

(3) *Loss of Certification.* A commenter posed several questions regarding the loss of certification. The commenter's questions and our responses are as follows.

How will consumers and affected regulatory agencies know if a grower or handler loses its certification? We will provide public notification of suspensions and revocations of certified operations through means such as the NOP website.

What will the effect of a lost certification be? Suspension or revocation of a producer's or handler's certification will require that the producer or handler immediately cease its sale, labeling, and representation of agricultural products as organically produced or handled as provided in the suspension or revocation order. A

production or handling operation or a person responsibly connected with an operation whose certification has been suspended may at any time, unless otherwise stated in the notification of suspension, submit a new request for certification in accordance with section 205.401. The request must be accompanied by evidence demonstrating correction of each noncompliance and corrective actions taken to comply with and remain in compliance with the Act and the regulations in this part. An operation or a person responsibly connected with an operation whose certification has been revoked will be ineligible to receive certification for a period of not more than 5 years following the date of such revocation, as determined by the Secretary. Any producer or handler who sells, labels, or represents its product as organic contrary to the provisions of the suspension or revocation order would be subject to prosecution under 7 U.S.C. 6519 of the Act.

Will the certifying agent give a future effective date for loss of certification, or could the loss of certification be immediate or even retroactive?

Suspension or revocation will become effective as specified in the suspension or revocation order once it becomes final and effective. The operation, upon suspension or revocation, will be prohibited from selling, labeling, and representing its product as organic per the provisions of the suspension or revocation order.

If organic products already on the market were grown or handled by someone whose certification is revoked or suspended, would USDA require that the products be recalled and relabeled? USDA will not, unless the noncompliance involves a food safety issue under FSIS, require the recall or relabeling of product in the channels of commerce prior to the issuance of a suspension or revocation order. First, at the time the product was produced, it may have been produced in compliance with the Act and these regulations. Second, USDA does not have the authority, under the Act, to issue a stop sale order for product sold, labeled, or represented as organic and placed in the channels of commerce prior to suspension or revocation of a certified operation's certification. The Act, however, provides at 7 U.S.C. 6519(a) for the prosecution of any person who knowingly sells or labels a product as organic, except in accordance with the Act. Such persons shall be subject to a civil penalty of not more than \$10,000 per violation.

(4) *Investigations.* A commenter suggested that we amend section

205.661(a) to require that all complaints must be investigated in accordance with the certifying agent's complaints policy. The commenter also stated that the Administrator should know which complaints were not investigated. We disagree that all complaints must be investigated since, upon review of the alleged noncompliance, some complaints may lack grounds for investigation. For example, a concerned citizen could allege that an organic producer was seen applying a pesticide to a specific field. Upon review of the allegation, the certifying agent could determine that the producer in question was a split operation and that the field in question was part of the conventional side of the production operation. Accordingly, there would be no need for an investigation. However, the certifying agent will be expected to: (1) take each allegation seriously, (2) review each complaint received, (3) make a determination as to whether there may be a basis for conducting an investigation, (4) investigate all allegations when it is believed that there may be a basis for conducting the investigation, and (5) maintain a detailed log of all complaints received and their disposition. The actions taken by the certifying agent must be in conformance with the certifying agent's procedures for reviewing and investigating certified operation compliance.

(5) *Deadline for the Correction of a Noncompliance.* Several commenters requested that 205.662(a)(3) be amended by adding: "The deadline for correction of the noncompliance may be extended at the discretion of the certifier if substantial progress has been made to correct the noncompliance." We believe that the requested amendment is unnecessary. Section 205.662(a)(3) requires that the notification of noncompliance include a date by which the certified operation must rebut or correct each noncompliance and submit supporting documentation of each correction when correction is possible. There is no prohibition preventing the certifying agent from extending the deadline specified when the certifying agent believes that the certified operation has made a good faith effort at correcting each noncompliance.

(6) *Compliance with SOP.* Several States requested that section 205.665 be amended to clarify how States may handle a private certifying agent found to be in noncompliance with SOP's approved by the Secretary. A majority of these commenters also asked if NOP intends to suspend or revoke the accreditation of certifying agents on a State-by-State basis. Section 205.668(c)

authorizes an SOP's governing State official to review and investigate complaints of noncompliance with the Act or regulations concerning accreditation of certifying agents operating in the State. When such review or investigation reveals any noncompliance, the SOP's governing State official shall send a written report of noncompliance to the NOP Program Manager. The report shall provide a description of each noncompliance and the facts upon which the noncompliance is based. The NOP Program Manager will then employ the noncompliance procedures for certifying agents as found in section 205.665. This may include additional investigative work by AMS. Only USDA may suspend or revoke a certifying agent's accreditation.

SOP's must meet the general requirements for organic programs specified in the Act and be at least equivalent to these regulations. Accordingly, noncompliances worthy of suspension or revocation would in all probability be worthy of national suspension or revocation of accreditation for one or more areas of accreditation. Therefore, USDA does not anticipate suspending or revoking accreditations, or areas of accreditation, on a State-by-State basis. It is possible, however, that the Secretary may decide to only suspend or revoke a certifying agent's accreditation or an area of accreditation to certify producers or handlers within a given State. Such a decision would in all probability be tied to a State's more restrictive requirements.

Inspection and Testing, Reporting, and Exclusion from Sale

This portion of subpart G sets forth the inspection and testing requirements for agricultural products that have been produced on organic production operations or handled through organic handling operations.

Residue testing plays an important role in organic certification by providing a means for monitoring compliance with the National Organic Program (NOP) and by discouraging the mislabeling of agricultural products. This testing program provides State organic programs' (SOP) governing State officials and certifying agents with a tool for ensuring compliance with three areas for testing: (1) preharvest residue testing, (2) postharvest residue testing, and (3) testing for unavoidable residual environmental contamination levels.

Description of Regulations

General Requirements

Under the residue testing requirements of the NOP, all agricultural products sold, labeled, or represented as organically produced must be available for inspection by the Administrator, SOP's governing State official, or certifying agent. Organic farms and handling operations must be made available for inspection under subpart E, Certification. In addition, products from the aforementioned organic operations may be required by the SOP's governing State official or certifying agent to undergo preharvest or postharvest testing when there is reason to believe that agricultural inputs used in organic agriculture production or agricultural products to be sold or labeled as organically produced have come into contact with prohibited substances or have been produced using excluded methods. The cost of such testing will be borne by the applicable certifying agent and is considered a cost of doing business. Accordingly, certifying agents should make provisions for the cost of preharvest or postharvest residue testing when structuring certification fees.

Preharvest and Postharvest Residue Testing

The main objectives of the residue testing program are to: (1) ensure that certified organic production and handling operations are in compliance with the requirements set forth in this final rule and (2) serve as a means for monitoring drift and unavoidable residue contamination of agricultural products to be sold or labeled as organically produced. Any detectable residues of a prohibited substance or a product produced using excluded methods found in or on samples during analysis will serve as a warning indicator to the certifying agent.

The Administrator, SOP's governing State official, or certifying agent may require preharvest or postharvest testing of any agricultural input used in organic agricultural production or any agricultural product to be sold or labeled as "100 percent organic," "organic," or "made with organic (specified ingredients or food group(s))." It is based on the Administrator's, SOP's governing State official's, or certifying agent's belief that an agricultural product or agricultural input has come into contact with one or more prohibited substances or has been produced using excluded methods. Certifying agents do not have to conduct residue tests if they do not have reason to believe that there is a need for testing.

Certifying agents must ensure, however, that certified organic operations are operating in accordance with the Act and the regulations set forth in this part.

The "reason to believe" could be triggered by various situations, for example: (1) The applicable authority receiving a formal, written complaint regarding the practices of a certified organic operation; (2) an open container of a prohibited substance found on the premises of a certified organic operation; (3) the proximity of a certified organic operation to a potential source of drift; (4) suspected soil contamination by historically persistent substances; or (5) the product from a certified organic operation being unaffected when neighboring fields or crops are infested with pests. These situations do not represent all of the possible occurrences that would trigger an investigation. Preharvest or postharvest residue testing will occur on a case-by-case basis.

In each case, an inspector representing the Administrator, SOP's governing State official, or certifying agent or will conduct sampling. According to subpart F, Accreditation, private or State entities accredited as certifying agents under the NOP must ensure that its responsibly connected persons, employees, and contractors with inspection, analysis, and decision-making responsibilities have sufficient expertise to successfully perform the duties assigned. Therefore, all inspectors employed by certifying agents to conduct sampling must have sufficient expertise in methods of chain-of-custody sampling. Moreover, testing for chemical residues must be performed in an accredited laboratory. When conducting chemical analyses, the laboratory must incorporate the analytical methods described in the most current edition of the *Official Methods of Analysis of the AOAC International* or other current applicable validated methodology for determining the presence of contaminants in agricultural products. Results of all analyses and tests performed under section 205.670 must be promptly provided to the Administrator, *except*, that, where an SOP exists, all test results and analyses should be provided to the SOP's governing State official by the applicable certifying party that requested testing. Residue test results and analyses must also be, according to section 205.403(e)(2), provided to the owner of the certified organic operation whose product was tested. All other parties desiring to obtain such information must request it from the applicable certifying agent.

OFPA requires certifying agents, to the extent of their awareness, to report violations of applicable laws relating to food safety to appropriate health agencies such as EPA and FDA. When residue testing indicates that an agricultural product contains pesticide residues or environmental contaminants that exceed either the EPA tolerance level or FDA action level, as applicable, the certifying agent must promptly report data revealing such information to the Federal agency whose regulatory tolerance or action level has been exceeded.

Residue Testing and Monitoring Tools

When testing indicates that an agricultural product to be sold or labeled as organically produced contains residues of prohibited substances, certifying agents will compare the level of detected residues with 5 percent of the Environmental Protection Agency (EPA) tolerance for the specific residue detected on the agricultural product intended to be sold as organically produced. This compliance measure, 5 percent of EPA tolerance for the detected prohibited residue, will serve as a standard for the Administrator, SOP's governing State officials, and certifying agents to assist in monitoring for illegal use violations.

In addition, we intend to establish levels of unavoidable residual environmental contamination (UREC) for crop- and site-specific agricultural commodities to be sold, labeled, or represented as "100 percent organic," "organic," or "made with . . ." These levels will represent limits at which USDA may take compliance action to suspend the use of a contaminated area for organic agricultural production. Currently, USDA is seeking scientifically sound principles and measures by which it can establish UREC levels to most effectively address issues of unavoidable residual environmental contamination with respect to this rule. However, in the interim, UREC will be defined as the Food and Drug Administration's (FDA) action levels for poisonous or deleterious substances in human food or animal feed. UREC levels will be initially set for persistent prohibited substances (aldrin, dieldrin, chlordane, DDE, etc.) in the environment. They may become more inclusive of prohibited residues as additional information becomes available. Unavoidable residual environmental contamination levels will be based on the unavoidability of the chemical substances and do not represent permissible levels of contamination where it is avoidable.

Analyses and test results will be available for public access unless the residue testing is part of an ongoing compliance investigation. Information relative to an ongoing compliance investigation will be confidential and restricted to the public.

Detection of Prohibited Substances or Products Derived from Excluded Methods

In the case of residue testing and the detection of prohibited substances in or on agricultural products to be sold, labeled, or represented as "100 percent organic," "organic," or "made with . . ." products with detectable residues of prohibited substances that exceed 5 percent of the EPA tolerance for the specific residue or UREC cannot be sold or labeled as organically produced. When such an agricultural crop is in violation of these requirements, the certification of that crop will be suspended for the period that the crop is in production. Certifying agents must follow the requirements specified in sections 205.662 and 205.663 of subpart G, Compliance.

The "5 percent of EPA tolerance" standard is considered a level above which an agricultural product cannot be sold as organic, regardless of how the product may have come into contact with a potential prohibited substance. This standard has been established to: (1) satisfy consumer expectations that organic agricultural products will contain minimal chemical residues and (2) respond to the organic industry's request to implement a standard comparable to current industry practices. However, the "5 percent of EPA tolerance" standard cannot be used to automatically qualify agricultural products as organically produced, even if the level of chemical residues detected on an agricultural product is below 5 percent of the EPA tolerance for the respective prohibited substance. This final rule is a comprehensive set of standards and regulations that determines whether a product can or cannot be considered to carry the specified organic labeling terms in subpart D, Labeling. Therefore, in addition to this section of subpart G, Administrative, all other requirements of this part must be met by certified organic operations to have an agricultural product considered "organically produced."

When residue testing detects the presence of *any* prohibited substance, whether above or below 5 percent of the EPA tolerance for the specific pesticide or UREC, the SOP's governing State official or certifying agent may conduct an investigation of the certified organic

operation to determine the cause of the prohibited substance or product in or on the agricultural product to be sold or labeled as organically produced. The same shall occur if testing detects a product produced using excluded methods. If the investigation reveals that the presence of the prohibited substance or product produced using excluded methods in or on an agricultural product intended to be sold as organically produced is the result of an intentional application of a prohibited substance or use of excluded methods, the certified organic operation shall be subject to suspension or revocation of its organic certification. In addition, any person who knowingly sells, labels, or represents an agricultural product as organically produced in violation of the Act or these regulations shall be subject to a civil penalty of not more than \$10,000 per violation.

Emergency Pest or Disease Treatment Programs

When a prohibited substance is applied to an organic production or handling operation due to a Federal or State emergency pest or disease treatment program and the organic handling or production operation otherwise meets the requirements of this final rule, the certification status of the operation shall not be affected as a result of the application of the prohibited substance, except that: (1) Any harvested crop or plant part to be harvested that has contact with a prohibited substance applied as the result of a Federal or State emergency pest or disease treatment program cannot be sold, labeled, or represented as "100 percent organic," "organic," or "made with . . ." and (2) any livestock that are treated with a prohibited substance applied as the result of a Federal or State emergency pest or disease treatment program or product derived from such treated livestock cannot be sold, labeled, or represented as "100 percent organic," "organic," or "made with . . ."

However, milk or milk products may be labeled or sold as organically produced beginning 12 months following the last date that the dairy animal was treated with the prohibited substance. Additionally, the offspring of gestating mammalian breeder stock treated with a prohibited substance may be considered organic if the breeder stock was not in the last third of gestation on the date that the breeder stock was treated with the prohibited substance.

Residue Testing—Changes Based on Comments

This portion of subpart G differs from our proposal in several respects as follows:

(1) *Reporting Requirements.* Commenters were not satisfied with the language in section 205.670(d)(1) that required results of all analyses and tests performed under section 205.670 to be provided to the Administrator promptly upon receipt. They asked that the paragraph be amended to include that: (1) Results of all analyses and tests performed under section 205.670 be provided by the Administrator to the appropriate SOP's governing State official; and (2) test results be made immediately available to the owner of the material sampled. They stated that since State organic certification programs are responsible for enforcement within their State, results of residue tests conducted by certifying agents must be provided to the SOP's governing State official for routine monitoring and for investigating possible violations of the Act.

We agree with the commenters and have responded to their concerns accordingly. To ensure that SOP's receive results of all tests and analyses conducted under the inspection and testing requirements of subpart G, section 205.670(d) has been amended to include that the results of all analyses and residue tests must be provided to the Administrator promptly upon receipt; Except: That where an SOP exists, all test results and analyses should be provided to the SOP's governing State official.

In regard to the commenters' request that certified organic operations be provided with a copy of test results from samples taken by an inspector, an additional paragraph, section 205.403(e)(2), has been added to subpart E, Certification, that assures that such information is provided to the owners of certified organic operations by the certifying agents.

(2) *Integrity Of Organic Samples.* We have modified language in section 205.670(c) to clarify our intent regarding the maintenance of sample integrity. The proposed rule stated that "sample integrity must be maintained in transit, and residue testing must be performed in an accredited laboratory." During the final rulemaking process, we did not believe that our intent was clear on this subject. Our intent is to ensure that sample integrity is maintained throughout the entire chain of custody during the residue testing process. Proposed language only suggests that sample integrity be maintained in

transit. Therefore, we have changed the second sentence in section 205.670(c) to state that "sample integrity must be maintained throughout the chain of custody, and residue testing must be performed in an accredited laboratory."

(3) *Reporting Residue and Other Food Safety Violations to Appropriate Health Agencies.* In the proposed rule, section 205.671(b) under Exclusion from Organic Sale states, "If test results indicate a specific agricultural product contains pesticide residues or environmental contaminants that exceed the FDA's or the EPA's regulatory tolerances, the data must be reported promptly to the appropriate public health agencies." During the final rulemaking process, a group of commenters suggested that we move section 205.671(b) into section 205.670 as paragraph (e). They recommended that we move section 205.671(b) because it does not specifically address the sale of organically produced products, as indicated by the section heading. They recommended that section 205.671(b) be placed under section 205.670 as paragraph (e) because it dealt with the reporting of residues that exceed Federal regulatory tolerances. The commenters further stated that, while section 205.671(b) creates a duty to report, it is not specific as to who must report.

We have accepted the suggestions of the commenters and have responded accordingly. We have removed section 205.671(b) and relocated it under section 205.670 as paragraph (e). We have also modified the regulatory text of paragraph (e) to include language that instructs certifying agents to report, when residue testing indicates that an agricultural product contains pesticide residues or environmental contaminants that exceed either the EPA tolerance level or FDA action level, as applicable, data revealing such information to the Federal agency whose regulatory tolerance or action level has been exceeded.

(4) *Exclusion from Organic Sale.* We have reviewed section 205.671(a), removed the requirement to implement the Pesticide Data Program (pdp) estimated national mean as a compliance tool in monitoring for the presence of unacceptable levels of prohibited substances in agricultural products intended to be sold as organic, and added the "5 percent of EPA tolerance" standard.

Commenters voiced the opinion that the estimated national mean would be a difficult standard in organic agricultural production for several reasons. Some stated that the estimated national mean was a new concept that would confuse

producers and handlers because they would not know the exact definition of "estimated national mean" and how it would be determined. Others stated that the PDP was too limited in scope to employ an estimated national mean for all commodity/pesticide combinations. Commenters reasoned that PDP data were limited in terms of the agricultural commodities that are sampled and tested.

Another group of commenters stated that PDP data would be unfair to use in the NOP's residue testing plan. They argued PDP data should not be used to set maximum residue levels for organic agricultural products because PDP samples its products as close to the point of consumption as possible. As a result, commenters believe that PDP data may not be totally reflective of residue levels of agricultural products at the farmgate level. Since most residue testing in organic agricultural production takes place at the farmgate, these commenters argued that it would be an inappropriate standard for organic agricultural production.

As a result, a large number of commenters suggested that we reconsider using the estimated national mean as a standard for the maximum allowable residues on organically produced products. Instead, commenters recommended that the NOP incorporate the National Organic Standards Board's (NOSB) recommendation and current industry practice of using 5 percent of the EPA tolerance as a maximum level of pesticide residue on organic agricultural products. Commenters argued that using 5 percent of the EPA tolerance provides a sense of confidence to the consumers of organic agricultural products.

In many respects, we agree with the commenters. We have revisited using PDP data to establish an estimated national mean for commodity/pesticide combinations and for setting a maximum level of pesticide residue that could exclude agricultural products from being sold, labeled, or represented as organic. As a result, we have concluded that such an approach may be somewhat underdeveloped to incorporate into the NOP. We have reached this conclusion based on many of the same arguments presented by commenters (i.e., limited scope of agricultural products tested under PDP, product sampling based upon market availability, testing near the point of consumption, etc.). Also, we estimated that there would be a considerable time lag between the implementation of the NOP and defining a comprehensive list of estimated national means for all commodity/pesticide combinations.

Thus, we have decided not to use the estimated national mean as a tool for monitoring organic agricultural products for the presence of prohibited substances and as a standard to exclude agricultural products from being sold, labeled, or represented as organically produced.

Instead, we have decided to follow the recommendation of the commenters by replacing the estimated national mean for specific commodity/pesticide pairs with 5 percent of the EPA tolerance for the specific pesticide. Therefore, when residue testing detects prohibited substances at levels that are greater than 5 percent of the EPA tolerance for the specific pesticide detected on the particular product samples, the agricultural product must not be sold or labeled as organically produced.

We fully understand that the EPA tolerance is defined as the maximum legal level of a pesticide residue in or on a raw or processed agricultural commodity. We also acknowledge that the EPA tolerance is a health-based standard. We are *not* trying to employ the 5 percent standard in a manner similar to that of EPA. As mentioned in our proposal, the national organic standards, including provisions governing prohibited substances, are based on the method of production, not the content of the product. The primary purpose of the residue testing approach described in this final rule, then, is to provide an additional tool for SOP's governing State officials and certifying agents to use in monitoring and ensuring compliance with the NOP.

(5) *Unavoidable Residual Environmental Contamination.* We have defined, as an interim measure, UREC as the FDA action levels for poisonous or deleterious substances in human food or animal feed.

Section 205.671 proposed the use of UREC to serve as a residue testing tool for compliance. Commenters believed UREC levels, as prescribed in section 205.671 of the proposed rule, would be problematic as a standard because they were undefined. Commenters argued that it would be impractical and very expensive to establish UREC levels for every organic crop and region in the United States. They suggested that UREC levels be managed as a practice standard or program manual issue. They also expressed the concern that inconsistent application of UREC levels could create difficulties for certifying agents and certified operations.

We agree that UREC levels should be defined. We are seeking scientifically sound principles and measures by which we can establish UREC levels to

most effectively address issues of unavoidable residual contamination with respect to this rule. However, in the interim, the ability to implement an undefined standard would be difficult for certifying agents. Therefore, we have included language in the preamble that temporarily defines UREC as the FDA action levels for poisonous or deleterious substances in human food or animal feed. When residue testing detects the presence of a prohibited substance on an agricultural product greater than such levels mentioned, the agricultural product cannot be sold as organic. We have decided to use FDA action levels for UREC because they encompass many of the toxic, persistent chemicals and heavy metals that are present in the environment and may be found on food and animal feed. As mentioned earlier, the FDA action levels are being employed in this part as temporary measures for compliance. We will continue to seek scientifically sound principles and measures by which to establish UREC levels that more appropriately satisfy the purposes of this part.

Residue Testing—Changes Requested But Not Made

This subpart retains from the proposed rule regulations on which we received comments as follows:

(1) *Residue Testing Responsibility.* Commenters petitioned that we remove the requirement in section 205.670(b) that states residue tests must be conducted by the applicable SOP's governing State official or the certifying agent at the official's or certifying agent's own expense. The commenters expressed the opinion that we were practicing "micromanagement." They also said that there was no need for the proposal to be so detailed with respect to who pays for residue testing. Based on the commenters' responses, residue analyses are reportedly paid by producers, buyers, brokers, certifiers, and government residue testing programs.

We have not adopted the suggestion of the commenters. In the proposal, we stated that conducting residue tests was considered a cost of doing business for certifying agents. Our position has not changed. Certifying agents can factor residue testing costs into certification fees. It is not our intention to "micromanage" the way that certifying agents conduct business. Section 2107(a)(6) of the Act requires that certifying agents conduct residue testing of agricultural products that have been produced on certified organic farms and handled through certified organic handling operations. OFPA also

requires, under section 2112(a) through (c), that certifying agents enforce its provisions by implementing a system of residue testing to test products sold or labeled as organically produced. In addition, subpart E, Certification, authorizes certifying agents to conduct on-site inspections, which may include residue testing, of certified organic operations to verify that the operation is complying with the provisions in the Act and the regulations in this part. Certifying agents are responsible for monitoring organic operations for the presence of prohibited substances; we view residue testing as a cost of doing business. Therefore, we believe that certifying agents should factor monitoring costs associated with implementing the provisions in the Act and Rule into their certification fees.

(2) *Reporting to Federal Regulatory Agencies.* Commenters disagree with section 205.671(b) of the proposed rule which states that if test results indicate a specific agricultural product contains pesticide residues or environmental contaminants that exceed the FDA action level or EPA tolerance, the data must be reported promptly to appropriate public health agencies. Commenters believe that since results of all analyses and tests must be provided to the Administrator, USDA should be responsible for communicating such test results to other Federal agencies such as FDA or EPA if regulatory tolerances or action levels are exceeded. They also suggested that section 205.671(b) be removed from the national regulations. Commenters expressed the view that such a requirement is not related to organic certification.

We do not agree with the commenters. It is not our intent to create additional responsibility for the certifying agent. Section 205.671(b), redesignated as section 205.670(e), is a statutory requirement. Section 2107(a)(6) of the Organic Food Production Act of 1990 requires certifying agents, to the extent of their awareness, to report violations of applicable laws relating to food safety to appropriate health agencies such as EPA and FDA. Therefore, due to section 2107 of the Act, section 205.670(e) has been included in the national regulations.

(3) *“Threshold” for Genetic Contamination.* Many commenters suggested that we establish a “threshold” for the unintended or adventitious presence of products of excluded methods in organic products. Some commenters argued that a threshold is necessary because, without the mandatory labeling of biotechnology-derived products, organic operations and certifying agents could

not be assured that products of excluded methods were not being used. Others argued that, without an established threshold, the regulations would constitute a “zero tolerance” for products of excluded methods, which would be impossible to achieve.

We do not believe there is sufficient consensus upon which to establish such a standard at this time. Much of the basic, baseline information about the prevalence of genetically engineered products in the conventional agricultural marketplace that would be necessary to set such a threshold—e.g., the effects of pollen drift where it may be a factor, the extent of mixing at various points throughout the marketing chain, the adventitious presence of genetically engineered seed in nonengineered seed lots—is still largely unknown. Our understanding of how the use of biotechnology in conventional agricultural production might affect organic crop production is even less well developed.

Also, as was pointed out in some comments, the testing methodology for the presence of products of excluded methods has not yet been fully validated. Testing methods for some biotechnology traits in some commodities are becoming commercially available. Without recognized methods of testing for and quantifying of all traits in a wide range of food products, however, it would be very difficult to establish a reliable numerical tolerance.

There are publicly and privately funded research projects underway that may provide useful baseline information. Efforts of Federal agencies to clarify the marketing and labeling of biotechnology- and nonbiotechnology-derived crops may also help address these concerns. FDA, for example, is developing guidance for food producers who voluntarily chose to label biotechnology- and nonbiotechnology-derived foods. USDA is also preparing a **Federal Register** Notice to seek public comment on the appropriate role, if any, that it can play in facilitating the marketing of agricultural products through the development of “quality assurance” type programs that help to preserve the identity of agricultural commodities. USDA, in cooperation with the technology providers, is also working to validate testing procedures and laboratories for some commodities.

All of these efforts may help to provide information on this issue. Practices for preserving product identity, including segregating genetically engineered and nongenetically engineered products, are evolving in some conventional markets.

As we discussed in the preamble to the proposed rule, we anticipate that these evolving industry best practices and standards will become the standards for implementing the provisions in this regulation relating to the use of excluded methods. As was also discussed in the proposed rule, these regulations do not establish a “zero tolerance” standard. As with other substances not approve for use in organic production systems, a positive detection of a product of excluded methods would trigger an investigation by the certifying agent to determine if a violation of organic production or handling standards occurred. The presence of a detectable residue alone does not necessarily indicate use of a product of excluded methods that would constitute a violation of the standards.

(4) *Certification Status After Emergency Pest or Disease Treatment.* We have not modified language in section 205.672 that would affect the certification status of a certified organic operation if the operation had been subjected to a Federal or State emergency pest or disease treatment program.

Section 205.672 states that when a prohibited substance is applied to a certified operation due to a Federal or State emergency pest or disease treatment program and the certified operation otherwise meets the requirements of this part, the certification status of the operation shall not be affected as a result of the application of the prohibited substance: Provided, That, the certified operation adheres to certain requirements prescribed by the NOP. One group of commenters informed us that they did not support maintaining the organic status of an operation that has been directly treated with prohibited substances, regardless of the reason for treatment. They believe that Federal and State emergency pest or disease treatment programs should provide alternatives for organic operations whenever feasible. If no alternative measure is feasible, the organic operation should choose between voluntary surrender of their organic status on targeted parts of the operation or destruction of the crop to eliminate pest habitat. The commenters also suggested that compensation should be provided to organic producers whose crops must be destroyed to eliminate habitat. They feel that allowing the application of prohibited materials to certified organic land without affecting the certification status violates the trust consumers place in organic certification.

We disagree with the position of the commenters. Historically, residues from emergency pest or disease treatment programs have been treated as drift cases by certifiers. In these cases, the specific crop may not be sold as organic, but the organic status of future crop years are not affected. We intend to handle such cases in a similar manner. We understand that commenters would like us to remove the certification of an organic operation that has been treated with a prohibited substance, but organic certification is a production claim, not a content claim. We, along with the commenters, are concerned with consumers trusting organic certification. At the same time, we are concerned with the welfare of certified organic operations. We have tried to include language in section 205.672 that would address both issues. We believe that, if a certified organic grower has been a good steward of his/her land and has managed the production of his/her product(s) in accordance with all regulations in the Act and other requirements in this part, the certification status of the operation should not be affected. The application of a prohibited substance as part of a Federal or State emergency pest or disease treatment program is outside the control of the certified operation. We also believe that maintaining consumer trust is important. Thus, section 205.672 states that any harvested crop or plant part to be harvested that has been treated with a prohibited substance as part of a Federal or State emergency pest or disease treatment program cannot be sold as organically produced. Therefore, the certified organic operation can retain its certification status, and the consumer can be assured that a product from a certified organic operation that has been in contact with a prohibited substance as the result of a Federal or State pest or disease treatment program will not enter the organic marketplace. Accordingly, we have not made the change to section 205.672 as proposed by the commenters.

(5) *Emergency Pest or Disease Treatment Programs.* Commenters suggested that the Department add a new paragraph to section 205.672 that states “the certifying agent must monitor production operations that have been subjected to a Federal or State emergency pest or disease treatment program, and may require testing of following crops, or an extended transition period for affected production sites, if residue test results indicate the presence of a prohibited substance.” Commenters said the language in the proposed rule did not clearly establish

that a transition period could be needed after contamination of a certified organic operation by a government-mandated spray program. They felt that there may be a need for a case-by-case determination by the certifying agent as to when it would be best for a certified organic operation to begin selling its products as organically produced after it has been subject to a government mandated spray program.

We understand that commenters would like USDA to mandate certifying agents to monitor operations that have been subject to Federal or State emergency pest or disease treatment programs; however, we do not see a need to prescribe such a provision. Based on the responsibilities of being a USDA-accredited certifier, it is our belief that certifying agents would monitor a certified organic operation that has been subjected to a Federal or State emergency pest or disease treatment program to make sure that product being produced for organic sale is actually being produced in accordance with the Act and the regulations in this part. Certifying agents have been granted the authority to conduct additional on-site inspections of certified organic operations to determine compliance with the Act and national standards under subpart E, section 205.403. Commenters requested that we include language that would allow certifying agents to recommend an extended transition period for affected production sites if residue tests indicate the presence of a prohibited substance. Again, we understand the commenters’ concern, but we are not aware of comprehensive soil residue data that could guide certifying agents in determining appropriate withdrawal intervals for operations that have been subjected to emergency pest or disease treatment programs.

Residue Testing—Clarifications

Clarification is given on the following issues raised by commenters as follows:

(1) Sampling and Testing.

Commenters stated that the purpose of residue testing under the Act is to assure that organically produced agricultural products that are sold as organic do not contain pesticide residues or residues of other prohibited substances that exceed levels as specified by the NOP. Based on language in section 205.670(b) of the proposed rule, commenters expressed the opinion that the Agricultural Marketing Service (AMS) was, not only requiring residue testing of organic agricultural products, but also of “any” agricultural input used or agricultural

product intended to be sold as “100 percent organic,” “organic,” or “made with * * *” when there is reason to believe that the agricultural input or product has come into contact with a prohibited substance. Commenters believe that organic certifying agents may be required to test many nonorganic agricultural inputs (such as seeds, compost, straw, sawdust, and plastic) and nonorganic agricultural products and ingredients used in products labeled as “made with * * *”. They also argued that such testing would be unnecessary, burdensome, and expensive because such materials are more likely to have come into contact with a prohibited substance. Therefore, commenters suggested that we amend section 205.670(b) by deleting “agricultural inputs” and replacing “agricultural product” with “organically produced agricultural product.” They also recommended that we replace the second occurrence of “product” with “organic product.” Thus section 205.670(b) would suggest that only *organic* agricultural products could be required to be tested by the certifying agent.

We understand the concerns of the commenters but believe that the commenters have misinterpreted the intent of section 205.670(b). It is not our intent to mandate residue testing of all inputs and ingredients used in the production of organic agricultural products. Neither is it our intent for certifying agents to abuse residue testing responsibility by conducting residue tests of certified organic operations without reason to believe that the agricultural input or product intended to be sold as organic has come into contact with prohibited substances. Our intent is to make it clear that certifying agents have the authority to test any agricultural input used or agricultural product intended to be sold as organically produced when there is reason to believe that the agricultural input or product has come into contact with a prohibited substance. Section 205.670(b) allows for testing of inputs and agricultural products, but it does not require that all inputs of a product intended to be sold as organically produced must be tested. However, certifying agents must be able to ensure that certified organic operations are operating in accordance with the Act and the regulations set forth in this part. To assure that certifying agents have established fair and effective procedures for enforcing residue testing requirements, section 205.504(b)(6) provides that they must submit to USDA a copy of the procedures to be used for

sampling and residue testing pursuant to section 205.670.

(2) *Chain Of Custody Training.* A commenter suggested that section 205.670(c) address chain of custody training for inspectors that will be performing preharvest or postharvest tissue test sample collection on behalf of the Administrator, SOP's governing State official, or certifying agent. The commenter proposed that all inspectors should be trained to handle chain of custody samples in order to maintain the integrity of the samples.

We agree that inspectors should be appropriately trained to handle chain-of-custody samples in order to maintain the integrity of the samples taken from a certified organic operation. However, we do not believe that the language in section 205.670(c) must be modified to address such an issue. As a USDA-accredited body, a private or State entity operating as a certifying agent must ensure that its responsibly connected persons, employees, and contractors with inspection, analysis, and decision-making responsibilities have sufficient expertise in organic production or handling techniques to successfully perform the duties assigned. The certifying agent must also submit a description of the training that has been provided or intends to be provided to personnel to ensure that they comply with and implement the requirements of the Act and the regulations in this part. In addition, certifying agents must submit a copy of the procedure to be used for sampling and residue testing for approval by the Administrator. Through the accreditation process, therefore, we will be able to assess the expertise of the individuals employed by the certifying agent and provide guidance in areas where additional training is needed to comply with the requirements of the Act and the regulations in this part.

(3) *Exclusion from Organic Sale.* Commenters expressed that section 205.671(a) could be easily misinterpreted. They said that section 205.671(a) did not make clear that residue testing may not be used to qualify crops to be sold as organic if a direct application of prohibited materials occurred. Commenters suggested that section 205.671(a) include: "Any crop or product to which prohibited materials have been directly applied shall not be sold, labeled, or represented as organically produced."

We do not believe this additional language is necessary. Residue testing cannot be used to qualify any agricultural crop or product to which a prohibited material has been purposefully/directly applied. The

presence of any prohibited substance on an agricultural product to be sold as organic warrants an investigation as to why the detected prohibited substance is present on the agricultural product. It does not matter if the product has come into contact with a prohibited substance through means of drift or intentional application. If the outcome of the investigation reveals that the presence of the detected prohibited substance is the result of an intentional application, the certified operation will be subject to suspension or revocation of its organic certification and/or a civil penalty of not more than \$10,000 if he/she knowingly sells the product as organic. The use of prohibited substances is not allowed in the Act or this final rule. Residue testing is not a means of qualifying a crop or product as organic if a prohibited substance has been intentionally/directly applied. It is a tool for monitoring compliance with the regulations set forth in the Act and in this part.

(4) *Emergency Pest or Disease Treatment Programs.* Commenters requested that we make a clear distinction between crops or agricultural products that have had prohibited substances directly applied to them and those that have come into contact with prohibited substances through chemical drift. They have proposed that we amend section 205.672(a) to address this issue. Section 205.672(a) of the proposal states that any harvested crop or plant part to be harvested that has had contact with a prohibited substance applied as the result of a Federal or State emergency pest or disease treatment program cannot be sold as organically produced. Commenters did not find this language acceptable because it did not distinguish between the two types of ways that products can come into contact with prohibited substances (drift and direct/intentional application) and how each situation would be addressed with respect to the national organic standards. Commenters believed that section 205.672(a) was fairly ambiguous and open for misinterpretation. Commenters requested that we amend language in section 205.672(a) to include that "Any harvested crop or plant part to be harvested that has contact with a prohibited substance *directly applied* to the crop as the result of a Federal or State emergency pest or disease treatment program cannot be sold, labeled, or represented as organically produced."

We do not accept the commenters' request and believe that the commenters have misinterpreted section 205.672 of the proposed rule. Section 205.672

specifically addresses certified organic operations that have had prohibited substances applied to them due to a Federal or State pest or disease treatment program. Section 205.672 does not include those organic operations that may have been drifted upon by prohibited substances that have been applied to a neighboring farm as a result of a Federal or State emergency pest or disease treatment program. Any potential drift from a mandatory pest and disease treatment program will be treated in the same manner as drift from any other source.

Adverse Action Appeal Process

This portion of subpart G sets forth the procedures for appealing adverse actions under the National Organic Program (NOP). These procedures will be used by: (1) Producers and handlers appealing denial of certification and proposed suspension or revocation of certification decisions; and (2) certifying agents appealing denial of accreditation and proposed suspension or revocation of accreditation decisions. The Act and the Administrative Procedure Act (APA) (5 U.S.C. 553–559) provides affected persons with the right to appeal any adverse actions taken against their application for certification or accreditation or their certification or accreditation.

The Administrator will handle certification appeals from operations in States that do not have an approved State organic program (SOP). The Administrator will also handle appeals of accreditation decisions of the NOP Program Manager. The Administrator will issue decisions to sustain or deny appeals. If an appeal is denied, the Administrator will initiate a formal adjudicatory proceeding to deny, suspend, or revoke certification or accreditation. Such proceedings will be conducted pursuant to USDA's Rules of Practice Governing Formal Adjudicatory Proceedings Instituted by the Secretary Under Various Statutes, 7 CFR 1.130 through 1.151. Under these rules of practice, if the Administrative Law Judge denies the appeal, the appellant may appeal the Administrative Law Judge's decision to the Judicial Officer. If the Judicial Officer denies the appeal, the appellant may appeal the Judicial Officer's decision to the United States District Court for the district in which the appellant is located.

In States with approved SOP's, the SOP will oversee certification compliance proceedings and handle appeals from certified operations in the State. An SOP's appeal procedures and rules of procedure must be approved by the Secretary and must be equivalent to

those of the NOP and USDA. The final decision on an appeal under the SOP may be appealed by the appellant to United States District Court for the district in which the appellant is located.

Description of Regulations

These appeal procedures provide that: (1) Persons, subject to the Act, who believe they are adversely affected by a noncompliance decision of the NOP's Program Manager may appeal such decision to the Administrator; (2) persons, subject to the Act, who believe they are adversely affected by a noncompliance decision of an SOP may appeal such decision to the SOP's governing State official who will initiate handling of the appeal in accordance with the appeal procedures approved by the Secretary; and (3) persons, subject to the Act, who believe they are adversely affected by a noncompliance decision of a certifying agent may appeal such decision to the Administrator unless the person is subject to an approved SOP, in which case the appeal must be made to the SOP.

All written communications between parties involved in appeal proceedings must be sent to the recipient's place of business by a delivery service which provides dated return receipts. All appeals filed under these procedures will be reviewed, heard, and decided by persons not involved with the decision being appealed.

Certification Appeals

Applicants for certification may appeal a certifying agent's notice of denial of certification. Certified operations may appeal a notification of proposed suspension or revocation of their certification issued by their certifying agent. Such appeals will be made to the Administrator unless the person is subject to an approved SOP, in which case the appeal must be made to the SOP.

If the Administrator or SOP sustains an appeal, the applicant or certified operation will be granted certification or continued certification, as applicable to the operation's status. The act of sustaining the appeal will not be considered an adverse action and may not be appealed by the certifying agent which issued the notice of denial of certification or notification of proposed suspension or revocation of certification.

If the Administrator or SOP denies an appeal, a formal administrative proceeding will be initiated to deny, suspend, or revoke the certification. Such proceeding will be conducted in accordance with USDA's Uniform Rules

of Practice or the SOP's rules of procedure.

Accreditation Appeals

Applicants for accreditation may appeal the Program Manager's notification of accreditation denial. Accredited certifying agents may appeal a notification of proposed suspension or revocation of their accreditation issued by the Program Manager. Such appeals will be made to the Administrator. If the Administrator sustains an appeal, the applicant or certifying agent will be granted accreditation or continued accreditation, as applicable to the operation's status. If the Administrator denies an appeal, a formal administrative proceeding will be initiated to deny, suspend, or revoke the accreditation. Such proceeding will be conducted in accordance with USDA's Uniform Rules of Practice.

Filing Period

An appeal of a noncompliance decision must be filed within the time period provided in the letter of notification or within 30 days from the date of receipt of the notification, whichever occurs later. The appeal will be considered "filed" on the date received by the Administrator or, when applicable, the SOP. Unless appealed in a timely manner, a notification to deny, suspend, or revoke a certification or accreditation will become final. The applicant, certified operation, or certifying agent that does not file an appeal in the time period provided waives the right to further appeal of the compliance proceeding.

Where and What to File

Appeals to the Administrator must be filed in writing and sent to: Administrator, USDA-AMS, Room 3071-S, P.O. Box 96456, Washington, DC 20090-6456. Appeals to the SOP must be filed in writing to the address and person identified in the letter of notification. All appeals must include a copy of the adverse decision to be reviewed and a statement of the appellant's reasons for believing that the decision was not proper or made in accordance with applicable program regulations, policies, or procedures.

Appeals—Changes Based On Comments

This portion of subpart G differs from the proposal in several respects as follows:

(1) *To Whom an Appeal Is Made.* We have amended section 205.680 to clarify to whom an appeal is made when the noncompliance decision is made by the NOP's Program Manager, an SOP, or a certifying agent. Several commenters

requested that we amend section 205.680 to make it consistent with the provision providing that appeals to the Administrator are not allowed in the case of an SOP decision, because such appeals have to be made to the SOP's governing State official.

We agree that section 205.680 did not convey sufficient explanation of to whom an appeal is made. Accordingly, we have amended the language in section 205.680 to clarify through paragraphs (a), (b), and (c) that: (1) Persons, subject to the Act, who believe they are adversely affected by a noncompliance decision of the NOP's Program Manager may appeal such decision to the Administrator; (2) persons, subject to the Act, who believe they are adversely affected by a noncompliance decision of an SOP may appeal such decision to the SOP's governing State official who will initiate handling of the appeal pursuant to appeal procedures approved by the Secretary; and (3) persons, subject to the Act, who believe they are adversely affected by a noncompliance decision of a certifying agent may appeal such decision to the Administrator unless the person is subject to an approved SOP, in which case the appeal must be made to the SOP.

(2) *Written Communications.* We have added a new paragraph (d) to section 205.680, which provides that all written communications between parties involved in appeal proceedings must be sent to the recipient's place of business by a delivery service which provides dated return receipts. We have taken this action to further clarify the appeals process. This addition to section 205.680 implements the same requirements for appeal documents as our addition of new paragraph (d) to section 205.660 stipulates for compliance documents.

(3) *Who Shall Handle Appeals.* We have added a new paragraph (e) to section 205.680, which provides that all appeals must be reviewed, heard, and decided by persons not involved with the decision being appealed. This provision was added to section 205.680 to allay the fears of commenters that the person making the decision would be the person deciding the appeal. A couple of commenters recommended that an appeal be heard by persons other than those who made the decision being appealed. Specifically, they want the appeal conducted by independent hearing officers who are not responsible for implementation or administration of the NOP. They also want the final decision-making authority in the administrative review process placed in the hands of the Secretary.

Under the NOP, once the compliance procedures are completed at the certifying agent level, the certified operation may appeal the decision of the certifying agent to the Administrator or to the SOP when the certified operation is located within a State with an approved SOP. The Administrator or the SOP will review the case and render an opinion on the appeal. When the appeal is sustained, the certified operation and certifying agent are notified and the case ends. However, if the appeal is denied the certified operation and certifying agent are notified and the certified operation is given an opportunity to appeal the decision of the Administrator or SOP.

Appeals of decisions made by the Administrator will be heard by an Administrative Law Judge. If the Administrative Law Judge rules against the certified operation, the Administrative Law Judge's decision may be appealed by the certified operation to the Judicial Officer. The Judicial Officer is the USDA official delegated authority by the Secretary as the final deciding officer in adjudication proceedings. If the Judicial Officer rules against the certified operation, the Judicial Officer's decision may be appealed by the certified operation to the United States District Court for the district in which the certified operation is located. For additional information see USDA's Uniform Rules of Practice found at 7 CFR part 1, subpart H.

Appeals of decisions made by an SOP will follow procedures comparable to those just described for an appeal of a decision made by the Administrator. As with a final decision of USDA, a final decision of the State that goes against the certified operation may be appealed to the United States District Court for the district in which the certified operation is located.

(4) *Filing Period.* We have amended the first sentence of section 205.681(c) by replacing "at least" with "within" and by adding the words, "whichever occurs later," to the end thereof. This amendment has been made to clarify our intent that persons affected by a noncompliance proceeding decision receive not less than 30 days in which to file their appeal of the decision.

(5) *Where To File an Appeal.* We have amended section 205.681(d) to clarify where appeals are to be filed. First, we have amended what is now paragraph (1) by removing the requirement that the appellant send a copy of the appeal to the certifying agent. This action shifts the responsibility of notifying the certifying agent of the appeal from the appellant to USDA or, when applicable, the SOP. Second, we have added

language at paragraph (2) which clarifies that appeals to the SOP must be filed in writing to the address and person identified in the letter of notification. Finally, we have amended what is now paragraph (3) of section 205.681 by replacing "position" with "reasons for believing" to clarify the intended scope and purpose of the appellant's appeal statement. Clarification of section 205.681(d) was prompted by a commenter who stated that it is discriminatory to require clients of private certifying agents to appeal to USDA in Washington, when State program clients can appeal locally.

There are various levels of appeal within the NOP. Clients of certifying agents (State and private) are provided with an opportunity to rebut the noncompliance findings of the certifying agent. Once the certified operation has exhausted its options at the certifying agent level, the certified operation may appeal the decision of the certifying agent to the Administrator or to the SOP when the certified operation is located within a State with an approved SOP.

The Administrator will review the case and render an opinion on the appeal. This level of appeal will not require the certified operation's representative to travel to the Administrator. An appeal of a decision made by the Administrator will be heard by an Administrative Law Judge as near as possible to the certified operation's representative's place of business or residence. An appeal of a decision made by the Administrative Law Judge will be heard by the Judicial Officer. Again the certified operation's representative will not be required to travel outside of the representative's place of business or residence. If the certified operation appeals the decision of the Judicial Officer, the appeal would be heard by the United States District Court for the district in which the certified operation is located.

Appeals of decisions made by an SOP will follow procedures comparable to those just described for an appeal of a decision made by the Administrator. As with a final decision of USDA, a final decision of the State that goes against the certified operation may be appealed to the United States District Court for the district in which the certified operation is located.

(6) *Appeal Reports.* We will submit an annual report on appeals to the National Organic Standards Board (NOSB), which will include nonconfidential compliance information. A commenter requested that we report quarterly to the NOSB on appeals (number, outcome, kinds, and problems). We agree that it

would be appropriate for the NOP to submit an appeals report to the NOSB. We will compile appeal data such as the number, outcome, kinds, and problems encountered. We will maintain this information under the compliance program to be developed within the NOP. We do not believe that it is necessary to put this type of detail or activity into the regulations. Further, we do not believe, at this time, that reporting more frequently than annually will be needed. The NOP, however, will work closely with the NOSB to provide it with the information it may need to recommend program amendments designed to address compliance and appeal issues.

(7) *Availability of Appeal Information.* We will develop and distribute appeal information. A commenter requested that section 205.680 be amended to require the distribution of an appeal information brochure to any applicant for accreditation or certification. We agree that the development and distribution of such information is a good idea. We do not believe, however, that it is necessary or appropriate to put this type of detail or activity into the regulations. We plan to provide program information, including appeals and related issues, on the NOP website.

Appeals—Changes Requested But Not Made

This portion of subpart G retains from the proposed rule, regulations on which we received comments as follows:

(1) *National Appeals Division.* Several commenters recommend amending sections 205.680 and 205.681 to provide for appeals to the National Appeals Division under the provisions at 7 CFR part 11. We disagree with the request that the NOP use the National Appeals Division Rules of Procedure. The Act and its implementing regulations are subject to the APA for rulemaking and adjudication. The provisions of the APA generally applicable to agency adjudication are not applicable to proceedings under 7 CFR part 11, National Appeals Division Rules of Procedure. USDA uses 7 CFR part 1, Rules of Practice Governing Formal Adjudicatory Proceedings Instituted by the Secretary Under Various Statutes, for adjudicatory proceedings involving the denial, suspension, and revocation of certification and accreditation.

Appeals—Clarifications

Clarification is given on the following issues raised by commenters:

(1) *Appeals.* A commenter stated that appeals of certification decisions should always be taken first to the certifying

agent to provide an opportunity to rectify any possible error. Another commenter requested an appeals process that includes private certifying agents.

Section 205.662(a) requires a written notification of noncompliance with opportunity to rebut or correct. When the noncompliance has been resolved due to rebuttal or correction, a written notification of noncompliance resolution is issued in accordance with section 205.662(b). When rebuttal is unsuccessful or correction of the noncompliance is not completed within the prescribed time period, a written notification of proposed suspension or revocation will be issued in accordance with section 205.662(c). This notification will advise the certified operation of its right to request mediation or file an appeal with the Administrator or, when applicable, an SOP. We believe this process of providing a notification of noncompliance with opportunity to rebut or correct, followed by a notification of proposed suspension or revocation, provides ample opportunity for the certified operation to work with its certifying agent to resolve issues of noncompliance.

(2) *Timely Notification.* A few commenters requested that we amend section 205.680 to include mandatory procedures for timely written notice of an adverse decision, the reasons for the decision, the person's appeal rights, and the procedures for filing an appeal. We recognize that all compliance activities need to be carried out as quickly and expeditiously as possible within the confines of due process. We believe that the commenters' concerns are addressed through various sections of these regulations. Section 205.402(a) requires review of an application upon acceptance of the application. Section 205.405, on denial of certification, requires a notification of noncompliance, followed, as applicable, by a notice of denial of certification. In accordance with section 205.405(d), the notice of denial of certification will state the reasons for denial and the applicant's right to request mediation or appeal the decision. Section 205.507 on denial of accreditation requires a notification of noncompliance, followed, as applicable, by a denial of accreditation. The notification of accreditation denial will state the reasons for denial and the applicant's right to appeal the decision. Compliance sections 205.662 for certified operations and 205.665 for certifying agents require a notification of noncompliance with an opportunity to correct or rebut the noncompliance(s). Sections 205.662 and

205.665, when applicable, require the issuance of a notification of proposed suspension or revocation. Such notice must describe the noncompliance and the entity's right to an appeal. Section 205.681 provides the procedures for filing an appeal.

Miscellaneous

Section 205.690 provisions the Office of Management and Budget control number assigned to the information collection requirements of these regulations. Sections 205.691 through 205.699 are reserved.

List of Subjects in 7 CFR Part 205

Administrative practice and procedure, Agriculture, Animals, Archives and records, Imports, Labeling, Organically produced products, Plants, Reporting and recordkeeping requirements, Seals and insignia, Soil conservation.

For the reasons set forth in the preamble, Title 7, Chapter I of the Code of Federal Regulations is amended as follows:

PARTS 205–209 [REMOVED]

1. Parts 205 through 209, which are currently reserved in subchapter K (Federal Seed Act), are removed.
2. A new subchapter M consisting of parts 205 through 209 is added to read as follows:

SUBCHAPTER M—ORGANIC FOODS PRODUCTION ACT PROVISIONS

PART 205—NATIONAL ORGANIC PROGRAM

Subpart A—Definitions

Sec.

- 205.1 Meaning of words.
- 205.2 Terms defined.

Subpart B—Applicability

- 205.100 What has to be certified.
- 205.101 Exemptions and exclusions from certification.
- 205.102 Use of the term, “organic.”
- 205.103 Recordkeeping by certified operations.
- 205.104 [Reserved]
- 205.105 Allowed and prohibited substances, methods, and ingredients in organic production and handling.
- 205.106–205.199 [Reserved]

Subpart C—Organic Production and Handling Requirements

- 205.200 General.
- 205.201 Organic production and handling system plan.
- 205.202 Land requirements.
- 205.203 Soil fertility and crop nutrient management practice standard.
- 205.204 Seeds and planting stock practice standard.
- 205.205 Crop rotation practice standard.

- 205.206 Crop pest, weed, and disease management practice standard.
- 205.207 Wild-crop harvesting practice standard.
- 205.208–205.235 [Reserved]
- 205.236 Origin of livestock.
- 205.237 Livestock feed.
- 205.238 Livestock health care practice standard.
- 205.239 Livestock living conditions.
- 205.240–205.269 [Reserved]
- 205.270 Organic handling requirements.
- 205.271 Facility pest management practice standard.
- 205.272 Commingling and contact with prohibited substance prevention practice standard.
- 205.273–205.289 [Reserved]
- 205.290 Temporary variances.
- 205.291–205.299 [Reserved]

Subpart D—Labels, Labeling, and Market Information

- 205.300 Use of the term, “organic.”
- 205.301 Product composition.
- 205.302 Calculating the percentage of organically produced ingredients.
- 205.303 Packaged products labeled “100 percent organic” or “organic.”
- 205.304 Packaged products labeled “made with organic (specified ingredients or food group(s)).”
- 205.305 Multiingredient packaged products with less than 70 percent organically produced ingredients.
- 205.306 Labeling of livestock feed.
- 205.307 Labeling of nonretail containers used for only shipping or storage of raw or processed agricultural products labeled as “100 percent organic,” “organic,” or “made with organic (specified ingredients or food group(s)).”
- 205.308 Agricultural products in other than packaged form at the point of retail sale that are sold, labeled, or represented as “100 percent organic” or “organic.”
- 205.309 Agricultural products in other than packaged form at the point of retail sale that are sold, labeled, or represented as “made with organic (specified ingredients or food group(s)).”
- 205.310 Agricultural products produced on an exempt or excluded operation.
- 205.311 USDA Seal.
- 205.312–205.399 [Reserved]

Subpart E—Certification

- 205.400 General requirements for certification.
- 205.401 Application for certification.
- 205.402 Review of application.
- 205.403 On-site inspections.
- 205.404 Granting certification.
- 205.405 Denial of certification.
- 205.406 Continuation of certification.
- 205.407–205.499 [Reserved]

Subpart F—Accreditation of Certifying Agents

- 205.500 Areas and duration of accreditation.
- 205.501 General requirements for accreditation.
- 205.502 Applying for accreditation.
- 205.503 Applicant information.
- 205.504 Evidence of expertise and ability.
- 205.505 Statement of agreement.

- 205.506 Granting accreditation.
- 205.507 Denial of accreditation.
- 205.508 Site evaluations.
- 205.509 Peer review panel.
- 205.510 Annual report, recordkeeping, and renewal of accreditation.
- 205.511–205.599 [Reserved]

Subpart G—Administrative

The National List of Allowed and Prohibited Substances

- 205.600 Evaluation criteria for allowed and prohibited substances, methods, and ingredients.
- 205.601 Synthetic substances allowed for use in organic crop production.
- 205.602 Nonsynthetic substances prohibited for use in organic crop production.
- 205.603 Synthetic substances allowed for use in organic livestock production.
- 205.604 Nonsynthetic substances prohibited for use in organic livestock production.
- 205.605 Nonagricultural (nonorganic) substances allowed as ingredients in or on processed products labeled as “organic,” or “made with organic (specified ingredients or food group(s)).”
- 205.606 Nonorganically produced agricultural products allowed as ingredients in or on processed products labeled as “organic” or “made with organic (specified ingredients or food group(s)).”
- 205.607 Amending the National List.
- 205.608–205.619 [Reserved]

State Organic Programs

- 205.620 Requirements of State organic programs.
- 205.621 Submission and determination of proposed State organic programs and amendments to approved State organic programs.
- 205.622 Review of approved State organic programs.
- 205.623–205.639 [Reserved]

Fees

- 205.640 Fees and other charges for accreditation.
- 205.641 Payment of fees and other charges.
- 205.642 Fees and other charges for certification.
- 205.643–205.649 [Reserved]

Compliance

- 205.660 General.
- 205.661 Investigation of certified operations.
- 205.662 Noncompliance procedure for certified operations.
- 205.663 Mediation.
- 205.664 [Reserved]
- 205.665 Noncompliance procedure for certifying agents.
- 205.666–205.667 [Reserved]
- 205.668 Noncompliance procedures under State Organic Programs.
- 205.699 [Reserved]

Inspection and Testing, Reporting, and Exclusion from Sale

- 205.670 Inspection and testing of agricultural product to be sold or labeled “organic.”

- 205.671 Exclusion from organic sale.
- 205.672 Emergency pest or disease treatment.
- 205.673–205.679 [Reserved]

Adverse Action Appeal Process

- 205.680 General.
- 205.681 Appeals.
- 205.682–205.689 [Reserved]

Miscellaneous

- 205.690 OMB control number.
- 205.691–205.699 [Reserved]
- Authority: 7 U.S.C. 6501–6522.

Subpart A—Definitions

§ 205.1 Meaning of words.

For the purpose of the regulations in this subpart, words in the singular form shall be deemed to impart the plural and vice versa, as the case may demand.

§ 205.2 Terms defined.

Accreditation. A determination made by the Secretary that authorizes a private, foreign, or State entity to conduct certification activities as a certifying agent under this part.

Act. The Organic Foods Production Act of 1990, as amended (7 U.S.C. 6501 et seq.).

Action level. The limit at or above which the Food and Drug Administration will take legal action against a product to remove it from the market. Action levels are based on unavailability of the poisonous or deleterious substances and do not represent permissible levels of contamination where it is avoidable.

Administrator. The Administrator for the Agricultural Marketing Service, United States Department of Agriculture, or the representative to whom authority has been delegated to act in the stead of the Administrator.

Agricultural inputs. All substances or materials used in the production or handling of organic agricultural products.

Agricultural product. Any agricultural commodity or product, whether raw or processed, including any commodity or product derived from livestock, that is marketed in the United States for human or livestock consumption.

Agricultural Marketing Service (AMS). The Agricultural Marketing Service of the United States Department of Agriculture.

Allowed synthetic. A substance that is included on the National List of synthetic substances allowed for use in organic production or handling.

Animal drug. Any drug as defined in section 201 of the Federal Food, Drug, and Cosmetic Act, as amended (21 U.S.C. 321), that is intended for use in livestock, including any drug intended

for use in livestock feed but not including such livestock feed.

Annual seedling. A plant grown from seed that will complete its life cycle or produce a harvestable yield within the same crop year or season in which it was planted.

Area of operation. The types of operations: crops, livestock, wild-crop harvesting or handling, or any combination thereof that a certifying agent may be accredited to certify under this part.

Audit trail. Documentation that is sufficient to determine the source, transfer of ownership, and transportation of any agricultural product labeled as “100 percent organic,” the organic ingredients of any agricultural product labeled as “organic” or “made with organic (specified ingredients)” or the organic ingredients of any agricultural product containing less than 70 percent organic ingredients identified as organic in an ingredients statement.

Biodegradable. Subject to biological decomposition into simpler biochemical or chemical components.

Biologics. All viruses, serums, toxins, and analogous products of natural or synthetic origin, such as diagnostics, antitoxins, vaccines, live microorganisms, killed microorganisms, and the antigenic or immunizing components of microorganisms intended for use in the diagnosis, treatment, or prevention of diseases of animals.

Breeder stock. Female livestock whose offspring may be incorporated into an organic operation at the time of their birth.

Buffer zone. An area located between a certified production operation or portion of a production operation and an adjacent land area that is not maintained under organic management. A buffer zone must be sufficient in size or other features (e.g., windbreaks or a diversion ditch) to prevent the possibility of unintended contact by prohibited substances applied to adjacent land areas with an area that is part of a certified operation.

Bulk. The presentation to consumers at retail sale of an agricultural product in unpackaged, loose form, enabling the consumer to determine the individual pieces, amount, or volume of the product purchased.

Certification or certified. A determination made by a certifying agent that a production or handling operation is in compliance with the Act and the regulations in this part, which is documented by a certificate of organic operation.

Certified operation. A crop or livestock production, wild-crop harvesting or handling operation, or portion of such operation that is certified by an accredited certifying agent as utilizing a system of organic production or handling as described by the Act and the regulations in this part.

Certifying agent. Any entity accredited by the Secretary as a certifying agent for the purpose of certifying a production or handling operation as a certified production or handling operation.

Certifying agent's operation. All sites, facilities, personnel, and records used by a certifying agent to conduct certification activities under the Act and the regulations in this part.

Claims. Oral, written, implied, or symbolic representations, statements, or advertising or other forms of communication presented to the public or buyers of agricultural products that relate to the organic certification process or the term, "100 percent organic," "organic," or "made with organic (specified ingredients or food group(s))," or, in the case of agricultural products containing less than 70 percent organic ingredients, the term, "organic," on the ingredients panel.

Commercially available. The ability to obtain a production input in an appropriate form, quality, or quantity to fulfill an essential function in a system of organic production or handling, as determined by the certifying agent in the course of reviewing the organic plan.

Commingle. Physical contact between unpackaged organically produced and nonorganically produced agricultural products during production, processing, transportation, storage or handling, other than during the manufacture of a multiingredient product containing both types of ingredients.

Compost. The product of a managed process through which microorganisms break down plant and animal materials into more available forms suitable for application to the soil. Compost must be produced through a process that combines plant and animal materials with an initial C:N ratio of between 25:1 and 40:1. Producers using an in-vessel or static aerated pile system must maintain the composting materials at a temperature between 131° F and 170° F for 3 days. Producers using a windrow system must maintain the composting materials at a temperature between 131° F and 170° F for 15 days, during which time, the materials must be turned a minimum of five times.

Control. Any method that reduces or limits damage by populations of pests,

weeds, or diseases to levels that do not significantly reduce productivity.

Crop. A plant or part of a plant intended to be marketed as an agricultural product or fed to livestock.

Crop residues. The plant parts remaining in a field after the harvest of a crop, which include stalks, stems, leaves, roots, and weeds.

Crop rotation. The practice of alternating the annual crops grown on a specific field in a planned pattern or sequence in successive crop years so that crops of the same species or family are not grown repeatedly without interruption on the same field. Perennial cropping systems employ means such as alley cropping, intercropping, and hedgerows to introduce biological diversity in lieu of crop rotation.

Crop year. That normal growing season for a crop as determined by the Secretary.

Cultivation. Digging up or cutting the soil to prepare a seed bed; control weeds; aerate the soil; or work organic matter, crop residues, or fertilizers into the soil.

Cultural methods. Methods used to enhance crop health and prevent weed, pest, or disease problems without the use of substances; examples include the selection of appropriate varieties and planting sites; proper timing and density of plantings; irrigation; and extending a growing season by manipulating the microclimate with green houses, cold frames, or wind breaks.

Detectable residue. The amount or presence of chemical residue or sample component that can be reliably observed or found in the sample matrix by current approved analytical methodology.

Disease vectors. Plants or animals that harbor or transmit disease organisms or pathogens which may attack crops or livestock.

Drift. The physical movement of prohibited substances from the intended target site onto an organic operation or portion thereof.

Emergency pest or disease treatment program. A mandatory program authorized by a Federal, State, or local agency for the purpose of controlling or eradicating a pest or disease.

Employee. Any person providing paid or volunteer services for a certifying agent.

Excluded methods. A variety of methods used to genetically modify organisms or influence their growth and development by means that are not possible under natural conditions or processes and are not considered compatible with organic production.

Such methods include cell fusion, microencapsulation and macroencapsulation, and recombinant DNA technology (including gene deletion, gene doubling, introducing a foreign gene, and changing the positions of genes when achieved by recombinant DNA technology). Such methods do not include the use of traditional breeding, conjugation, fermentation, hybridization, in vitro fertilization, or tissue culture.

Feed. Edible materials which are consumed by livestock for their nutritional value. Feed may be concentrates (grains) or roughages (hay, silage, fodder). The term, "feed," encompasses all agricultural commodities, including pasture ingested by livestock for nutritional purposes.

Feed additive. A substance added to feed in micro quantities to fulfill a specific nutritional need; i.e., essential nutrients in the form of amino acids, vitamins, and minerals.

Feed supplement. A combination of feed nutrients added to livestock feed to improve the nutrient balance or performance of the total ration and intended to be:

(1) Diluted with other feeds when fed to livestock;

(2) Offered free choice with other parts of the ration if separately available; or

(3) Further diluted and mixed to produce a complete feed.

Fertilizer. A single or blended substance containing one or more recognized plant nutrient(s) which is used primarily for its plant nutrient content and which is designed for use or claimed to have value in promoting plant growth.

Field. An area of land identified as a discrete unit within a production operation.

Forage. Vegetative material in a fresh, dried, or ensiled state (pasture, hay, or silage), which is fed to livestock.

Governmental entity. Any domestic government, tribal government, or foreign governmental subdivision providing certification services.

Handle. To sell, process, or package agricultural products, except such term shall not include the sale, transportation, or delivery of crops or livestock by the producer thereof to a handler.

Handler. Any person engaged in the business of handling agricultural products, including producers who handle crops or livestock of their own production, except such term shall not include final retailers of agricultural products that do not process agricultural products.

Handling operation. Any operation or portion of an operation (except final retailers of agricultural products that do not process agricultural products) that receives or otherwise acquires agricultural products and processes, packages, or stores such products.

Immediate family. The spouse, minor children, or blood relatives who reside in the immediate household of a certifying agent or an employee, inspector, contractor, or other personnel of the certifying agent. For the purpose of this part, the interest of a spouse, minor child, or blood relative who is a resident of the immediate household of a certifying agent or an employee, inspector, contractor, or other personnel of the certifying agent shall be considered to be an interest of the certifying agent or an employee, inspector, contractor, or other personnel of the certifying agent.

Inert ingredient. Any substance (or group of substances with similar chemical structures if designated by the Environmental Protection Agency) other than an active ingredient which is intentionally included in any pesticide product (40 CFR 152.3(m)).

Information panel. That part of the label of a packaged product that is immediately contiguous to and to the right of the principal display panel as observed by an individual facing the principal display panel, unless another section of the label is designated as the information panel because of package size or other package attributes (e.g., irregular shape with one usable surface).

Ingredient. Any substance used in the preparation of an agricultural product that is still present in the final commercial product as consumed.

Ingredients statement. The list of ingredients contained in a product shown in their common and usual names in the descending order of predominance.

Inspection. The act of examining and evaluating the production or handling operation of an applicant for certification or certified operation to determine compliance with the Act and the regulations in this part.

Inspector. Any person retained or used by a certifying agent to conduct inspections of certification applicants or certified production or handling operations.

Label. A display of written, printed, or graphic material on the immediate container of an agricultural product or any such material affixed to any agricultural product or affixed to a bulk container containing an agricultural product, except for package liners or a display of written, printed, or graphic material which contains only

information about the weight of the product.

Labeling. All written, printed, or graphic material accompanying an agricultural product at any time or written, printed, or graphic material about the agricultural product displayed at retail stores about the product.

Livestock. Any cattle, sheep, goat, swine, poultry, or equine animals used for food or in the production of food, fiber, feed, or other agricultural-based consumer products; wild or domesticated game; or other nonplant life, except such term shall not include aquatic animals or bees for the production of food, fiber, feed, or other agricultural-based consumer products.

Lot. Any number of containers which contain an agricultural product of the same kind located in the same conveyance, warehouse, or packing house and which are available for inspection at the same time.

Manure. Feces, urine, other excrement, and bedding produced by livestock that has not been composted.

Market information. Any written, printed, audiovisual, or graphic information, including advertising, pamphlets, flyers, catalogues, posters, and signs, distributed, broadcast, or made available outside of retail outlets that are used to assist in the sale or promotion of a product.

Mulch. Any nonsynthetic material, such as wood chips, leaves, or straw, or any synthetic material included on the National List for such use, such as newspaper or plastic that serves to suppress weed growth, moderate soil temperature, or conserve soil moisture.

Narrow range oils. Petroleum derivatives, predominately of paraffinic and naphthenic fractions with 50 percent boiling point (10 mm Hg) between 415° F and 440° F.

National List. A list of allowed and prohibited substances as provided for in the Act.

National Organic Program (NOP). The program authorized by the Act for the purpose of implementing its provisions.

National Organic Standards Board (NOSB). A board established by the Secretary under 7 U.S.C. 6518 to assist in the development of standards for substances to be used in organic production and to advise the Secretary on any other aspects of the implementation of the National Organic Program.

Natural resources of the operation. The physical, hydrological, and biological features of a production operation, including soil, water, wetlands, woodlands, and wildlife.

Nonagricultural substance. A substance that is not a product of

agriculture, such as a mineral or a bacterial culture, that is used as an ingredient in an agricultural product. For the purposes of this part, a nonagricultural ingredient also includes any substance, such as gums, citric acid, or pectin, that is extracted from, isolated from, or a fraction of an agricultural product so that the identity of the agricultural product is unrecognizable in the extract, isolate, or fraction.

Nonsynthetic (natural). A substance that is derived from mineral, plant, or animal matter and does not undergo a synthetic process as defined in section 6502(21) of the Act (7 U.S.C. 6502(21)). For the purposes of this part, nonsynthetic is used as a synonym for natural as the term is used in the Act.

Nonretail container. Any container used for shipping or storage of an agricultural product that is not used in the retail display or sale of the product.

Nontoxic. Not known to cause any adverse physiological effects in animals, plants, humans, or the environment.

Organic. A labeling term that refers to an agricultural product produced in accordance with the Act and the regulations in this part.

Organic matter. The remains, residues, or waste products of any organism.

Organic production. A production system that is managed in accordance with the Act and regulations in this part to respond to site-specific conditions by integrating cultural, biological, and mechanical practices that foster cycling of resources, promote ecological balance, and conserve biodiversity.

Organic system plan. A plan of management of an organic production or handling operation that has been agreed to by the producer or handler and the certifying agent and that includes written plans concerning all aspects of agricultural production or handling described in the Act and the regulations in subpart C of this part.

Pasture. Land used for livestock grazing that is managed to provide feed value and maintain or improve soil, water, and vegetative resources.

Peer review panel. A panel of individuals who have expertise in organic production and handling methods and certification procedures and who are appointed by the Administrator to assist in evaluating applicants for accreditation as certifying agents.

Person. An individual, partnership, corporation, association, cooperative, or other entity.

Pesticide. Any substance which alone, in chemical combination, or in any formulation with one or more substances is defined as a pesticide in

section 2(u) of the Federal Insecticide, Fungicide, and Rodenticide Act (7 U.S.C. 136(u) *et seq.*)

Petition. A request to amend the National List that is submitted by any person in accordance with this part.

Planting stock. Any plant or plant tissue other than annual seedlings but including rhizomes, shoots, leaf or stem cuttings, roots, or tubers, used in plant production or propagation.

Practice standard. The guidelines and requirements through which a production or handling operation implements a required component of its production or handling organic system plan. A practice standard includes a series of allowed and prohibited actions, materials, and conditions to establish a minimum level performance for planning, conducting, and maintaining a function, such as livestock health care or facility pest management, essential to an organic operation.

Principal display panel. That part of a label that is most likely to be displayed, presented, shown, or examined under customary conditions of display for sale.

Private entity. Any domestic or foreign nongovernmental for-profit or not-for-profit organization providing certification services.

Processing. Cooking, baking, curing, heating, drying, mixing, grinding, churning, separating, extracting, slaughtering, cutting, fermenting, distilling, eviscerating, preserving, dehydrating, freezing, chilling, or otherwise manufacturing and includes the packaging, canning, jarring, or otherwise enclosing food in a container.

Processing aid. (1) Substance that is added to a food during the processing of such food but is removed in some manner from the food before it is packaged in its finished form;

(2) a substance that is added to a food during processing, is converted into constituents normally present in the food, and does not significantly increase the amount of the constituents naturally found in the food; and

(3) a substance that is added to a food for its technical or functional effect in the processing but is present in the finished food at insignificant levels and does not have any technical or functional effect in that food.

Producer. A person who engages in the business of growing or producing food, fiber, feed, and other agricultural-based consumer products.

Production lot number/identifier. Identification of a product based on the production sequence of the product showing the date, time, and place of production used for quality control purposes.

Prohibited substance. A substance the use of which in any aspect of organic production or handling is prohibited or not provided for in the Act or the regulations of this part.

Records. Any information in written, visual, or electronic form that documents the activities undertaken by a producer, handler, or certifying agent to comply with the Act and regulations in this part.

Residue testing. An official or validated analytical procedure that detects, identifies, and measures the presence of chemical substances, their metabolites, or degradations products in or on raw or processed agricultural products.

Responsibly connected. Any person who is a partner, officer, director, holder, manager, or owner of 10 percent or more of the voting stock of an applicant or a recipient of certification or accreditation.

Retail food establishment. A restaurant; delicatessen; bakery; grocery store; or any retail outlet with an in-store restaurant, delicatessen, bakery, salad bar, or other eat-in or carry-out service of processed or prepared raw and ready-to-eat-food.

Routine use of parasiticide. The regular, planned, or periodic use of parasiticides.

Secretary. The Secretary of Agriculture or a representative to whom authority has been delegated to act in the Secretary's stead.

Sewage sludge. A solid, semisolid, or liquid residue generated during the treatment of domestic sewage in a treatment works. Sewage sludge includes but is not limited to: domestic septage; scum or solids removed in primary, secondary, or advanced wastewater treatment processes; and a material derived from sewage sludge. Sewage sludge does not include ash generated during the firing of sewage sludge in a sewage sludge incinerator or grit and screenings generated during preliminary treatment of domestic sewage in a treatment works.

Slaughter stock. Any animal that is intended to be slaughtered for consumption by humans or other animals.

Soil and water quality. Observable indicators of the physical, chemical, or biological condition of soil and water, including the presence of environmental contaminants.

Split operation. An operation that produces or handles both organic and nonorganic agricultural products.

State. Any of the several States of the United States of America, its territories, the District of Columbia, and the Commonwealth of Puerto Rico.

State certifying agent. A certifying agent accredited by the Secretary under the National Organic Program and operated by the State for the purposes of certifying organic production and handling operations in the State.

State organic program (SOP). A State program that meets the requirements of section 6506 of the Act, is approved by the Secretary, and is designed to ensure that a product that is sold or labeled as organically produced under the Act is produced and handled using organic methods.

State organic program's governing State official. The chief executive official of a State or, in the case of a State that provides for the statewide election of an official to be responsible solely for the administration of the agricultural operations of the State, such official who administers a State organic certification program.

Synthetic. A substance that is formulated or manufactured by a chemical process or by a process that chemically changes a substance extracted from naturally occurring plant, animal, or mineral sources, except that such term shall not apply to substances created by naturally occurring biological processes.

Tolerance. The maximum legal level of a pesticide chemical residue in or on a raw or processed agricultural commodity or processed food.

Transplant. A seedling which has been removed from its original place of production, transported, and replanted.

Unavoidable residual environmental contamination (UREC). Background levels of naturally occurring or synthetic chemicals that are present in the soil or present in organically produced agricultural products that are below established tolerances.

Wild crop. Any plant or portion of a plant that is collected or harvested from a site that is not maintained under cultivation or other agricultural management.

Subpart B—Applicability

§ 205.100 What has to be certified.

(a) Except for operations exempt or excluded in § 205.101, each production or handling operation or specified portion of a production or handling operation that produces or handles crops, livestock, livestock products, or other agricultural products that are intended to be sold, labeled, or represented as “100 percent organic,” “organic,” or “made with organic (specified ingredients or food group(s))” must be certified according to the provisions of subpart E of this part and

must meet all other applicable requirements of this part.

(b) Any production or handling operation or specified portion of a production or handling operation that has been already certified by a certifying agent on the date that the certifying agent receives its accreditation under this part shall be deemed to be certified under the Act until the operation's next anniversary date of certification. Such recognition shall only be available to those operations certified by a certifying agent that receives its accreditation within 18 months from February 20, 2001.

(c) Any operation that:

(1) Knowingly sells or labels a product as organic, except in accordance with the Act, shall be subject to a civil penalty of not more than \$10,000 per violation.

(2) Makes a false statement under the Act to the Secretary, a governing State official, or an accredited certifying agent shall be subject to the provisions of section 1001 of title 18, United States Code.

§ 205.101 Exemptions and exclusions from certification.

(a) *Exemptions.* (1) A production or handling operation that sells agricultural products as "organic" but whose gross agricultural income from organic sales totals \$5,000 or less annually is exempt from certification under subpart E of this part and from submitting an organic system plan for acceptance or approval under § 205.201 but must comply with the applicable organic production and handling requirements of subpart C of this part and the labeling requirements of § 205.310. The products from such operations shall not be used as ingredients identified as organic in processed products produced by another handling operation.

(2) A handling operation that is a retail food establishment or portion of a retail food establishment that handles organically produced agricultural products but does not process them is exempt from the requirements in this part.

(3) A handling operation or portion of a handling operation that only handles agricultural products that contain less than 70 percent organic ingredients by total weight of the finished product (excluding water and salt) is exempt from the requirements in this part, except:

(i) The provisions for prevention of contact of organic products with prohibited substances set forth in § 205.272 with respect to any

organically produced ingredients used in an agricultural product;

(ii) The labeling provisions of §§ 205.305 and 205.310; and

(iii) The recordkeeping provisions in paragraph (c) of this section.

(4) A handling operation or portion of a handling operation that only identifies organic ingredients on the information panel is exempt from the requirements in this part, except:

(i) The provisions for prevention of contact of organic products with prohibited substances set forth in § 205.272 with respect to any organically produced ingredients used in an agricultural product;

(ii) The labeling provisions of §§ 205.305 and 205.310; and

(iii) The recordkeeping provisions in paragraph (c) of this section.

(b) *Exclusions.* (1) A handling operation or portion of a handling operation is excluded from the requirements of this part, except for the requirements for the prevention of commingling and contact with prohibited substances as set forth in § 205.272 with respect to any organically produced products, if such operation or portion of the operation only sells organic agricultural products labeled as "100 percent organic," "organic," or "made with organic (specified ingredients or food group(s))" that:

(i) Are packaged or otherwise enclosed in a container prior to being received or acquired by the operation; and

(ii) Remain in the same package or container and are not otherwise processed while in the control of the handling operation.

(2) A handling operation that is a retail food establishment or portion of a retail food establishment that processes, on the premises of the retail food establishment, raw and ready-to-eat food from agricultural products that were previously labeled as "100 percent organic," "organic," or "made with organic (specified ingredients or food group(s))" is excluded from the requirements in this part, except:

(i) The requirements for the prevention of contact with prohibited substances as set forth in § 205.272; and

(ii) The labeling provisions of § 205.310.

(c) *Records to be maintained by exempt operations.* (1) Any handling operation exempt from certification pursuant to paragraph (a)(3) or (a)(4) of this section must maintain records sufficient to:

(i) Prove that ingredients identified as organic were organically produced and handled; and

(ii) Verify quantities produced from such ingredients.

(2) Records must be maintained for no less than 3 years beyond their creation and the operations must allow representatives of the Secretary and the applicable State organic programs' governing State official access to these records for inspection and copying during normal business hours to determine compliance with the applicable regulations set forth in this part.

§ 205.102 Use of the term, "organic."

Any agricultural product that is sold, labeled, or represented as "100 percent organic," "organic," or "made with organic (specified ingredients or food group(s))" must be:

(a) Produced in accordance with the requirements specified in § 205.101 or §§ 205.202 through 205.207 or §§ 205.236 through 205.239 and all other applicable requirements of part 205; and

(b) Handled in accordance with the requirements specified in § 205.101 or §§ 205.270 through 205.272 and all other applicable requirements of this part 205.

§ 205.103 Recordkeeping by certified operations.

(a) A certified operation must maintain records concerning the production, harvesting, and handling of agricultural products that are or that are intended to be sold, labeled, or represented as "100 percent organic," "organic," or "made with organic (specified ingredients or food group(s))."

(b) Such records must:

(1) Be adapted to the particular business that the certified operation is conducting;

(2) Fully disclose all activities and transactions of the certified operation in sufficient detail as to be readily understood and audited;

(3) Be maintained for not less than 5 years beyond their creation; and

(4) Be sufficient to demonstrate compliance with the Act and the regulations in this part.

(c) The certified operation must make such records available for inspection and copying during normal business hours by authorized representatives of the Secretary, the applicable State program's governing State official, and the certifying agent.

§ 205.104 [Reserved]

§ 205.105 Allowed and prohibited substances, methods, and ingredients in organic production and handling.

To be sold or labeled as "100 percent organic," "organic," or "made with

organic (specified ingredients or food group(s)),” the product must be produced and handled without the use of:

- (a) Synthetic substances and ingredients, except as provided in § 205.601 or § 205.603;
- (b) Nonsynthetic substances prohibited in § 205.602 or § 205.604;
- (c) Nonagricultural substances used in or on processed products, except as otherwise provided in § 205.605;
- (d) Nonorganic agricultural substances used in or on processed products, except as otherwise provided in § 205.606;
- (e) Excluded methods, except for vaccines: *Provided*, That, the vaccines are approved in accordance with § 205.600(a);
- (f) Ionizing radiation, as described in Food and Drug Administration regulation, 21 CFR 179.26; and
- (g) Sewage sludge.

§§ 205.106–205.199 [Reserved]

Subpart C—Organic Production and Handling Requirements

§ 205.200 General.

The producer or handler of a production or handling operation intending to sell, label, or represent agricultural products as “100 percent organic,” “organic,” or “made with organic (specified ingredients or food group(s))” must comply with the applicable provisions of this subpart. Production practices implemented in accordance with this subpart must maintain or improve the natural resources of the operation, including soil and water quality.

§ 205.201 Organic production and handling system plan.

(a) The producer or handler of a production or handling operation, except as exempt or excluded under § 205.101, intending to sell, label, or represent agricultural products as “100 percent organic,” “organic,” or “made with organic (specified ingredients or food group(s))” must develop an organic production or handling system plan that is agreed to by the producer or handler and an accredited certifying agent. An organic system plan must meet the requirements set forth in this section for organic production or handling. An organic production or handling system plan must include:

- (1) A description of practices and procedures to be performed and maintained, including the frequency with which they will be performed;
- (2) A list of each substance to be used as a production or handling input, indicating its composition, source,

location(s) where it will be used, and documentation of commercial availability, as applicable;

(3) A description of the monitoring practices and procedures to be performed and maintained, including the frequency with which they will be performed, to verify that the plan is effectively implemented;

(4) A description of the recordkeeping system implemented to comply with the requirements established in § 205.103;

(5) A description of the management practices and physical barriers established to prevent commingling of organic and nonorganic products on a split operation and to prevent contact of organic production and handling operations and products with prohibited substances; and

(6) Additional information deemed necessary by the certifying agent to evaluate compliance with the regulations.

(b) A producer may substitute a plan prepared to meet the requirements of another Federal, State, or local government regulatory program for the organic system plan: *Provided*, That, the submitted plan meets all the requirements of this subpart.

§ 205.202 Land requirements.

Any field or farm parcel from which harvested crops are intended to be sold, labeled, or represented as “organic,” must:

(a) Have been managed in accordance with the provisions of §§ 205.203 through 205.206;

(b) Have had no prohibited substances, as listed in § 205.105, applied to it for a period of 3 years immediately preceding harvest of the crop; and

(c) Have distinct, defined boundaries and buffer zones such as runoff diversions to prevent the unintended application of a prohibited substance to the crop or contact with a prohibited substance applied to adjoining land that is not under organic management.

§ 205.203 Soil fertility and crop nutrient management practice standard.

(a) The producer must select and implement tillage and cultivation practices that maintain or improve the physical, chemical, and biological condition of soil and minimize soil erosion.

(b) The producer must manage crop nutrients and soil fertility through rotations, cover crops, and the application of plant and animal materials.

(c) The producer must manage plant and animal materials to maintain or improve soil organic matter content in

a manner that does not contribute to contamination of crops, soil, or water by plant nutrients, pathogenic organisms, heavy metals, or residues of prohibited substances. Animal and plant materials include:

(1) Raw animal manure, which must be composted unless it is:

(i) Applied to land used for a crop not intended for human consumption;

(ii) Incorporated into the soil not less than 120 days prior to the harvest of a product whose edible portion has direct contact with the soil surface or soil particles; or

(iii) Incorporated into the soil not less than 90 days prior to the harvest of a product whose edible portion does not have direct contact with the soil surface or soil particles;

(2) Composted plant and animal materials produced through a process that:

(i) Established an initial C:N ratio of between 25:1 and 40:1; and

(ii) Maintained a temperature of between 131° F and 170° F for 3 days using an in-vessel or static aerated pile system; or

(iii) Maintained a temperature of between 131° F and 170° F for 15 days using a windrow composting system, during which period, the materials must be turned a minimum of five times.

(3) Uncomposted plant materials.

(d) A producer may manage crop nutrients and soil fertility to maintain or improve soil organic matter content in a manner that does not contribute to contamination of crops, soil, or water by plant nutrients, pathogenic organisms, heavy metals, or residues of prohibited substances by applying:

(1) A crop nutrient or soil amendment included on the National List of synthetic substances allowed for use in organic crop production;

(2) A mined substance of low solubility;

(3) A mined substance of high solubility: *Provided*, That, the substance is used in compliance with the conditions established on the National List of nonsynthetic materials prohibited for crop production;

(4) Ash obtained from the burning of a plant or animal material, except as prohibited in paragraph (e) of this section: *Provided*, That, the material burned has not been treated or combined with a prohibited substance or the ash is not included on the National List of nonsynthetic substances prohibited for use in organic crop production; and

(5) A plant or animal material that has been chemically altered by a manufacturing process: *Provided*, That, the material is included on the National

List of synthetic substances allowed for use in organic crop production established in § 205.601.

(e) The producer must not use:

(1) Any fertilizer or composted plant and animal material that contains a synthetic substance not included on the National List of synthetic substances allowed for use in organic crop production;

(2) Sewage sludge (biosolids) as defined in 40 CFR part 503; and (3) Burning as a means of disposal for crop residues produced on the operation: *Except*, That, burning may be used to suppress the spread of disease or to stimulate seed germination.

§ 205.204 Seeds and planting stock practice standard.

(a) The producer must use organically grown seeds, annual seedlings, and planting stock: *Except*, That,

(1) Nonorganically produced, untreated seeds and planting stock may be used to produce an organic crop when an equivalent organically produced variety is not commercially available: *Except*, That, organically produced seed must be used for the production of edible sprouts;

(2) Nonorganically produced seeds and planting stock that have been treated with a substance included on the National List of synthetic substances allowed for use in organic crop production may be used to produce an organic crop when an equivalent organically produced or untreated variety is not commercially available;

(3) Nonorganically produced annual seedlings may be used to produce an organic crop when a temporary variance has been granted in accordance with § 205.290(a)(2);

(4) Nonorganically produced planting stock to be used to produce a perennial crop may be sold, labeled, or represented as organically produced only after the planting stock has been maintained under a system of organic management for a period of no less than 1 year; and

(5) Seeds, annual seedlings, and planting stock treated with prohibited substances may be used to produce an organic crop when the application of the materials is a requirement of Federal or State phytosanitary regulations.

(b) [Reserved]

§ 205.205 Crop rotation practice standard.

The producer must implement a crop rotation including but not limited to sod, cover crops, green manure crops, and catch crops that provide the following functions that are applicable to the operation:

(a) Maintain or improve soil organic matter content;

(b) Provide for pest management in annual and perennial crops;

(c) Manage deficient or excess plant nutrients; and

(d) Provide erosion control.

§ 205.206 Crop pest, weed, and disease management practice standard.

(a) The producer must use management practices to prevent crop pests, weeds, and diseases including but not limited to:

(1) Crop rotation and soil and crop nutrient management practices, as provided for in §§ 205.203 and 205.205;

(2) Sanitation measures to remove disease vectors, weed seeds, and habitat for pest organisms; and

(3) Cultural practices that enhance crop health, including selection of plant species and varieties with regard to suitability to site-specific conditions and resistance to prevalent pests, weeds, and diseases.

(b) Pest problems may be controlled through mechanical or physical methods including but not limited to:

(1) Augmentation or introduction of predators or parasites of the pest species;

(2) Development of habitat for natural enemies of pests;

(3) Nonsynthetic controls such as lures, traps, and repellents.

(c) Weed problems may be controlled through:

(1) Mulching with fully biodegradable materials;

(2) Mowing;

(3) Livestock grazing;

(4) Hand weeding and mechanical cultivation;

(5) Flame, heat, or electrical means; or

(6) Plastic or other synthetic mulches: *Provided*, That, they are removed from the field at the end of the growing or harvest season.

(d) Disease problems may be controlled through:

(1) Management practices which suppress the spread of disease organisms; or

(2) Application of nonsynthetic biological, botanical, or mineral inputs.

(e) When the practices provided for in paragraphs (a) through (d) of this section are insufficient to prevent or control crop pests, weeds, and diseases, a biological or botanical substance or a substance included on the National List of synthetic substances allowed for use in organic crop production may be applied to prevent, suppress, or control pests, weeds, or diseases: *Provided*, That, the conditions for using the substance are documented in the organic system plan.

(f) The producer must not use lumber treated with arsenate or other prohibited

materials for new installations or replacement purposes in contact with soil or livestock.

§ 205.207 Wild-crop harvesting practice standard.

(a) A wild crop that is intended to be sold, labeled, or represented as organic must be harvested from a designated area that has had no prohibited substance, as set forth in § 205.105, applied to it for a period of 3 years immediately preceding the harvest of the wild crop.

(b) A wild crop must be harvested in a manner that ensures that such harvesting or gathering will not be destructive to the environment and will sustain the growth and production of the wild crop.

§§ 205.208—205.235 [Reserved]

§ 205.236 Origin of livestock.

(a) Livestock products that are to be sold, labeled, or represented as organic must be from livestock under continuous organic management from the last third of gestation or hatching: *Except*, That:

(1) *Poultry*. Poultry or edible poultry products must be from poultry that has been under continuous organic management beginning no later than the second day of life;

(2) *Dairy animals*. Milk or milk products must be from animals that have been under continuous organic management beginning no later than 1 year prior to the production of the milk or milk products that are to be sold, labeled, or represented as organic: *Except*, That, when an entire, distinct herd is converted to organic production, the producer may:

(i) For the first 9 months of the year, provide a minimum of 80-percent feed that is either organic or raised from land included in the organic system plan and managed in compliance with organic crop requirements; and

(ii) Provide feed in compliance with § 205.237 for the final 3 months.

(iii) Once an entire, distinct herd has been converted to organic production, all dairy animals shall be under organic management from the last third of gestation.

(3) *Breeder stock*. Livestock used as breeder stock may be brought from a nonorganic operation onto an organic operation at any time: *Provided*, That, if such livestock are gestating and the offspring are to be raised as organic livestock, the breeder stock must be brought onto the facility no later than the last third of gestation.

(b) The following are prohibited:

(1) Livestock or edible livestock products that are removed from an

organic operation and subsequently managed on a nonorganic operation may be not sold, labeled, or represented as organically produced.

(2) Breeder or dairy stock that has not been under continuous organic management since the last third of gestation may not be sold, labeled, or represented as organic slaughter stock.

(c) The producer of an organic livestock operation must maintain records sufficient to preserve the identity of all organically managed animals and edible and nonedible animal products produced on the operation.

§ 205.237 Livestock feed.

(a) The producer of an organic livestock operation must provide livestock with a total feed ration composed of agricultural products, including pasture and forage, that are organically produced and, if applicable, organically handled: *Except*, That, nonsynthetic substances and synthetic substances allowed under § 205.603 may be used as feed additives and supplements.

(b) The producer of an organic operation must not:

(1) Use animal drugs, including hormones, to promote growth;

(2) Provide feed supplements or additives in amounts above those needed for adequate nutrition and health maintenance for the species at its specific stage of life;

(3) Feed plastic pellets for roughage;

(4) Feed formulas containing urea or manure;

(5) Feed mammalian or poultry slaughter by-products to mammals or poultry; or

(6) Use feed, feed additives, and feed supplements in violation of the Federal Food, Drug, and Cosmetic Act.

§ 205.238 Livestock health care practice standard.

(a) The producer must establish and maintain preventive livestock health care practices, including:

(1) Selection of species and types of livestock with regard to suitability for site-specific conditions and resistance to prevalent diseases and parasites;

(2) Provision of a feed ration sufficient to meet nutritional requirements, including vitamins, minerals, protein and/or amino acids, fatty acids, energy sources, and fiber (ruminants);

(3) Establishment of appropriate housing, pasture conditions, and sanitation practices to minimize the occurrence and spread of diseases and parasites;

(4) Provision of conditions which allow for exercise, freedom of

movement, and reduction of stress appropriate to the species;

(5) Performance of physical alterations as needed to promote the animal's welfare and in a manner that minimizes pain and stress; and

(6) Administration of vaccines and other veterinary biologics.

(b) When preventive practices and veterinary biologics are inadequate to prevent sickness, a producer may administer synthetic medications: *Provided*, That, such medications are allowed under § 205.603. Parasiticides allowed under § 205.603 may be used on:

(1) Breeder stock, when used prior to the last third of gestation but not during lactation for progeny that are to be sold, labeled, or represented as organically produced; and

(2) Dairy stock, when used a minimum of 90 days prior to the production of milk or milk products that are to be sold, labeled, or represented as organic.

(c) The producer of an organic livestock operation must not:

(1) Sell, label, or represent as organic any animal or edible product derived from any animal treated with antibiotics, any substance that contains a synthetic substance not allowed under § 205.603, or any substance that contains a nonsynthetic substance prohibited in § 205.604.

(2) Administer any animal drug, other than vaccinations, in the absence of illness;

(3) Administer hormones for growth promotion;

(4) Administer synthetic parasiticides on a routine basis;

(5) Administer synthetic parasiticides to slaughter stock;

(6) Administer animal drugs in violation of the Federal Food, Drug, and Cosmetic Act; or

(7) Withhold medical treatment from a sick animal in an effort to preserve its organic status. All appropriate medications must be used to restore an animal to health when methods acceptable to organic production fail. Livestock treated with a prohibited substance must be clearly identified and shall not be sold, labeled, or represented as organically produced.

§ 205.239 Livestock living conditions.

(a) The producer of an organic livestock operation must establish and maintain livestock living conditions which accommodate the health and natural behavior of animals, including:

(1) Access to the outdoors, shade, shelter, exercise areas, fresh air, and direct sunlight suitable to the species, its stage of production, the climate, and the environment;

(2) Access to pasture for ruminants;

(3) Appropriate clean, dry bedding. If the bedding is typically consumed by the animal species, it must comply with the feed requirements of § 205.237;

(4) Shelter designed to allow for:

(i) Natural maintenance, comfort behaviors, and opportunity to exercise;

(ii) Temperature level, ventilation, and air circulation suitable to the species; and

(iii) Reduction of potential for livestock injury;

(b) The producer of an organic livestock operation may provide temporary confinement for an animal because of:

(1) Inclement weather;

(2) The animal's stage of production;

(3) Conditions under which the health, safety, or well being of the animal could be jeopardized; or

(4) Risk to soil or water quality.

(c) The producer of an organic livestock operation must manage manure in a manner that does not contribute to contamination of crops, soil, or water by plant nutrients, heavy metals, or pathogenic organisms and optimizes recycling of nutrients.

§§ 205.240—205.269 [Reserved]

§ 205.270 Organic handling requirements.

(a) Mechanical or biological methods, including but not limited to cooking, baking, curing, heating, drying, mixing, grinding, churning, separating, distilling, extracting, slaughtering, cutting, fermenting, eviscerating, preserving, dehydrating, freezing, chilling, or otherwise manufacturing, and the packaging, canning, jarring, or otherwise enclosing food in a container may be used to process an organically produced agricultural product for the purpose of retarding spoilage or otherwise preparing the agricultural product for market.

(b) Nonagricultural substances allowed under § 205.605 and nonorganically produced agricultural products allowed under § 205.606 may be used:

(1) In or on a processed agricultural product intended to be sold, labeled, or represented as "organic," pursuant to § 205.301(b), if not commercially available in organic form.

(2) In or on a processed agricultural product intended to be sold, labeled, or represented as "made with organic (specified ingredients or food group(s))," pursuant to § 205.301(c).

(c) The handler of an organic handling operation must not use in or on agricultural products intended to be sold, labeled, or represented as "100 percent organic," "organic," or "made

with organic (specified ingredients or food group(s)),” or in or on any ingredients labeled as organic:

(1) Practices prohibited under paragraphs (e) and (f) of § 205.105.

(2) A volatile synthetic solvent or other synthetic processing aid not allowed under § 205.605: *Except*, That, nonorganic ingredients in products labeled “made with organic (specified ingredients or food group(s))” are not subject to this requirement.

§ 205.271 Facility pest management practice standard.

(a) The producer or handler of an organic facility must use management practices to prevent pests, including but not limited to:

(1) Removal of pest habitat, food sources, and breeding areas;

(2) Prevention of access to handling facilities; and

(3) Management of environmental factors, such as temperature, light, humidity, atmosphere, and air circulation, to prevent pest reproduction.

(b) Pests may be controlled through:

(1) Mechanical or physical controls including but not limited to traps, light, or sound; or

(2) Lures and repellents using nonsynthetic or synthetic substances consistent with the National List.

(c) If the practices provided for in paragraphs (a) and (b) of this section are not effective to prevent or control pests, a nonsynthetic or synthetic substance consistent with the National List may be applied.

(d) If the practices provided for in paragraphs (a), (b), and (c) of this section are not effective to prevent or control facility pests, a synthetic substance not on the National List may be applied: *Provided*, That, the handler and certifying agent agree on the substance, method of application, and measures to be taken to prevent contact of the organically produced products or ingredients with the substance used.

(e) The handler of an organic handling operation who applies a nonsynthetic or synthetic substance to prevent or control pests must update the operation’s organic handling plan to reflect the use of such substances and methods of application. The updated organic plan must include a list of all measures taken to prevent contact of the organically produced products or ingredients with the substance used.

(f) Notwithstanding the practices provided for in paragraphs (a), (b), (c), and (d) of this section, a handler may otherwise use substances to prevent or control pests as required by Federal, State, or local laws and regulations:

Provided, That, measures are taken to prevent contact of the organically produced products or ingredients with the substance used.

§ 205.272 Commingling and contact with prohibited substance prevention practice standard.

(a) The handler of an organic handling operation must implement measures necessary to prevent the commingling of organic and nonorganic products and protect organic products from contact with prohibited substances.

(b) The following are prohibited for use in the handling of any organically produced agricultural product or ingredient labeled in accordance with subpart D of this part:

(1) Packaging materials, and storage containers, or bins that contain a synthetic fungicide, preservative, or fumigant;

(2) The use or reuse of any bag or container that has been in contact with any substance in such a manner as to compromise the organic integrity of any organically produced product or ingredient placed in those containers, unless such reusable bag or container has been thoroughly cleaned and poses no risk of contact of the organically produced product or ingredient with the substance used.

§§ 205.273–205.289 [Reserved]

§ 205.290 Temporary variances.

(a) Temporary variances from the requirements in §§ 205.203 through 205.207, 205.236 through 205.239, and 205.270 through 205.272 may be established by the Administrator for the following reasons:

(1) Natural disasters declared by the Secretary;

(2) Damage caused by drought, wind, flood, excessive moisture, hail, tornado, earthquake, fire, or other business interruption; and

(3) Practices used for the purpose of conducting research or trials of techniques, varieties, or ingredients used in organic production or handling.

(b) A State organic program’s governing State official or certifying agent may recommend in writing to the Administrator that a temporary variance from a standard set forth in subpart C of this part for organic production or handling operations be established: *Provided*, That, such variance is based on one or more of the reasons listed in paragraph (a) of this section.

(c) The Administrator will provide written notification to certifying agents upon establishment of a temporary variance applicable to the certifying agent’s certified production or handling operations and specify the period of

time it shall remain in effect, subject to extension as the Administrator deems necessary.

(d) A certifying agent, upon notification from the Administrator of the establishment of a temporary variance, must notify each production or handling operation it certifies to which the temporary variance applies.

(e) Temporary variances will not be granted for any practice, material, or procedure prohibited under § 205.105.

§§ 205.291–205.299 [Reserved]

Subpart D—Labels, Labeling, and Market Information

§ 205.300 Use of the term, “organic.”

(a) The term, “organic,” may only be used on labels and in labeling of raw or processed agricultural products, including ingredients, that have been produced and handled in accordance with the regulations in this part. The term, “organic,” may not be used in a product name to modify a nonorganic ingredient in the product.

(b) Products for export, produced and certified to foreign national organic standards or foreign contract buyer requirements, may be labeled in accordance with the organic labeling requirements of the receiving country or contract buyer: *Provided*, That, the shipping containers and shipping documents meet the labeling requirements specified in § 205.307(c).

(c) Products produced in a foreign country and exported for sale in the United States must be certified pursuant to subpart E of this part and labeled pursuant to this subpart D.

(d) Livestock feeds produced in accordance with the requirements of this part must be labeled in accordance with the requirements of § 205.306.

§ 205.301 Product composition.

(a) *Products sold, labeled, or represented as “100 percent organic.”* A raw or processed agricultural product sold, labeled, or represented as “100 percent organic” must contain (by weight or fluid volume, excluding water and salt) 100 percent organically produced ingredients. If labeled as organically produced, such product must be labeled pursuant to § 205.303.

(b) *Products sold, labeled, or represented as “organic.”* A raw or processed agricultural product sold, labeled, or represented as “organic” must contain (by weight or fluid volume, excluding water and salt) not less than 95 percent organically produced raw or processed agricultural products. Any remaining product ingredients must be organically produced, unless not commercially

available in organic form, or must be nonagricultural substances or nonorganically produced agricultural products produced consistent with the National List in subpart G of this part. If labeled as organically produced, such product must be labeled pursuant to § 205.303.

(c) *Products sold, labeled, or represented as "made with organic (specified ingredients or food group(s))."* Multiingredient agricultural product sold, labeled, or represented as "made with organic (specified ingredients or food group(s))" must contain (by weight or fluid volume, excluding water and salt) at least 70 percent organically produced ingredients which are produced and handled pursuant to requirements in subpart C of this part. No ingredients may be produced using prohibited practices specified in paragraphs (f)(1), (2), and (3) of § 205.301. Nonorganic ingredients may be produced without regard to paragraphs (f)(4), (5), (6), and (7) of § 205.301. If labeled as containing organically produced ingredients or food groups, such product must be labeled pursuant to § 205.304.

(d) *Products with less than 70 percent organically produced ingredients.* The organic ingredients in multiingredient agricultural product containing less than 70 percent organically produced ingredients (by weight or fluid volume, excluding water and salt) must be produced and handled pursuant to requirements in subpart C of this part. The nonorganic ingredients may be produced and handled without regard to the requirements of this part. Multiingredient agricultural product containing less than 70 percent organically produced ingredients may represent the organic nature of the product only as provided in § 205.305.

(e) *Livestock feed.* (1) A raw or processed livestock feed product sold, labeled, or represented as "100 percent organic" must contain (by weight or fluid volume, excluding water and salt) not less than 100 percent organically produced raw or processed agricultural product.

(2) A raw or processed livestock feed product sold, labeled, or represented as "organic" must be produced in conformance with § 205.237.

(f) All products labeled as "100 percent organic" or "organic" and all ingredients identified as "organic" in the ingredient statement of any product must not:

(1) Be produced using excluded methods, pursuant to § 201.105(e) of this chapter;

(2) Be produced using sewage sludge, pursuant to § 201.105(f) of this chapter;

(3) Be processed using ionizing radiation, pursuant to § 201.105(g) of this chapter;

(4) Be processed using processing aids not approved on the National List of Allowed and Prohibited Substances in subpart G of this part: Except, That, products labeled as "100 percent organic," if processed, must be processed using organically produced processing aids;

(5) Contain sulfites, nitrates, or nitrites added during the production or handling process, Except, that, wine containing added sulfites may be labeled "made with organic grapes";

(6) Be produced using nonorganic ingredients when organic ingredients are available; or

(7) Include organic and nonorganic forms of the same ingredient.

§ 205.302 Calculating the percentage of organically produced ingredients.

(a) The percentage of all organically produced ingredients in an agricultural product sold, labeled, or represented as "100 percent organic," "organic," or "made with organic (specified ingredients or food group(s))," or that include organic ingredients must be calculated by:

(1) Dividing the total net weight (excluding water and salt) of combined organic ingredients at formulation by the total weight (excluding water and salt) of the finished product.

(2) Dividing the fluid volume of all organic ingredients (excluding water and salt) by the fluid volume of the finished product (excluding water and salt) if the product and ingredients are liquid. If the liquid product is identified on the principal display panel or information panel as being reconstituted from concentrates, the calculation should be made on the basis of single-strength concentrations of the ingredients and finished product.

(3) For products containing organically produced ingredients in both solid and liquid form, dividing the combined weight of the solid ingredients and the weight of the liquid ingredients (excluding water and salt) by the total weight (excluding water and salt) of the finished product.

(b) The percentage of all organically produced ingredients in an agricultural product must be rounded down to the nearest whole number.

(c) The percentage must be determined by the handler who affixes the label on the consumer package and verified by the certifying agent of the handler. The handler may use information provided by the certified operation in determining the percentage.

§ 205.303 Packaged products labeled "100 percent organic" or "organic."

(a) Agricultural products in packages described in § 205.301(a) and (b) may display, on the principal display panel, information panel, and any other panel of the package and on any labeling or market information concerning the product, the following:

(1) The term, "100 percent organic" or "organic," as applicable, to modify the name of the product;

(2) For products labeled "organic," the percentage of organic ingredients in the product; (The size of the percentage statement must not exceed one-half the size of the largest type size on the panel on which the statement is displayed and must appear in its entirety in the same type size, style, and color without highlighting.)

(3) The term, "organic," to identify the organic ingredients in multiingredient products labeled "100 percent organic";

(4) The USDA seal; and/or

(5) The seal, logo, or other identifying mark of the certifying agent which certified the production or handling operation producing the finished product and any other certifying agent which certified production or handling operations producing raw organic product or organic ingredients used in the finished product: *Provided*, That, the handler producing the finished product maintain records, pursuant to this part, verifying organic certification of the operations producing such ingredients, and: *Provided further*, That, such seals or marks are not individually displayed more prominently than the USDA seal.

(b) Agricultural products in packages described in § 205.301(a) and (b) must:

(1) For products labeled "organic," identify each organic ingredient in the ingredient statement with the word, "organic," or with an asterisk or other reference mark which is defined below the ingredient statement to indicate the ingredient is organically produced. Water or salt included as ingredients cannot be identified as organic.

(2) On the information panel, below the information identifying the handler or distributor of the product and preceded by the statement, "Certified organic by * * *," or similar phrase, identify the name of the certifying agent that certified the handler of the finished product and may display the business address, Internet address, or telephone number of the certifying agent in such label.

§ 205.304 Packaged products labeled “made with organic (specified ingredients or food group(s)).”

(a) Agricultural products in packages described in § 205.301(c) may display on the principal display panel, information panel, and any other panel and on any labeling or market information concerning the product:

(1) The statement:

(i) “Made with organic (specified ingredients)”: *Provided*, That, the statement does not list more than three organically produced ingredients; or

(ii) “Made with organic (specified food groups)”: *Provided*, That, the statement does not list more than three of the following food groups: beans, fish, fruits, grains, herbs, meats, nuts, oils, poultry, seeds, spices, sweeteners, and vegetables or processed milk products; and, *Provided further*, That, all ingredients of each listed food group in the product must be organically produced; and

(iii) Which appears in letters that do not exceed one-half the size of the largest type size on the panel and which appears in its entirety in the same type size, style, and color without highlighting.

(2) The percentage of organic ingredients in the product. The size of the percentage statement must not exceed one-half the size of the largest type size on the panel on which the statement is displayed and must appear in its entirety in the same type size, style, and color without highlighting.

(3) The seal, logo, or other identifying mark of the certifying agent that certified the handler of the finished product.

(b) Agricultural products in packages described in § 205.301(c) must:

(1) In the ingredient statement, identify each organic ingredient with the word, “organic,” or with an asterisk or other reference mark which is defined below the ingredient statement to indicate the ingredient is organically produced. Water or salt included as ingredients cannot be identified as organic.

(2) On the information panel, below the information identifying the handler or distributor of the product and preceded by the statement, “Certified organic by * * *,” or similar phrase, identify the name of the certifying agent that certified the handler of the finished product: *Except*, That, the business address, Internet address, or telephone number of the certifying agent may be included in such label.

(c) Agricultural products in packages described in § 205.301(c) must not display the USDA seal.

§ 205.305 Multi-ingredient packaged products with less than 70 percent organically produced ingredients.

(a) An agricultural product with less than 70 percent organically produced ingredients may only identify the organic content of the product by:

(1) Identifying each organically produced ingredient in the ingredient statement with the word, “organic,” or with an asterisk or other reference mark which is defined below the ingredient statement to indicate the ingredient is organically produced, and

(2) If the organically produced ingredients are identified in the ingredient statement, displaying the product’s percentage of organic contents on the information panel.

(b) Agricultural products with less than 70 percent organically produced ingredients must not display:

(1) The USDA seal; and

(2) Any certifying agent seal, logo, or other identifying mark which represents organic certification of a product or product ingredients.

§ 205.306 Labeling of livestock feed.

(a) Livestock feed products described in § 205.301(e)(1) and (e)(2) may display on any package panel the following terms:

(1) The statement, “100 percent organic” or “organic,” as applicable, to modify the name of the feed product;

(2) The USDA seal;

(3) The seal, logo, or other identifying mark of the certifying agent which certified the production or handling operation producing the raw or processed organic ingredients used in the finished product, *Provided*, That, such seals or marks are not displayed more prominently than the USDA seal;

(4) The word, “organic,” or an asterisk or other reference mark which is defined on the package to identify ingredients that are organically produced. Water or salt included as ingredients cannot be identified as organic.

(b) Livestock feed products described in § 205.301(e)(1) and (e)(2) must:

(1) On the information panel, below the information identifying the handler or distributor of the product and preceded by the statement, “Certified organic by * * *,” or similar phrase, display the name of the certifying agent that certified the handler of the finished product. The business address, Internet address, or telephone number of the certifying agent may be included in such label.

(2) Comply with other Federal agency or State feed labeling requirements as applicable.

§ 205.307 Labeling of nonretail containers used for only shipping or storage of raw or processed agricultural products labeled as “100 percent organic,” “organic,” or “made with organic (specified ingredients or food group(s)).”

(a) Nonretail containers used only to ship or store raw or processed agricultural product labeled as containing organic ingredients may display the following terms or marks:

(1) The name and contact information of the certifying agent which certified the handler which assembled the final product;

(2) Identification of the product as organic;

(3) Special handling instructions needed to maintain the organic integrity of the product;

(4) The USDA seal;

(5) The seal, logo, or other identifying mark of the certifying agent that certified the organic production or handling operation that produced or handled the finished product.

(b) Nonretail containers used to ship or store raw or processed agricultural product labeled as containing organic ingredients must display the production lot number of the product if applicable.

(c) Shipping containers of domestically produced product labeled as organic intended for export to international markets may be labeled in accordance with any shipping container labeling requirements of the foreign country of destination or the container labeling specifications of a foreign contract buyer: *Provided*, That, the shipping containers and shipping documents accompanying such organic products are clearly marked “For Export Only” and: *Provided further*, That, proof of such container marking and export must be maintained by the handler in accordance with recordkeeping requirements for exempt and excluded operations under § 205.101.

§ 205.308 Agricultural products in other than packaged form at the point of retail sale that are sold, labeled, or represented as “100 percent organic” or “organic.”

(a) Agricultural products in other than packaged form may use the term, “100 percent organic” or “organic,” as applicable, to modify the name of the product in retail display, labeling, and display containers: *Provided*, That, the term, “organic,” is used to identify the organic ingredients listed in the ingredient statement.

(b) If the product is prepared in a certified facility, the retail display, labeling, and display containers may use:

(1) The USDA seal; and

(2) The seal, logo, or other identifying mark of the certifying agent that

certified the production or handling operation producing the finished product and any other certifying agent which certified operations producing raw organic product or organic ingredients used in the finished product: *Provided*, That, such seals or marks are not individually displayed more prominently than the USDA seal.

§ 205.309 Agricultural products in other than packaged form at the point of retail sale that are sold, labeled, or represented as “made with organic (specified ingredients or food group(s)).”

(a) Agricultural products in other than packaged form containing between 70 and 95 percent organically produced ingredients may use the phrase, “made with organic (specified ingredients or food group(s)),” to modify the name of the product in retail display, labeling, and display containers.

(1) Such statement must not list more than three organic ingredients or food groups, and

(2) In any such display of the product’s ingredient statement, the organic ingredients are identified as “organic.”

(b) If prepared in a certified facility, such agricultural products labeled as “made with organic (specified ingredients or food group(s))” in retail displays, display containers, and market information may display the certifying agent’s seal, logo, or other identifying mark.

§ 205.310 Agricultural products produced on an exempt or excluded operation.

(a) An agricultural product organically produced or handled on an exempt or excluded operation must not:

(1) Display the USDA seal or any certifying agent’s seal or other identifying mark which represents the exempt or excluded operation as a certified organic operation, or

(2) Be represented as a certified organic product or certified organic ingredient to any buyer.

(b) An agricultural product organically produced or handled on an exempt or excluded operation may be identified as an organic product or organic ingredient in a multiingredient product produced by the exempt or excluded operation. Such product or ingredient must not be identified or represented as “organic” in a product processed by others.

(c) Such product is subject to requirements specified in paragraph (a) of § 205.300, and paragraphs (f)(1) through (f)(7) of § 205.301.

§ 205.311 USDA Seal.

(a) The USDA seal described in paragraphs (b) and (c) of this section

may be used only for raw or processed agricultural products described in paragraphs (a), (b), (e)(1), and (e)(2) of § 205.301.

(b) The USDA seal must replicate the form and design of the example in figure 1 and must be printed legibly and conspicuously:

(1) On a white background with a brown outer circle and with the term, “USDA,” in green overlaying a white upper semicircle and with the term, “organic,” in white overlaying the green lower half circle; or

(2) On a white or transparent background with black outer circle and black “USDA” on a white or transparent upper half of the circle with a contrasting white or transparent “organic” on the black lower half circle.

(3) The green or black lower half circle may have four light lines running from left to right and disappearing at the point on the right horizon to resemble a cultivated field.



Figure 1

§§ 205.312–205.399 [Reserved]

Subpart E—Certification

§ 205.400 General requirements for certification.

A person seeking to receive or maintain organic certification under the regulations in this part must:

(a) Comply with the Act and applicable organic production and handling regulations of this part;

(b) Establish, implement, and update annually an organic production or handling system plan that is submitted to an accredited certifying agent as provided for in § 205.200;

(c) Permit on-site inspections with complete access to the production or handling operation, including noncertified production and handling areas, structures, and offices by the certifying agent as provided for in § 205.403;

(d) Maintain all records applicable to the organic operation for not less than 5 years beyond their creation and allow authorized representatives of the Secretary, the applicable State organic

program’s governing State official, and the certifying agent access to such records during normal business hours for review and copying to determine compliance with the Act and the regulations in this part, as provided for in § 205.104;

(e) Submit the applicable fees charged by the certifying agent; and

(f) Immediately notify the certifying agent concerning any:

(1) Application, including drift, of a prohibited substance to any field, production unit, site, facility, livestock, or product that is part of an operation; and

(2) Change in a certified operation or any portion of a certified operation that may affect its compliance with the Act and the regulations in this part.

§ 205.401 Application for certification.

A person seeking certification of a production or handling operation under this subpart must submit an application for certification to a certifying agent. The application must include the following information:

(a) An organic production or handling system plan, as required in § 205.200;

(b) The name of the person completing the application; the applicant’s business name, address, and telephone number; and, when the applicant is a corporation, the name, address, and telephone number of the person authorized to act on the applicant’s behalf;

(c) The name(s) of any organic certifying agent(s) to which application has previously been made; the year(s) of application; the outcome of the application(s) submission, including, when available, a copy of any notification of noncompliance or denial of certification issued to the applicant for certification; and a description of the actions taken by the applicant to correct the noncompliances noted in the notification of noncompliance, including evidence of such correction; and

(d) Other information necessary to determine compliance with the Act and the regulations in this part.

§ 205.402 Review of application.

(a) Upon acceptance of an application for certification, a certifying agent must:

(1) Review the application to ensure completeness pursuant to § 205.401;

(2) Determine by a review of the application materials whether the applicant appears to comply or may be able to comply with the applicable requirements of subpart C of this part;

(3) Verify that an applicant who previously applied to another certifying agent and received a notification of

noncompliance or denial of certification, pursuant to § 205.405, has submitted documentation to support the correction of any noncompliances identified in the notification of noncompliance or denial of certification, as required in § 205.405(e); and

(4) Schedule an on-site inspection of the operation to determine whether the applicant qualifies for certification if the review of application materials reveals that the production or handling operation may be in compliance with the applicable requirements of subpart C of this part.

(b) The certifying agent shall within a reasonable time:

(1) Review the application materials received and communicate its findings to the applicant;

(2) Provide the applicant with a copy of the on-site inspection report, as approved by the certifying agent, for any on-site inspection performed; and

(3) Provide the applicant with a copy of the test results for any samples taken by an inspector.

(c) The applicant may withdraw its application at any time. An applicant who withdraws its application shall be liable for the costs of services provided up to the time of withdrawal of its application. An applicant that voluntarily withdrew its application prior to the issuance of a notice of noncompliance will not be issued a notice of noncompliance. Similarly, an applicant that voluntarily withdrew its application prior to the issuance of a notice of certification denial will not be issued a notice of certification denial.

§ 205.403 On-site inspections.

(a) *On-site inspections.* (1) A certifying agent must conduct an initial on-site inspection of each production unit, facility, and site that produces or handles organic products and that is included in an operation for which certification is requested. An on-site inspection shall be conducted annually thereafter for each certified operation that produces or handles organic products for the purpose of determining whether to approve the request for certification or whether the certification of the operation should continue.

(2) (i) A certifying agent may conduct additional on-site inspections of applicants for certification and certified operations to determine compliance with the Act and the regulations in this part.

(ii) The Administrator or State organic program's governing State official may require that additional inspections be performed by the certifying agent for the purpose of determining compliance

with the Act and the regulations in this part.

(iii) Additional inspections may be announced or unannounced at the discretion of the certifying agent or as required by the Administrator or State organic program's governing State official.

(b) *Scheduling.* (1) The initial on-site inspection must be conducted within a reasonable time following a determination that the applicant appears to comply or may be able to comply with the requirements of subpart C of this part: *Except*, That, the initial inspection may be delayed for up to 6 months to comply with the requirement that the inspection be conducted when the land, facilities, and activities that demonstrate compliance or capacity to comply can be observed.

(2) All on-site inspections must be conducted when an authorized representative of the operation who is knowledgeable about the operation is present and at a time when land, facilities, and activities that demonstrate the operation's compliance with or capability to comply with the applicable provisions of subpart C of this part can be observed, except that this requirement does not apply to unannounced on-site inspections.

(c) *Verification of information.* The on-site inspection of an operation must verify:

(1) The operation's compliance or capability to comply with the Act and the regulations in this part;

(2) That the information, including the organic production or handling system plan, provided in accordance with §§ 205.401, 205.406, and 205.200, accurately reflects the practices used or to be used by the applicant for certification or by the certified operation;

(3) That prohibited substances have not been and are not being applied to the operation through means which, at the discretion of the certifying agent, may include the collection and testing of soil; water; waste; seeds; plant tissue; and plant, animal, and processed products samples.

(d) *Exit interview.* The inspector must conduct an exit interview with an authorized representative of the operation who is knowledgeable about the inspected operation to confirm the accuracy and completeness of inspection observations and information gathered during the on-site inspection. The inspector must also address the need for any additional information as well as any issues of concern.

(e) *Documents to the inspected operation.* (1) At the time of the inspection, the inspector shall provide

the operation's authorized representative with a receipt for any samples taken by the inspector. There shall be no charge to the inspector for the samples taken.

(2) A copy of the on-site inspection report and any test results will be sent to the inspected operation by the certifying agent.

§ 205.404 Granting certification.

(a) Within a reasonable time after completion of the initial on-site inspection, a certifying agent must review the on-site inspection report, the results of any analyses for substances conducted, and any additional information requested from or supplied by the applicant. If the certifying agent determines that the organic system plan and all procedures and activities of the applicant's operation are in compliance with the requirements of this part and that the applicant is able to conduct operations in accordance with the plan, the agent shall grant certification. The certification may include requirements for the correction of minor noncompliances within a specified time period as a condition of continued certification.

(b) The certifying agent must issue a certificate of organic operation which specifies the:

(1) Name and address of the certified operation;

(2) Effective date of certification;

(3) Categories of organic operation, including crops, wild crops, livestock, or processed products produced by the certified operation; and

(4) Name, address, and telephone number of the certifying agent.

(c) Once certified, a production or handling operation's organic certification continues in effect until surrendered by the organic operation or suspended or revoked by the certifying agent, the State organic program's governing State official, or the Administrator.

§ 205.405 Denial of certification.

(a) When the certifying agent has reason to believe, based on a review of the information specified in § 205.402 or § 205.404, that an applicant for certification is not able to comply or is not in compliance with the requirements of this part, the certifying agent must provide a written notification of noncompliance to the applicant. When correction of a noncompliance is not possible, a notification of noncompliance and a notification of denial of certification may be combined in one notification. The notification of noncompliance shall provide:

(1) A description of each noncompliance;

(2) The facts upon which the notification of noncompliance is based; and

(3) The date by which the applicant must rebut or correct each noncompliance and submit supporting documentation of each such correction when correction is possible.

(b) Upon receipt of such notification of noncompliance, the applicant may:

(1) Correct noncompliances and submit a description of the corrective actions taken with supporting documentation to the certifying agent;

(2) Correct noncompliances and submit a new application to another certifying agent: *Provided*, That, the applicant must include a complete application, the notification of noncompliance received from the first certifying agent, and a description of the corrective actions taken with supporting documentation; or

(3) Submit written information to the issuing certifying agent to rebut the noncompliance described in the notification of noncompliance.

(c) After issuance of a notification of noncompliance, the certifying agent must:

(1) Evaluate the applicant's corrective actions taken and supporting documentation submitted or the written rebuttal, conduct an on-site inspection if necessary, and

(i) When the corrective action or rebuttal is sufficient for the applicant to qualify for certification, issue the applicant an approval of certification pursuant to § 205.404; or

(ii) When the corrective action or rebuttal is not sufficient for the applicant to qualify for certification, issue the applicant a written notice of denial of certification.

(2) Issue a written notice of denial of certification to an applicant who fails to respond to the notification of noncompliance.

(3) Provide notice of approval or denial to the Administrator, pursuant to § 205.501(a)(14).

(d) A notice of denial of certification must state the reason(s) for denial and the applicant's right to:

(1) Reapply for certification pursuant to §§ 205.401 and 205.405(e);

(2) Request mediation pursuant to § 205.663 or, if applicable, pursuant to a State organic program; or

(3) File an appeal of the denial of certification pursuant to § 205.681 or, if applicable, pursuant to a State organic program.

(e) An applicant for certification who has received a written notification of noncompliance or a written notice of

denial of certification may apply for certification again at any time with any certifying agent, in accordance with §§ 205.401 and 205.405(e). When such applicant submits a new application to a certifying agent other than the agent who issued the notification of noncompliance or notice of denial of certification, the applicant for certification must include a copy of the notification of noncompliance or notice of denial of certification and a description of the actions taken, with supporting documentation, to correct the noncompliances noted in the notification of noncompliance.

(f) A certifying agent who receives a new application for certification, which includes a notification of noncompliance or a notice of denial of certification, must treat the application as a new application and begin a new application process pursuant to § 205.402.

(g) Notwithstanding paragraph (a) of this section, if a certifying agent has reason to believe that an applicant for certification has willfully made a false statement or otherwise purposefully misrepresented the applicant's operation or its compliance with the certification requirements pursuant to this part, the certifying agent may deny certification pursuant to paragraph (c)(1)(ii) of this section without first issuing a notification of noncompliance.

§ 205.406 Continuation of certification.

(a) To continue certification, a certified operation must annually pay the certification fees and submit the following information, as applicable, to the certifying agent:

(1) An updated organic production or handling system plan which includes:

(i) A summary statement, supported by documentation, detailing any deviations from, changes to, modifications to, or other amendments made to the previous year's organic system plan during the previous year; and

(ii) Any additions or deletions to the previous year's organic system plan, intended to be undertaken in the coming year, detailed pursuant to § 205.200;

(2) Any additions to or deletions from the information required pursuant to § 205.401(b);

(3) An update on the correction of minor noncompliances previously identified by the certifying agent as requiring correction for continued certification; and

(4) Other information as deemed necessary by the certifying agent to determine compliance with the Act and the regulations in this part.

(b) Following the receipt of the information specified in paragraph (a) of this section, the certifying agent shall within a reasonable time arrange and conduct an on-site inspection of the certified operation pursuant to § 205.403: *Except*, That, when it is impossible for the certifying agent to conduct the annual on-site inspection following receipt of the certified operation's annual update of information, the certifying agent may allow continuation of certification and issue an updated certificate of organic operation on the basis of the information submitted and the most recent on-site inspection conducted during the previous 12 months: *Provided*, That, the annual on-site inspection, required pursuant to § 205.403, is conducted within the first 6 months following the certified operation's scheduled date of annual update.

(c) If the certifying agent has reason to believe, based on the on-site inspection and a review of the information specified in § 205.404, that a certified operation is not complying with the requirements of the Act and the regulations in this part, the certifying agent shall provide a written notification of noncompliance to the operation in accordance with § 205.662.

(d) If the certifying agent determines that the certified operation is complying with the Act and the regulations in this part and that any of the information specified on the certificate of organic operation has changed, the certifying agent must issue an updated certificate of organic operation pursuant to § 205.404(b).

§§ 205.407–205.499 [Reserved]

Subpart F—Accreditation of Certifying Agents

§ 205.500 Areas and duration of accreditation.

(a) The Administrator shall accredit a qualified domestic or foreign applicant in the areas of crops, livestock, wild crops, or handling or any combination thereof to certify a domestic or foreign production or handling operation as a certified operation.

(b) Accreditation shall be for a period of 5 years from the date of approval of accreditation pursuant to § 205.506.

(c) In lieu of accreditation under paragraph (a) of this section, USDA will accept a foreign certifying agent's accreditation to certify organic production or handling operations if:

(1) USDA determines, upon the request of a foreign government, that the standards under which the foreign government authority accredited the

foreign certifying agent meet the requirements of this part; or

(2) The foreign government authority that accredited the foreign certifying agent acted under an equivalency agreement negotiated between the United States and the foreign government.

§ 205.501 General requirements for accreditation.

(a) A private or governmental entity accredited as a certifying agent under this subpart must:

(1) Have sufficient expertise in organic production or handling techniques to fully comply with and implement the terms and conditions of the organic certification program established under the Act and the regulations in this part;

(2) Demonstrate the ability to fully comply with the requirements for accreditation set forth in this subpart;

(3) Carry out the provisions of the Act and the regulations in this part, including the provisions of §§ 205.402 through 205.406 and § 205.670;

(4) Use a sufficient number of adequately trained personnel, including inspectors and certification review personnel, to comply with and implement the organic certification program established under the Act and the regulations in subpart E of this part;

(5) Ensure that its responsibly connected persons, employees, and contractors with inspection, analysis, and decision-making responsibilities have sufficient expertise in organic production or handling techniques to successfully perform the duties assigned.

(6) Conduct an annual performance evaluation of all persons who review applications for certification, perform on-site inspections, review certification documents, evaluate qualifications for certification, make recommendations concerning certification, or make certification decisions and implement measures to correct any deficiencies in certification services;

(7) Have an annual program review of its certification activities conducted by the certifying agent's staff, an outside auditor, or a consultant who has expertise to conduct such reviews and implement measures to correct any noncompliances with the Act and the regulations in this part that are identified in the evaluation;

(8) Provide sufficient information to persons seeking certification to enable them to comply with the applicable requirements of the Act and the regulations in this part;

(9) Maintain all records pursuant to § 205.510(b) and make all such records

available for inspection and copying during normal business hours by authorized representatives of the Secretary and the applicable State organic program's governing State official;

(10) Maintain strict confidentiality with respect to its clients under the applicable organic certification program and not disclose to third parties (with the exception of the Secretary or the applicable State organic program's governing State official or their authorized representatives) any business-related information concerning any client obtained while implementing the regulations in this part, except as provided for in § 205.504(b)(5);

(11) Prevent conflicts of interest by:

(i) Not certifying a production or handling operation if the certifying agent or a responsibly connected party of such certifying agent has or has held a commercial interest in the production or handling operation, including an immediate family interest or the provision of consulting services, within the 12-month period prior to the application for certification;

(ii) Excluding any person, including contractors, with conflicts of interest from work, discussions, and decisions in all stages of the certification process and the monitoring of certified production or handling operations for all entities in which such person has or has held a commercial interest, including an immediate family interest or the provision of consulting services, within the 12-month period prior to the application for certification;

(iii) Not permitting any employee, inspector, contractor, or other personnel to accept payment, gifts, or favors of any kind, other than prescribed fees, from any business inspected: *Except*, That, a certifying agent that is a not-for-profit organization with an Internal Revenue Code tax exemption or, in the case of a foreign certifying agent, a comparable recognition of not-for-profit status from its government, may accept voluntary labor from certified operations;

(iv) Not giving advice or providing consultancy services, to certification applicants or certified operations, for overcoming identified barriers to certification;

(v) Requiring all persons who review applications for certification, perform on-site inspections, review certification documents, evaluate qualifications for certification, make recommendations concerning certification, or make certification decisions and all parties responsibly connected to the certifying agent to complete an annual conflict of interest disclosure report; and

(vi) Ensuring that the decision to certify an operation is made by a person different from those who conducted the review of documents and on-site inspection.

(12)(i) Reconsider a certified operation's application for certification and, if necessary, perform a new on-site inspection when it is determined, within 12 months of certifying the operation, that any person participating in the certification process and covered under § 205.501(a)(11)(ii) has or had a conflict of interest involving the applicant. All costs associated with a reconsideration of application, including onsite inspection costs, shall be borne by the certifying agent.

(ii) Refer a certified operation to a different accredited certifying agent for recertification and reimburse the operation for the cost of the recertification when it is determined that any person covered under § 205.501(a)(11)(i) at the time of certification of the applicant had a conflict of interest involving the applicant.

(13) Accept the certification decisions made by another certifying agent accredited or accepted by USDA pursuant to § 205.500;

(14) Refrain from making false or misleading claims about its accreditation status, the USDA accreditation program for certifying agents, or the nature or qualities of products labeled as organically produced;

(15) Submit to the Administrator a copy of:

(i) Any notice of denial of certification issued pursuant to § 205.405, notification of noncompliance, notification of noncompliance correction, notification of proposed suspension or revocation, and notification of suspension or revocation sent pursuant to § 205.662 simultaneously with its issuance; and

(ii) A list, on January 2 of each year, including the name, address, and telephone number of each operation granted certification during the preceding year;

(16) Charge applicants for certification and certified production and handling operations only those fees and charges for certification activities that it has filed with the Administrator;

(17) Pay and submit fees to AMS in accordance with § 205.640;

(18) Provide the inspector, prior to each on-site inspection, with previous on-site inspection reports and notify the inspector of its decision regarding certification of the production or handling operation site inspected by the inspector and of any requirements for

the correction of minor noncompliances;

(19) Accept all production or handling applications that fall within its area(s) of accreditation and certify all qualified applicants, to the extent of its administrative capacity to do so without regard to size or membership in any association or group; and

(20) Demonstrate its ability to comply with a State's organic program to certify organic production or handling operations within the State.

(21) Comply with, implement, and carry out any other terms and conditions determined by the Administrator to be necessary.

(b) A private or governmental entity accredited as a certifying agent under this subpart may establish a seal, logo, or other identifying mark to be used by production and handling operations certified by the certifying agent to indicate affiliation with the certifying agent: *Provided, That*, the certifying agent:

(1) Does not require use of its seal, logo, or other identifying mark on any product sold, labeled, or represented as organically produced as a condition of certification and

(2) Does not require compliance with any production or handling practices other than those provided for in the Act and the regulations in this part as a condition of use of its identifying mark: *Provided, That*, certifying agents certifying production or handling operations within a State with more restrictive requirements, approved by the Secretary, shall require compliance with such requirements as a condition of use of their identifying mark by such operations.

(c) A private entity accredited as a certifying agent must:

(1) Hold the Secretary harmless for any failure on the part of the certifying agent to carry out the provisions of the Act and the regulations in this part;

(2) Furnish reasonable security, in an amount and according to such terms as the Administrator may by regulation prescribe, for the purpose of protecting the rights of production and handling operations certified by such certifying agent under the Act and the regulations in this part; and

(3) Transfer to the Administrator and make available to any applicable State organic program's governing State official all records or copies of records concerning the person's certification activities in the event that the certifying agent dissolves or loses its accreditation; *Provided, That*, such transfer shall not apply to a merger, sale, or other transfer of ownership of a certifying agent.

(d) No private or governmental entity accredited as a certifying agent under this subpart shall exclude from participation in or deny the benefits of the National Organic Program to any person due to discrimination because of race, color, national origin, gender, religion, age, disability, political beliefs, sexual orientation, or marital or family status.

§ 205.502 Applying for accreditation.

(a) A private or governmental entity seeking accreditation as a certifying agent under this subpart must submit an application for accreditation which contains the applicable information and documents set forth in §§ 205.503 through 205.505 and the fees required in § 205.640 to: Program Manager, USDA—AMS—TNP—NOP, Room 2945—South Building, P.O. Box 96456, Washington, DC 20090—6456.

(b) Following the receipt of the information and documents, the Administrator will determine, pursuant to § 205.506, whether the applicant for accreditation should be accredited as a certifying agent.

§ 205.503 Applicant information.

A private or governmental entity seeking accreditation as a certifying agent must submit the following information:

(a) The business name, primary office location, mailing address, name of the person(s) responsible for the certifying agent's day-to-day operations, contact numbers (telephone, facsimile, and Internet address) of the applicant, and, for an applicant who is a private person, the entity's taxpayer identification number;

(b) The name, office location, mailing address, and contact numbers (telephone, facsimile, and Internet address) for each of its organizational units, such as chapters or subsidiary offices, and the name of a contact person for each unit;

(c) Each area of operation (crops, wild crops, livestock, or handling) for which accreditation is requested and the estimated number of each type of operation anticipated to be certified annually by the applicant along with a copy of the applicant's schedule of fees for all services to be provided under these regulations by the applicant;

(d) The type of entity the applicant is (e.g., government agricultural office, for-profit business, not-for-profit membership association) and for:

(1) A governmental entity, a copy of the official's authority to conduct certification activities under the Act and the regulations in this part,

(2) A private entity, documentation showing the entity's status and organizational purpose, such as articles of incorporation and by-laws or ownership or membership provisions, and its date of establishment; and

(e) A list of each State or foreign country in which the applicant currently certifies production and handling operations and a list of each State or foreign country in which the applicant intends to certify production or handling operations.

§ 205.504 Evidence of expertise and ability.

A private or governmental entity seeking accreditation as a certifying agent must submit the following documents and information to demonstrate its expertise in organic production or handling techniques; its ability to fully comply with and implement the organic certification program established in §§ 205.100 and 205.101, §§ 205.201 through 205.203, §§ 205.300 through 205.303, §§ 205.400 through 205.406, and §§ 205.661 and 205.662; and its ability to comply with the requirements for accreditation set forth in § 205.501:

(a) *Personnel.* (1) A copy of the applicant's policies and procedures for training, evaluating, and supervising personnel;

(2) The name and position description of all personnel to be used in the certification operation, including administrative staff, certification inspectors, members of any certification review and evaluation committees, contractors, and all parties responsibly connected to the certifying agent;

(3) A description of the qualifications, including experience, training, and education in agriculture, organic production, and organic handling, for:

(i) Each inspector to be used by the applicant and

(ii) Each person to be designated by the applicant to review or evaluate applications for certification; and

(4) A description of any training that the applicant has provided or intends to provide to personnel to ensure that they comply with and implement the requirements of the Act and the regulations in this part.

(b) *Administrative policies and procedures.* (1) A copy of the procedures to be used to evaluate certification applicants, make certification decisions, and issue certification certificates;

(2) A copy of the procedures to be used for reviewing and investigating certified operation compliance with the Act and the regulations in this part and the reporting of violations of the Act

and the regulations in this part to the Administrator;

(3) A copy of the procedures to be used for complying with the recordkeeping requirements set forth in § 205.501(a)(9);

(4) A copy of the procedures to be used for maintaining the confidentiality of any business-related information as set forth in § 205.501(a)(10);

(5) A copy of the procedures to be used, including any fees to be assessed, for making the following information available to any member of the public upon request:

(i) Certification certificates issued during the current and 3 preceding calendar years;

(ii) A list of producers and handlers whose operations it has certified, including for each the name of the operation, type(s) of operation, products produced, and the effective date of the certification, during the current and 3 preceding calendar years;

(iii) The results of laboratory analyses for residues of pesticides and other prohibited substances conducted during the current and 3 preceding calendar years; and

(iv) Other business information as permitted in writing by the producer or handler; and

(6) A copy of the procedures to be used for sampling and residue testing pursuant to § 205.670.

(c) *Conflicts of interest.* (1) A copy of procedures intended to be implemented to prevent the occurrence of conflicts of interest, as described in § 205.501(a)(11).

(2) For all persons who review applications for certification, perform on-site inspections, review certification documents, evaluate qualifications for certification, make recommendations concerning certification, or make certification decisions and all parties responsibly connected to the certifying agent, a conflict of interest disclosure report, identifying any food- or agriculture-related business interests, including business interests of immediate family members, that cause a conflict of interest.

(d) *Current certification activities.* An applicant who currently certifies production or handling operations must submit: (1) A list of all production and handling operations currently certified by the applicant;

(2) Copies of at least 3 different inspection reports and certification evaluation documents for production or handling operations certified by the applicant during the previous year for each area of operation for which accreditation is requested; and

(3) The results of any accreditation process of the applicant's operation by an accrediting body during the previous year for the purpose of evaluating its certification activities.

(e) *Other information.* Any other information the applicant believes may assist in the Administrator's evaluation of the applicant's expertise and ability.

§ 205.505 Statement of agreement.

(a) A private or governmental entity seeking accreditation under this subpart must sign and return a statement of agreement prepared by the Administrator which affirms that, if granted accreditation as a certifying agent under this subpart, the applicant will carry out the provisions of the Act and the regulations in this part, including:

(1) Accept the certification decisions made by another certifying agent accredited or accepted by USDA pursuant to § 205.500;

(2) Refrain from making false or misleading claims about its accreditation status, the USDA accreditation program for certifying agents, or the nature or qualities of products labeled as organically produced;

(3) Conduct an annual performance evaluation of all persons who review applications for certification, perform on-site inspections, review certification documents, evaluate qualifications for certification, make recommendations concerning certification, or make certification decisions and implement measures to correct any deficiencies in certification services;

(4) Have an annual internal program review conducted of its certification activities by certifying agent staff, an outside auditor, or a consultant who has the expertise to conduct such reviews and implement measures to correct any noncompliances with the Act and the regulations in this part;

(5) Pay and submit fees to AMS in accordance with § 205.640; and

(6) Comply with, implement, and carry out any other terms and conditions determined by the Administrator to be necessary.

(b) A private entity seeking accreditation as a certifying agent under this subpart must additionally agree to:

(1) Hold the Secretary harmless for any failure on the part of the certifying agent to carry out the provisions of the Act and the regulations in this part;

(2) Furnish reasonable security, in an amount and according to such terms as the Administrator may by regulation prescribe, for the purpose of protecting the rights of production and handling operations certified by such certifying

agent under the Act and the regulations in this part; and

(3) Transfer to the Administrator and make available to the applicable State organic program's governing State official all records or copies of records concerning the certifying agent's certification activities in the event that the certifying agent dissolves or loses its accreditation; *Provided*, That such transfer shall not apply to a merger, sale, or other transfer of ownership of a certifying agent.

§ 205.506 Granting accreditation.

(a) Accreditation will be granted when:

(1) The accreditation applicant has submitted the information required by §§ 205.503 through 205.505;

(2) The accreditation applicant pays the required fee in accordance with § 205.640(c); and

(3) The Administrator determines that the applicant for accreditation meets the requirements for accreditation as stated in § 205.501, as determined by a review of the information submitted in accordance with §§ 205.503 through 205.505 and, if necessary, a review of the information obtained from a site evaluation as provided for in § 205.508.

(b) On making a determination to approve an application for accreditation, the Administrator will notify the applicant of the granting of accreditation in writing, stating:

(1) The area(s) for which accreditation is given;

(2) The effective date of the accreditation;

(3) Any terms and conditions for the correction of minor noncompliances; and

(4) For a certifying agent who is a private entity, the amount and type of security that must be established to protect the rights of production and handling operations certified by such certifying agent.

(c) The accreditation of a certifying agent shall continue in effect until such time as the certifying agent fails to renew accreditation as provided in § 205.510(c), the certifying agent voluntarily ceases its certification activities, or accreditation is suspended or revoked pursuant to § 205.665.

§ 205.507 Denial of accreditation.

(a) If the Program Manager has reason to believe, based on a review of the information specified in §§ 205.503 through 205.505 or after a site evaluation as specified in § 205.508, that an applicant for accreditation is not able to comply or is not in compliance with the requirements of the Act and the regulations in this part, the Program

Manager shall provide a written notification of noncompliance to the applicant. Such notification shall provide:

(1) A description of each noncompliance;

(2) The facts upon which the notification of noncompliance is based; and

(3) The date by which the applicant must rebut or correct each noncompliance and submit supporting documentation of each such correction when correction is possible.

(b) When each noncompliance has been resolved, the Program Manager will send the applicant a written notification of noncompliance resolution and proceed with further processing of the application.

(c) If an applicant fails to correct the noncompliances, fails to report the corrections by the date specified in the notification of noncompliance, fails to file a rebuttal of the notification of noncompliance by the date specified, or is unsuccessful in its rebuttal, the Program Manager will provide the applicant with written notification of accreditation denial. An applicant who has received written notification of accreditation denial may apply for accreditation again at any time in accordance with § 205.502, or appeal the denial of accreditation in accordance with § 205.681 by the date specified in the notification of accreditation denial.

(d) If the certifying agent was accredited prior to the site evaluation and the certifying agent fails to correct the noncompliances, fails to report the corrections by the date specified in the notification of noncompliance, or fails to file a rebuttal of the notification of noncompliance by the date specified, the Administrator will begin proceedings to suspend or revoke the certifying agent's accreditation. A certifying agent who has had its accreditation suspended may at any time, unless otherwise stated in the notification of suspension, submit a request to the Secretary for reinstatement of its accreditation. The request must be accompanied by evidence demonstrating correction of each noncompliance and corrective actions taken to comply with and remain in compliance with the Act and the regulations in this part. A certifying agent whose accreditation is revoked will be ineligible for accreditation for a period of not less than 3 years following the date of such determination.

§ 205.508 Site evaluations.

(a) Site evaluations of accredited certifying agents shall be conducted for

the purpose of examining the certifying agent's operations and evaluating its compliance with the Act and the regulations of this part. Site evaluations shall include an on-site review of the certifying agent's certification procedures, decisions, facilities, administrative and management systems, and production or handling operations certified by the certifying agent. Site evaluations shall be conducted by a representative(s) of the Administrator.

(b) An initial site evaluation of an accreditation applicant shall be conducted before or within a reasonable period of time after issuance of the applicant's "notification of accreditation." A site evaluation shall be conducted after application for renewal of accreditation but prior to the issuance of a notice of renewal of accreditation. One or more site evaluations will be conducted during the period of accreditation to determine whether an accredited certifying agent is complying with the general requirements set forth in § 205.501.

§ 205.509 Peer review panel.

The Administrator shall establish a peer review panel pursuant to the Federal Advisory Committee Act (FACA) (5 U.S.C. App. 2 et seq.). The peer review panel shall be composed of not less than 3 members who shall annually evaluate the National Organic Program's adherence to the accreditation procedures in this subpart F and ISO/IEC Guide 61, General requirements for assessment and accreditation of certification/registration bodies, and the National Organic Program's accreditation decisions. This shall be accomplished through the review of accreditation procedures, document review and site evaluation reports, and accreditation decision documents or documentation. The peer review panel shall report its finding, in writing, to the National Organic Program's Program Manager.

§ 205.510 Annual report, recordkeeping, and renewal of accreditation.

(a) *Annual report and fees.* An accredited certifying agent must submit annually to the Administrator, on or before the anniversary date of the issuance of the notification of accreditation, the following reports and fees:

(1) A complete and accurate update of information submitted pursuant to §§ 205.503 and 205.504;

(2) Information supporting any changes being requested in the areas of accreditation described in § 205.500;

(3) A description of the measures implemented in the previous year and any measures to be implemented in the coming year to satisfy any terms and conditions determined by the Administrator to be necessary, as specified in the most recent notification of accreditation or notice of renewal of accreditation;

(4) The results of the most recent performance evaluations and annual program review and a description of adjustments to the certifying agent's operation and procedures implemented or to be implemented in response to the performance evaluations and program review; and

(5) The fees required in § 205.640(a).

(b) *Recordkeeping.* Certifying agents must maintain records according to the following schedule:

(1) Records obtained from applicants for certification and certified operations must be maintained for not less than 5 years beyond their receipt;

(2) Records created by the certifying agent regarding applicants for certification and certified operations must be maintained for not less than 10 years beyond their creation; and

(3) Records created or received by the certifying agent pursuant to the accreditation requirements of this subpart F, excluding any records covered by §§ 205.510(b)(2), must be maintained for not less than 5 years beyond their creation or receipt.

(c) *Renewal of accreditation.* (1) The Administrator shall send the accredited certifying agent a notice of pending expiration of accreditation approximately 1 year prior to the scheduled date of expiration.

(2) An accredited certifying agent's application for accreditation renewal must be received at least 6 months prior to the fifth anniversary of issuance of the notification of accreditation and each subsequent renewal of accreditation. The accreditation of certifying agents who make timely application for renewal of accreditation will not expire during the renewal process. The accreditation of certifying agents who fail to make timely application for renewal of accreditation will expire as scheduled unless renewed prior to the scheduled expiration date. Certifying agents with an expired accreditation must not perform certification activities under the Act and the regulations of this part.

(3) Following receipt of the information submitted by the certifying agent in accordance with paragraph (a) of this section and the results of a site evaluation, the Administrator will determine whether the certifying agent remains in compliance with the Act and

the regulations of this part and should have its accreditation renewed.

(d) *Notice of renewal of accreditation.* Upon a determination that the certifying agent is in compliance with the Act and the regulations of this part, the Administrator will issue a notice of renewal of accreditation. The notice of renewal will specify any terms and conditions that must be addressed by the certifying agent and the time within which those terms and conditions must be satisfied.

(e) *Noncompliance.* Upon a determination that the certifying agent is not in compliance with the Act and the regulations of this part, the Administrator will initiate proceedings to suspend or revoke the certifying agent's accreditation.

(f) *Amending accreditation.* Amendment to scope of an accreditation may be requested at any time. The application for amendment shall be sent to the Administrator and shall contain information applicable to the requested change in accreditation, a complete and accurate update of the information submitted pursuant to §§ 205.503 and 205.504, and the applicable fees required in § 205.640.

§§ 205.511–205.599 [Reserved]

Subpart G—Administrative

The National List of Allowed and Prohibited Substances

§ 205.600 Evaluation criteria for allowed and prohibited substances, methods, and ingredients.

The following criteria will be utilized in the evaluation of substances or ingredients for the organic production and handling sections of the National List:

(a) Synthetic and nonsynthetic substances considered for inclusion on or deletion from the National List of allowed and prohibited substances will be evaluated using the criteria specified in the Act (7 U.S.C. 6517 and 6518).

(b) In addition to the criteria set forth in the Act, any synthetic substance used as a processing aid or adjuvant will be evaluated against the following criteria:

(1) The substance cannot be produced from a natural source and there are no organic substitutes;

(2) The substance's manufacture, use, and disposal do not have adverse effects on the environment and are done in a manner compatible with organic handling;

(3) The nutritional quality of the food is maintained when the substance is used, and the substance, itself, or its breakdown products do not have an adverse effect on human health as

defined by applicable Federal regulations;

(4) The substance's primary use is not as a preservative or to recreate or improve flavors, colors, textures, or nutritive value lost during processing, except where the replacement of nutrients is required by law;

(5) The substance is listed as generally recognized as safe (GRAS) by Food and Drug Administration (FDA) when used in accordance with FDA's good manufacturing practices (GMP) and contains no residues of heavy metals or other contaminants in excess of tolerances set by FDA; and

(6) The substance is essential for the handling of organically produced agricultural products.

(c) Nonsynthetics used in organic processing will be evaluated using the criteria specified in the Act (7 U.S.C. 6517 and 6518).

§ 205.601 Synthetic substances allowed for use in organic crop production.

In accordance with restrictions specified in this section, the following synthetic substances may be used in organic crop production:

(a) As algicide, disinfectants, and sanitizer, including irrigation system cleaning systems.

(1) Alcohols.

(i) Ethanol.

(ii) Isopropanol.

(2) Chlorine materials—*Except*, That, residual chlorine levels in the water shall not exceed the maximum residual disinfectant limit under the Safe Drinking Water Act.

(i) Calcium hypochlorite.

(ii) Chlorine dioxide.

(iii) Sodium hypochlorite.

(3) Hydrogen peroxide.

(4) Soap-based algicide/demisters.

(b) As herbicides, weed barriers, as applicable.

(1) Herbicides, soap-based—for use in farmstead maintenance (roadways, ditches, right of ways, building perimeters) and ornamental crops.

(2) Mulches.

(i) Newspaper or other recycled paper, without glossy or colored inks.

(ii) Plastic mulch and covers (petroleum-based other than polyvinyl chloride (PVC)).

(c) As compost feedstocks—Newspapers or other recycled paper, without glossy or colored inks.

(d) As animal repellents—Soaps, ammonium—for use as a large animal repellent only, no contact with soil or edible portion of crop.

(e) As insecticides (including acaricides or mite control).

(1) Ammonium carbonate—for use as bait in insect traps only, no direct contact with crop or soil.

(2) Boric acid—structural pest control, no direct contact with organic food or crops.

(3) Elemental sulfur.

(4) Lime sulfur—including calcium polysulfide.

(5) Oils, horticultural—narrow range oils as dormant, suffocating, and summer oils.

(6) Soaps, insecticidal.

(7) Sticky traps/barriers.

(f) As insect attractants—Pheromones.

(g) As rodenticides.

(1) Sulfur dioxide—underground rodent control only (smoke bombs).

(2) Vitamin D₃.

(h) As slug or snail bait—None.

(i) As plant disease control.

(1) Coppers, fixed—copper hydroxide, copper oxide, copper oxychloride, includes products exempted from EPA tolerance, *Provided*, That, copper-based materials must be used in a manner that minimizes accumulation in the soil and shall not be used as herbicides.

(2) Copper sulfate—Substance must be used in a manner that minimizes accumulation of copper in the soil.

(3) Hydrated lime—must be used in a manner that minimizes copper accumulation in the soil.

(4) Hydrogen peroxide.

(5) Lime sulfur.

(6) Oils, horticultural, narrow range oils as dormant, suffocating, and summer oils.

(7) Potassium bicarbonate.

(8) Elemental sulfur.

(9) Streptomycin, for fire blight control in apples and pears only.

(10) Tetracycline (oxytetracycline calcium complex), for fire blight control only.

(j) As plant or soil amendments.

(1) Aquatic plant extracts (other than hydrolyzed)—Extraction process is limited to the use of potassium hydroxide or sodium hydroxide; solvent amount used is limited to that amount necessary for extraction.

(2) Elemental sulfur.

(3) Humic acids—naturally occurring deposits, water and alkali extracts only.

(4) Lignin sulfonate—chelating agent, dust suppressant, floatation agent.

(5) Magnesium sulfate—allowed with a documented soil deficiency.

(6) Micronutrients—not to be used as a defoliant, herbicide, or desiccant. Those made from nitrates or chlorides are not allowed. Soil deficiency must be documented by testing.

(i) Soluble boron products.

(ii) Sulfates, carbonates, oxides, or silicates of zinc, copper, iron, manganese, molybdenum, selenium, and cobalt.

(7) Liquid fish products—can be pH adjusted with sulfuric, citric or

phosphoric acid. The amount of acid used shall not exceed the minimum needed to lower the pH to 3.5.

(8) Vitamins, B₁, C, and E.

(k) As plant growth regulators—Ethylene—for regulation of pineapple flowering.

(l) As floating agents in postharvest handling.

(1) Lignin sulfonate.

(2) Sodium silicate—for tree fruit and fiber processing.

(m) As synthetic inert ingredients as classified by the Environmental Protection Agency (EPA), for use with nonsynthetic substances or synthetic substances listed in this section and used as an active pesticide ingredient in accordance with any limitations on the use of such substances.

(1) EPA List 4—Inerts of Minimal Concern.

(n)–(z) [Reserved]

§ 205.602 Nonsynthetic substances prohibited for use in organic crop production.

The following nonsynthetic substances may not be used in organic crop production:

(a) Ash from manure burning.

(b) Arsenic.

(c) Lead salts.

(d) Sodium fluoaluminate (mined).

(e) Strychnine.

(f) Tobacco dust (nicotine sulfate).

(g) Potassium chloride—unless derived from a mined source and applied in a manner that minimizes chloride accumulation in the soil.

(h) Sodium nitrate—unless use is restricted to no more than 20% of the crop's total nitrogen requirement.

(i)–(z) [Reserved]

§ 205.603 Synthetic substances allowed for use in organic livestock production.

In accordance with restrictions specified in this section the following synthetic substances may be used in organic livestock production:

(a) As disinfectants, sanitizer, and medical treatments as applicable.

(1) Alcohols.

(i) Ethanol—disinfectant and sanitizer only, prohibited as a feed additive.

(ii) Isopropanol—disinfectant only.

(2) Aspirin—approved for health care use to reduce inflammation

(3) Chlorine materials—disinfecting and sanitizing facilities and equipment. Residual chlorine levels in the water shall not exceed the maximum residual disinfectant limit under the Safe Drinking Water Act.

(i) Calcium hypochlorite.

(ii) Chlorine dioxide.

(iii) Sodium hypochlorite.

(4) Chlorohexidine—Allowed for surgical procedures conducted by a

veterinarian. Allowed for use as a teat dip when alternative germicidal agents and/or physical barriers have lost their effectiveness.

(5) Electrolytes—without antibiotics.

(6) Glucose.

(7) Glycerin—Allowed as a livestock teat dip, must be produced through the hydrolysis of fats or oils.

(8) Iodine.

(9) Hydrogen peroxide.

(10) Magnesium sulfate.

(11) Oxytocin—use in postparturition therapeutic applications.

(12) Parasiticides—Ivermectin—prohibited in slaughter stock, allowed in emergency treatment for dairy and breeder stock when organic system plan-approved preventive management does not prevent infestation. Milk or milk products from a treated animal cannot be labeled as provided for in subpart D of this part for 90 days following treatment. In breeder stock, treatment cannot occur during the last third of gestation if the progeny will be sold as organic and must not be used during the lactation period of breeding stock.

(13) Phosphoric acid—allowed as an equipment cleaner, *Provided*, That, no direct contact with organically managed livestock or land occurs.

(14) Biologics—Vaccines.

(b) As topical treatment, external parasiticide or local anesthetic as applicable.

(1) Iodine.

(2) Lidocaine—as a local anesthetic. Use requires a withdrawal period of 90 days after administering to livestock intended for slaughter and 7 days after administering to dairy animals.

(3) Lime, hydrated—(bordeaux mixes), not permitted to cauterize physical alterations or deodorize animal wastes.

(4) Mineral oil—for topical use and as a lubricant.

(5) Procaine—as a local anesthetic, use requires a withdrawal period of 90 days after administering to livestock intended for slaughter and 7 days after administering to dairy animals.

(6) Copper sulfate.

(c) As feed supplements—Milk replacers without antibiotics, as emergency use only, no nonmilk products or products from BST treated animals.

(d) As feed additives.

(1) Trace minerals, used for enrichment or fortification when FDA approved, including:

(i) Copper sulfate.

(ii) Magnesium sulfate.

(2) Vitamins, used for enrichment or fortification when FDA approved.

(e) As synthetic inert ingredients as classified by the Environmental

Protection Agency (EPA), for use with nonsynthetic substances or a synthetic substances listed in this section and used as an active pesticide ingredient in accordance with any limitations on the use of such substances.

(f) EPA List 4—Inerts of Minimal Concern.

(g)–(z) [Reserved]

§ 205.604 Nonsynthetic substances prohibited for use in organic livestock production.

The following nonsynthetic substances may not be used in organic livestock production:

(a) Strychnine.

(b)–(z) [Reserved]

§ 205.605 Nonagricultural (nonorganic) substances allowed as ingredients in or on processed products labeled as “organic” or “made with organic (specified ingredients or food group(s)).”

The following nonagricultural substances may be used as ingredients in or on processed products labeled as “organic” or “made with organic (specified ingredients or food group(s))” only in accordance with any restrictions specified in this section.

(a) *Nonsynthetics allowed:*

(1) Acids.

(i) Alginic.

(ii) Citric—produced by microbial fermentation of carbohydrate substances.

(iii) Lactic.

(2) Bentonite.

(3) Calcium carbonate.

(4) Calcium chloride.

(5) Colors, nonsynthetic sources only.

(6) Dairy cultures.

(7) Diatomaceous earth—food filtering aid only.

(8) Enzymes—must be derived from edible, nontoxic plants, nonpathogenic fungi, or nonpathogenic bacteria.

(9) Flavors, nonsynthetic sources only and must not be produced using synthetic solvents and carrier systems or any artificial preservative.

(10) Kaolin.

(11) Magnesium sulfate, nonsynthetic sources only.

(12) Nitrogen—oil-free grades.

(13) Oxygen—oil-free grades.

(14) Perlite—for use only as a filter aid in food processing.

(15) Potassium chloride.

(16) Potassium iodide.

(17) Sodium bicarbonate.

(18) Sodium carbonate.

(19) Waxes—nonsynthetic.

(i) Carnauba wax.

(ii) Wood resin.

(20) Yeast—nonsynthetic, growth on petrochemical substrate and sulfite waste liquor is prohibited.

(i) Autolysate.

(ii) Bakers.
 (iii) Brewers.
 (iv) Nutritional.
 (v) Smoked—nonsynthetic smoke flavoring process must be documented.
 (b) *Synthetics allowed:*
 (1) Alginates.
 (2) Ammonium bicarbonate—for use only as a leavening agent.
 (3) Ammonium carbonate—for use only as a leavening agent.
 (4) Ascorbic acid.
 (5) Calcium citrate.
 (6) Calcium hydroxide.
 (7) Calcium phosphates (monobasic, dibasic, and tribasic).
 (8) Carbon dioxide.
 (9) Chlorine materials—disinfecting and sanitizing food contact surfaces, *Except*, That, residual chlorine levels in the water shall not exceed the maximum residual disinfectant limit under the Safe Drinking Water Act.
 (i) Calcium hypochlorite.
 (ii) Chlorine dioxide.
 (iii) Sodium hypochlorite.
 (10) Ethylene—allowed for postharvest ripening of tropical fruit.
 (11) Ferrous sulfate—for iron enrichment or fortification of foods when required by regulation or recommended (independent organization).
 (12) Glycerides (mono and di)—for use only in drum drying of food.
 (13) Glycerin—produced by hydrolysis of fats and oils.
 (14) Hydrogen peroxide.
 (15) Lecithin—bleached.
 (16) Magnesium carbonate—for use only in agricultural products labeled “made with organic (specified ingredients or food group(s)),” prohibited in agricultural products labeled “organic”.
 (17) Magnesium chloride—derived from sea water.
 (18) Magnesium stearate—for use only in agricultural products labeled “made with organic (specified ingredients or food group(s)),” prohibited in agricultural products labeled “organic”.
 (19) Nutrient vitamins and minerals, in accordance with 21 CFR 104.20, Nutritional Quality Guidelines For Foods.
 (20) Ozone.
 (21) Pectin (low-methoxy).
 (22) Phosphoric acid—cleaning of food-contact surfaces and equipment only.
 (23) Potassium acid tartrate.
 (24) Potassium tartrate made from tartaric acid.
 (25) Potassium carbonate.
 (26) Potassium citrate.
 (27) Potassium hydroxide—prohibited for use in lye peeling of fruits and vegetables.

(28) Potassium iodide—for use only in agricultural products labeled “made with organic (specified ingredients or food group(s)),” prohibited in agricultural products labeled “organic”.

(29) Potassium phosphate—for use only in agricultural products labeled “made with organic (specific ingredients or food group(s)),” prohibited in agricultural products labeled “organic”.

(30) Silicon dioxide.

(31) Sodium citrate.

(32) Sodium hydroxide—prohibited for use in lye peeling of fruits and vegetables.

(33) Sodium phosphates—for use only in dairy foods.

(34) Sulfur dioxide—for use only in wine labeled “made with organic grapes,” *Provided*, That, total sulfite concentration does not exceed 100 ppm.

(35) Tocopherols—derived from vegetable oil when rosemary extracts are not a suitable alternative.

(36) Xanthan gum.

(c)-(z) [Reserved]

§ 205.606 Nonorganically produced agricultural products allowed as ingredients in or on processed products labeled as “organic” or “made with organic (specified ingredients or food group(s)).”

The following nonorganically produced agricultural products may be used as ingredients in or on processed products labeled as “organic” or “made with organic (specified ingredients or food group(s))” only in accordance with any restrictions specified in this section.

Any nonorganically produced agricultural product may be used in accordance with the restrictions specified in this section and when the product is not commercially available in organic form.

(a) Cornstarch (native)

(b) Gums—water extracted only (arabic, guar, locust bean, carob bean)

(c) Kelp—for use only as a thickener and dietary supplement

(d) Lecithin—unbleached

(e) Pectin (high-methoxy)

§ 205.607 Amending the National List.

(a) Any person may petition the National Organic Standard Board for the purpose of having a substance evaluated by the Board for recommendation to the Secretary for inclusion on or deletion from the National List in accordance with the Act.

(b) A person petitioning for amendment of the National List should request a copy of the petition procedures from the USDA at the address in § 205.607(c).

(c) A petition to amend the National List must be submitted to: Program

Manager, USDA/AMS/TMP/NOP, Room 2945, South Building, P.O. Box 96456, Washington, DC 20090-6456.

§§ 205.608–205.619 [Reserved]

State Organic Programs

§ 205.620 Requirements of State organic programs.

(a) A State may establish a State organic program for production and handling operations within the State which produce and handle organic agricultural products.

(b) A State organic program must meet the requirements for organic programs specified in the Act.

(c) A State organic program may contain more restrictive requirements because of environmental conditions or the necessity of specific production or handling practices particular to the State or region of the United States.

(d) A State organic program must assume enforcement obligations in the State for the requirements of this part and any more restrictive requirements approved by the Secretary.

(e) A State organic program and any amendments to such program must be approved by the Secretary prior to being implemented by the State.

§ 205.621 Submission and determination of proposed State organic programs and amendments to approved State organic programs.

(a) A State organic program’s governing State official must submit to the Secretary a proposed State organic program and any proposed amendments to such approved program.

(1) Such submission must contain supporting materials that include statutory authorities, program description, documentation of the environmental conditions or specific production and handling practices particular to the State which necessitate more restrictive requirements than the requirements of this part, and other information as may be required by the Secretary.

(2) Submission of a request for amendment of an approved State organic program must contain supporting materials that include an explanation and documentation of the environmental conditions or specific production and handling practices particular to the State or region, which necessitates the proposed amendment. Supporting material also must explain how the proposed amendment furthers and is consistent with the purposes of the Act and the regulations of this part.

(b) Within 6 months of receipt of submission, the Secretary will: Notify the State organic program’s governing

State official of approval or disapproval of the proposed program or amendment of an approved program and, if disapproved, the reasons for the disapproval.

(c) After receipt of a notice of disapproval, the State organic program's governing State official may submit a revised State organic program or amendment of such a program at any time.

§ 205.622 Review of approved State organic programs.

The Secretary will review a State organic program not less than once during each 5-year period following the date of the initial program approval. The Secretary will notify the State organic program's governing State official of approval or disapproval of the program within 6 months after initiation of the review.

§§ 205.623–205.639 [Reserved]

Fees

§ 205.640 Fees and other charges for accreditation.

Fees and other charges equal as nearly as may be to the cost of the accreditation services rendered under the regulations, including initial accreditation, review of annual reports, and renewal of accreditation, shall be assessed and collected from applicants for initial accreditation and accredited certifying agents submitting annual reports or seeking renewal of accreditation in accordance with the following provisions:

(a) *Fees-for-service.* (1) Except as otherwise provided in this section, fees-for-service shall be based on the time required to render the service provided calculated to the nearest 15-minute period, including the review of applications and accompanying documents and information, evaluator travel, the conduct of on-site evaluations, review of annual reports and updated documents and information, and the time required to prepare reports and any other documents in connection with the performance of service. The hourly rate shall be the same as that charged by the Agricultural Marketing Service, through its Quality Systems Certification Program, to certification bodies requesting conformity assessment to the International Organization for Standardization "General Requirements for Bodies Operating Product Certification Systems" (ISO Guide 65).

(2) Applicants for initial accreditation and accredited certifying agents submitting annual reports or seeking renewal of accreditation during the first

18 months following the effective date of subpart F of this part shall receive service without incurring an hourly charge for service.

(3) Applicants for initial accreditation and renewal of accreditation must pay at the time of application, effective 18 months following February 20, 2001, a nonrefundable fee of \$500.00 which shall be applied to the applicant's fees-for-service account.

(b) *Travel charges.* When service is requested at a place so distant from the evaluator's headquarters that a total of one-half hour or more is required for the evaluator(s) to travel to such place and back to the headquarters or at a place of prior assignment on circuitous routing requiring a total of one-half hour or more to travel to the next place of assignment on the circuitous routing, the charge for such service shall include a mileage charge administratively determined by the U.S. Department of Agriculture and travel tolls, if applicable, or such travel prorated among all the applicants and certifying agents furnished the service involved on an equitable basis or, when the travel is made by public transportation (including hired vehicles), a fee equal to the actual cost thereof. Travel charges shall become effective for all applicants for initial accreditation and accredited certifying agents on February 20, 2001. The applicant or certifying agent will not be charged a new mileage rate without notification before the service is rendered.

(c) *Per diem charges.* When service is requested at a place away from the evaluator's headquarters, the fee for such service shall include a per diem charge if the employee(s) performing the service is paid per diem in accordance with existing travel regulations. Per diem charges to applicants and certifying agents will cover the same period of time for which the evaluator(s) receives per diem reimbursement. The per diem rate will be administratively determined by the U.S. Department of Agriculture. Per diem charges shall become effective for all applicants for initial accreditation and accredited certifying agents on February 20, 2001. The applicant or certifying agent will not be charged a new per diem rate without notification before the service is rendered.

(d) *Other costs.* When costs, other than costs specified in paragraphs (a), (b), and (c) of this section, are associated with providing the services, the applicant or certifying agent will be charged for these costs. Such costs include but are not limited to equipment rental, photocopying, delivery, facsimile, telephone, or

translation charges incurred in association with accreditation services. The amount of the costs charged will be determined administratively by the U.S. Department of Agriculture. Such costs shall become effective for all applicants for initial accreditation and accredited certifying agents on February 20, 2001.

§ 205.641 Payment of fees and other charges.

(a) Applicants for initial accreditation and renewal of accreditation must remit the nonrefundable fee, pursuant to § 205.640(a)(3), along with their application. Remittance must be made payable to the Agricultural Marketing Service, USDA, and mailed to: Program Manager, USDA-AMS-TMP-NOP, Room 2945-South Building, P.O. Box 96456, Washington, DC 20090-6456 or such other address as required by the Program Manager.

(b) Payments for fees and other charges not covered under paragraph (a) of this section must be:

(1) Received by the due date shown on the bill for collection;

(2) Made payable to the Agricultural Marketing Service, USDA; and

(3) Mailed to the address provided on the bill for collection.

(c) The Administrator shall assess interest, penalties, and administrative costs on debts not paid by the due date shown on a bill for collection and collect delinquent debts or refer such debts to the Department of Justice for litigation.

§ 205.642 Fees and other charges for certification.

Fees charged by a certifying agent must be reasonable, and a certifying agent shall charge applicants for certification and certified production and handling operations only those fees and charges that it has filed with the Administrator. The certifying agent shall provide each applicant with an estimate of the total cost of certification and an estimate of the annual cost of updating the certification. The certifying agent may require applicants for certification to pay at the time of application a nonrefundable fee which shall be applied to the applicant's fees-for-service account. The certifying agent may set the nonrefundable portion of certification fees; however, the nonrefundable portion of certification fees must be explained in the fee schedule submitted to the Administrator. The fee schedule must explain what fee amounts are nonrefundable and at what stage during the certification process fees become nonrefundable. The certifying agent shall provide all persons inquiring

about the application process with a copy of its fee schedule.

§§ 205.643–205.649 [Reserved]

Compliance

§ 205.660 General.

(a) The National Organic Program's Program Manager, on behalf of the Secretary, may inspect and review certified production and handling operations and accredited certifying agents for compliance with the Act or regulations in this part.

(b) The Program Manager may initiate suspension or revocation proceedings against a certified operation:

(1) When the Program Manager has reason to believe that a certified operation has violated or is not in compliance with the Act or regulations in this part; or

(2) When a certifying agent or a State organic program's governing State official fails to take appropriate action to enforce the Act or regulations in this part.

(c) The Program Manager may initiate suspension or revocation of a certifying agent's accreditation if the certifying agent fails to meet, conduct, or maintain accreditation requirements pursuant to the Act or this part.

(d) Each notification of noncompliance, rejection of mediation, noncompliance resolution, proposed suspension or revocation, and suspension or revocation issued pursuant to § 205.662, § 205.663, and § 205.665 and each response to such notification must be sent to the recipient's place of business via a delivery service which provides dated return receipts.

§ 205.661 Investigation of certified operations.

(a) A certifying agent may investigate complaints of noncompliance with the Act or regulations of this part concerning production and handling operations certified as organic by the certifying agent. A certifying agent must notify the Program Manager of all compliance proceedings and actions taken pursuant to this part.

(b) A State organic program's governing State official may investigate complaints of noncompliance with the Act or regulations in this part concerning organic production or handling operations operating in the State.

§ 205.662 Noncompliance procedure for certified operations.

(a) *Notification.* When an inspection, review, or investigation of a certified operation by a certifying agent or a State

organic program's governing State official reveals any noncompliance with the Act or regulations in this part, a written notification of noncompliance shall be sent to the certified operation. Such notification shall provide:

(1) A description of each noncompliance;

(2) The facts upon which the notification of noncompliance is based; and

(3) The date by which the certified operation must rebut or correct each noncompliance and submit supporting documentation of each such correction when correction is possible.

(b) *Resolution.* When a certified operation demonstrates that each noncompliance has been resolved, the certifying agent or the State organic program's governing State official, as applicable, shall send the certified operation a written notification of noncompliance resolution.

(c) *Proposed suspension or revocation.* When rebuttal is unsuccessful or correction of the noncompliance is not completed within the prescribed time period, the certifying agent or State organic program's governing State official shall send the certified operation a written notification of proposed suspension or revocation of certification of the entire operation or a portion of the operation, as applicable to the noncompliance. When correction of a noncompliance is not possible, the notification of noncompliance and the proposed suspension or revocation of certification may be combined in one notification. The notification of proposed suspension or revocation of certification shall state:

(1) The reasons for the proposed suspension or revocation;

(2) The proposed effective date of such suspension or revocation;

(3) The impact of a suspension or revocation on future eligibility for certification; and

(4) The right to request mediation pursuant to § 205.663 or to file an appeal pursuant to § 205.681.

(d) *Willful violations.*

Notwithstanding paragraph (a) of this section, if a certifying agent or State organic program's governing State official has reason to believe that a certified operation has willfully violated the Act or regulations in this part, the certifying agent or State organic program's governing State official shall send the certified operation a notification of proposed suspension or revocation of certification of the entire operation or a portion of the operation, as applicable to the noncompliance.

(e) *Suspension or revocation.* (1) If the certified operation fails to correct the

noncompliance, to resolve the issue through rebuttal or mediation, or to file an appeal of the proposed suspension or revocation of certification, the certifying agent or State organic program's governing State official shall send the certified operation a written notification of suspension or revocation.

(2) A certifying agent or State organic program's governing State official must not send a notification of suspension or revocation to a certified operation that has requested mediation pursuant to § 205.663 or filed an appeal pursuant to § 205.681, while final resolution of either is pending.

(f) *Eligibility.* (1) A certified operation whose certification has been suspended under this section may at any time, unless otherwise stated in the notification of suspension, submit a request to the Secretary for reinstatement of its certification. The request must be accompanied by evidence demonstrating correction of each noncompliance and corrective actions taken to comply with and remain in compliance with the Act and the regulations in this part.

(2) A certified operation or a person responsibly connected with an operation whose certification has been revoked will be ineligible to receive certification for a period of 5 years following the date of such revocation, *Except*, That, the Secretary may, when in the best interest of the certification program, reduce or eliminate the period of ineligibility.

(g) *Violations of Act.* In addition to suspension or revocation, any certified operation that:

(1) Knowingly sells or labels a product as organic, except in accordance with the Act, shall be subject to a civil penalty of not more than \$10,000 per violation.

(2) Makes a false statement under the Act to the Secretary, a State organic program's governing State official, or a certifying agent shall be subject to the provisions of section 1001 of title 18, United States Code.

§ 205.663 Mediation.

Any dispute with respect to denial of certification or proposed suspension or revocation of certification under this part may be mediated at the request of the applicant for certification or certified operation and with acceptance by the certifying agent. Mediation shall be requested in writing to the applicable certifying agent. If the certifying agent rejects the request for mediation, the certifying agent shall provide written notification to the applicant for certification or certified operation. The written notification shall advise the

applicant for certification or certified operation of the right to request an appeal, pursuant to § 205.681, within 30 days of the date of the written notification of rejection of the request for mediation. If mediation is accepted by the certifying agent, such mediation shall be conducted by a qualified mediator mutually agreed upon by the parties to the mediation. If a State organic program is in effect, the mediation procedures established in the State organic program, as approved by the Secretary, will be followed. The parties to the mediation shall have no more than 30 days to reach an agreement following a mediation session. If mediation is unsuccessful, the applicant for certification or certified operation shall have 30 days from termination of mediation to appeal the certifying agent's decision pursuant to § 205.681. Any agreement reached during or as a result of the mediation process shall be in compliance with the Act and the regulations in this part. The Secretary may review any mediated agreement for conformity to the Act and the regulations in this part and may reject any agreement or provision not in conformance with the Act or the regulations in this part.

§ 205.664 [Reserved]

§ 205.665 Noncompliance procedure for certifying agents.

(a) *Notification.* When an inspection, review, or investigation of an accredited certifying agent by the Program Manager reveals any noncompliance with the Act or regulations in this part, a written notification of noncompliance shall be sent to the certifying agent. Such notification shall provide:

- (1) A description of each noncompliance;
- (2) The facts upon which the notification of noncompliance is based; and
- (3) The date by which the certifying agent must rebut or correct each noncompliance and submit supporting documentation of each correction when correction is possible.

(b) *Resolution.* When the certifying agent demonstrates that each noncompliance has been resolved, the Program Manager shall send the certifying agent a written notification of noncompliance resolution.

(c) *Proposed suspension or revocation.* When rebuttal is unsuccessful or correction of the noncompliance is not completed within the prescribed time period, the Program Manager shall send a written notification of proposed suspension or revocation of accreditation to the

certifying agent. The notification of proposed suspension or revocation shall state whether the certifying agent's accreditation or specified areas of accreditation are to be suspended or revoked. When correction of a noncompliance is not possible, the notification of noncompliance and the proposed suspension or revocation may be combined in one notification. The notification of proposed suspension or revocation of accreditation shall state:

- (1) The reasons for the proposed suspension or revocation;
- (2) The proposed effective date of the suspension or revocation;
- (3) The impact of a suspension or revocation on future eligibility for accreditation; and
- (4) The right to file an appeal pursuant to § 205.681.

(d) *Willful violations.* Notwithstanding paragraph (a) of this section, if the Program Manager has reason to believe that a certifying agent has willfully violated the Act or regulations in this part, the Program Manager shall send a written notification of proposed suspension or revocation of accreditation to the certifying agent.

(e) *Suspension or revocation.* When the accredited certifying agent fails to file an appeal of the proposed suspension or revocation of accreditation, the Program Manager shall send a written notice of suspension or revocation of accreditation to the certifying agent.

(f) *Cessation of certification activities.* A certifying agent whose accreditation is suspended or revoked must:

- (1) Cease all certification activities in each area of accreditation and in each State for which its accreditation is suspended or revoked.
- (2) Transfer to the Secretary and make available to any applicable State organic program's governing State official all records concerning its certification activities that were suspended or revoked.

(g) *Eligibility.* (1) A certifying agent whose accreditation is suspended by the Secretary under this section may at any time, unless otherwise stated in the notification of suspension, submit a request to the Secretary for reinstatement of its accreditation. The request must be accompanied by evidence demonstrating correction of each noncompliance and corrective actions taken to comply with and remain in compliance with the Act and the regulations in this part.

(2) A certifying agent whose accreditation is revoked by the Secretary shall be ineligible to be accredited as a certifying agent under the Act and the

regulations in this part for a period of not less than 3 years following the date of such revocation.

§§ 205.666–205.667 [Reserved]

§ 205.668 Noncompliance procedures under State organic programs.

(a) A State organic program's governing State official must promptly notify the Secretary of commencement of any noncompliance proceeding against a certified operation and forward to the Secretary a copy of each notice issued.

(b) A noncompliance proceeding, brought by a State organic program's governing State official against a certified operation, shall be appealable pursuant to the appeal procedures of the State organic program. There shall be no subsequent rights of appeal to the Secretary. Final decisions of a State may be appealed to the United States District Court for the district in which such certified operation is located.

(c) A State organic program's governing State official may review and investigate complaints of noncompliance with the Act or regulations concerning accreditation of certifying agents operating in the State. When such review or investigation reveals any noncompliance, the State organic program's governing State official shall send a written report of noncompliance to the Program Manager. The report shall provide a description of each noncompliance and the facts upon which the noncompliance is based.

§ 205.669 [Reserved]

Inspection and Testing, Reporting, and Exclusion from Sale

§ 205.670 Inspection and testing of agricultural product to be sold or labeled "organic."

(a) All agricultural products that are to be sold, labeled, or represented as "100 percent organic," "organic," or "made with organic (specified ingredients or food group(s))" must be made accessible by certified organic production or handling operations for examination by the Administrator, the applicable State organic program's governing State official, or the certifying agent.

(b) The Administrator, applicable State organic program's governing State official, or the certifying agent may require preharvest or postharvest testing of any agricultural input used or agricultural product to be sold, labeled, or represented as "100 percent organic," "organic," or "made with organic (specified ingredients or food group(s))" when there is reason to believe that the agricultural input or product has come

into contact with a prohibited substance or has been produced using excluded methods. Such tests must be conducted by the applicable State organic program's governing State official or the certifying agent at the official's or certifying agent's own expense.

(c) The preharvest or postharvest tissue test sample collection pursuant to paragraph (b) of this section must be performed by an inspector representing the Administrator, applicable State organic program's governing State official, or certifying agent. Sample integrity must be maintained throughout the chain of custody, and residue testing must be performed in an accredited laboratory. Chemical analysis must be made in accordance with the methods described in the most current edition of the *Official Methods of Analysis of the AOAC International* or other current applicable validated methodology determining the presence of contaminants in agricultural products.

(d) Results of all analyses and tests performed under this section:

(1) Must be promptly provided to the Administrator; *Except*, That, where a State organic program exists, all test results and analyses shall be provided to the State organic program's governing State official by the applicable certifying party that requested testing; and

(2) Will be available for public access, unless the testing is part of an ongoing compliance investigation.

(e) If test results indicate a specific agricultural product contains pesticide residues or environmental contaminants that exceed the Food and Drug Administration's or the Environmental Protection Agency's regulatory tolerances, the certifying agent must promptly report such data to the Federal health agency whose regulatory tolerance or action level has been exceeded.

§ 205.671 Exclusion from organic sale.

When residue testing detects prohibited substances at levels that are greater than 5 percent of the Environmental Protection Agency's tolerance for the specific residue detected or unavoidable residual environmental contamination, the agricultural product must not be sold, labeled, or represented as organically produced. The Administrator, the applicable State organic program's governing State official, or the certifying agent may conduct an investigation of the certified operation to determine the cause of the prohibited substance.

§ 205.672 Emergency pest or disease treatment.

When a prohibited substance is applied to a certified operation due to a Federal or State emergency pest or disease treatment program and the certified operation otherwise meets the requirements of this part, the certification status of the operation shall not be affected as a result of the application of the prohibited substance: *Provided*, That:

(a) Any harvested crop or plant part to be harvested that has contact with a prohibited substance applied as the result of a Federal or State emergency pest or disease treatment program cannot be sold, labeled, or represented as organically produced; and

(b) Any livestock that are treated with a prohibited substance applied as the result of a Federal or State emergency pest or disease treatment program or product derived from such treated livestock cannot be sold, labeled, or represented as organically produced: *Except*, That:

(1) Milk or milk products may be sold, labeled, or represented as organically produced beginning 12 months following the last date that the dairy animal was treated with the prohibited substance; and

(2) The offspring of gestating mammalian breeder stock treated with a prohibited substance may be considered organic: *Provided*, That, the breeder stock was not in the last third of gestation on the date that the breeder stock was treated with the prohibited substance.

§§ 205.673–205.679 [Reserved]

Adverse Action Appeal Process

§ 205.680 General.

(a) Persons subject to the Act who believe they are adversely affected by a noncompliance decision of the National Organic Program's Program Manager may appeal such decision to the Administrator.

(b) Persons subject to the Act who believe that they are adversely affected by a noncompliance decision of a State organic program may appeal such decision to the State organic program's governing State official who will initiate handling of the appeal pursuant to appeal procedures approved by the Secretary.

(c) Persons subject to the Act who believe that they are adversely affected by a noncompliance decision of a certifying agent may appeal such decision to the Administrator, *Except*, That, when the person is subject to an approved State organic program, the

appeal must be made to the State organic program.

(d) All written communications between parties involved in appeal proceedings must be sent to the recipient's place of business by a delivery service which provides dated return receipts.

(e) All appeals shall be reviewed, heard, and decided by persons not involved with the decision being appealed.

§ 205.681 Appeals.

(a) *Certification appeals.* An applicant for certification may appeal a certifying agent's notice of denial of certification, and a certified operation may appeal a certifying agent's notification of proposed suspension or revocation of certification to the Administrator, *Except*, That, when the applicant or certified operation is subject to an approved State organic program the appeal must be made to the State organic program which will carry out the appeal pursuant to the State organic program's appeal procedures approved by the Secretary.

(1) If the Administrator or State organic program sustains a certification applicant's or certified operation's appeal of a certifying agent's decision, the applicant will be issued organic certification, or a certified operation will continue its certification, as applicable to the operation. The act of sustaining the appeal shall not be an adverse action subject to appeal by the affected certifying agent.

(2) If the Administrator or State organic program denies an appeal, a formal administrative proceeding will be initiated to deny, suspend, or revoke the certification. Such proceeding shall be conducted pursuant to the U.S. Department of Agriculture's Uniform Rules of Practice or the State organic program's rules of procedure.

(b) *Accreditation appeals.* An applicant for accreditation and an accredited certifying agent may appeal the Program Manager's denial of accreditation or proposed suspension or revocation of accreditation to the Administrator.

(1) If the Administrator sustains an appeal, an applicant will be issued accreditation, or a certifying agent will continue its accreditation, as applicable to the operation.

(2) If the Administrator denies an appeal, a formal administrative proceeding to deny, suspend, or revoke the accreditation will be initiated. Such proceeding shall be conducted pursuant to the U.S. Department of Agriculture's Uniform Rules of Practice, 7 CFR part 1, Subpart H.

(c) *Filing period.* An appeal of a noncompliance decision must be filed within the time period provided in the letter of notification or within 30 days from receipt of the notification, whichever occurs later. The appeal will be considered "filed" on the date received by the Administrator or by the State organic program. A decision to deny, suspend, or revoke certification or accreditation will become final and nonappealable unless the decision is appealed in a timely manner.

(d) *Where and what to file.* (1) Appeals to the Administrator must be filed in writing and addressed to Administrator, USDA-AMS, Room 3071-S, P.O. Box 96456, Washington, DC 20090-6456.

(2) Appeals to the State organic program must be filed in writing to the address and person identified in the letter of notification.

(3) All appeals must include a copy of the adverse decision and a statement of the appellant's reasons for believing that the decision was not proper or made in accordance with applicable program regulations, policies, or procedures.

§§ 205.682–205.689 [Reserved]

Miscellaneous

§ 205.690 OMB control number.

The control number assigned to the information collection requirements in this part by the Office of Management and Budget pursuant to the Paperwork Reduction Act of 1995, 44 U.S.C. Chapter 35, is OMB number 0581-0181.

§§ 205.691–205.699 [Reserved]

PARTS 206–209 [Reserved]

Dated: December 13, 2000.

Kathleen A. Merrigan,
Administrator, Agricultural Marketing Service.

Appendixes to Preamble

Appendix A—Regulatory Impact Assessment for Final Rule Implementing the Organic Foods Production Act of 1990

The following regulatory assessment is provided to fulfill the requirements of Executive Order 12866. This assessment consists of a statement of the need for national organic standards, a description of the baseline for the analysis, a summary of the provisions of the final U.S. Department of Agriculture (USDA) rule and the alternative approaches that were examined, and an analysis of the benefits and costs. Much of the analysis is necessarily descriptive of the anticipated effects of the final rule. Because basic market data on the prices and quantities of organic goods and the costs of organic production are limited,

it is not possible to provide quantitative estimates of all benefits and costs of the final rule. The cost of fees and recordkeeping in the final USDA rule are quantified, but the anticipated benefits and other costs are not. Consequently, the analysis does not estimate the magnitude or the direction (positive or negative) of net benefits.

Under the final rule, USDA will implement a program of uniform standards of production and certification, as mandated by the Organic Foods Production Act of 1990 (OFPA). The primary benefits from implementation of USDA's National Organic Program (NOP) are standardizing the definitions and the manner in which organic product information is presented to consumers, which may reduce the cost associated with enforcement actions in consumer fraud cases, and improved access to domestic and international markets from harmonizing the various State and private organic standards and elevating reciprocity negotiations to the national level.

The costs of this rule are the direct costs for accreditation and the costs of complying with the specific standards in the proposal, including the reporting and recordkeeping requirements. Certifiers will be charged fees based on the actual costs of the accreditation work done by USDA staff. Smaller certifiers with less complex programs are expected to pay somewhat lower fees. Organic farmers, ranchers, wild-crop harvesters, and handlers will have to pay fees for organic certification from a State or private certifier but will not be charged any additional fees by USDA. The direct accreditation costs to an estimated 59 certifying agents (including all 49 current U.S. certifiers and an estimated 10 foreign agents) during the first 18 months following the final rule are estimated to be approximately \$92,000 to \$124,000 and are being subsidized with appropriated funds derived from the taxpayers. In addition, USDA will use appropriated funds to cover approximately \$270,000–\$448,000 in hourly charges for site evaluation during this period and for other costs associated with starting up the NOP. The magnitude of other compliance costs for adhering to this regulation—including the costs of becoming familiar with and adopting the national standards—have not been measured. For organic farmers who adhere to State regulations or undergo third-party inspection and certification, the compliance cost may not be large. For those who don't, the costs may be more substantial. The impact of this regulation on small certifying agents and other small businesses has also not been measured but may be significant.

To account for significant rule changes from the proposal and to reflect more up-to-date information, we revised some estimates of benefits and costs. We have raised our estimates of current certification fees and USDA accreditation fees. Also, we now project higher USDA accreditation fees after the 18-month implementation period. We revised our estimates of the certification fees charged by a representative set of public and private certifiers in the U.S. based on new data, and our new estimates are about 25 percent higher for small and midsized farmers. Small and midsized farmers are now

estimated to pay \$579 and \$1,414 for their first-year certification, respectively. Accreditation costs after the 18-month implementation period are substantially above those estimated in the proposed rule, reflecting a slight increase in the government per diem travel allowance since the proposed rule was published and a change in the projected number of reviewers needed for site evaluations and renewals after the 18-month implementation period. In the proposed rule, USDA had projected that only one reviewer would be needed for site evaluations and renewals that took place after the 18-month implementation period but has changed that projection to two reviewers based on additional experience with the International Organization for Standardization (ISO Guide 65) program. We estimate that initial accreditation costs after the 18-month implementation period will range from \$6,120 to \$9,700, approximately double our estimate in the March 2000 proposed rule.

Marginal changes have been made in the final rule, in response to comments on the March 2000 proposal, which generally clarify or add flexibility to producer and handler provisions or make them better reflect current industry standards. One key change was to raise the threshold for labeling products as "made with organic ingredients" from 50 percent organic content to 70 percent to be consistent with international industry standards. Although not quantified, we believe that this will increase the cost of the rule. Another key change was to reduce the transition period for a dairy operation to make a whole-herd conversion to organic production in order to make conversion affordable for a wider range of dairy farms, including smaller operations. Although not quantified, we believe that this will decrease the cost of the rule.

The Need for National Standards

Over the last several decades, as market demand has grown from a handful of consumers bargaining directly with farmers to millions of consumers acquiring goods from supermarket shelves as well as market stalls, a patchwork of State and private institutions has evolved to set standards and verify label claims. Organically produced food cannot be distinguished visually from conventional food and cannot necessarily be distinguished by taste; therefore, consumers must rely on labels and other advertising tools for product information. Farmers, food handlers, and other businesses that produce and handle organically grown food have a financial incentive to advertise that information because consumers have been willing to pay a price premium for these goods. However, consumers face difficulties in discerning the organic attributes of a product, and many producers and handlers have sought third-party certification of organic claims.

State and private initiatives have resulted in a fairly robust system of standards and certification, and the difficulties in consumer verification have been partially overcome by these initiatives. Private organizations, mostly nonprofits, began developing certification standards in the early 1970's as

a way to support organic farming, as well as to strengthen legitimate product claims. The first organization to offer third-party certification, California Certified Organic Farmers, was formed in the early 1970's, and the first State regulations and laws on organic labeling were also passed in the 1970's. Currently, 13 State and 36 private certification programs are operating in the United States, and about half the States currently have some form of regulation. While most States still do not mandate third-party certification and many organic producers still market goods without certification, large food processors, grain traders, and retailers are increasingly requiring certification, and many growers have turned to certification as a marketing tool.

However, even with increasing pressure for growers to use third-party certification services and increasing availability of these services from State and private certifiers, the discrepancies between the certifiers on organic standards and between the States on certification requirements have resulted in several impediments to market development. The patchwork of variable standards has made producer access to organic markets, international and domestic, uneven. The recent emergence of the industry-developed standards may have mitigated some domestic access problems, but two important impediments remain. They are: multiingredient certification disputes and barriers to foreign markets.

Difficulty Certifying Multiingredient Products

Although the State and private organic standards that have developed over the last several decades have many areas of overlap, particularly for crop production, the differences have caused disagreements among certifying agents over whose standards apply to multiingredient organic processed products. These disagreements have created sourcing problems for food. Disagreements about standards also create sourcing problems for handlers of these multiingredient products. Certifying agents are able to negotiate and maintain reciprocity agreements at some cost. These reciprocity agreements specify the conditions under which certifying agents recognize each other's standards. Although new organic product offerings have emerged at a fast pace during the 1990's, this pace could eventually slow, assuming that the need for costly reciprocity agreements will continue to persist in the absence of national standards.

Barriers to Foreign Organic Markets

In the absence of a national standard, U.S. producers have taken on costs of private accreditation or shipment-by-shipment certification required to gain access to some foreign markets such as the European Union (EU). However, even with these actions, U.S. organic products may have had some difficulties entering other foreign markets due to high information and search costs on the part of foreign buyers. Some foreign buyers of U.S. organic products may incur costs to determine the compatibility of standards. Such costs may have discouraged purchases of U.S. organic products.

Congress passed the OFPA—Title XXI of the Food, Agriculture, Conservation and Trade Act of 1990, U.S.C. Title 7—largely to address these marketing problems. The OFPA mandates that the Secretary of Agriculture develop a national organic program, and USDA's statutory responsibility is the primary reason why USDA has carried out this rulemaking process. The OFPA requires the Secretary to establish an organic certification program for farmers, wild-crop harvesters, and handlers of agricultural products that have been produced using organic methods as provided for in the OFPA. This legislation requires the Secretary to establish and implement a program to accredit a State program official or any private person who meets the requirements of the Act as a certifying agent to certify that farm, wild-crop harvesting, or handling operations are in compliance with the standards set out in the regulation. As stated by the OFPA in section 6501, the regulations are for the following purposes: (1) To establish national standards governing the marketing of certain agricultural products as organically produced products, (2) to assure consumers that organically produced products meet a consistent standard, and (3) to facilitate interstate commerce in fresh and processed food that is organically produced.

Baseline

After struggling to build market recognition and supply capacity for many decades, the organic farming industry became one of the fastest growing segments of U.S. agriculture during the last decade. Certified organic cropland more than doubled in the United States between 1992 and 1997, and two organic livestock sectors—eggs and dairy—grew even faster (Greene, 2000a). USDA's Economic Research Service estimates that over 1.3 million acres of U.S. farmland were certified in 1997, and more recent data from some of the certifiers indicate that this momentum is continuing (Greene, 2000b). Although national estimates of the amount of uncertified organic acreage are not available, data from California, the largest U.S. producer of organic specialty crops, indicates that most of the State's organic acreage and about half of the growers were certified during the 1997/98 crop year (Klonsky et al., 2000).

Growth in U.S. sales of organic products during the 1990's mirrors the growth in acreage devoted to producing these goods. According to industry data, total organic product sales more than doubled between 1992 and 1996 to \$3.5 billion in sales (table 1). More recent industry data on organic sales through natural product stores, the largest outlet for organic products, show annual sales growth continuing in the general range of 20–25 percent annually.

The recent growth in organic production and sales has taken place in the absence of national organic standards but with industry expectation that these standards were forthcoming. While the U.S. organic industry is characterized by an array of certification, production, processing, and marketing practices, there are commonalities throughout the industry.

Certification

The number of U.S. certification groups has fluctuated between 40 and 50 during the last decade. Currently, 49 organizations—36 private and 13 State—are advertising that they provide certification services to farmers, handlers (a category that USDA defines to include processors), retailers, or other segments of the food industry. Some certifiers provide services to multiple segments of the food industry. Private certifying agents range from small nonprofit associations that certify only a few growers to large for-profit businesses operating in numerous States and certifying hundreds of producers. Typically, certifying agents review organic production plans, inspect the farm fields and facilities to be certified, periodically reinspect, and may conduct soil tests and tests for residues of prohibited substances. In some cases, certifying agents negotiate reciprocity agreements with other agents.

State laws vary widely on organic certification and registration. Some States, such as California, require only that an organic producer register and make certification voluntary. Other States, including Texas, require certification by the State's own agents, while Minnesota and others accept certification by a private certifying agent. Approximately half of the States have laws that regulate organic production and processing. In many States producers may claim their product is organic but operate without certification or well-defined standards. Many organic producers in States with no State programs voluntarily secure third-party certification to well-defined standards. Certification costs vary with farm size and across certifying agents. Illustrative certification costs are presented in tables 2A and 2B.

Very few certifying agents operate with an external accreditation for the following reasons. There is no law which requires them to be accredited: the price may be unacceptably high in relation to expected benefits; the certifying agent may be unable to find an accrediting party willing to accredit the particular organic program the certifying agent is marketing; and State programs may believe that their status as a government entity obviates the need for external accreditation.

In 1999, USDA began accrediting certifying agents as meeting ISO Guide 65. It is a valuable recognition that the certifying entity satisfies the business capacity standards of ISO Guide 65. EU authorities have accepted verification of certifying agents to ISO Guide 65 as an interim measure to facilitate exports pending the establishment of a national organic program.

Organic Crop and Livestock Production

In 1997, farmers in 49 States used organic production systems and third-party organic certification services on over a million acres of farmland and were raising certified organic livestock production in nearly half the States, according to USDA data (Greene, 2000a). Two-thirds of the farmland was used for growing crops, with Idaho, California, North Dakota, Montana, Minnesota, Wisconsin, Iowa, and Florida as the top producers.

Colorado and Alaska had the most organic pasture and rangeland. California overwhelmingly had the most certified organic fruit and vegetable acreage in 1997, but farmers were growing small plots of certified organic vegetables for direct marketing to consumers in over half the States. About 2 percent of the U.S. apple, grape, lettuce, and carrot crops were certified organic in 1997, while only one-tenth of 1 percent of the U.S. corn and soybean crops were grown under certified organic farming systems. USDA has not estimated the amount of acreage devoted to organic production systems that has not been certified, although data from California suggest that a large number of farmers, mostly those with small operations, produce and market organic goods without third-party certification.

Key production practices followed by certified organic producers include: abstaining from use of certain crop chemicals and animal drugs; ecologically based pest and nutrient management; segregation of organic fields and animals from nonorganic fields and animals; following an organic system plan with multiple goals, including sustainability; and recordkeeping to document practices and progress toward the plan's goals. Specific elements of organic production vary, but organic systems generally share a core set of practices. For example, the certification standards of virtually all State and private U.S. certifying agents prohibit the use of synthetic chemical pesticides or animal growth hormones. And most certification standards include a 3-year ban on the use of prohibited substances on cropland before production can be certified as organic.

On the other hand, certification standards for organic livestock production have been more variable for pasture, feed, and other practices. Until 1999, the USDA Food Safety and Inspection Service (FSIS) withheld approval for the use of organic labels on meat and poultry products pending the outcome of this rulemaking. However, the Secretary announced a change in policy in January 1999. Meat and poultry products may be labeled "certified organic by (name of the certifying agent)" if handlers obtain prior label approval from FSIS and the claim meets certain basic criteria. Organic labels have been permitted on eggs and dairy products—which are regulated by the Food and Drug Administration (FDA)—throughout the 1990's, but most certifiers have not yet offered certification services for these products.

We provide a summary of the New Hampshire organic program to highlight the similarities in the core set of practices. It is important to note that this discussion is intended to highlight the conceptual similarities between State and private programs and is not intended to suggest that these programs are identical to each other or to the NOP. Production standards include: a written rotation plan; tillage systems that incorporate organic matter wastes into the topsoil; compliance with limits on the sources of manure and the timing of its application; prohibitions on the use of certain substances (e.g., sewage sludge, synthetic sources of nitrates, synthetic

growth regulators, and anhydrous ammonia); a list of accepted and prohibited weed and pest control practices; segregation of organic and nonorganic production; recordkeeping regarding fertilization, cropping, and pest management histories; separate sales records for organic and nonorganic production; and records of all laboratory analyses. Residue testing may be required if USDA believes that the products or soil used for producing certified products may have become contaminated with prohibited substances.

The New Hampshire program requires growers to pay a \$100 annual inspection fee and to provide a written description of their farm operation, including the size of the farm; a field map; a 3-year history of crop production, pest control, and fertilizer use; a crop rotation and a soil management plan; and a description of postharvest storage and handling methods. Applicants for certification must also agree to comply with regulations controlling the use of the New Hampshire certified organic logo.

Organic Food Handling

In addition to growers, who actually produce and harvest products to be marketed as organic, there are handlers who transform and resell the organic products. Not all certifiers have standards for handling organic products. And some certifiers have standards for parts of the food marketing system, such as restaurants, which are not explicitly covered by the OFPA nor encompassed by this final regulation.

Definitions of processing and handling differ across certifying agents and State laws. Some States, such as Washington, distinguish between a processor and a handler, specifying 21 actions which constitute processing and defining a handler as anyone who sells, distributes, or packs organic products. Other States do not distinguish between food processors and handlers. Under the final rule, the term, "handler," includes processors but not final retailers of agricultural products that do not process agricultural products.

Organic Product Marketing

The two largest marketing outlets for organically produced goods are natural foods stores and direct markets—which include farmers markets, roadside stands, and 'community supported agriculture' arrangements—according to industry data. USDA does not have official national level statistics on organic retail sales, but an industry trade publication, the Natural Foods Merchandiser (NFM), reported estimates of total retail sales of organic foods for years 1990–96 and continues to report estimates of natural product stores sales (table 1). The last NFM estimate of total organic sales through all marketing outlets was \$3.5 billion in 1996 (\$3.7 billion in 1999 dollars), less than one percent of total food expenditures by families and individuals that year.

Natural foods stores increased in size and presence in the United States during the 1990's—many are now the size of conventional supermarkets—and about two-thirds of estimated total organic sales during the 1990's were through this outlet (table 1). Natural foods supermarkets, which are

similar to conventional in the breadth of supermarket offerings and amount of total sales, accounted for close to 1 percent of total supermarket sales by 1997 (Kaufman 1998). Organic product sales through the natural foods stores outlet, alone, in 1999 were estimated at \$4 billion, and sales through this outlet increased about 20–25 percent annually through the 1990's.

Direct-to-consumer market sales ranged from \$270 to \$390 million during the early 1990's, accounting for between 17 and 22 percent of total organic sales during this period, according to NFM estimates (table 1). Conventional food stores (mass markets) accounted for 6–7 percent of total sales during this period, and export sales accounted for 3–8 percent of the total. A draft report on the U.S. organic export market, partly funded by USDA, indicates that current U.S. export sales are under 5 percent of total organic product sales (Fuchshofen and Fuchshofen 2000).

The United States is both an importer and an exporter of organic foods. The United States does not restrict imports of organic foods. In fact, U.S. Customs accounts do not distinguish between organic and conventional products. The largest markets for organic foods outside the United States are in Europe, Japan, and Canada. There is increasing pressure, particularly in Europe and Japan, for U.S. exports to demonstrate that they meet a national standard rather than a variety of private and State standards. France, for example, has indicated to USDA that it prefers to negotiate with a single national organic program, rather than the dozens of different State and private certifying programs currently operating in the U.S.

The EU is the largest market for organic food outside the United States. The organic food market in the EU was estimated to be worth \$5.2 billion in 1997 (International Trade Centre UNCTAD/WTO 1999). The largest organic retail sales markets in the EU in 1997 were Germany (\$1.8 billion), France (\$720 million), and Italy (\$750 million). Large organic markets outside the EU include Canada and Australia, with approximately \$60 million and \$68 million, respectively, in organic retail sales in 1997 (Lohr 1998). Import share of the organic food market in Europe ranged from 10 percent in France to 70 percent in the United Kingdom, was 80 percent in Canada, and varied from 0 to 13 percent in various Australian States.

Japan is another important market for U.S. organic products. Currently, Japan has voluntary labeling guidelines for 6 categories of nonconventional agricultural products: organic, transitional organic, no pesticide, reduced pesticide, no chemical fertilizer, and reduced chemical fertilizer. Total sales, including foods marketed as "no chemical" and "reduced chemical," are forecast to jump 15 percent in 1999 to almost \$3 billion. Imports of organic agricultural products were valued at \$90 million in 1998. Given Japan's limited agricultural acreage, imports will likely provide an increasingly significant share of Japan's organic food supply (USDA FAS 1999a).

Recently, these markets have adopted or are considering adoption of procedures that

may impede the importing of organic food. The EU regulations establishing the basis for equivalency in organic production among EU members and for imports from outside the EU were adopted in 1991 (Council Regulation 2092/91). The EU regulations only allow imports from non-EU countries whose national standards have been recognized as equivalent to the EU standards (Commission Regulation 94/92).

The Ministry of Agriculture, Forestry, and Fisheries (MAFF) in Japan recently announced proposed standards and third-party certification requirements. Under Japan's proposed standards, certifying agents from countries without national organic standards administered by a federal government will face additional financial and administrative costs.

Requirements of the Final Rule

The final rule follows the structure established in the OFPA. By adopting this alternative, the Department is following the legislative direction in the OFPA. All products marketed as organic will have to be produced and handled as provided in the OFPA and these regulations. Compared to current organic practices, the final rule sets a somewhat more stringent system of requirements.

Among many alternatives, two alternatives to the final rule are discussed in this section: continuation of the status quo and use of industry-developed standards. Given the statutory responsibility, USDA is implementing the requirements of the OFPA. However, under the status quo alternative, there would be no national standard or national program of accreditation and certification. No Federal funds would be used, there would be no transfer from Federal taxpayers at large to organic market participants, and there would be no Federal regulatory barriers to entry into organic production and handling. However, growers and handlers would still not have level access, under uniform standards, to the domestic market, and there may be significant enforcement gaps at the State level. International pressure for additional verification would continue to build and would be likely to lead to an increased use of public and private verification and accreditation services, which are provided on a user-fee basis with full cost recovery. Establishing reciprocity between certifying agents in the domestic organic market would continue to be costly and may stifle growth in trade of organic products, although the magnitude of these costs and their effects on growth are unknown. Without further analysis that includes quantification and monetization of benefits and costs, it is not clear whether the net benefits associated with this alternative are greater or less than those associated with the final rule.

Under the other industry-developed standards alternative, USDA could eliminate the costs associated with establishing reciprocity in the domestic market and establish equivalency for access to international markets, but it would be difficult for industry to develop consensus standards. For example, the industry-developed standards recently proposed by

the Organic Trade Association were developed with significant industry input but with little public comment. In contrast, several hundred thousand comments have been submitted in the course of the USDA rulemaking process. In addition, the OFPA mandated an advisory role for a 15-member National Organic Standards Board (NOSB), which has wide representation from the organic community and includes members who are farmers, handlers, retailers, environmentalists, consumers, scientists, and certifiers. The NOSB has assisted in developing the standards promulgated in this final rule and will play an advisory role for the NOP even after the final rule is in place. Without further analysis that includes quantification and monetization of benefits and costs, it is not clear whether the net benefits associated with this alternative are greater or less than those associated with the final rule.

USDA's final rule will be implemented by the NOP staff in the Agricultural Marketing Service (AMS). Major features of the NOP include:

Accreditation and Certification

The rule specifies the accreditation and certification process. Persons providing certification services for organic production and handling must be accredited by USDA through the NOP. Applicants for accreditation must document their abilities to certify according to the national standards and to oversee their client's compliance with the requirements of the OFPA and NOP regulations. Producers and handlers of organic products must be certified by an accredited certifying agent. Producers and handlers are required to document their organic plans and procedures to ensure compliance with the OFPA.

All certifying agents would have to be accredited, and certification by producers and handlers would be mandatory. The exceptions are: (1) growers and handlers with gross organic sales of \$5,000 or less would be exempt from certification, and (2) a handling operation may be exempt or excluded from certification according to provisions described in the rule's subpart B, Applicability.

USDA will charge applicants for accreditation and accreditation renewal (required every 5 years) a \$500 fee at the time of application. USDA will also charge applicants for costs over \$500 for site evaluation of the applicant's business. The applicant would be charged for travel costs, per diem expenses, and any miscellaneous costs incurred with a site evaluation. USDA will also charge accredited certifiers at an hourly rate to review their annual reports.

Producers and handlers will not pay certification fees to USDA. Certification fees will be established by the accredited certifying agents. USDA will not set fees. The rule requires certifying agents to submit a copy of their fee schedules to USDA, post their fees, and provide applicants estimates of the costs for initial certification and for renewal of certification.

Production and Handling

The rule establishes standards for organic production of crops and livestock and

handling of organic products. These standards were developed from specific requirements in the OFPA, recommendations from the NOSB, review of existing organic industry practices and standards, public comments received on the 1997 proposal and subsequent issue papers, public meetings, and comments received on the 2000 proposal.

The final rule establishes a number of requirements for producers and handlers of organic food. These requirements will affect farming operations, packaging operations, processing operations and retailers. Some of the major provisions are: (1) land requirements, (2) crop nutrient requirements, (3) crop rotation requirements, (4) pest management requirements, (5) livestock management requirements, (6) processing and handling requirements, and (7) commingling requirements.

National List

The National List lists allowed synthetic substances and prohibited nonsynthetic substances that may or may not be used in organic production and handling operations. The list identifies those synthetic substances, which would otherwise be prohibited, that may be used in organic production based on the recommendations of the NOSB. Only those synthetic substances on the National List may be used. The National List also identifies those natural substances that may not be used in organic production, as determined by the Secretary based on the NOSB recommendations.

Testing

When certifying agents have reason to believe organic products contain a prohibited substance, they may conduct residue tests.

Labeling

The rule also states how organic products may be labeled and permitted uses of the USDA organic seal. In addition to the USDA seal and the certifying agent's seal, information on organic food content may be displayed. Small businesses that are certified may use the USDA seal.

Recordkeeping

The rule requires certifying agents, producers, and handlers to keep certain records. Certifying agents are required to file periodic reports with USDA. Producers and handlers are required to notify and submit reports to their certifying agent. While recordkeeping is a standard practice in conventional and organic farming, the final rule adds recordkeeping and reporting requirements that do not exist for growers and handlers operating without certification. Similarly, certifying agents would face additional recordkeeping and reporting requirements, particularly those certifying agents operating without external accreditation. The rule permits certifying agent logos and requires the name of the certifying agent on processed organic foods.

Enforcement

Organic operations that falsely sell or label a product as organic will be subject to civil penalties of up to \$10,000 per violation. The provisions of the final regulation apply to all

persons who sell, label, or represent their agricultural product as organic, including operations that aren't certified, and the civil penalties of up to \$10,000 apply to these operations as well. Certifying agents, State organic programs' governing State officials, and USDA will receive complaints alleging violations of the Act or these regulations. In States where there is no State organic program, USDA will investigate allegations of violations of the Act.

Number of Affected Parties and Projections

In assessing the impacts of the rule, we have attempted to determine the number of certifying agents, private and State, that are currently operating and considered the factors likely to affect the number of certifying agents after the rule is implemented. We have attempted to determine the number of currently operating producers and handlers that would be affected. And, we have considered the factors that might affect the number of producers and handlers after the program has been implemented.

For the analysis, USDA assumes the following:

1. Forty-nine domestic certifying agents and ten foreign certifying agents will be affected by the regulation.

2. Approximately 13,650 certified and noncertified organic producers will be affected by the regulation. With the assumed growth rate of 14 percent for certified organic producers and approximately 8 percent for noncertified organic producers, the number of organic producers will grow to 17,150 in 2002.

3. Approximately 1,600 handlers of organic food will be affected by the regulation. This number will grow to 2,250 by 2002.

Certifying Entities

We place the number of certifying agents currently operating at 49, including 13 State programs. The number of certifying agents has remained fairly stable, between 40 and 50, for some years, with entries and exits tending to offset each other. For purposes of estimating the paperwork burden described elsewhere, we assume no growth in the number of domestic certifying agents but project 10 foreign certifying agents will seek and receive USDA accreditation in the first 3 years of the program.

Organic Producers

While some USDA data on the number of certified organic producers in the United States exist, no national data have been collected on the number of producers that produce and market organic goods without third-party certification. Organic farming was not distinguished from conventional agriculture in the last Census of Agriculture in 1997. USDA and Organic Farming Research Foundation (OFRF) data were used in the Regulatory Impact Analysis (RIA) of the March 2000 proposed rule to help estimate the number of certified U.S. growers affected by the regulation. California Department of Food and Agriculture (CDFA) data were used to help estimate the number of uncertified U.S. growers affected by the regulation. All three of these data sources have updated their estimates of the number

of certified and uncertified organic producers since the RIA of the proposed rule was published earlier this year. However, the updated numbers do not indicate trends that would fundamentally alter the assumptions used in the RIA of the proposed rule to calculate the number of affected growers, and the estimates made for the March 2000 RIA are retained in this assessment of the final rule.

USDA datum indicates the average annual growth rate in the number of U.S. certified organic growers between 1991 and 1994 was about 14 percent (Dunn 1995b). In April 2000, USDA's Economic Research Service estimated that 5,021 certified organic growers operated 1.347 million acres of U.S. farmland in 1997, indicating that the increase in acreage had outpaced the increase in growers, and showing only an 8 percent annual growth rate in growers between 1994 and 1997 (Greene, 2000b). However, USDA's study indicated that the pace of growth in certified acreage had quickened considerably since 1997, with the amount of certified acreage increasing 38 to 150 percent between 1997 and 1999 by several large certifying organizations across the U.S. And a nonprofit organic research foundation, OFRF, estimates that the number of certified organic producers in the certification organizations that they track—the ones that will release data to them—grew over 20 percent annually between 1997 and 1999, from 4,638 to 6,600 (OFRF 2000). Also, one certifier, Washington State, responded to our request for data on the growth rate, indicating that the number of certified organic producers has increased an average of 17 percent per year between 1994 and 1999 in that State and noting that certification became mandatory by State law in 1993.

In the March 2000 RIA, USDA estimated that the number of certified U.S. organic producers potentially affected by this legislation is approximately 9,350 in 2000 and will be approximately 12,150 in 2002, based on a straight line projection of the 14-percent annual growth rate trend shown by USDA data for 1991–1994. The period, 2000–2002, was chosen for analysis because it encompasses both the period of final rulemaking and the 18-month implementation period. Congress passed the OFPA in 1990, and the 14-percent growth rate in certified growers during the 1991–1994 period reflects their expectation that national organic regulations were forthcoming. Since the recent estimates of industry growth during the 1990's are uneven and the actual growth rate in the number of growers who will become certified after this legislation is implemented is uncertain, the March 2000 estimates are retained in this assessment of the final rule.

The March 2000 RIA also estimated the number of producers who are practicing organic agriculture but who are currently uncertified that would be affected by the rule. In California, where organic growers are required to register with the State but not to be certified, a large proportion of growers are uncertified. The most recent State data, for the 1997/98 crop year, indicate that 1,526 growers registered as organic, but only 41 percent of them obtained third-party

certification (Klonsky et al., 2000). While only a small percentage of growers in the lowest organic sales category (0–\$10,000), where the largest number of growers were clustered, obtained certification, three-quarters or more of the growers earning at least \$50,000 obtained certification, and all of the growers in the highest sales class were certified. USDA did not use the California ratios of certified to uncertified growers in the March 2000 RIA to estimate the number of uncertified growers because the farming structure of California may not be representative of the Nation. For example, California sells at least three times more specialty crops than any other State in the United States and has an unusual registration program that many growers use instead of certification.

USDA made two assumptions about uncertified production for the March 2000 estimate. The first assumption was that the rate of growth in uncertified production is less than the rate for certified farms because certification has value and organic producers would be expected to take advantage of the marketing advantages of certification. This assumption is consistent with California data that showed an increase in the percent of organic farmers obtaining certification between 1996/97 and 1997/98 in virtually every sales class (Klonsky et al. 2000). Second, the emergence of State certification programs with lower certification fees than private certification entities may have encouraged more organic producers to be certified. Based on these assumptions, USDA assumed that the number of uncertified organic producers is about 4,300 in 2000 and will be about 5,000 in 2002, making the total number of farms potentially affected by the rule about 13,650 in 2000 and 17,150 in 2002.

Organic Handlers

Little information exists on the number of organic product handlers, such as organic soup manufacturers, organic food packaging operations, organic food wholesalers, and feed millers. USDA has estimated that there were 600 entities in this category in 1994 (Dunn 1995b). AMS estimated that the growth rate was 11 percent from 1990 through 1994 (Dunn 1995b). More recent data from CDFA registration records suggest a growth rate of about 28 percent (California Department of Health Services 1999). For projection purposes, we use a growth rate of 20 percent and estimate there are about 1,600 in 2000 and there will be about 2,250 handlers in 2002. Reasons for growth include the general increase in organic production and growth in the market for processed organic foods, including multiingredient products. Again, these projections are based on limited data from the early 1990's, and growth may have slowed or increased. These estimates of organic product handlers are slightly higher than the estimates made in the March 2000 RIA because they include about 100 feed millers that were not included in the earlier calculation.

Retail Food Establishments

Retailers of organic food are grocery stores, bakeries and other establishments that

process or prepare raw and ready-to-eat food. Most are not currently subject to either voluntary practices or mandatory standards of the organic industry. Although they are excluded from the certification requirements under the final rule, they are subject to other processing, handling, and other production related requirements of the final rule. Some of the grocery stores in the United States, particularly the natural foods stores, sell processed or prepared organic foods and will be affected by these requirements. USDA does not have an estimate of the number of entities affected.

Foreign Entities

In addition to domestic certifying agents, foreign certifying agents may also apply for accreditation under the NOP. At this time, we have no information regarding the number of foreign certifying agents that may seek USDA accreditation. Foreign applicants will face the same base costs for accreditation as domestic applicants but the overall levels of cost are expected to be higher due to the generally higher costs of foreign travel and per diem expenses for site evaluation and miscellaneous costs such as for translation of documents. For purposes of estimating the paperwork burden described elsewhere, we assume 10 foreign certifying agents will seek and obtain accreditation during the first 3 years of the program.

Benefits of the Final Rule

The benefits of implementing national uniform standards of production and certification include: (1) Providing a common set of definitions on organic attributes and standardizing the manner in which the product information is presented, which may reduce the cost associated with enforcement actions in consumer fraud cases; (2) reduced administrative costs; and (3) improved access to organic markets. Not all benefits that may arise from the rule are quantifiable. Where economic data are available, they may relate to costs and are generally not adequate to quantify economic benefits. The regulatory changes in the final rule are not expected to reduce the benefits from those described under the March 2000 proposed rule.

Information

Potential benefits to consumers as a result of the final rule include providing a common set of definitions on organic attributes and standardizing the manner in which the product information is presented. This standardization may reduce the cost associated with enforcement actions in consumer fraud cases.

Organic products cannot be distinguished from conventionally produced products by sight inspection, and consumers rely on verification methods such as certification to ensure that organic claims are true. Self-policing by certifiers of growers and handlers that are certified has been difficult because some certifiers have been under pressure to use weak standards and lax enforcement procedures in order to keep their producer and processor clients from taking their business to other certifiers (Scowcroft 1998).

Anecdotal evidence suggests that consumer fraud involving organic food does occur, and several States successfully pursued civil and

criminal prosecution of these cases during the 1990's. The Attorney General of Minnesota successfully prosecuted felony charges in 1997 against the president of Glacial Ridge Foods, a wholesale supplier of beans and grains, for repackaging conventionally produced product and selling approximately \$700,000 worth labeled as certified organic (Mergentime 1997). The San Diego City Attorney's office successfully prosecuted felony charges against Petrou Foods, Inc., an organic oil and vinegar distributor, for misbranding conventional product, based on an investigation by the California Department of Health Services (Scott 1997). Also the California Department of Food and Agriculture conducted spot checks of 51 uncertified organic growers during the mid-1990's, based on complaints, and found 32 violations of California's organic standards (Farmers Market Outlook). However, only about half of the States have any organic legislation, and few of those States have laws with enough teeth to permit prosecution of organic fraud. In States without similar laws, the costs associated with remedies via the tort system may be high. The NOP established in this final rule is expected to fill in important State and regional gaps in enforcement in organic fraud cases.

The USDA organic seal will also provide consumers a quick tool to verify that goods offered for sale as organic are in fact organic.

Reduced Administrative Costs

The rule addresses the problem of existing certifying agents using different standards and not granting reciprocity to other certifying agents. By accrediting certifying agents, the rule establishes the requirements and enforcement mechanisms that would reduce inconsistent certification services and lack of reciprocity between certifying agents. In the current system, the certifying agent of a final product is not required to recognize the certification of an intermediate product. Both primary farmers and food handlers may face a risk of being unable to sell a certified organic product when more than one certifying agent is involved. By imposing a uniform standard of certification and production, the costs associated with establishing reciprocity between certifying agents will be eliminated, and the market dampening effects that these costs impose will be eliminated. Industry-wide training costs may also decrease. USDA's uniform standards of production and certification should enable organic inspectors to move more easily from one certifying agent to another than under the current system.

Domestic and International Markets

The final rule is expected to improve access to domestic and foreign markets for organically produced goods. The current patchwork of differing State certification requirements and variable State and private standards has given producers and handlers uneven access to the domestic organic market and to the price premiums associated with this market. Livestock producers, in particular, may have limited their organic production because they lacked access to a State or private organic livestock certification

program or were uncertain about the standards that would be implemented under the NOP.

The final rule could also improve access to EU and other foreign markets for U.S. organic products. For example, the EU may determine that the NOP is acceptable vis-a-vis EU regulation 2092/91. Article 11 of EU Reg. 2092/91 establishes the conditions under which organic products may be imported from third countries and addresses the framework for equivalency. The NOP is a national program that should be acceptable to the EU and other governments. Foreign acceptance of the U.S. national standard would reduce costs of negotiating and documenting shipment by shipment. Reducing these transaction costs may reduce entry costs for U.S. producers to foreign organic markets. These benefits would not accrue until after negotiations for an equivalency agreement have been held and completed successfully, which could be a lengthy process.

An estimated 5 percent of total U.S. sales are from exports. Currently, despite restricted access to the European market, the United States is the most important non-EU supplier of organic products to EU countries (Foreign Agriculture Service (FAS), 1995). Import authorizations have been granted for a number of raw and processed commodities, including sunflowers, buckwheat, beans, sugar, and apples. Demand is strong throughout the European market, and the organic market share was 1–2 percent of total food sales in 1997 (Collins 1999). Medium-term growth rate forecasts range from 5–10 percent for Germany to 30–40 percent for Denmark, and is 20–30 percent in most of the EU countries, according to the International Trade Centre UNCTAD/WTO. However, most analysts are basing their projected future growth rates on straight-line extrapolations of current sales and growth rates without understanding the underlying market mechanisms and price elasticities (Lohr 1998).

Costs of the Final Rule

The costs of the regulation are the direct costs of complying with the specific standards. It is important to note that while some costs associated with accreditation and certification are quantified, costs stemming from other provisions of the final regulations are not. In addition, this is a short-run analysis. The analysis examines the costs that may be incurred through 2002. It is not possible at this time to conduct a longer run analysis because we do not know enough about the fundamental supply and demand relationships to make economically sound long-run projections.

Accreditation Costs

USDA has identified 36 private certifying agents and 13 State programs providing certification in the United States. These 49 entities are considered likely applicants during the first 18 months during which USDA will not charge application fees or hourly fees for accreditation. An unknown number of new entrants to the certifying business may also apply. However, over the last 10 years, the number of certifying agents

does not appear to have grown significantly, with the net effect of entries and exits maintaining a population of certifying agents at about 40–50.

The final rule allows USDA to collect fees from certifying agents for USDA accreditation. The first proposal would have permitted USDA to collect fees from producers and handlers as well, but USDA decided that it would be administratively simpler to collect fees only from certifiers and would enable State programs that want to keep client costs low to be able to do so.

Applicants for accreditation will be required to submit a nonrefundable fee of \$500 at the time of application, which will be applied to the applicant's fees for service account. This means that the \$500 fee paid at the time of application is credited against any subsequent costs of accreditation arising from the initial review and the site evaluation. The \$500 fee is the direct cost to applicants who are denied accreditation based on the initial review of the information submitted with their application. Charges for the site evaluation visit will cover travel costs from the duty station of USDA employees, per diem expenses for USDA employees performing the site evaluation, an hourly charge (per each employee) for services during normal working hours (higher hourly rates will be charged for overtime and for work on holidays), and other costs associated with providing service to the applicant or certifying agent.

At present, the base per diem for places in the United States is \$85 (\$55 for lodging and \$30 for meals and incidental expenses). Per diem rates are higher than \$85 in most large cities and urbanized places, but over half of the current U.S. certifiers are located in places that have an \$85 per diem rate, and that is the rate used to calculate average certifier expenses in table 3. A review of domestic travel by USDA staff during fiscal year 1999 indicates transportation costs ranging from \$500 to \$600 per person. Miscellaneous costs are estimated to add another \$50 to each site visit.

The hourly rate that USDA anticipates charging for accreditation is the rate that USDA currently charges for services under the Quality Systems Certification Program (QSCP). Our preliminary estimate that this rate will be no more than \$95 per hour is presented to give the public some indication of the rate that will be charged following the 18-month transition period. QSCP is an audit-based program administered by AMS, which provides meat producers, handlers (packers and processors), and other businesses in the livestock and meat trade with the opportunity to have special processes or documented quality management systems verified. The procedures for accreditation evaluation are similar to those used to certify other types of product or system certification programs under QSCP.

Accreditation will include verification of adherence to ISO Guide 65 and the regulations. Although much of the site evaluation for accreditation will involve comparisons against ISO Guide 65, additional hours will be required because USDA will be evaluating additional aspects

of the applicant's operation to determine if the applicant is qualified to perform as an accredited agent for the NOP. Based on experience with the QSCP and more limited experience performing audits verifying that certifying agents meet ISO Guide 65, we project that a site evaluation visit for small applicants with a simple business structure will require 3 days of review, and for those large applicants with more complex business structure will require 5 days of review.

USDA will use two reviewers for each site evaluation visit during the 18-month implementation period, as well as for new applicants after that period. One reviewer will come from the QSCP audit staff and will be familiar with the ISO Guide 65 verification; the other reviewer will come from the NOP staff and will be familiar with requirements of the organic program. The two will conduct the site evaluation jointly. Two reviewers will also be needed for the site evaluation visits for the accreditation renewals, which will take place every 5 years. In the proposed rule, USDA had projected that only one reviewer would be needed for site evaluations and renewals that took place after the 18-month implementation period but has changed that projection based on additional experience with the ISO Guide 65 program.

During the 18-month implementation period, applicants will be charged for travel and per diem costs for two persons and for miscellaneous expenses but will not be charged application fees or hourly fees. The estimated expenditures for these initial accreditations is \$1,560–\$2,100, with \$510–\$850 for per diem expenses, \$1,000–\$1,200 for travel expenses, and \$50 for miscellaneous expenses (table 3). The cost of initial site evaluation visits will vary with the cost of travel from the USDA reviewer's duty station to the applicant's place of business. In general, more distant and remote locations will involve higher travel costs.

USDA estimates the costs of a site evaluation visit after the transition period may average \$6,120–\$9,700, depending on the characteristics of the applicant, including \$4,500–\$7,600 for the hourly site evaluation charges that are not billed to the certifier during the first 18 months (table 3). USDA has received appropriated funds to pay for the hourly site evaluation charges only during the first 18 months of the program.

Currently, few private certifying agents are operating with third-party accreditation. Fetter (1999) reports that in a sample of 18 certification programs, four programs were accredited, and one had accreditation pending. All of these were large, private certifying agents. Those certifying agents currently accredited by third parties will likely pay less for USDA accreditation. In its first proposal, USDA stated at FR 62:65860, "We are aware that certifiers currently may pay in excess of \$15,000 for accreditation by a private organization." Commenters thought this figure was too high. One commenter, which operates the International Federation of Organic Agriculture Movements (IFOAM) Accreditation Programme under license to IFOAM, stated, "It is possible that the largest programme operating a chapter system with activities in many countries (which is

included in their IFOAM evaluation) paid this amount in their first year. On the other hand the average cost to a medium sized certifier works out at around \$3000 to \$4000 per year." Another commenter stated, "At the present time IFOAM accreditation costs less than \$10,000/year for the largest certifier and \$3–5,000 for smaller certifiers."

The 18-month NOP implementation period affects the distribution of program costs between the organic industry and the taxpayer. Some of the costs of accreditation would be absorbed by the NOP operation budget appropriated by Congress. In effect, the taxpayers are subsidizing the organic industry. Without this subsidy, the total cost of accreditation would approach \$1 million.

The direct accreditation costs to an estimated 59 certifying agents (including all 49 current U.S. certifiers and an estimated 10 foreign certifiers) during the first 18 months following the final rule, are approximately \$92,000 to \$124,000. This figure is derived from the per-firm costs in table 3. In addition, USDA will use appropriated funds to cover approximately \$270,000–\$448,000 in hourly charges for site evaluation. USDA will also use appropriated funds to cover the costs of producing and publishing an accreditation handbook in several languages, translating USDA reports to foreign clients, and developing and funding a peer review panel to evaluate NOP's adherence to its accreditation procedures. And if more than the estimated 59 certifiers apply for accreditation during the first 18 months of the program, USDA will use appropriated funds to cover additional hourly charges for site evaluation.

Private certifying agents and State programs that do not mirror the regulation may incur additional costs to change their programs to adopt the national standards. The discussion on the effect of the regulation on existing State programs is in "State Program Costs." The cost associated with changing existing private certifying programs is not quantified.

Also, certifying agents who have been operating without third party accreditation will face new costs. For certifying agents who currently obtain third-party accreditation, the direct costs of USDA accreditation, which are only incurred every 5 years, may be lower on an annual basis compared to the direct costs for third-party certification of \$3,000–\$5,000 per year indicated by the commenters. The direct costs for certifying agents obtaining accreditation during the first 18 months, when USDA will not impose an application fee or hourly charges, will be limited to travel, per diem, and miscellaneous expenses.

A national accreditation program may shrink the market for a third-party accreditation. Certifying agents will have little incentive to maintain or seek a second accreditation by a private organization unless that accreditation sufficiently enhances the market value of the certifying agent's services. Thus, the market will determine whether other accrediting entities continue to have a U.S. market for their services.

Training programs are currently offered by the Independent Organic Inspectors Association (IOIA), an organization of

approximately 165 organic certification inspectors, and by some of the larger certifying agents (IOIA). Costs to existing certifying agents to provide additional training to other staff are difficult to measure in the absence of information on current staff skill levels or the existence of formal training other than inspector training. Some agencies rely on volunteer staff who may have had no formal training, but the extent of this practice is unknown. AMS intends to offer assistance to certifying agents, producers, and handlers by providing accreditation training for certification agents and other printed material that would enable participants to better understand the regulations. In addition, AMS intends to continue open and frequent communication with certifying agents and inspectors to provide as much information as possible to aid them in fulfilling the requirements of the regulations.

The OFPA requires that private certifying agents furnish reasonable security for the purpose of protecting the rights of participants in the organic certification program. It is expected that there will be costs to certifying agents from these requirements.

Implementation of the final rule will also impose a less tangible cost on some certifiers. Some private certifiers have advertised their program and logo as representing higher standards than other programs. The brand value associated with the logos of these certifiers will be lost when uniform standards are implemented as part of the national program. However, certifiers will still be able to distinguish themselves to clients based on the quality of their services and other characteristics.

A key change was made in the final rule, based on comments to the March 2000 proposal, to make the standard used by certifiers to determine maximum allowable pesticide residues (the level above which a product could not be called organic) consistent with the current industry standard and with NOSB recommendations. In the final rule, the standard will be set at 5 percent of the pesticide residue tolerances calculated by the Environmental Protection Agency (EPA). This change could conceptually reduce costs, but the magnitude of this reduction is uncertain.

Certification Costs

Under the final rule, USDA will not impose any direct fees on producers and handlers. Certifying agents will establish a fee schedule for their certification services that will be filed with the Secretary. Certifying agents will provide all persons inquiring about the application process with a copy of their fees. The certifying agent will provide each applicant with an estimate of the total cost of certification and an estimate of the annual costs of updating the certification. Under the proposed rule, certifiers could charge a maximum of \$250 at the time of application, but under the final rule, certifiers are not limited in the amount of certification fees that they may charge at the time of application.

Some States charge minimal fees for certification by subsidizing operating costs from general revenues. The majority of

certifying agents structure their fee schedules on a sliding scale based on a measure of size, usually represented by the client's gross sales of organic products but sometimes based on the acres operated (Fetter 1999 and Graf and Lohr 1999). Some certifying agents charge an hourly rate for inspection and audit services.

Graf and Lohr have applied fee schedules provided by ten certifying agents to four hypothetical farms, small, medium, large, and a super farm. Tables 2A and 2B summarize the fees that Graf and Lohr found by applying schedules of each certifying agent to hypothetical farms. Total first-year costs and subsequent-year (renewal) costs for certification are shown. The average cost for each size class should be interpreted with care because it is not weighted by the number of clients certified. In their study, the Texas Department of Agriculture program is the low-cost certifying agent for all-size operations. The high-cost certifying agent differs across farm sizes. None of these certification programs mentions costs for residue testing, which the NOP will require in the form of preharvest testing when there is reason to believe that agricultural products have come into contact with prohibited substances. Preharvest testing is expected to be infrequent. Some certifying agents currently require soil nutrient testing and water quality testing. The estimated total initial costs for a producer or handler to become certified are presented in table 3.

We have not extended the average costs reported in Tables 2A and 2B to aggregate certification costs for all organic farms because the number of organic farms is not known with precision, nor is their geographic location, and there are no data to distribute the population of organic farms across size classes. The data from California suggest that a large number of small farmers produce and market organic goods without third-party certification, but those data may not be representative of the national trend. Although many of the smallest farms would qualify for the small farm exemption from certification, if consumers accept the labeling practices required by this final rule, small farmers may obtain certification to stay in the organic market, which may involve some cost.

In response to comments, the March 2000 proposal was changed to provide that if a conflict of interest is identified within 12 months of certification, the certifying agent must reconsider the application and may reinspect the operation if necessary. Additionally, if a conflict of interest is identified, the certifying agent must refer the operation to a different accredited certifying agent. These provisions would likely increase costs to certifiers; however, the magnitude of this increase is unknown.

Production and Handling Costs

Producers and handlers currently active in the organic industry may bear costs under the national standards. We believe that while most provisions of the program mirror current industry practices, there are some differences. In addition to the cost associated with becoming familiar with the national program, any adjustments stemming from these differences will result in costs. These

costs were qualitatively discussed in the March 2000 RIA for major provisions of the rule and are described below. The March 2000 proposal adhered closely to recommendations from the NOSB and largely reflected current industry standards. Marginal changes have been made in the final rule in response to comments on the March 2000 proposal. These changes have been made in concert with NOSB recommendations and, in general, have been made to clarify or add flexibility to producer and handler provisions or to make them better reflect current industry standards.

Producers

Producers of organic food will face numerous provisions that will regulate their production methods. As indicated in the Baseline section, many of the requirements are currently followed by certified organic farmers. Farming operations that are not certified but are registered with a State government, such as California, receive copies of the State laws to which they must comply. The costs associated with adjusting to provisions in the final rule may be minimal for certified and State-registered growers but may be more substantial for noncertified organic producers that do not follow a specific set of guidelines or regulations. Some organic producers are neither certified nor registered and, therefore, may not practice the requirements in the final rule. Major provisions of the final rule—the withdrawal period required for land to be free of prohibited substances, National List, animal drug use, and residue tests—are discussed to illustrate costs; other provisions may also impose additional costs.

A 3-year withdrawal period, during which prohibited materials cannot be applied to a field to be certified as organic, is currently required by most private and State organic standards, and the final rule also specifies a 3-year period. The effect of this provision on the currently certified organic farming operations may be minimal, but the effect on farming operations that are neither certified nor registered may be significant. Farming operations that have completed a 3-year withdrawal period will not be affected by this requirement. To stay in the organic industry, those who have not completed the 3-year period must comply with this requirement. They may incur the cost of organic production for a significant length of time, yet not be allowed to sell their products as organic. Hence, some small organic operations may exit the industry.

The impact of the National List, which lists allowed synthetic substances and prohibited nonsynthetic substances that may or may not be used in organic production and handling operations, will be determined by how the national standards differ from current certification standards and from actual practice. Lists of approved synthetic materials, including soil amendments and pesticides, vary from one certification program to another, but a detailed analysis of specific differences in the various existing materials lists shows them to be overlapping in most cases with each other and with the National List. The degree of overlap should mitigate the costs for certified operations, but

farming operations, particularly those that aren't certified, may need to make some adjustments to comply with the list. These adjustments will impose costs on these operations. The magnitude of the costs resulting from these adjustments is not quantified.

Where livestock standards have been adopted by existing State programs and by private certifying agents, most prohibit the use of animal drugs except for the treatment of a specific disease condition, and use of animal drugs is generally prohibited within 90 days prior to the sale of milk or eggs as organic. Some State and private certifiers allow the use of animal drugs in animals for slaughter under certain conditions, while others prohibit the use of animal drugs. The standards in the final rule would prohibit the sale as organic of edible products derived from an animal treated with antibiotics or other unapproved substances. The standards may not differ from existing State or private standards in prohibiting the use of drugs on healthy animals. However, the effect of this provision may differ among certified and registered organic farms. The effect on the certified farming operations is unknown. We assume that this provision may have costs, but the magnitude of these costs is not quantified.

Additional costs may be imposed by several further changes to the March 2000 proposal. These changes involve the use of treated lumber, confinement requirements, and the commercial availability of ingredients in products labeled "organic."

The replacement of lumber treated with prohibited substances that comes into contact with soil, crops, or livestock under organic management with treated lumber is now specifically prohibited in organic systems. Since the use of lumber treated with prohibited substances for the purpose of preventing degradation is not a common practice in livestock production, this prohibition is not expected to increase producer costs substantially. The exact magnitude of any increase is uncertain and mainly dependent upon the number of producers seeking organic certification that currently use treated lumber in their operations and are planning to replace that lumber.

The confinement provisions in the March 2000 proposal have been slightly modified. Access to the outdoors is now an explicitly required element for all organically raised livestock. We expect this change to have a minor impact on overall producer costs, since we assume most producers raising organic livestock already provide access to the outdoors. Additionally, the term, "pasture," has been defined to emphasize that livestock producers must manage their land to provide nutritional benefit to grazing animals while maintaining or improving soil, water, and vegetative resources of the operation. To the extent producers desiring to raise organic livestock do not currently manage pasture in this manner, we expect livestock production costs to increase.

The organic plan now requires using organically produced minor agricultural ingredients unless not commercially available. This applies to the previously

allowed 5-percent nonorganic agricultural and other ingredients in products labeled "organic." Handlers of organically produced minor ingredients, especially herbs and spices, are likely to benefit from this market incentive, while producers of nonorganic minor ingredients will likely be adversely affected. Producers will also realize a burden associated with providing the documentation of commercial availability for ingredients in the 5-percent component. Since the criteria to determine commercial availability will be developed after additional comments and information are considered, the magnitude of the cost and benefit implications from this standard are currently unquantifiable but will likely be largely dependent upon the stringency of the developed criteria.

Producers will also have administrative costs for reporting and recordkeeping, although producers who currently are active in the organic industry already perform most of these administrative functions, and additional costs to them would depend upon the extent to which their current practices are different from the requirements of the final rule. The annual reporting and recordkeeping burden on producers is estimated at 24 hours for certified producers and 1 hour of recordkeeping for small producers who choose to operate as exempt entities and is valued at \$23 per hour.

Other provisions of the final rule, such as those on residue testing, livestock housing and feed, and health care practices, may vary enough from those followed by some growers that they may impose costs due to the variability in current housing, feed, and health care practices, but lacking information, we have not quantified these costs.

There were also several key changes made in the final rule, based on comments to the March 2000 proposal, that will add flexibility to producer standards. A specific type of production facility was required for composting manure in the proposal, and this provision has been modified to ensure that manure is adequately composted while allowing variation in the type of facility that is used. Also, the transition period of a dairy operation to make a whole-herd conversion to organic production has been reduced in order to make conversion affordable for a wider range of dairy farms, including smaller operations. Finally, the requirement that slaughter stock sold, labeled, or represented as organic be under continuous organic management from birth was changed to require continuous organic management from the last third of gestation. This change is also expected to provide possible cost savings and added flexibility for producers.

Handlers

Handlers of organic food are defined and regulated differently across different certifying agents and States. Due to this variability, handlers may incur some cost associated with complying with the requirements of the regulation. Several key changes were made in the final rule, based on comments to the March 2000 proposal, to make handler standards more consistent with current industry standards. The proposal prohibited the addition of sulfites to wine as

required by OFPA. The statute has been changed since March, and the final rule will permit added sulfites in wine labeled "made with organic grapes," consistent with industry standards and NOSB recommendations.

Also, the March proposal required products labeled "made with organic ingredients" to have ingredients that were at least 50 percent organic, and this threshold has been raised to 70 percent in the final rule. Some certifiers set their thresholds at 50 percent, others at 70 percent, while others restrict labeling to individual ingredients only. The international industry standard outside the United States is set at 70 percent. The threshold is set at 70 percent in the final rule in response to comments received on the proposal and to be consistent with international standards, which will help ease export of U.S. organic product into those markets. Alternatively, to the extent handlers do not currently meet the 70-percent threshold to label products "made with organic ingredients," handlers may incur additional costs to reach the threshold or exit the industry. The magnitude of those effects is unknown.

In addition to the labeling requirement, a handler's current use of nonsynthetic and synthetic substances may change in response to the final rule. The March 2000 proposal provided for the use of any prohibited substance to prevent or control pests. This provision has been changed to first limit the use of nonsynthetic and synthetic substances to substances which are on the National List before allowing the use of any synthetic substance. To the extent to which handlers are now required to consider substances on the National List before using a prohibited substance and these substances on the National List are priced differently from the substance otherwise used, handlers may incur a change in production costs. This requirement may increase costs on handlers, but the magnitude of this increase is unknown.

In addition, the commercial availability requirement in the final rule, described in the producer costs section, may also create a burden on handlers to consistently apply the standard. To the extent to which sourcing organically produced ingredients in excess of 95 percent of the finished product is more expensive than sourcing nonorganically produced ingredients, handlers seeking the "organic" label for their products will incur additional costs. As previously described, the magnitude of the cost implications from this standard is currently unquantifiable but will likely be largely dependent upon the stringency of the standard that is developed.

Handlers will also have administrative costs for reporting and recordkeeping, although handlers who currently are active in the organic industry already perform most of these administrative functions, and additional costs to them would depend upon the extent to which their current practices are different from the requirements of the final rule. The annual reporting and recordkeeping burden on handlers is estimated at 63 hours for certified handlers and 1 hour of recordkeeping for small handlers who choose to operate as exempt entities and is valued at \$23 per hour.

Retail Food Establishments

Most retailers are not currently subject to either voluntary practices or mandatory standards of the organic industry. Retailers that have organic processing operations, such as organic food delis and bakeries, are not required to be certified in the final rule. However, retailers will be subject to requirements such as prevention of contamination of organic products with prohibited substances, and commingling organic with nonorganic products. Obtaining certification and complying with these provisions will incur some cost.

Labeling Costs

Certified handlers will have to comply with requirements regarding the approved use of labels. In addition, any producers, handlers, and retailers who are not currently certified but who package organic products are also subject to the labeling requirements. The estimated annual cost for handlers to determine the composition of 20 products to be reported on labels is \$1,647,000. This figure is based on an average of 1 hour per product per handler and an hourly cost of \$27. Similarly, certified handlers will have to design their labels to comply with the regulation. This is expected to take 1 hour per label at \$27 per hour for a compliance cost of \$1,647,000. Total label costs for handlers are \$3.3 million. Any changes to existing labels and new labels that need to conform to the regulation will incur a cost. The costs associated with these activities are not quantified. Hence, the lower bound on the labeling cost is approximately \$4 million.

State Program Costs

The national program may impose additional costs on States by requiring changes in their existing programs. The rule encompasses most of the principles of existing State programs. However, there are also departures.

Where State standards are below Federal standards or where elements of the Federal standards are missing from a State program, these States would be required to make changes in their programs that they might otherwise not make. Where State programs have standards in addition to the Federal standards and they are not approved by the Secretary, States also would be required to make changes in their programs. States without organic standards or whose current standards either would conform to those of the national program or would be approved by the Secretary would not incur additional costs resulting from required changes. Currently, USDA cannot predict which States may be required to adjust their existing programs.

States that conduct certification activities will be charged for accreditation, something none of them pay for now. The cost associated with this provision is discussed in the Accreditation section.

Enforcement costs

Enforcement costs will fall upon USDA's NOP, States operating State organic programs, and on State and private certifying agents. Certifying agents will review clients' operations and will notify clients of

deficiencies. Certifying agents can initiate suspension or revocation of certification. Certifying agents will be aware of these overhead costs, and we assume that they will establish fee schedules that will cover these costs. Actual costs to certifying agents for enforcement activities will depend on the number of clients, how well informed clients are of their obligations, and client conduct. State certifying agents will face the same obligations and types of costs as private certifying agents.

In States operating State organic programs (SOP), State enforcement costs are costs associated with ensuring that certified operations fulfill their obligations. These States will bear the costs of investigating complaints, monitoring use of the State organic seal and organic labeling, and taking corrective action when needed. These States will bear costs related to reviewing an applicant's or certified operation's appeal and for administrative proceedings. Many of these activities are already a routine part of the certification program in States that have programs, and USDA will fill in gaps in enforcement in States that choose not to have programs.

USDA's enforcement costs are costs associated with ensuring that certifying agents fulfill their obligations. In States without an organic program, USDA will bear the costs of investigating complaints, monitoring use of the USDA organic seal and organic labeling, and taking corrective action when needed. USDA will bear costs related to reviewing an applicant's or certified or accredited operation's appeal and for administrative proceedings. USDA expects to effectively carry out its enforcement responsibilities using funds that are already allocated for operating the NOP. To the extent to which we did not estimate the likely noncompliance rate, the cost associated with enforcement remains unknown.

Reporting and Recordkeeping Costs

The Paperwork Reduction Act of 1995 requires an estimate of the annual reporting and recordkeeping burden of the NOP. The estimated annual reporting and recordkeeping burden reported is approximately \$13 million. This figure should be understood within the context of the requirements of the Paperwork Reduction Act. The Paperwork Reduction Act requires the estimation of the amount of time necessary for participants to comply with the regulation in addition to the burden they currently have. Information gathered by AMS in auditing activities in conjunction with ISO Guide 65 verifications leads us to believe that the paperwork burden on current certifying agents and certified operators will be 10 to 15 percent greater than their current business practices as a result of this final rule.

Certifying Agents. The regulation will impose administrative costs on certifying agents for reporting and recordkeeping. The actual amount of the additional administrative costs that would be imposed by the rule is expected to be different for those entities that would begin their activities only after the national program is implemented. Certifying agents that currently

are active in the organic industry already perform most of these administrative functions; therefore, the additional costs to them would depend upon the extent to which their current practices are different from the requirements of the regulation. An estimate of the cost of compliance is the annual reporting and recordkeeping burden documented in the Paperwork Reduction Act of 1995 analysis. Table 4 shows the estimated annual costs for certifying agents. Certifying agencies each have an estimated burden of 1,068 hours valued at roughly \$27,729.

The following list describes several of the most significant administrative requirements or optional submissions and the probable resources required for compliance. Details on the reporting and recordkeeping burdens estimated for each item are in the paperwork analysis.

1. A list of farmers, wild-crop harvesters, and handlers currently certified. This information can be compiled from existing records. After implementation, certifying agents will be required to submit on a quarterly basis a list of operations certified during that quarter.

2. A copy of procedures used for certification decisions, complying with recordkeeping requirements, maintaining confidentiality of client's business-related information, preventing conflicts of interest, sampling and residue testing, training and supervising personnel, and public disclosure of prescribed information concerning operations they have certified and laboratory analyses. These policies may have to be created or modified to conform to the regulation.

3. Documentation on the qualifications of all personnel used in the certification operation, annual performance appraisals for each inspector and personnel involved in the certification, and an annual internal program evaluation. Existing certifying agents may already perform these operations. New certifying agents will have to establish procedures to achieve these things.

4. Documentation on the financial capacity and compliance with other administrative requirements (e.g., fee structure, reasonable security to protect the rights of the certifying agent's clients as provided in the NOP, and business relationships showing absence of conflicts of interest). Some of this information can be compiled from existing records, e.g., fee schedules, and some may be generated from other sources.

5. Copies must be submitted to USDA of all notices that are issued on certification denial, noncompliance, and suspension or revocation of certification. This requirement will be fulfilled simultaneously with sending notices to applicants or clients.

6. An annual report to the Administrator including an update of previously submitted business information, information supporting any requested changes in the areas of accreditation, and steps taken to respond to previously identified concerns of the Administrator regarding the certifying agent's suitability for continued accreditation. The annual report requirement will draw on records created in the normal course of business.

7. Retention of records created by the certifying agent regarding applicants and

certified operations for not less than 10 years, retention of records obtained from applicants and certified operations for not less than 5 years, and retention of other records created or received for USDA accreditation for not less than 5 years. This activity requires records, database management capabilities, and resources (storage space, file cabinets, electronic storage, etc.). In an informal inquiry, AMS found that most existing certifying agents currently retain records for at least 10 years and use both electronic and paper storage. We believe that this requirement will not pose an additional burden on existing certifying agents.

8. Public access to certification records, such as a list of certified farmers and handlers, their dates of certification, products produced, and the results of pesticide residue tests. This requirement will have minimal impact given the requirements for retaining records.

9. Providing program information to certification applicants. To comply with this requirement, certifying agents may need to modify existing standards and practices. The criteria for qualified personnel in the rule may likely result in an increase in labor costs for some existing certifying agents and, initially, an increase in training costs. The amount of additional costs to these certifying agents would depend on the level of expertise among current certification agency staff, the extent to which certifying agents currently rely on volunteers, and the current costs of training certification staff.

Producers and Handlers. The regulation will impose administrative costs on producers and handlers for reporting and recordkeeping. The actual amount of the additional administrative costs that would be imposed by the final rule is expected to be different for those entities that would begin their activities only after the national program is implemented. Producers and handlers who currently are active in the organic industry already perform most of these administrative functions; therefore, the additional costs to them would depend upon the extent to which their current practices are different from the requirements of the final regulation. An estimate of the cost of compliance is the annual reporting and recordkeeping burden documented in the Paperwork Reduction Act of 1995 analysis.

The following list describes several administrative requirements or optional submissions and the probable resources required for compliance.

1. Establish, implement, and update annually an organic production or handling plan. Organic plans are a standard feature in the organic industry and are required by certifying agents. Thus, producers and handlers who are already involved in organics can rely on their current plan with revisions as needed to meet elements of the national program which are new to them or differ from their current practice. Although producers and handlers are generally aware of the goals of organic plans, current practice may fall short of the rigor that will be required by the national program. New producers and handlers will have higher costs because they will have to prepare a plan from scratch.

2. Maintain records pertaining to their organic operation for at least 5 years and allow authorized representatives of the Secretary, the applicable State organic program's governing State official, and the certifying agent access to records. Existing organic producers and handlers maintain records. New producers and handlers will have to develop records systems. Access is expected to be infrequent, will require little time of the certified entity, and will not require buildings or equipment other than what is required for storing records.

3. Notify the certifying agent as required (e.g., when drift of a prohibited substance may have occurred) and complete a statement of compliance with the provisions of the NOP. Notifications are expected to be infrequent.

The total reporting burden includes creation and submission of documents. It covers the greatest amount of reporting burden that might occur for any single creation or submission of a document during any one of the first 3 years following program implementation; i.e., 2000, 2001, and 2002. The total estimated reporting burden reflects the average burden for each reporting activity that might occur in 1 year of this 3-year period.

The total recordkeeping burden is the amount of time needed to store and maintain records. For the purpose of measuring the recordkeeping burden, the year 2002 is used as the reporting year for which the largest number of records might be stored and maintained.

The annual reporting and recordkeeping burden on producers, handlers, and certifying agents is summarized in table 4. The annual burden on certified producers is estimated at 24 hours and \$552. Certified handlers have an estimated burden of 63 hours valued at \$1,449. The burden on small producers and handlers who choose to operate as exempt entities is minimal, 1 hour of recordkeeping valued at \$23. If this cost is applied to the total estimated number of affected producers, the reporting and recordkeeping cost would be \$5,260,100 in 2000 and \$6,835,554 in 2002. By applying this cost figure to the estimated total number of affected handlers, the reporting and recordkeeping cost would be \$2,143,002 in 2000 and \$3,013,552 in 2002.

Barriers to Entry—Importers of Organic Products

Currently, there are no Federal restrictions on importing organic products to the United States in addition to those regulations applying to conventional products. If the imposition of the NOP decreases the importation of organic food into the United States, then this regulatory action may result in some cost.

Small Business Ramifications

USDA's final rule has an 18-month period during which applicants for accreditation would not be billed for hourly services. The rationale for this transition period is to reduce the costs to certifying agents and, thus, increase the prospect that certifying agents, producers, and handlers will be able to afford to participate in the national

program. The choice of 18 months is intended to provide sufficient time for parties desiring accreditation to submit their application and prepare for a site evaluation.

USDA will operate the program partially with appropriated funds, in effect sharing the cost of the program between taxpayers and the organic industry, to respond to public concerns regarding the effects of the regulation on small businesses. Thousands of comments were received opposing the first proposal's fee provisions with most focusing on the substantial impact on small certifying agents.

Congress has expressed public policy concern with the impacts of regulations on small entities generally and with the impacts on the NOP regulations on small entities particularly. The Small Business Regulatory Enforcement Fairness Act of 1996 and the Regulatory Flexibility Act express Congressional concern regarding regulatory burden on small businesses. The Report from the Committee on Appropriations regarding the Agriculture, Rural Development, Food and Drug Administration, and Related Agencies Appropriations Bill, 2000, includes the following language (U.S. Senate 1999):

"The Committee continues to recognize the importance of organic markets for small farmers and fishermen. The Committee expects the Secretary to construct a national organic program that takes into consideration the needs of small farmers and fishermen."

* * * Furthermore, the Committee expects that of the funding available for the National Organic Program, necessary funds should be used to offset the initial costs of accreditation services, a subsidy necessary due to the lack of expertise in the Department of Agriculture in the areas of organic accreditation and insufficient data on the industry."

Certifying agents applying for accreditation during the first 18 months following the final regulation will face lower direct costs than subsequent applicants. The cost for later applicants for accreditation will be higher because they will have to pay a \$500 application fee and hourly charges for completing their site evaluation. The requirement for accreditation was established in the OFPA in 1990 and the accreditation program was part of the 1997 proposal. Because in this final rule, USDA is using appropriated funds to cover some of the costs of initial accreditation during the first 18 months of the program, certifying agents may set lower fees initially benefiting the producers and handlers who are certified during this period.

It is important to note that many small organic operations may not be certified currently. In California, for example, many small farms are registered but not certified. Even if certifying agents pass on the cost savings of the 18-month period provision to applicants for certification, the cost of certification may be higher than the cost of registration. Hence, becoming a certified operation for small organic producers and handlers may be more costly than the current practices.

The costs imposed on small operations may be mitigated by a \$5000 certification exemption to aid the smallest organic operations. However, these operations are

still subject to other requirements of the regulation. To the extent that these requirements differ from their current practices, complying with the national standards may be costly for exempt operations.

In addition, the certification exemption allowed under the regulation includes limits on what an exempt operation may do. Without the certification, small organic operations may not display the USDA seal and may not use a certifying agent's seal. If the consumers of organic food view the seals as important information tools on organic food; that is, if consumers of organic products insist on only certified organic products, the inability of small operations to display these seals may prevent them from realizing the price premiums associated with certified organic products.

Industry Composition

The imposition of the national standards may change the composition of the organic industry. Even with the small business exemptions, some small organic operations may choose to exit the industry, and small organic operations may also be discouraged from entering the industry, resulting in a higher concentration of larger firms. On the other hand, it may be easier for small operations to comply with certain NOP standards, such as the livestock standards that prohibit confinement production systems and require 100 percent organic feed. And State and Federal certification and conservation cost-share programs and other government programs may help lower the impact on small producers.

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TABLE 1.—U.S. ORGANIC PRODUCT SALES, 1990-99
(\$ billions)

Year	Export	Direct	Export/ direct subtotal	Mass market	Natural foods stores	Natural foods stores (1999 \$)	Total sales	Total sales (1999 \$)
1990							1	1.27
1991	0.04	0.27	0.31	0.09	0.85	1.04	1.25	1.53
1992	0.07	0.32	0.39	0.12	1.03	1.22	1.54	1.83
1993	0.11	0.36	0.47	0.14	1.29	1.49	1.90	2.19
1994	0.20	0.39	0.60	0.17	1.54	1.73	2.31	2.60
1995	1	1	0.71	0.21	1.87	2.04	2.79	3.05
1996			1	1	1	1	3.5	3.72
1997					2			
1998					3.28	3.35		
1999					4.00	4.00		

Source: *Natural Foods Merchandiser*, *New Hope Communications*.—= Not reported.

¹ New Hope Communications reported a combined estimate for export and direct sales in 1995 and reported a different set of subcategories in 1996 and has reported only on sales in natural foods stores since 1996.

² New Hope Communications did not estimate natural product store sales in 1997, but the Hartman Group estimated these sales at \$4.9 billion.

TABLE 2A.—FIRST-YEAR CERTIFICATION COSTS, FROM GRAF AND LOHR ANALYSIS
(dollars)

Certifying agent	Small farm	Medium farm	Large farm	Super farm
CCOF	850	1,750	4,850	51,250
FVO	698	1,737	5,214	51,550
FOG	810	1,860	4,860	51,210
NOFA-VT	335	535	585	585
NC/SCS	700	900	1,000	2,000
OGBA	1,290	3,300	12,300	33,296
OTCO-In	608	1,603	2,517	150,300
OTCO-Out	768	1,698	2,852	12,052
OCIA-WI	315	1,590	6,090	75,090
OCIA-VA	258	320	495	1,745
TDA	90	155	200	575
WSDA	480	1,555	3,040	12,480
Average cost	579	1,414	3,623	33,276

Notes:

CCOF—California Certified Organic Farmers

FVO—Farm Verified Organic

FOG—Florida Certified Organic Growers & Consumers

NOFA-VT—Northeast Organic Farming Association—Vermont

NC/SCS—NutriClean/Scientific Certification Systems

OBBA—Organic Growers and Buyers Association

OTCO-In—Oregon Tilth Certified Organic, inside Oregon

OTCO-Out—Oregon Tilth Certified Organic, outside Oregon

OCIA-WI—Organic Crop Improvement Association, Wisconsin chapter

OCIA-VA—Organic Crop Improvement Association, Virginia chapter

TDA—Texas Department of Agriculture

WSDA—Washington State Department of Agriculture

Small farm—25 acres with annual sales of \$30,000.

Medium farm—150 acres with annual sales of \$200,000.

Large farm—500 acres with annual sales of \$800,000.

Super farm—3,000 acres with annual sales of \$10,000,000.

TABLE 2B.—SUBSEQUENT-YEAR CERTIFICATION COSTS, FROM GRAF AND LOHR ANALYSIS
(dollars)

Certifying agent	Small farm	Medium farm	Large farm	Super farm
CCOF	425	1,300	4,350	50,550
FVO	510	1,499	4,851	51,187
FOG	325	845	2,525	25,525
NOFA-VT	300	500	550	550
OTCO-In	454	1,611	2,362	11,363
OTCO-Out	424	1,353	2,207	11,208
OCIA-WI	290	1,565	6,065	75,065
OCIA-VA	233	295	470	1,720
TDA	90	155	200	515
WSDA	330	1,375	2,800	12,000
NC/SCS	700	900	1,000	2,000
Average cost	371	1,036	2,489	21,971

Notes:

CCOF—California Certified Organic Farmers

FVO—Farm Verified Organic

FOG—Florida Certified Organic Growers & Consumers

NOFA-VT—Northeast Organic Farming Association—Vermont

NC/SCS—NutriClean/Scientific Certification Systems

OBBA—Organic Growers and Buyers Association

OTCO-In—Oregon Tilth Certified Organic, inside Oregon

OTCO-Out—Oregon Tilth Certified Organic, outside Oregon

OCIA-WI—Organic Crop Improvement Association, Wisconsin chapter

OCIA-VA—Organic Crop Improvement Association, Virginia chapter

TDA—Texas Department of Agriculture

WSDA—Washington State Department of Agriculture

Small farm—25 acres with annual sales of \$30,000.

Medium farm—150 acres with annual sales of \$200,000.

Large farm—500 acres with annual sales of \$800,000.

Super farm—3,000 acres with annual sales of \$10,000,000.

TABLE 3.—COSTS OF ACCREDITATION AND CERTIFICATION

Estimated costs to certifying agents during first 18 months	
Application fee ¹	\$0.
Site evaluation costs (two person team):	
Per diem (3 to 5 days at \$85/day)	\$510 to \$850.
Travel (domestic)	\$1,000 to \$1,200.
Hourly charges (not billed during the first 18 months)	\$0.
Miscellaneous charges (copying, phone, and similar costs)	\$50.
Total	\$1,560 to \$2,100.
Estimated costs to certifying agents for initial accreditation after first 18 months	
Site evaluation costs (two person team):	
Per diem (3 to 5 days)	\$510 to \$850.
Travel (domestic)	\$1,000 to \$1,200.
Hourly charges (24 to 40 hours at \$95/hour)	\$4,560 to \$7,600.
Miscellaneous charges (copying, phone, and similar costs)	\$50.
Total	\$6,120 to \$9,700.
Annual review fees for certifying agents (2 to 8 hours at \$95/hour) ²	\$190 to \$760.
Estimated costs to producers for certification ³	
Certification fee (renewals)	\$730.
Estimated costs to handlers for certification ⁴	
Certification fee (initial certification)	\$2,337.
Certification fee (renewals)	\$1,665.

¹ Nonrefundable fee that will be applied to the applicant's fee-for-service account.² Certifying agents are required to submit annual reports to USDA. Review of these reports is expected to range from 2 to 8 hours at an approximate rate of \$95 per hour.³ Estimated certification fees are calculated from Graf and Lohr 1999 which, for a selection of certification agents, provides certification costs for four hypothetical farm sizes: (1) small farm (family farm): 25 acres, \$30,000 annual sales, 5 hours to certify; (2) medium farm (cottage industry): 150 acres, \$200,000 annual sales, 6 hours to certify; (3) large farm (commercial farm): 500 acres, \$800,000 annual sales, 8 hours to certify; and (4) super farm: 3,000 acres, \$10,000,000 annual sales, 16 hours to certify. Our estimated certification fees only include those charged for small and medium farms because most organic producers fall into these categories as defined by Graf and Lohr. In the 1997 OFRF survey, 90 percent of respondents had gross organic farming income of less than \$250,000, with 82 percent less than \$100,000.

The average current certification cost for most organic producers is about \$1,025 for the first year of certification (\$579 for small and \$1,414 for medium farms) and about \$705 for subsequent years (\$371 for small and \$1,036 for medium farms). Approximately \$25 is added to cover the costs associated with the National Organic Program for an estimated first-year certification fee of \$1,000 and subsequent-year certification fee of \$730 for producers. Larger producers could expect higher fees.

⁴ Because Graf and Lohr do not estimate certification fees for handlers, we estimate these fees by applying a ratio of handler-to-producer certification fees from the regulatory impact assessment from 1997. The ratio is 2:28 and results in estimated fees of \$2,337 and \$2,665, respectively.

TABLE 4.—ESTIMATED ANNUAL REPORTING AND RECORDKEEPING BURDEN

Type of respondent	Annual hourly per respondent	Hourly rate	Annual cost
Certified producer	24	\$23	\$552
Certified handler	63	23	1,449
Exempt producers and handlers	1	23	23
Certifying agency	1,068	27	27,729

Note: Estimates derived from Paperwork Reduction Act of 1995 analysis.

Appendix B—Unfunded Mandates Reform Act

This rule has been reviewed under the Unfunded Mandates Reform Act (Pub. L. 104–4). The Act requires that agencies prepare a qualitative and quantitative assessment of the anticipated costs and benefits before issuing any rule that may result in annual expenditures by State, local, and tribal governments, in the aggregate, or by the private sector of \$100 million (adjusted annually for inflation) in any 1 year. According to the Act, the term, “Federal mandate,” means any provision in legislation, statute, or regulation that would impose an enforceable duty upon State, local, or tribal governments or the private sector, except a duty arising from participation in a voluntary Federal program.

The National Organic Foods Production Act (OFPA) of 1990 mandates that the Secretary develop a national organic program to accredit eligible governing State officials or private persons as certifying agents who would certify producers or handlers of agricultural products that have been produced using organic methods as provided for in the OFPA. The OFPA also permits a governing State official to voluntarily establish a State organic program (SOP) if the program is approved by the Secretary and meets the requirements of the OFPA. The OFPA does not require that States establish their own SOP’s or that State, local, or tribal governments or the private sector become accredited; therefore, the OFPA is not subject to the Unfunded Mandates Reform Act because it is a voluntary program.

Although the U.S. Department of Agriculture has determined that this rule is not subject to the Unfunded Mandates Reform Act, USDA has sought to consider the rule’s impact on various entities. USDA prepared a Regulatory Impact Assessment (RIA) that is discussed in the section entitled “Executive Order 12866” (also attached as an appendix to this regulation). The RIA consists of a statement of the need for the action, an examination of alternative approaches, and an analysis of the benefits and costs. Much of the analysis is necessarily descriptive of the anticipated impacts of the rule. Because basic market data on the prices and quantities of organic goods and services and the costs of organic production are

limited, it is not possible to provide quantitative estimates of all benefits and costs of the rule. The cost of fees and recordkeeping required by USDA are quantified, but the anticipated benefits are not. Consequently, the analysis does not contain an estimate of net benefits.

The analysis employed in reaching a determination that this rule is the least costly and least burdensome to the regulated parties is discussed in the sections entitled “The Regulatory Flexibility Act and the Effects on Small Businesses” and “Paperwork Reduction Act of 1995.” The rule has been designed to be as consistent as possible with existing industry practices, while satisfying the specific requirements of the OFPA.

We have had numerous occasions during which to communicate with various entities during the development of the rule; States, for example. Currently, there are 32 States with some standards governing the production or handling of organic food and 13 States with organic certifying programs. Representatives of State governments have participated in public meetings with the National Organic Standards Board, while the NOP staff has made presentations, received comments, and consulted with States and local and regional organic conferences, workshops, and trade shows. States have been actively involved in training sessions for organic inspectors; public hearings concerning standards for livestock products during 1994; a national Organic Certifiers meeting on July 21, 1995; a USDA-hosted meeting on February 26, 1996; a State certifiers meeting in February 1999; and an International Organization for Standardization (ISO) 65 assessment training session for certifiers in April-May 1999. More detail about contact with States regarding this rule is in the Federalism section. It is unknown at this time how many States, if any, might voluntarily establish their own SOP’s pursuant to the OFPA and the regulations.

Appendix C—Final Regulatory Flexibility Analysis

The Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*) requires agencies to consider the economic impact of each rule on small entities and evaluate alternatives that would accomplish the objectives of the rule without

unduly burdening small entities or erecting barriers that would restrict their ability to compete in the market. The purpose is to fit regulatory actions to the scale of businesses subject to the action.

1. Need for and objectives of the National Organic Rule.

Currently, organic certification is voluntary and self-imposed. Members of organic industries across the United States have experienced numerous problems marketing their organically produced and handled agricultural products. Inconsistent and conflicting organic production standards may have been an obstacle to the effective marketing of organic products. There are currently 36 private and 13 State organic certification agencies (certifying agents) in the United States, each with its own standards and identifying marks.

Some existing private certifying agents are concerned that States might impose registration or licensing fees which would limit or prevent private certification activities in those States. Labeling problems have confronted manufacturers of multiingredient organic food products containing ingredients certified by different certifying agents because reciprocity agreements have to be negotiated between certifying agents. Consumer confusion may exist because of the variety of seals, labels, and logos used by certifying agents and State programs. Also, there is no industrywide agreement on an accepted list of substances that should be permitted or prohibited for use in organic production and handling. Finally, a lack of national organic standards may inhibit organic producers and handlers in taking full advantage of international organic markets and may reduce consumer choices in the variety of organic products available in the marketplace.

To address these problems in the late 1980’s, the organic industry attempted to establish a national voluntary organic certification program. At that time, the industry could not develop consensus on the standards that should be adopted, so Congress was petitioned by the Organic Trade Association to establish national standards for organic food and fiber products.

In 1990, Congress enacted the Organic Foods Production Act of 1990, as amended (7 U.S.C. 6501 *et seq.*) (OFPA). The OFPA

requires all agricultural products labeled as "organically produced" to originate from farms or handling operations certified by a State or private agency that has been accredited by USDA.

The purposes of the OFPA, set forth in section 2102 (7 U.S.C. 6501), are to: (1) Establish national standards governing the marketing of certain agricultural products as organically produced products; (2) assure consumers that organically produced products meet a consistent standard; and (3) facilitate commerce in fresh and processed food that is organically produced. The National Organic Program (NOP) is the result of the OFPA.

Recently, the Organic Trade Association published American Organic Standards, Guidelines for the Organic Industry (AOS). However, not all participants in the organic industry elected to participate in developing the AOS. Many certifying agents preferred to wait for implementation of the national standards, and some certifying agents disagree with portions of the AOS. For these reasons, USDA will implement a regulation for the NOP.

2. Summary of the significant issues raised by public comments in response to the Initial Regulatory Flexibility Analysis (IRFA), a summary of agency assessment of such issues, and a statement of any changes made in the final rule as a result of such comments.

Although we received many individual comments in reference to the proposed rule's IRFA, they were, for the most part, variations of several form letters. Most of the concern on the part of commenters regarded the fees that small certifying agents would be subject to under the rule.

Comments Accepted

(1) We received numerous comments to the effect that the fees, recordkeeping, and paperwork requirements for producer and handler certification must be kept as low as possible while still offering a quality certification program. We believe that we have made every effort in this rule to minimize the cost and paperwork burden to certifiers and certified operations as much as possible. We have permitted certifiers and certified operations to develop their own recordkeeping and reporting systems—so long as they conform to the needs of the program. For the most part, the paperwork and recordkeeping requirements for certified operations conform to the requirements that they presently face under existing certification programs. In order to minimize the cost to the industry of transitioning to a system where certifying agents are accredited (assuming that there will be a learning curve as agents familiarize themselves with the requirements of accreditation), we have waived the per-hour cost that USDA will charge to conduct an accreditation review for the first 18 months of the program.

(2) In the proposed rule, we requested comment on the benefits of an exemption for small certifiers similar to that for small producers. We received comments in opposition to such an exemption because commenters wanted to maintain documented verification of standards that is afforded by certification and accreditation. They felt that

exemptions weakened the organic system in its ability to assure consumers of products that meet a consistent standard. We concurred with this comment and have not developed an exemption for certifiers in the final rule.

Comments Rejected

(3) We received comments suggesting that, in order to lower the direct cost of accreditation to smaller certifier applicants, we should eliminate on-site visits during accreditation or extend the time beyond the initial on-site visit for a subsequent visit. Although eliminating the on-site visits would certainly lower the applicant's costs, we have not made the change to reduce or eliminate on-site visits. We did not see how USDA could make an informed decision about whether or not to continue to accredit a certifying agent without complete access to the relevant records documenting the agent's business practices. This can only be efficiently done through a site visit.

(4) We received numerous comments that the fees proposed by USDA will result in certification fees that are excessive for small farming operations. The commenters suggested that USDA impose fees on a sliding scale based on a farmer's income so as not to drive these farmers out of business and deprive consumers of the benefits of these operations. We received a similar comment to the Fees section of the proposed rule, and our response is the same. Although one of our top priorities is assisting the small farmer, AMS is primarily a user-fee-based Federal agency. We are aware that our accreditation fees will figure into the fees that certifiers charge their clients. However, the fee we will charge to accredit an applicant is based not on earning profits, but on recovery of costs. In addition, our waiver of the hourly service charges for accreditation during the first 18 months of the program should help to keep the cost of accreditation to certifying agents down. We believe the requirements that fees charged by a certifying agent must be reasonable and that certifiers must file a fee schedule for approval by the Administrator will help to keep costs under control. Since certifiers are required to provide their approved fee schedules to applicants for certification, the applicants will be able to base their selection of certifying agent on price if the applicants so choose. In addition, nothing in the regulations precludes certifying agents from pricing their services on a sliding scale so long as their fees are consistent and nondiscriminatory and are approved during the accreditation process.

(5) Other commenters were concerned that in the rule USDA neglects to establish "reasonable fees" annually for farm/site/wild crop production and handling operation certification. Commenters did not believe that a valid Regulatory Flexibility Act analysis could be made without the annual farm and handling operation fee projection. We have not established guidelines for what constitutes a "reasonable fee" in the final rule. Accredited certifying agents will be required to submit a proposed fee schedule as a part of their application. At that time, we will work with applicants for

accreditation to ensure that their fees are appropriate. In addition, certifying agents will be required to send a copy of their fee schedule to anyone who requests one. This will allow operations that wish to be certified to shop around and will provide a disincentive for accredited agents to price themselves out of the market.

3. Description of and an estimate of the number of small entities to which the rule will apply.

Small business size standards, Standard Industrial Code (SIC) (13 CFR part 121), are developed by an interagency group, published by the Office of Management and Budget, and used by the Small Business Administration (SBA) to identify small businesses. These standards represent the number of employees or annual receipts constituting the largest size that a for-profit enterprise (together with its affiliates) may be and remain eligible as a small business for various SBA and other Federal Government programs.

There are three categories of operations that contain small business entities that would be affected by this rule: Certifying agents, organic producers, and/or organic handlers. The term, "certifying agent," means the chief executive officer of a State or, in the case of a State that provides for the statewide election of an official to be responsible solely for the administration of the agricultural operations of a State, such official and any person (including private entities) who is accredited by the Secretary as a certifying agent for the purpose of certifying a farm or handling operation as a certified organic farm or handling operation.

According to the most complete data available to USDA's Agricultural Marketing Service (AMS), there are 49 certifying agents (36 private and 13 State) in the United States. More than half of the private and State certifying agents certify both producers and handlers, while the others certify only producers. Over three-fourths of private and State certifying agents each certify fewer than 150 producers and 20 handlers. The number of certifying agents has remained fairly stable, between 40 and 50, for some years, with entries and exits tending to offset each other. The NOP staff anticipates that, in addition to the 49 domestic certifying agents, 10 foreign certifying agents may seek accreditation during the initial phase of the program.

Small businesses in the agricultural services sector, such as certifying agents, include firms with average annual revenues of less than \$5 million (SIC Division A Major Group 7). Based on SBA's small business size standards for the agricultural services sector, it is not likely that many, if any, of the 49 domestic certifying agents have annual revenue greater than \$5 million. All private, nonprofit certifying agents would be considered small by SBA's standards. Based on anecdotal information, only a few private, for-profit, certifying agents might be categorized as large businesses. In addition, the 13 State certifying agents, although not exceeding the revenue threshold, would not be considered to be small entities under the Act as only government jurisdictions with populations under 50,000 are considered to

be small entities under section 601(5). Therefore, at least 30 certifying agents would qualify as a small business.

The term, "producer," means a person who engages in the business of growing or producing food or feed. It is more difficult to establish the number of organic producers. Organic farming was not distinguished from conventional agriculture in the 1997 Census of Agriculture. There are sources which give insight into the number of producers. The Organic Farming Research Foundation (OFRF), a California-based nonprofit organization, has conducted three nationwide surveys of certified organic producers from lists provided by cooperating certifying agents. The most recent survey applies to the 1997 production year (1). □ □ □ OFRF sent its 1997 survey to 4,638 names and received 1,192 responses. Because OFRF did not obtain lists from all certifying organizations or their chapters (55 out of a total of 64 identified entities provided lists), its list count is likely an understatement of the number of certified organic producers. Note that the estimated number of organic producers includes only certified organic farms. Comments filed in response to the first proposal and studies indicate that the total number of organic farms is higher.

Dunn has estimated the number of certified organic producers in the United States (2, 3) Dunn's 1995 work, a USDA study, estimated the number of certified producers at 4,060 in 1994; this estimate was used in the first proposal. Dunn's 1997 work reported 4,060 certified organic farms in 1994 and 4,856 in 1995.

Data collected by AMS indicate that the number of organic farmers increased about 12 percent per year during the period 1990 to 1994. OFRF survey efforts indicate that growth has continued, although it is not clear whether the growth rate has changed. Similarly, growth in retail sales, the addition of meat and poultry to organic production, and the possibility of increased exports suggest that the number of operations has continued to increase. Lacking an alternative estimate of the growth rate for the number of certified organic producers, we use the average growth rate of about 14 percent from Dunn's 1997 study. The true rate of growth could be higher or lower. Applying the 14-percent growth rate to Dunn's estimate of certified producers in 1995 gives an estimate of 8,200 organic producers for 1999.

An adjustment is needed to account for the number of producers who are practicing organic agriculture but who are not certified and who would be affected by this regulation. We assume that the number of organic but not certified producers in 1999 is about 4,000. This assumption is based on very limited information about the number of registered but not certified organic producers in California in 1995. Thus, the total number of certified organic producers used in assessing the impact of the rule is 12,176.

Producers with crop production (SIC Division A Major Group 1) and annual average revenues under \$500,000 are small businesses. Producers with livestock or animal specialties are also considered small if annual average revenues are under \$500,000 (SIC Division A Major Group 2),

with the exception of custom beef cattle feedlots and chicken eggs, which are considered small if annual average revenues are under \$1,500,000.

Based on SBA's small business size standards for producers, it is likely that almost all organic producers would be considered small. The OFRF survey asked for the producer's total gross organic farming income during 1997. Only 35 (less than 3 percent) of the survey respondents reported gross income greater than \$500,000, the SBA's cutoff between small and large businesses. Over 70 percent reported gross income of less than \$50,000. The OFRF survey does caution readers about potential survey "errors." It is particularly important to emphasize potential "non-response error"; that is, it is unknown if those who responded to the survey accurately represent the entire population of certified organic growers. Also, some producers combine organic and conventional production on the same operation, some with total sales that may exceed \$500,000. However, it is likely that a majority of organic producers would be considered small. We have estimated that there would be 12,176 producers certified in the first year and of those 97 percent, or 11,811, based on OFRF's survey results, would qualify as a small business.

The term, "handler," means any person engaged in the business of handling agricultural products, excluding final retailers of agricultural products that do not process agricultural products. Little information exists on the numbers of handlers and processors. USDA has estimated that there were 600 entities in this category in 1994. In California, there were 208 registered organic processed food firms in 1995 and 376 in 1999, a growth rate of 20 percent (4). We assume that this growth rate is applicable to the U.S. and project 2,077 certified handlers in 2001. This figure includes 100 livestock feed handlers who would become certified organic. Again, the rate of growth could be higher or lower.

In handling operations, a small business has fewer than 500 employees (SIC Division D Major Group 20). It is also likely that the vast majority of handlers would be considered small, based on SBA's small business size standards for handlers. Based on informal conversations with organic certifying agents, currently, about 25 (about 2 percent) of the estimated 1,250 organic handlers in 1999 had more than 500 employees. This includes firms that handle or process both organic and conventional foods. We have estimated that 2,077 handlers would be certified organic in the first year. Based on this information, 98 percent or 2,035 would qualify as a small business.

4. An estimate of the projected reporting, recordkeeping, and other compliance requirements of the rule, including an estimate of the classes of small entities which will be subject to the requirement and the type of professional skills necessary for preparation of the report or record.

The reporting, recordkeeping, and compliance requirements of the rule will directly affect three sectors of the organic industry that contain small business entities: accredited certifying agents, organic

producers, and organic handlers. We have examined the requirements of the rule as it pertains to each of these entities, however several requirements to complete this Regulatory Flexibility Analysis (RFA) overlap with the Regulatory Impact Assessment (RIA) and the Paperwork Reduction Act (PRA) section. In order to avoid duplication, we combine some analyses as allowed in section 605(b) of the Act. This RFA provides information specific to small entities, while the RIA or PRA should be referred to for more detail. For example, the RFA requires an analysis of the rule's costs to small entities. The RIA provides an analysis of the benefits and costs of this regulation. This RFA uses the RIA information to estimate the impact on small entities. Likewise, the RFA requires a description of the projected reporting, recordkeeping, and other compliance requirements of the final rule. The PRA section estimates the reporting and recordkeeping (information collection) requirements that would be required by this rule from individuals, businesses, other private institutions, and State and local governments. The burden of these requirements is measured in terms of the amount of time required of program participants and its cost. This RFA uses the PRA information to estimate the burden on small entities.

Certifying Agents

We have identified 36 private certifying agents and 13 State programs providing certification. These 49 domestic entities are considered likely applicants during the first 12 months, as are an estimated 10 foreign certifying agents. An unknown number of new entrants to the certifying business may also apply. However, over the last 10 years, the number of certifying agents does not appear to have grown significantly, with the net effect of entries and exits maintaining a population of U.S.-based certifying agents at about 40 to 50. Of the 49 domestic certifying agents, based on information discussed previously, we estimate that 30 of the 36 private certifying agents are small businesses.

The recordkeeping and paperwork requirements are outlined in the Paperwork Reduction Act section. The requirements for small and large certifying agents are identical. The recordkeeping and paperwork requirements for accreditation will be a new burden to most agents as the majority of them have not been accredited in the past. However, the actual amount of the additional administrative costs that would be imposed by the final rule is expected to be different for those entities that would begin their activities only after the national program is implemented. Certifying agents that currently are active in the organic industry already perform most of these required administrative functions; therefore, the additional costs to them would depend upon the extent to which their current practices are different from the requirements of the final regulation. Because the rule does not require any particular system or technology, it does not discriminate against small businesses. The ability of an agent to carry out the paperwork and recordkeeping sections of the rule will be more dependant on the

administrative skill and capacity of their particular organization than their size. We did not receive significant comments about the paperwork requirements of the proposed rule that would indicate that they will be onerous for small certifying agents.

Certifying agents will be the front line in monitoring and ensuring that certified operations stay in compliance with the Act and the regulations. However, most of the compliance requirements, with the exception of some reporting requirements, are consistent with what certifiers are currently expected to do. Like the paperwork and reporting requirements, the additional costs to an agent will depend on how different their current practices are from the final regulation.

The final, and probably most significant, area in which certifying agents are affected by the rule is in the fees that they must pay for accreditation. Certifying agents will be assessed for the actual time and travel expenses necessary for the NOP to perform accreditation services, including initial accreditations, 5-year renewals of accreditation, review of annual reports, and changes to accreditation. Although the fees have not been set yet, we are using as a starting point the hourly fees that are charged for the voluntary, fee-for-service program provided by AMS to certification bodies requesting conformity assessment to the ISO Guide 65, "General Requirements for Bodies Operating Product Certification Systems." We expect that at the time the NOP's final rule is implemented, the fees will be approximately \$95 per hour with higher overtime and holiday rates. Certifying agents will also be charged for travel, per diem, and other related costs associated with accreditation. To ease the financial burden of accreditation during the 18 month transition period after the NOP has been implemented, USDA will not impose hourly charges on certifying agents. The direct costs for certifying agents to obtain accreditation will be limited to per diem and transportation costs to the site evaluation. Review of the certifying agent's annual report is anticipated to range from 2 to 8 hours at the ISO Guide 65 hourly rate. Also, if certifying agents wish to become accredited in additional areas for which they were not accredited previously, a site evaluation (with associated fees) will be necessary. Detail about the expected costs of accreditation can be found in the RIA.

Several factors will influence the amount of time needed to complete an accreditation audit. An operation in which documents are well organized and that has few nonconformities within the quality system will require less time for an audit than an organization in which documents are scattered and there are many nonconformities (7). Similarly, in a followup audit, operations that lack organization in their documents and that had a large number of nonconformities during previous audits will require a greater amount of time. The scope of a followup audit is to verify the correction of nonconformities and to evaluate the effectiveness of the corrections. Certifying agents are able to control these cost factors by making certain that documents are well organized and by educating themselves about quality systems.

The complexity of a certification agency's organization also will affect the time needed to complete an audit. An agency with a central office in which all certification activities take place will require less time for document review and site evaluation than a chapter organization or a business structured so that responsibility for making certification decisions is delegated outside of the central office. In the latter cases, the auditors' document review would require additional time and site evaluation that would extend from the central office to one or more of the chapters or to the site to which the certification decision making is delegated.

Other factors determine the amount of time needed to complete an accreditation audit. For an agency with numerous clients, auditors may need to spend more time reviewing client files or examining business operations than they would have to spend for a smaller agency. Audit of an agency with a large number of processor clients may require an extended amount of time to follow audit trails, confirm that organic ingredients remain segregated from nonorganic ingredients, and establish that foreign-produced ingredients originate from approved entities. Finally, the complexity of the agricultural practices certified could influence the amount of time necessary to complete an accreditation audit. An agency whose certification covers only producers who grow and harvest one crop per field per year, such as wheat or sugar beets, could quickly be audited. An agency whose producers grow several different crops per field per year or an agency that certifies producers of crops and livestock as well as handlers would require a greater amount of time.

All of these factors will affect both small and large certifying agents. A small certifying agent could be assumed to have a less complex organization or have fewer clients, and, thus, potentially less time would be necessary for review. However, other factors, such as the degree of paperwork organization or the complexity of the agricultural practices certified, may influence the time needed for review for any size of business.

Currently, relatively few certifying agents have third-party accreditation because accreditation of certifying agents is voluntary. Fetter reports that in a sample of 18 certification programs, selected to include six large, private programs, six smaller private programs, and six State programs, four programs were accredited and one had accreditation pending (8). All of these were large private certifying agents. Three of the certifying agents identified by Fetter as accredited requested ISO Guide 65 assessments by USDA and have been approved for selling organic products into the international market. Those certifying agents currently accredited by third parties will likely pay less for USDA accreditation because their documents are organized and they have fewer nonconformities.

It is expected that all certifying agents will set their fee schedule to recover costs for their certification services, including the costs of accreditation. The larger the number of clients per certifying agent, the more fixed costs can be spread out. It is possible,

however, that small certifying agents could be significantly affected by this final rule and may not be able to continue in business from a financial standpoint.

Costs to Producers and Handlers

The OFPA established a small farmer exemption from certification and submission of organic plans for small producers with a maximum of \$5,000 in gross sales of organic products. For purposes of the exemption, the OFPA defines a "small farmer" as those who sell no more than \$5,000 annually in value of agricultural products. In this rule, we have clarified that the exemption applies to producers and handlers who sell no more than \$5,000 annually in value of organic products (9). In addition, handling operations are exempt if they: Are a retail food establishment that handles organically produced agricultural products but does not process them; handles agricultural products that contain less than 70 percent organic ingredients by weight of finished product; or does not use the word, "organic," on any package panel other than the information panel if the agricultural product contains at least 70 percent organic ingredients by weight of finished product.

A handling operation or specific portion of a handling operation is excluded from certification if it handles packaged certified organic products that were enclosed in their packages or containers prior to being acquired and remain in the same package and are not otherwise processed by the handler, or it is a retail food establishment that processes or prepares on its own premises raw and ready-to-eat food from certified organic products.

According to the OFRF survey, 27 percent of currently certified farms that responded to the survey would fall under the producer exemption. This percentage does not take into account those organic farms that are not currently certified by a private or State certifying agent. A study of California organic farms found that, of all organic farms (10) in 1994-95, about 66 percent have revenues less than \$10,000 (11). If California is representative and the distribution within the sub-\$10,000 category is uniform, then a third of the farms would be classified as small for purposes of the statutory exemption with annual sales less than \$5,000. Based on the California study and the OFRF survey results, we estimate that between 25 and 33 percent of organic producers are small and would qualify for exemption from the certification requirements.

We have estimated that there are 4,801 small organic producers and 173 handlers that will be exempt from certification (this figure does not include excluded operations). These operations would be required to comply with the production and handling standards and labeling requirements set forth under the NOP. They do not have to meet the paperwork requirements of certification and they must only keep records that document compliance with the law for 3 years (rather than 5 for certified operations). We anticipate that this exemption will be used primarily by small market gardeners and hobbyists who grow and process produce and other agricultural products for sale at farmers

markets and roadside stands to consumers within their communities.

Exempt producers will be allowed to market their products as organically produced without being certified by a certifying agent. Products marketed by exempt producers cannot be represented as certified organic or display the USDA organic seal. Products produced or handled on an exempt operation may be identified as organic ingredients in a multiingredient product produced by the exempt operation, but they may not be identified as organic in a product processed by others. These limitations may discourage some small producers from seeking exemption, who instead may choose to become certified. In this case, the costs of certification would apply. The value associated with having organic certification may outweigh the costs of certification.

As with accredited certifying agents, the regulation will impose administrative costs on certified producers and handlers for reporting, recordkeeping, residue testing, and other compliance requirements. The actual amount of the additional administrative costs that would be imposed by the final rule is expected to be different for those entities that become certified only after the national program is implemented. Producers and handlers who currently are active in the organic industry already perform most of these administrative functions; therefore, the additional costs to them would depend upon the extent to which their current practices differ from the requirements of the final regulation. Projected reporting, recordkeeping, and other compliance requirements of certifying agents are discussed in greater detail in the PRA and the RIA. The only distinction made in the final rule between large and small entities for reporting, recordkeeping, and compliance is for operators who produce less than \$5000 per year in organic products as stated above.

As with the certifying agents, most of the concern this rule generated for small certified operations revolves around fees. Under this rule, USDA will not impose any direct fees on producers and handlers. Certifying agents will establish a fee schedule for their certification services that will be filed with the Secretary and posted in a place accessible to the public. Certifying agents will provide all persons inquiring about the application process with a copy of their fees. The certifying agent may only charge those fees that it has filed with the Secretary. Furthermore, the certifying agent will provide each applicant with an estimate of the total cost of certification and an estimate of the annual costs of updating the certification.

Currently, supply and demand for certification services determine the fees charged in most areas. Some States charge minimal fees for certification and instead subsidize operating costs from general revenues. According to separate studies by Fetter, and Graf and Lohr, the majority of certifying agents structure their fee schedules on a sliding scale based on a measure of size, usually represented by the client's gross sales of organic products but sometimes based on the acres operated. Some certifying agents

charge an hourly rate for inspection and audit services.

Graf and Lohr's study indicates that even small farms require significant time for the certification process, and this time does not increase proportionately as farm size increases. None of the existing certification programs mention costs for residue testing, which the NOP will require in the form of preharvest testing when there is reason to believe that agricultural products have come into contact with prohibited substances. Preharvest testing is expected to be infrequent. Certifiers will recover the costs of preharvest testing through explicit charges to the producer whose crop is tested or through a generally higher fee structure that spreads the expected costs of tests over all clients.

This rule imposes no requirements that would cause certifying agents that are presently using a sliding-scale type fee schedule to abandon their current fee system. Certifying agents could recover their net additional costs by increasing their flat-fee component, their incremental charges, or both. Because accreditations are renewed only every 5 years, certifying agents will have 5 years to recover their net new costs. Certifying agents who become accredited during the first year of the program would have fewer direct costs to recover because they will not be charged the application fee and hourly charges for accreditation services.

Those currently receiving voluntary certification will likely see a modest increase as the certifying agent passes on its cost incurred under the NOP. Those not currently receiving certification and producing over \$5,000 annually in organic products will be required to become certified, and they will incur the actual costs of certification.

Some States, such as Texas and Washington, charge producers and handlers nominal fees for certification, and it is possible that more States might provide certification services as the NOP is implemented. Other States, such as Minnesota, have cost-share programs to help offset costs for organic producers.

Conclusion

This rule will primarily affect small businesses. We have, therefore, attempted to make the paperwork, recordkeeping, and compliance provisions as flexible as possible without sacrificing the integrity of the program. We are not requiring specific technologies or practices and with the 18-month phase-in of the program we are attempting to give both certifying agents and certified operators an opportunity to adapt their current practices to conform with the rule. Because we have attempted to make the rule conform with existing industry standards, including ISO guide 65 for certification and ISO guide 61 for accreditation, the changes for most organizations and operations should be relatively straightforward.

The fees required for accreditation will be the most significant change faced by most operations—and this was apparent in the comments received. While we understand the concerns of the affected organizations, in order to administer an accreditation program, it is necessary that we recover our costs. We

are hoping that the elimination of the hourly charges in the first round of accreditation will help to alleviate some of this burden.

1. Organic Farming Research Foundation. 1999. Final Results of the Third Biennial National Organic Farmers' Survey. Santa Cruz, CA.

2. Dunn, Julie Anton. 1995. Organic Food and Fiber: An Analysis of 1994 Certified Production in the United States. U.S. Department of Agriculture, Agricultural Marketing Service.

3. Dunn, Julie Anton. 1997. AgriSystems International Reports Certified Organic Production in the United States: Half a Decade of Growth. AgriSystems International: Wind Gap, PA.

4. California Department of Health Services (DHS). 1995. Report on the Registration of California Organic Processed Food Firms. Sacramento: State of California. September 1999 figures obtained via personal communication with California DHS.

5. Graf, Anita and Luanne Lohr. 1999. Analysis of certification program costs. Working Paper, Fund for Rural America project, Market Development for Organic Agriculture Products, Grant No. 97-36200-5.

6. During the first 18 months, site evaluation for initial accreditation will be conducted jointly by two reviewers. Two reviewers offers: (1) Anticipated faster turnaround; (2) different areas of expertise—one reviewer would come from the Quality Systems Certification Program audit staff and would be familiar with ISO Guide 65 verification, while the other reviewer would come from the NOP staff and would be familiar with the requirements of the program; and (3) consistency with the organic industry's desire to have reviewers from both areas of expertise during ISO Guide 65 assessments. AMS would consider sending one reviewer, rather than two, for the site evaluation of small certification agents if an individual possessing both reviewing skill and knowledge of the NOP is available. We anticipate only one reviewer would be required after the 18-month transition period.

7. Adequate advance notice will be given to certifying agents to allow them the opportunity to organize their records prior to the audit and minimize the costs of accreditation.

8. Fetter, Robert T. 1999. Economic Impacts of Alternative Scenarios of Organic Products Regulation. Senior Honors Thesis. University of Massachusetts, Amherst, MA.

9. We asked for comments on the first proposal as to whether the current statutory limitation of \$5,000 for exemption from certification should be raised to \$10,000 or to another amount and why such an increased monetary limitation for exemption from certification would be appropriate. Few commenters offered recommendations as to a maximum sales volume to exempt producers. Amounts ranged from \$2,000 to \$50,000, with a few suggesting \$10,000 and \$20,000 exemptions. These proposed exemption levels and justifications in comments received are not sufficiently consistent enough for us to recommend changing the statute requirement of the \$5,000 maximum sales volume exemption.

10. California State law requires organic farmers to register with the State. Certification is voluntary at the current time.

11. Klonsky, Karen, and Laura Tourte. 1998. Statistical Review of California's Organic Agriculture, 1992–95. Report prepared for the California Department of Food and Agriculture Organic Program. Cooperative Extension, Department of Agricultural Economics, University of California, Davis.

Appendix D—Executive Order 12988, Civil Justice Reform

Executive Order 12988, Civil Justice Reform, instructs each executive agency to adhere to certain requirements in the development of new and revised regulations in order to avoid unduly burdening the court system. The revised proposal was reviewed under this Executive Order. No comments were received on that review, and no additional related information has been obtained since then. This rule is not intended to have retroactive effect.

States and local jurisdictions are preempted under section 2115 of the Organic Foods Production Act (OFPA) (7 U.S.C. 6514) from creating programs of accreditation for private persons or State officials who want to become certifying agents of organic farms or handling operations. A governing State official would have to apply to USDA to be accredited as a certifying agent, as described in section 2115(b) of the OFPA (7 U.S.C. 6514(b)). States also are preempted under sections 2104 through 2108 of the OFPA (7 U.S.C. 6503 through 6507) from creating certification programs to certify organic farms or handling operations unless the State programs have been submitted to, and approved by, the Secretary as meeting the requirements of the OFPA.

Pursuant to section 2108(b)(2) of the OFPA (7 U.S.C. 6507(b)(2)), a State organic certification program may contain additional requirements for the production and handling of organically produced agricultural products that are produced in the State and for the certification of organic farm and handling operations located within the State under certain circumstances. Such additional requirements must: (a) further the purposes of the OFPA, (b) not be inconsistent with the OFPA, (c) not be discriminatory toward agricultural commodities organically produced in other States, and (d) not be effective until approved by the Secretary.

Pursuant to section 2120(f) of the OFPA (7 U.S.C. 6519(f)), this regulation would not alter the authority of the Secretary under the Federal Meat Inspection Act (21 U.S.C. 601 *et seq.*), the Poultry Products Inspections Act (21 U.S.C. 451 *et seq.*), or the Egg Products Inspection Act (21 U.S.C. 1031 *et seq.*), concerning meat, poultry, and egg products, nor any of the authorities of the Secretary of Health and Human Services under the Federal Food, Drug and Cosmetic Act (21 U.S.C. 301 *et seq.*), nor the authority of the Administrator of the Environmental Protection Agency (EPA) under the Federal Insecticide, Fungicide and Rodenticide Act (7 U.S.C. 136 *et seq.*).

Section 2121 of the OFPA (7 U.S.C. 6520) provides for the Secretary to establish an

expedited administrative appeals procedure under which persons may appeal an action of the Secretary, the applicable governing State official, or a certifying agent under this title that adversely affects such person or is inconsistent with the organic certification program established under this title. The Act also provides that the U.S. District Court for the district in which a person is located has jurisdiction to review the Secretary's decision.

Appendix E—Executive Order 13132, Federalism

This final rule has been reviewed under Executive Order 13132, Federalism. This Order requires that regulations that have federalism implications provide a federalism impact statement that: (1) Demonstrates the Agency consulted with the State and local officials before developing the final rule, (2) summarizes State concerns, (3) provides the Agency's position supporting the need for the regulation, and (4) describes how the concerns of State officials have been met. The Order indicates that, where National standards are required by Federal statutes, Agencies shall consult with appropriate State and local officials in developing those standards.

The Organic Foods Production Act (OFPA) of 1990 (7 U.S.C. 6501 *et seq.*) establishes national standards regarding the marketing of agricultural products as organically produced, assures consumers that organically produced products meet a consistent standard, and facilitates interstate commerce in fresh and processed food that is organically produced. There has been a great deal of support for this law and these regulations from the organic community.

OFPA and these regulations do preempt State statutes and regulations related to organic agriculture. OFPA establishes national standards regarding the marketing of agricultural products as organically produced, assures consumers that organically produced products meet a consistent standard, and facilitates interstate commerce in fresh and processed food that is organically produced. Currently, 32 States have organic statutes on their books and have implemented them to various degrees. However, the Act contemplates a significant role for the States and, in fact, envisions a partnership between the States and the Federal Government in meeting the requirements of the Statute. The Act allows the States to determine the degree to which they are involved in the organic program. States may choose to: (1) Carry out the requirements of the Act by establishing a State organic program (SOP) and becoming accredited to certify operations, (2) establish an SOP but utilize private accredited certifying agents, (3) become accredited to certify and operate under the National Organic Program (NOP) as implemented by the Secretary, or (4) not play an active role in the NOP. 7 U.S.C. 6507 provides that States may establish an SOP consistent with the national program. SOP's may contain more restrictive requirements than the NOP established by the Secretary of Agriculture. To be more restrictive, SOP's must: further the purposes of the Act, be consistent with

the Act, not discriminate against organic products of another State, and be approved by the Secretary.

Because implementation of OFPA will have a significant effect on many States' existing State statutes and programs, the U.S. Department of Agriculture (USDA) has reached out to States and actively sought their input throughout the entire process of developing the organic rule. On publication of the first proposal on December 16, 1997, an announcement and information packet summarizing the proposal was sent to more than 1,000 interested parties, including State governors and State department of agriculture secretaries, commissioners, or directors. Over a period of 6 years, numerous meetings were held to provide States an opportunity to provide information and feedback to the rule. In 1994, States were invited to participate in four public hearings held in Washington, DC; Rosemont, IL; Denver, CO; and Sacramento, CA, to gather information to guide development of standards for livestock products. States were also provided the opportunity to comment specifically on State issues at a National Organic Certifiers meeting held on July 21, 1995. They were invited to discuss accreditation issues at a meeting held on February 26, 1996. Following the publication of the first proposal, State and local jurisdictions had the opportunity to provide input at four listening sessions held in February and March 1998 in Austin, TX; Ames, IA; Seattle, WA; and New Brunswick, NJ. A meeting to discuss the role of States in the NOP was held in February 1999. A State organic certifiers meeting to discuss State issues was held at a March 2000 meeting with the National Association of State Organic Programs.

USDA also drew extensively on the expertise of States and the organic industry by working closely with the National Organic Standards Board. The Board met 12 times before publication of the proposed rule on December 16, 1997, and met five times during 1998 and 1999 and two times in 2000. States were invited to attend each of these meetings, and official State certifier representatives participated in Board deliberations in meetings held in July 1998, July 1999, and March 2000.

Public input sessions were held at each meeting to gather information from all interested persons, including State and local jurisdictions. NOP staff also received comments and consulted with States at public events. They made presentations, received comments, and consulted with States at local and regional organic conferences and workshops and at national and international organic and natural food shows. States were consulted in training sessions held for organic inspectors, as well as numerous question and answer sessions at speaking engagements of the Agricultural Marketing Service (AMS) Administrator, the NOP Program Manager, and NOP staff.

In addition, during August and September 2000, the Administrator and NOP staff engaged in extensive efforts to discuss the proposed rule. While many organizations declined opportunities for these briefings, AMS staff did meet with the National

Conference of State Legislatures (NCSL) and, at their request, in lieu of a meeting, provided information to the National Governor's Association (NGA). NGA and NCSL representatives stated they were aware of the development of the final rule but offered no comments during these consultations beyond those submitted by the individual States during the proposed rule's comment period. In addition, between August and October 2000, NOP staff had telephone or e-mail contact with the State organic program directors or other State department of agriculture representatives in 25 States to determine the scope and status of each State's organic program in the context of the issuance of the final rule. These State representatives stated that they were eagerly awaiting the publication of the final rule and had already begun adjusting their programs to conform with the March 2000 proposed rule in anticipation of the publication of the final rule. Finally, States have had the opportunity to comment on two proposed rules. More than 275,000 comments were received on the first proposal, and 40,000 on the second proposed rule—including extensive comments from twelve State departments of agriculture, one State legislator, two members of Congress, and the National Association of State Organic Programs.

Through this outreach and consultation process, States have both provided general feedback to the rule and expressed several specific concerns about how this rule will affect State programs. Overwhelmingly, States were extremely supportive of the March 2000 proposed rule. With a few exceptions, most notably who should bear the cost of enforcement of an SOP, States are supportive of the Federal legislation. We did not receive a single comment from a State that indicated that there should not be a national organic program.

The most prevalent issues they raised regarding the March 2000 proposed rule as to how this rule will affect organic programs in their States, along with USDA's response, are described below. We received no direct comments from States on the Federalism section in the proposed rule. Many of these concerns and others are addressed in more detail in the relevant sections of the rule.

Applicability

Regarding section 205.100(b), five States currently offer a "transition to organic" label for producers who are in the process of

becoming certified. Many of these States would like to continue to offer this label. However, OFPA does not authorize a "transition to organic" label. Although the States (or private certifiers) are free to come up with a different label for these farmers, they cannot utilize the term, organic, in any seal or labeling associated with the conversion period. There is no change in this provision from the proposed rule.

Accreditation

Regarding section 205.501(a), many States wanted the NOP to add an additional subsection to the Accreditation section requiring certifiers to prove that they can carry out a State's more restrictive standards in order to be accredited to certify in that State. AMS concurs with this suggestion and has added a new paragraph 205.502(a)(20) requiring the certifying agent to demonstrate its ability to comply with a State's additional requirements.

Regarding section 205.501(b), there was strong support by all of the States for the provision that States with SOP's are able to have higher standards than the NOP for operations within their State. However, there was not consensus among the States on the prohibition on private certifiers requiring more stringent standards.

Although most supported the prohibition on private certifiers imposing additional requirements as a condition of certification because they perceived that it lowered barriers to farmers and processors in their States, three States were strongly opposed to this provision. Because having a consistent national standard is one of the primary purposes of the legislation, there is no change in this provision from the proposed rule.

State Programs

There was general confusion about what is the difference between a State organic certification program and an SOP. In addition, some States wanted the scope of the NOP's oversight for State organic activities to be limited to certification. A State organic certification program is equivalent to a private or foreign certification program. States wishing to certify operations in their State must apply to the NOP for accreditation.

An SOP, on the other hand, requires the State to submit a plan to the NOP for approval to, in effect, administer the NOP within their State. Included in this is the

opportunity to include requirements that differ from the NOP. In creating an SOP, a State is also agreeing to take on enforcement activities that would otherwise be the responsibility of the NOP. One exception to a State's enforcement authority is that States with SOP's do not have jurisdiction over the accreditation of certifying agents and cannot revoke accreditation. They can investigate and report accreditation violations to the NOP. States with only an accredited certification program are only responsible for the level of enforcement that all accredited certifying agents, State, private, or foreign, are required to take on.

Regarding section 205.620(c), several States want broader language than "unique environmental conditions" to be the basis for a State to have the right to establish more restrictive requirements under an SOP. AMS does not concur. There is no change to this language in the final rule. It is the opinion of AMS that the current language is broad enough to cover the scope of more restrictive requirements as authorized by OFPA.

Regarding section 205.620(d), many States want it to be optional for States with SOP's to take on enforcement obligations; several want funding from USDA for enforcement activities. AMS does not concur with this change. AMS does not envision that participation under the NOP will impose additional fiscal costs on States with existing organic programs, other than the costs of accreditation.

Regarding section 205.621(b), several States commented that States with SOP's should not be required to publish proposed changes to their programs in the **Federal Register** for public comment. AMS concurs with this comment. This language was an oversight from the first proposed rule.

Fees

A few States commented that the proposed fees for accreditation could cost more than some States could afford to pay. They made some suggestions for reducing accreditation fees, ranging from no fees (a completely federally funded program) to charging reduced rates for travel or eliminating hourly charges. AMS has no plans to change the fee structure. As in the proposed rule, hourly charges for accreditation will be waived for all applicants in the first 18 months of the program to facilitate the conversion to a national accreditation system.

Compliance

Regarding section 205.665, several States wanted to know what their authority was to revoke the accreditation of private certifiers in their State who do not meet additional State standards under an SOP. An SOP's governing State official is authorized to review and investigate complaints of noncompliance with the Act or regulations concerning accreditation of certifying agents operating in their State. If they discover a noncompliance, they shall send a written report to the NOP program manager. Because accreditation is a Federal license, States do not have the authority to revoke a certifying agent's accreditation. There is no change in this section from the proposed rule

Appeals

Regarding section 205.668(b), several State commenters want appeals from SOP's to go

to State district court rather than Federal district court. AMS disagrees. The Act provides that a final decision of the Secretary may be appealed to the U.S. District Court for the district in which the person is located. AMS considers an approved SOP to be the NOP for that State. As such, AMS considers the governing State official of such State program to be the equivalent of a representative of the Secretary for the purpose of the appeals procedures under the NOP. Because the final decision of the governing State official is considered the final decision of the Secretary, under the Act it is then appealable to the U.S. District Court, *not* the State district court.

Regarding section 205.680, State commenters want a process by which people who feel they were adversely affected by the organic program in a State with an SOP may appeal to the SOP's governing State official,

rather than the Administrator. AMS has amended the language in section 205.680 to clarify to whom an appeal is made under various situations. If persons believe that they were adversely affected by a decision made by the NOP Program Manager, they appeal to the Administrator. If they were adversely affected by a decision made by a certifying agent (State, private, or foreign), they appeal to the Administrator unless they are in a State with an SOP, in which case, they appeal to the SOP's governing State official. If persons believe that they were adversely affected by a decision made by a representative of an SOP, they appeal such decision to the SOP's governing State official or such official's designee.

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Federal Register

**Thursday,
December 21, 2000**

Part V

**Department of
Housing and Urban
Development**

**Public Housing Assessment System;
Financial Condition Scoring Process;
Notice**

**DEPARTMENT OF HOUSING AND
URBAN DEVELOPMENT****[Docket No. FR-4509-N-17]****Public Housing Assessment System;
Financial Condition Scoring Process**

AGENCY: Office of the Assistant Secretary for Public and Indian Housing, and Office of the Director of the Real Estate Assessment Center, HUD.

ACTION: Notice.

SUMMARY: This notice provides additional information to Public Housing Agencies (PHAs) and members of the public about HUD's process for issuing scores under the Financial Condition Indicator of the Public Housing Assessment System (PHAS). This notice includes generally accepted accounting principles (GAAP)-based threshold values and associated scores for each Financial Condition Indicator component and peer group based on all available data as of October 15, 2000. This notice also provides additional clarification to the two audit flag and tier classification charts.

DATES: December 21, 2000.

FOR FURTHER INFORMATION CONTACT: For further information contact the Real Estate Assessment Center (REAC), Attention: Wanda Funk, U. S. Department of Housing and Urban Development, 1280 Maryland Avenue,

SW, Suite 800, Washington, DC 20024; telephone Technical Assistance Center, 1-888-245-4860 (this is a toll free number). Persons with hearing or speech impairments may access that number via TTY by calling the Federal Information Relay Service at (800) 877-8339. Additional information is available from the REAC Internet Site at <http://www.hud.gov/reac>.

SUPPLEMENTARY INFORMATION:**I. Background**

HUD published the first Public Housing Assessment System; Financial Condition Scoring Process Notice in the **Federal Register** (64 FR 26222) on May 13, 1999. On June 23, 1999, HUD republished the notice (64 FR 33700) to coincide with the June 22, 1999, publication of the Public Housing Assessment System proposed rule. Subsequently, HUD further revised the notice (65 FR 40008) to reflect additional changes to the financial scoring process on June 28, 2000. This notice is an update of the Financial Condition Scoring Process notice that was published on June 28, 2000. In the June 28, 2000, notice, HUD stated that any changes to the scoring process and any modifications to the thresholds would be communicated through a subsequent **Federal Register** notice. Accordingly, this notice updates the June 28, 2000, notice, and provides information on the revision made to the

Financial Condition Scoring Process Notice. By this notice, HUD is revising the thresholds based on a full year's worth of unaudited and available audited GAAP data.

This change has been made in accordance with the threshold reevaluation schedule set forth in the June 28, 2000, notice. The original thresholds were based on a sample of PHAs reporting under GAAP prior to September 30, 1999, and were used for all unaudited and audited financial submissions for fiscal year ends through June 30, 2000. As of September 30, 2000, the thresholds were to be reevaluated based on a full year's worth of unaudited and available audited GAAP data. This notice provides the revised thresholds based on data collected as of September 30, 2000, which includes unaudited and audited submissions received during an entire fiscal year. Hereafter, the REAC plans to keep the reevaluated thresholds constant for a three year period, unless there is a need for revision. Please refer to Appendix 2 for the revised thresholds.

II. Financial Condition Indicator

The chart below shows the six components that constitute the Financial Condition Indicator and their assigned points.

FINANCIAL CONDITION INDICATOR

Scoring Components	Measurement	Points
Current Ratio (CR)	Liquidity	9.0
Number of Months Expendable Fund Balance (MEFB)	Adequacy of reserves	9.0
Tenant Receivables Outstanding (TRO)	Ability to collect payments of tenant receivables	4.5
Occupancy Loss (OL)	Ability to lease up units and maximize rental income	4.5
Expense Management/Utility Consumption (EM/UC)	Ability to maintain expense ratios at a reasonable relative level to peers (adjusted for size and region).	1.5
Net Income or Loss as a Percentage of Expendable Fund Balance (NI).	Effect of current year operations on existing reserves	1.5

The values of the six components of the Financial Condition Indicator calculated from the financial data comprise the overall financial assessment of the PHA. The components and their relative importance to the total financial score are the result of studies of PHA financial performance and of industry portfolio management techniques to identify the most appropriate financial measures to gauge a PHA's financial position. These components represent measures that are appropriate benchmarks in any residential real estate environment. The score assigned to each component is based on the distributions of that

component's values and the relative relationship between the components and the PHA's overall financial performance.

Financial Assessment Focus

The PHAS financial assessment is based on the entity-wide operations of a PHA, which includes financial information on Section 8, Community Development Block Grants, and other HUD funding in its calculations, as well as funds from non-HUD sources. GAAP-based scores as of September 30, 2000, are enforceable and will be based on an entity-wide assessment.

Scoring Approach

Under PHAS, the components of the PHAS Financial Condition Indicator were developed to both fairly and accurately assess a PHA's financial performance and financial management. As part of the development, the components were tested to establish the correlation between PHA performance under each component and the fiscal health of a PHA. PHAs were evaluated and assigned scores based on a PHA's performance relative to its peers. In other words, all PHAs as a group determine the mean score and each PHA is then ranked accordingly. This peer assessment approach, which was

formulated following extensive economic and financial analysis, examination of well-accepted business principles, and discussions with PHA industry representatives and PHA staff, provides an equitable means of measuring the financial performance of PHAs.

Comparable Scoring Systems

The peer assessment process is not unique to the REAC. Companies in the mortgage housing and securities industries, and other Federal agencies utilize similar systems in assessing their constituents. Fannie Mae, the mortgage housing industry leader, developed an assessment system with financial indicators similar to those contained in HUD's financial assessment of PHAs. These indicators include vacancy, reserve balances, and net income. Like HUD, Fannie Mae uses these indicators to rank properties and identify those which require further attention. In the securities area, Standard & Poor's conducts peer assessment of a company's operational capabilities and cash flows relative to their peers. Among Federal agencies, the Department of Health and Human Services (HHS) contracts with state and local entities to perform financial audits of nursing homes and hospitals participating in the Federal Medicare program. Based on these financial audits, HHS determines the continued eligibility of these health service providers in the Medicare program.

III. GAAP Scoring Processes

GAAP-based scores are produced using data contained in the Financial Data Schedule (FDS). The GAAP-based financial data is first used to calculate the six financial ratios that measure various aspects of financial health, such as short term liquidity, EM/UC, and collection of tenant receivables. Ratios are then translated into scores based on its component value relative to its peers. Peer groupings are established according to the size of the PHA, based on the total number of units operated by the PHA for all programs and activities. For the expense management component only, low-rent only information plus the geographic location in which it falls is utilized.

The current size peer groupings are as follows:

Very Small (0–49 units)
Small (50–249 units)
Low Medium (250–499 units)
High Medium (500–1,249 units)
Large (1,250–9,999 units)
Extra-Large (10,000+ units)

In order to have a more equitable assessment of a PHA's expenses relative

to its peers, the REAC developed regional peer groupings for the EM/UC component, to supplement the size-based peer groups. Thus, a PHA is scored on EM/UC against a threshold that is calculated from all expense data in that PHA's similar size group and region. The regions are based on the first number of the PHA's zip code, and are divided as follows:

Region	States
0	CT, MA, ME, NH, NJ, RI, VT.
1	DE, NY, PA.
2	DC, MD, NC, SC, VA, WV.
3	AL, FL, GA, MS, TN, RQ, VQ.
4	IN, KY, MI, OH.
5	IA, MN, MT, ND, SD, WI.
6	IL, KS, MO, NE.
7	AR, LA, OK, TX.
8	AZ, CO, ID, NM, NV, UT, WY.
9	AK, CA, HI, OR, WA, GQ.

For the EM/UC component, the size-based peer groups were combined into three groups (small, medium and large) for analysis purposes because there is not sufficient statistical observations to differentiate all six size-based peer groups.

The minimum number of points (zero) and the maximum number of points (thirty) can each be achieved over a range of values. For example, on the Current Ratio, large PHAs receive zero points for a ratio that is less than one, while they receive nine points for a ratio between 1.8 and 3.9. Therefore, PHAs can target one range of values that they want to avoid and target one range that they should strive to achieve. Aside from these ranges, points are assigned to component values along a continuous line. This means that each component value will receive a different number of points.

This system ("continuous scoring") ensures that points are awarded equitably to PHAs along the distribution of component values because, in most cases, small differences in component values result in only small differences in the scores of the individual components. Therefore, two PHAs of a similar size whose values for their financial condition components are in close proximity will receive only slightly different scores to capture their performance relative to each other. For example, a large PHA with a Current Ratio of 1.1 would receive 5.4 points, while a PHA of the same size with a ratio of 1.2 would receive 5.9 points.

The number of points assigned to each component value or range of values is based on where the thresholds

for that component are set. The thresholds separate distinct ranges of scores along the distribution of component values. The thresholds and their associated scores are estimated based on well-accepted business principles and statistical distributions of values within the peer groupings of the PHAs.

Business Principles

Scoring of certain components follow generally recognized business principles. These principles indicate that there are certain absolute thresholds below which component values are clearly financially unacceptable and component values below that point should result in a score of zero. These principles are used in scoring the Current Ratio and Number of Months Expendable Fund Balance components. For both of these components, a value of less than one is financially unacceptable, regardless of PHA size, and therefore merits a score of zero.

Statistical Distributions

The thresholds are estimated by examining the distributions of component values by peer group. For the four most significant components (Current Ratio, Number of Months Expendable Fund Balance, Tenant Receivables Outstanding, and Occupancy Loss), thresholds are set such that approximately 50 percent of the distribution receives the maximum number of points, as long as 50 percent of the distribution have acceptable values for the component. Thus, the highest number of points is awarded to the PHAs whose financial measures are most reasonable both relative to their peers and in an absolute business sense. The specific percentiles that make this 50 percent of PHAs are established by identifying natural break points along the distributions. For example, for the Current Ratio and Number of Months Expendable Fund Balance, these break points fall at approximately the 30th and 80th percentiles. The remaining two components (Expense Management and Net Income as a Percentage of Fund Balance) assign zero points to PHAs that fall only in the extreme outer ranges of the distribution of values, and award 1.5 points to the remaining PHAs. The scoring functions and thresholds derived from these distributions can be found in Appendices 1 and 2.

IV. Audit Adjustments

Pursuant to 902.63(b)(2), the REAC calculates a revised FASS score once audited financial information is received. The revised FASS score,

which is based on the audited information, can either increase or decrease the initial score that was based on the unaudited financial information. There are two types of adjustments to the audited score that relate to financial audit information. The first type deals with the audit flags and reports that result from the audit itself. Reportable conditions and material weaknesses are considered to be audit flags, alerting the REAC to an internal control weakness or an instance of noncompliance with Federal laws and regulations. The second adjustment deals with significant differences between the unaudited and audited financial information reported to HUD pursuant to 902.63(b)(1).

Audit Opinion and Flags

As part of the analysis of the financial health of a PHA including assessment of the potential or actual waste, fraud or abuse at a PHA, HUD will look to the Audit Report to provide an additional

basis for accepting or adjusting financial component scores (See 63 FR 46607, September 1, 1998). The information collected from the annual audit report pertains to the type of audit opinion, details of the audit opinion, and the presence of reportable conditions and material weaknesses.

If the auditor's opinion is anything other than unqualified, points will be deducted from the PHA's audited financial score. The REAC will review audit flags to determine their significance as it directly pertains to the assessment of the PHA's financial condition. If the flag has no effect on the financial components or the overall financial condition of the PHA as it relates to the PHAS assessment, the audited score will not be adjusted. However, if the flags have an impact on the PHAS assessment, the PHA's audited score will be adjusted, in accordance with the seriousness of the reported finding.

These flags are collected by using the OMB A-133 Data Collection Form. The PHA completes this form for both the unaudited and audited submissions. At the time of the unaudited submission the form is used as a self-assessment tool and should reflect the PHA's knowledge of their financial and internal control condition and should acknowledge their understanding of what the auditor will report.

If the OMB A-133 Data Collection Form indicates that the auditor's opinion will be anything other than unqualified, points will be deducted from the PHAS score. The points have been established by the REAC using a three-tier system. The tiers are meant to give consideration to the seriousness of the audit qualification and to limit the deducted points to a reasonable portion of the PHA's total, actual score. The tiers, as established by the REAC, are defined below.

AUDIT FLAG TIERS

Tier	PHAS Points Deducted
Tier 1	100 percent of the PHA's total unadjusted FASS score.
Tier 2	10 percent of the PHA's adjusted FASS score.
Tier 3	Maximum of 5 percent of the PHA's adjusted FASS score. This maximum is cumulative and not to be assessed for each Tier 3 audit or internal control flag.

Each tier is assessed sequentially beginning with Tier 1; subsequent tier deductions are based on the initial score less any preceding tier deductions. Tier 3 audit flags are divided into levels which reflect the seriousness of the audit qualification and result in scoring adjustments based on the following criteria:

- Level 1—0.15 points per occurrence not to exceed three occurrences (.45 maximum point deduction).
- Level 2—0.15 points per occurrence not to exceed four occurrences (.6 maximum point deduction).
- Level 3—0.075 points per occurrence not to exceed six occurrences (.45 maximum point deduction).

Please refer to the table at the end of this section, titled "Audit Flags and Tier Classifications," that lists audit flags and associated tier classifications.

Review of Audited Versus Unaudited Submission

The purpose of a comparison of the ratios and scores resulting from the

current year's unaudited Financial Data Schedule submission to the ratios and scores resulting from the current year's audited submission is to:

1. Identify significant changes in ratio calculation results and/or scores from the unaudited submission to the audited submission;
2. Identify PHAs that consistently provide significantly different data from their unaudited submission to their audited submission;
3. Assess or alleviate penalties associated with the inability to provide reasonably accurate unaudited data within the required time period.

This review process will only be performed for the audited submission.

Materiality and Penalty Assessment

The REAC views the transmission of significantly inaccurate unaudited financial data as a serious condition. Therefore, PHAs are encouraged to assure financial data is as reliable as possible for their unaudited submissions.

A significant change penalty will be assessed for significant differences between the unaudited and audited submissions. A significant difference is considered to be an overall FASS score decrease of three or more points from the unaudited to the audited submission. The PHAS system automatically deducts the significant change penalty from the audited score and this reduction triggers the REAC analyst's review.

The REAC may waive the materiality penalty if the PHA provides reasonable documentation of the material difference in its submission. A materiality penalty is considered a Tier 3, level 2 audit flag, and will result in a reduction of points as associated with all other Tier 3 audit flags.

The table, below, summarizes the audit flags and associated tier classifications.

AUDIT FLAGS AND TIER CLASSIFICATIONS

Audit flag	Tier classification
Unqualified opinion	None
No audit opinion	Tier 1
Adverse opinion	Tier 1
Disclaimer of opinion	Tier 1
Qualified opinion:	
1. GAAP qualifications:	
A. Change in accounting principle	Tier 3, Level 1
B. Change in accounting estimate	Tier 3, Level 1
C. Change in accounting method	Tier 3, Level 1
D. Departure from GAAP	Tier 2
(1) Financial statements using basis other than GAAP	Tier 1
(2) Exclusion of alternate accounting for an account or group of accounts	Tier 2
(3) Inconsistently applied GAAP	Tier 2
(4) Omissions/Inadequate disclosure	Tier 2
2. GASS—Scope limitations	Tier 2
A. Imposed by management	Tier 2
B. Imposed by circumstance	Tier 2
C. Year 2000 (add back)	Tier 3, Level 1
3. Report on major program compliance	Tier 3, Level 1
4. Report on internal control	Tier 3, Level 1
Accounting principles used caused the financial statements to be materially misstated	Tier 3, Level 1
Inadequate records	Tier 2
Going concern	Tier 2
Material noncompliance disclosed	Tier 1
1. Internal control weakness	Tier 2
2. Compliance	Tier 3, Level 2
3. Opinion on supplemental schedules	Tier 3, Level 2
Reportable condition:	
1. Internal control	Tier 3, Level 2
2. Compliance	Tier 3, Level 3
Significant change penalty	Tier 3, Level 3
	Tier 3, Level 2

V. Appendices

The graphs shown in Appendix 1 depict the approximate GAAP-based scoring functions used for each of the six components of the Financial Indicator. Appendix 2 provides revised GAAP-based threshold values and associated scores for each component and peer group, based on the GAAP data

pool as of September 30, 2000. These thresholds, which are based on a full year of unaudited and available audited GAAP data, will remain in effect for all unaudited and audited PHA financial submissions for PHAs with fiscal year ends on or after September 30, 2000, for a three year period, unless the REAC finds a need for revisions. Any revisions

to the thresholds will be communicated through a Notice.

Dated: December 13, 2000.

Harold Lucas,

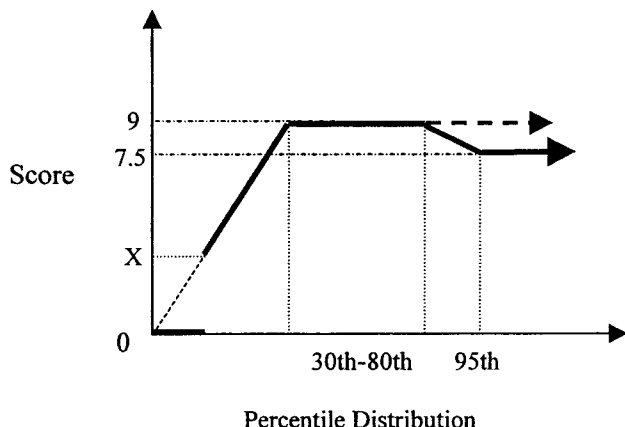
Assistant Secretary for Public and Indian Housing.

Donald J. LaVoy,

Director, Real Estate Assessment Center.

Appendix 1 – Graphs of GAAP-based Financial Indicators

Graph 1: Financial Indicators #1 & #2: Current Ratio & Months Expendable Fund Balance



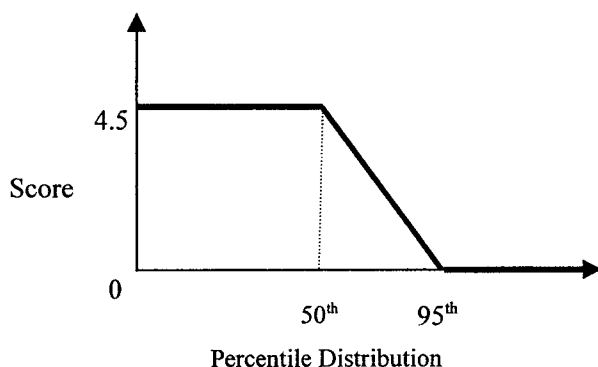
The scoring structure depicted above is established based on the distribution of data for each peer group. For both Current Ratio (CR) and Months Expendable Fund Balance (MEFB), a PHA receives zero points when the calculated ratio is less than one. With a value of one, they receive X points, which is determined by the distribution of the data, and therefore varies by size category. The maximum number of points is received between approximately the 30th and 80th percentiles. PHAs with values falling beyond the upper bound of this range receive incrementally fewer points up to a maximum deduction of 1.5 points. This reduction in points was established because HUD believes that PHAs with too high reserves and liquidity may be better utilizing their resources to improve the quality of housing or services to its residents.

However, in recognition of PHAs who are performing well in their quality of housing and resident services, HUD has modified this scoring methodology. If a PHA:

- has lost points in the Financial Assessment as a result of having too high reserves and/or liquidity (i.e. falling to the right of the 80th percentile), AND
- is a high performer under the Physical Assessment Subsystem, AND
- is not required to submit a follow-up plan under the Resident Satisfaction Assessment Subsystem

then these lost points will be restored (this is depicted in Graph #1 by the dashed arrow).

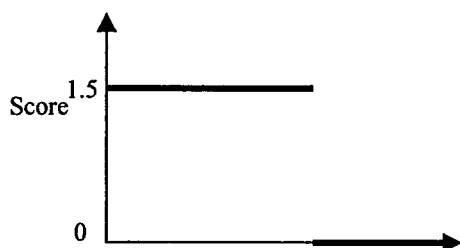
Graph 2: Financial Indicators #3 & #4: Occupancy Loss & Tenant Receivables Outstanding



For Occupancy Loss (OL) and Tenant Receivables Outstanding (TRO), the maximum number of possible points is 4.5, which is received up to approximately the 50th percentile. For values beyond approximately the 95th percentile, the PHA receives zero points.

For the OL calculation, the PHA may exclude the vacant units approved by HUD to be taken off-line for ongoing modernization, conversion, non-dwelling purposes, or demolition.

Graph 3: Financial Indicator #5: Expense Management



For Expense Management (EM), a PHA can receive either 1.5 or zero points.

There are six expense categories that comprise EM. A PHA's per unit, per month expense amount in each category is multiplied by the weights listed below, and summed to produce a weighted average. This summed number is compared to the threshold for that PHA's size and regional peer group. Each cross-section of size and region has one threshold that is set at 1.645 standard deviations (approximately the 95th percentile) from the mean of the distribution in that group. If the PHA's weighted average expense amount falls below the threshold, it receives 1.5 points; above the threshold, it receives zero points. With this weighted average methodology, a PHA may have high expenses in one category, for example, but may still receive 1.5 points if its other expense categories are reasonable relative to its peers. The weights are as follows:

<u>Expenses</u>	<u>Percent Weight</u>
Administrative Expense	34%
General Expense	33%
Tenant Service Expense	10%
Protective Service Expense	10%
Maintenance & Operation Expense	10%
Utilities Expense	3%
<i>Total</i>	100%

For example: The following PHA is in the Extra Large size category, is geographically located in region 0, and has the following expense totals:

<u>Expense</u>	<u>Amount</u>	<u>Weighted Average</u>
Administrative Expense	\$115	.34 * \$115 = \$39.10
General Expense	\$105	.33 * \$105 = \$34.65
Tenant Services	\$15	.10 * \$15 = \$1.50
Protective Service Expense	\$20	.10 * \$20 = \$2.00
Maintenance & Operation Expense	\$45	.10 * \$45 = \$4.50
Utilities Expense	\$150	.03 * \$150 = \$4.50
TOTAL		\$86.25

The threshold for an Extra Large PHA in Region 0 is \$107. Because the PHA has a weighted average expense total that is less than the applicable threshold, the PHA receives the full 1.5 points.

Graph 4: Financial Indicator #6: Net Income

	Negative Reserves	Positive Reserves
Positive Profits	I. Positive Profits and Negative Reserves Score = 1.5	III. Positive Profits and Positive Reserves Score = 1.5
Negative Profits	II. Negative Profits and Negative Reserves Score = 0	IV. Negative Profits and Positive Reserves If there is at least \$5 of Reserves for every \$1 of Loss, score = 1.5. If there is less than \$5 of Reserves for every \$1 of Loss, score = 0.

For Net Income (NI), a PHA can receive either 1.5 or zero points.

All PHAs that have a net income for the year receive the full score. If a PHA reports a net loss for the year, and has a positive expendable funds balance, as long as the loss does not exceed 20% of the EFB, the PHA will also receive the full score. This 20% threshold does not vary by region or size.

Appendix 2 – Threshold Tables for Entity-Wide GAAP Scoring

These tables can be interpreted in the following manner:

- Identify a size category for an indicator;
- The rows under that size category identify ranges of possible values for that indicator; and
- The column to the right labeled “Score” identifies the score or range of scores that is awarded to each range of indicator value for that size category.
- The thresholds presented here have been rounded for presentation purposes, whereas those used to calculate scores at REAC are not rounded.

Current Ratio (CR)							
Very Small	Score	Small	Score	Low Medium	Score	High Medium	Score
CR<1	0	CR<1	0	CR<1	0	CR<1	0
CR=1	1.8	CR=1	3.2	CR=1	3.6	CR=1	4.4
1<CR<4.9	1.8<Score<9	1<CR<2.8	3.2<Score<9	1<CR<2.5	3.6<Score<9	1<CR<2.1	4.4<Score<9
4.9≤CR≤14.0	9	2.8≤CR≤8.0	9	2.5≤CR≤5.9	9	2.1≤CR≤4.9	9
14.0<CR<24.0	9>Score>7.5	8.0<CR<14.9	9>Score>7.5	5.9<CR<10.3	9>Score>7.5	4.9<CR<7.8	9>Score>7.5
CR≥24.0	7.5	CR≥14.9	7.5	CR≥10.3	7.5	CR≥7.8	7.5

Current Ratio (CR)			
Large	Score	Extra Large	Score
CR<1	0	CR<1	0
CR=1	4.9	CR=1	6.4
1<CR<1.8	4.9<Score<9	1<CR<1.4	6.4<Score<9
1.8≤CR≤3.9	9	1.4≤CR≤2.3	9
3.9<CR<6.9	9>Score>7.5	2.3<CR<2.7	9>Score>7.5
CR≥6.9	7.5	CR≥2.7	7.5

Months Expendable Fund Balance (MEFB)							
Very Small	Score	Small	Score	Low Medium	Score	High Medium	Score
MEFB<1	0	MEFB<1	0	MEFB<1	0	MEFB<1	0
MEFB=1	1.5	MEFB=1	1.9	MEFB=1	1.8	MEFB=1	1.9
1<MEFB<6.0	1.5<Score<9	1<MEFB<4.6	1.9<Score<9	1<MEFB<4.9	1.8<Score<9	1<MEFB<4.7	1.9<Score<9
6.0≤MEFB≤16.3	9	4.6≤MEFB≤12.0	9	4.9≤MEFB≤11.5	9	4.7≤MEFB≤12.6	9
16.3<MEFB<28.8	9>Score>7.5	12.0<MEFB<18.4	9>Score>7.5	11.5<MEFB<21.4	9>Score>7.5	12.6<MEFB<21.2	9>Score>7.5
MEFB≥28.8	7.5	MEFB≥18.4	7.5	MEFB≥21.4	7.5	MEFB≥21.2	7.5

Months Expendable Fund Balance (MEFB)			
Large	Score	Extra Large	Score
MEFB<1	0	MEFB<1	0
MEFB=1	2.2	MEFB=1	4.8
1<MEFB<4.0	2.2<Score<9	1<MEFB<1.9	4.8<Score<9
4.0≤MEFB≤10.3	9	1.9≤MEFB≤7.8	9
10.3<MEFB<18.5	9>Score>7.5	7.8<MEFB<9.8	9>Score>7.5
MEFB≥18.5	7.5	MEFB≥9.8	7.5

Tenants Receivable Outstanding (TRO)

Very Small	Score	Small	Score	Low Medium	Score	High Medium	Score
TRO ≤ 1	4.5	TRO ≤ 2	4.5	TRO ≤ 4	4.5	TRO ≤ 5	4.5
1 < TRO < 37	4.5 > Score > 0	2 < TRO < 26	4.5 > Score > 0	4 < TRO < 31	4.5 > Score > 0	5 < TRO < 29	4.5 > Score > 0
TRO ≥ 37	0	TRO ≥ 26	0	TRO ≥ 31	0	TRO ≥ 29	0

Tenants Receivable Outstanding (TRO)

Large	Score	Extra Large	Score
TRO ≤ 7	4.5	TRO ≤ 13	4.5
7 < TRO < 33	4.5 > Score > 0	13 < TRO < 81	4.5 > Score > 0
TRO ≥ 33	0	TRO ≥ 81	0

Occupancy Loss (OL)

Very Small	Score	Small	Score	Low Medium	Score	High Medium	Score
OL ≤ 1%	4.5	OL ≤ 3%	4.5	OL ≤ 5%	4.5	OL ≤ 5%	4.5
1 < OL < 18%	4.5 > Score > 0	3 < OL < 21%	4.5 > Score > 0	5 < OL < 21%	4.5 > Score > 0	5 < OL < 21%	4.5 > Score > 0
OL ≥ 18%	0	OL ≥ 21%	0	OL ≥ 21%	0	OL ≥ 21%	0

Occupancy Loss (OL)

Large	Score	Extra Large	Score
OL ≤ 6%	4.5	OL ≤ 7%	4.5
6 < OL < 20%	4.5 > Score > 0	7 < OL < 22%	4.5 > Score > 0
OL ≥ 20%	0	OL ≥ 22%	0

Expenses**Percent Weight**

Administrative Expense	34%
General Expense	33%
Tenant Service Expense	10%
Protective Service Expense	10%
Maintenance & Operation Expense	10%
Utilities Expense	3%
<i>Total</i>	100%

Each expense management indicator will be weighted according to the table above. Non-tenant related expense categories are assigned higher weight to encourage PHAs to allocate resources to tenant-related expenses.

To calculate a score, the weighted thresholds for all six categories are summed. PHAs that have expenses per unit per month of less than the total threshold will receive 1.5 points. The expense management thresholds are expressed in dollars per unit per month and are organized by regional peer groupings.

Expense Management (EM)							
Region	Very small	Small	Low Medium	High Medium	Large	Extra Large	Score
0	EM<\$103.30	EM<\$103.30	EM<\$77.82	EM<\$77.82	EM<\$107.26	EM<107.26	1.5
0	EM≥\$103.30	EM≥\$103.30	EM≥\$77.82	EM≥\$77.82	EM≥\$107.26	EM≥107.26	0
1	EM<\$83.27	EM<\$83.27	EM<\$85.85	EM<\$85.85	EM<\$83.68	EM<83.68	1.5
1	EM≥\$83.27	EM≥\$83.27	EM≥\$85.85	EM≥\$85.85	EM≥\$83.68	EM≥83.68	0
2	EM<\$68.36	EM<\$68.36	EM<\$65.68	EM<\$65.68	EM<\$71.45	EM<71.45	1.5
2	EM≥\$68.36	EM≥\$68.36	EM≥\$65.68	EM≥\$65.68	EM≥\$71.45	EM≥71.45	0
3	EM<\$57.94	EM<\$57.94	EM<\$53.79	EM<\$53.79	EM<\$67.57	EM<67.57	1.5
3	EM≥\$57.94	EM≥\$57.94	EM≥\$53.79	EM≥\$53.79	EM≥\$67.57	EM≥67.57	0
4	EM<\$60.29	EM<\$60.29	EM<\$72.93	EM<\$72.93	EM<\$95.24	EM<95.24	1.5
4	EM≥\$60.29	EM≥\$60.29	EM≥\$72.93	EM≥\$72.93	EM≥\$95.24	EM≥95.24	0
5	EM<\$55.13	EM<\$55.13	EM<\$64.00	EM<\$64.00	EM<\$86.65	EM<86.65	1.5
5	EM≥\$55.13	EM≥\$55.13	EM≥\$64.00	EM≥\$64.00	EM≥\$86.65	EM≥86.65	0
6	EM<\$53.65	EM<\$53.65	EM<\$63.60	EM<\$63.60	EM<\$82.95	EM<82.95	1.5
6	EM≥\$53.65	EM≥\$53.65	EM≥\$63.60	EM≥\$63.60	EM≥\$82.95	EM≥82.95	0
7	EM<\$51.91	EM<\$51.91	EM<\$52.51	EM<\$52.51	EM<\$62.65	EM<62.65	1.5
7	EM≥\$51.91	EM≥\$51.91	EM≥\$52.51	EM≥\$52.51	EM≥\$62.65	EM≥62.65	0
8	EM<\$59.00	EM<\$59.00	EM<\$72.74	EM<\$72.74	EM<\$78.67	EM<78.67	1.5
8	EM≥\$59.00	EM≥\$59.00	EM≥\$72.74	EM≥\$72.74	EM≥\$78.67	EM≥78.67	0
9	EM<\$77.48	EM<\$77.48	EM<\$89.04	EM<\$89.04	EM<\$99.45	EM<99.45	1.5
9	EM≥\$77.48	EM≥\$77.48	EM≥\$89.04	EM≥\$89.04	EM≥\$99.45	EM≥99.45	0

[FR Doc. 00-32380 Filed 12-20-00; 8:45 am]

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Federal Register

**Thursday,
December 21, 2000**

Part VI

Department of the Interior

Fish and Wildlife Service

50 CFR Part 17

**Endangered and Threatened Wildlife and
Plants; Proposed Designation of Critical
Habitat for the Kootenai River Population
of the White Sturgeon; Proposed Rule**

DEPARTMENT OF THE INTERIOR**Fish and Wildlife Service****50 CFR Part 17****RIN 1018-AH06****Endangered and Threatened Wildlife and Plants; Proposed Designation of Critical Habitat for the Kootenai River Population of the White Sturgeon****AGENCY:** Fish and Wildlife Service, Interior.**ACTION:** Proposed rule; availability of supplementary information.

SUMMARY: We, the U.S. Fish and Wildlife Service, propose designation of critical habitat pursuant to the Endangered Species Act of 1973, as amended, for the Kootenai River population of the white sturgeon (*Acipenser transmontanus*). We are proposing as critical habitat a total of 18 river kilometers (11.2 river miles) of the Kootenai River in Idaho. If this proposed action is finalized, Federal agencies proposing actions that may affect the area designated as critical habitat must consult with us on the effects of the proposed actions on critical habitat, pursuant to section 7(a)(2) of the Act.

We solicit data and comments from the public on all aspects of this proposal, including data on the economic and other impacts of the proposed designation. We may revise this proposal to incorporate or address new information received during the comment period.

DATES: We will consider all comments on the proposed rule received from interested parties by February 20, 2001. We will hold a public hearing in Bonners Ferry, Idaho, on Thursday, January 18, 2001, from 6:00 p.m. until 8:00 p.m.

ADDRESSES: If you wish to comment, you may submit your comments and materials concerning this proposal by any one of several methods:

You may submit written comments and information to the Field Supervisor, U.S. Fish and Wildlife Service, Upper Columbia Fish and Wildlife Office, 11103 East Montgomery, Spokane, Washington 99206.

You may send comments by electronic mail (e-mail) to: FW1SPOK_crithab_stur@R1.fws.gov. See the Public Comments Solicited section below for file format and other information about electronic filing.

You may hand-deliver written comments to our Upper Columbia Fish and Wildlife Office, 11103 East Montgomery, Spokane, Washington.

You may provide comments at the public hearing on January 18, 2001, at the Bonners Ferry Kootenai River Inn, 7160 Plaza Street, Bonners Ferry, Idaho.

Comments and materials received, as well as supporting documentation used in the preparation of this proposed rule, will be available for public inspection, by appointment, during normal business hours at our Upper Columbia Fish and Wildlife Office. The draft economic analysis will be available during the public comment period. We will provide notice of its availability in local newspapers as well as the **Federal Register**.

FOR FURTHER INFORMATION CONTACT: Bob Hallock, Upper Columbia River Fish and Wildlife Office, at the above address; telephone 509-891-6839, facsimile 509-891-6748.

SUPPLEMENTARY INFORMATION:**Background**

The Kootenai River population of the white sturgeon (*Acipenser transmontanus*) is 1 of 18 land-locked populations of white sturgeon known to occur in western North America. The Kootenai River originates in Kootenay National Park in British Columbia, Canada, then flows south into Montana, northwest into Idaho, then north through the Kootenai Valley back into British Columbia, where it flows through Kootenay Lake and joins the Columbia River at Castlegar, British Columbia. Kootenai River white sturgeon occur in Idaho, Montana, and British Columbia, and are restricted to approximately 270 river kilometers (km) (168 river miles (mi)) of the Kootenai River extending from Kootenai Falls, Montana, located 50 river km (31 mi) below Libby Dam, Montana, downstream through Kootenay Lake to Corra Lynn Dam at the outflow from Kootenay Lake in British Columbia.

Bonnington Falls, a natural barrier downstream of Kootenay Lake, has isolated the Kootenai River population of white sturgeon since the last glacial advance roughly 10,000 years ago (Apperson 1992). Approximately 45 percent of the species' range, based on river kilometers, is located within British Columbia. Apperson and Anders (1991) found that at least 36 percent of the sturgeon tracked during 1989 overwintered in Kootenay Lake. They further believe that sturgeon do not commonly occur upstream of Bonners Ferry, Idaho, which includes most of the Kootenai River watershed in the United States.

The Kootenai River population of white sturgeon is threatened by factors including hydropower operations, flood

control operations, poor recruitment, loss of habitat, and, possibly, contaminants (water quality impacts). For more detailed discussions of the ecology of the Kootenai River population of white sturgeon, see the September 6, 1994, **Federal Register** notice listing this population as endangered (59 FR 45989), and the September 30, 1999, "Recovery Plan for the White Sturgeon (*Acipenser transmontanus*): Kootenai River Population" (USFWS 1999). The final rule and the recovery plan incorporate the best available biological information on Kootenai River white sturgeon.

In the September 6, 1994, final rule listing the Kootenai River population of white sturgeon as endangered, we, the U.S. Fish and Wildlife Service (Service), stated that the designation of critical habitat was not determinable. We believed there was insufficient biological information to accurately delineate the habitat essential to the species, and, in the absence of this delineation, the required analysis of impacts could not be completed accurately.

In the final listing rule we stated the following:

"* * * the Service identified the lack of natural flows in the Kootenai River below Libby Dam as the primary threat to this white sturgeon population. Other than a need for basic understanding of stream flow conditions necessary for providing spawning and early rearing habitat during the normal May through July sturgeon spawning season, the life history requirements for other life stages of white sturgeon are not sufficiently well known to permit identification of an area in the Kootenai River basin as designated critical habitat. Additionally, many Kootenai River white sturgeon migrate freely throughout the Kootenai River system and spend part of their life in Kootenay Lake in British Columbia, Canada. Critical habitat designation is not allowed outside the United States since only Federal agencies are under the jurisdiction of section 7 of the Endangered Species Act (Act).

"The Service is still gathering and reviewing information on the life history needs of the Kootenai River population of the white sturgeon and the potential economic consequences of designation of critical habitat. Additional biological information that may be useful in designating critical habitat for Kootenai River white sturgeon may include identification of specific river areas necessary for spawning, reproduction, and rearing of offspring; and water quality, temperature, and velocity in the Kootenai River required to meet some life history need (e.g., spawning and early rearing)."

Previous Federal Action

Federal action on the Kootenai River population of white sturgeon began on

November 21, 1991, when we included this population as a candidate species in the Animal Notice of Review (56 FR 58804), based on field studies conducted by the Idaho Department of Fish and Game. Candidate species are taxa for which the Service has on file enough substantial information on biological vulnerability and threats to propose them for endangered or threatened status. On June 11, 1992, the Service received a petition from the Idaho Conservation League, North Idaho Audubon, and the Boundary Backpackers to list the Kootenai River population of white sturgeon as threatened or endangered under the Act. The petition cited the lack of natural flows affecting juvenile recruitment as the primary threat to the continued existence of the wild sturgeon population. Pursuant to section 4(b)(A) of the Act, the Service determined that the petition presented substantial information indicating that the requested action may be warranted, and published this finding in the **Federal Register** on April 14, 1993 (58 FR 19401). A proposed rule to list the Kootenai River population of white sturgeon as endangered was published on July 7, 1993 (58 FR 36379), with a final rule following on September 6, 1994 (59 FR 45989).

Section 4(a)(3) of the Act and its implementing regulations (50 CFR 424.12) require that, to the maximum extent prudent and determinable, the Secretary designate critical habitat at the time the species is determined to be endangered or threatened. Our regulations (50 CFR 424.12(a)) state that designation of critical habitat is not determinable if information sufficient to perform required analysis of the impacts of designation are not sufficiently well known to permit identification of an area as critical habitat. Our regulations (50 CFR 424.12(a)(1)) also state that designation of critical habitat is not prudent when one or both of the following situations exist: (1) the species is threatened by taking or other human activity, and identification of critical habitat can be expected to increase the degree of threat to the species, or (2) such designation of critical habitat would not be beneficial to the species.

At the time of listing, we found critical habitat not determinable because the necessary information to perform the required impacts analyses of such a designation was lacking. In addition, specific areas of critical habitat could not be identified without additional information on the life history and habitat requirements of the sturgeon. Biological information needs then

identified by the Service included information concerning specific river reaches or areas necessary for spawning, reproduction, and rearing of offspring; and water quality, temperature, and velocity required to meet the needs of various life history stages (e.g., spawning, early rearing, and juvenile migration).

We published a final recovery plan on September 30, 1999 (USFWS 1999). The recovery strategy identified in this recovery plan emphasized the importance of reestablishing successful, natural spawning of Kootenai River white sturgeon, minimizing the loss of genetic variability, and successfully mitigating the biological and physical habitat changes caused by human development within the Kootenai River basin.

Critical Habitat

Critical habitat is defined in section 3(5)(A) of the Act as “(i) the specific areas within the geographic area occupied by the species, at the time it is listed in accordance with the Act, on which are found those physical or biological features (I) essential to the conservation of the species and (II) that may require special management considerations or protection; and (ii) specific areas outside the geographic area occupied by a species at the time it is listed, upon determination that such areas are essential for conservation of the species”. The term “conservation” as defined in section 3(3) of the Act means “to use and the use of all methods and procedures which are necessary to bring any endangered species or threatened species to the point at which the measures provided pursuant to this Act are no longer necessary” (*i.e.*, the species is recovered and removed from the list of endangered and threatened species). Section 3 of the Act further states that, except where determined by the Secretary of the Interior, critical habitat shall not include the entire geographic area which can be occupied by threatened or endangered species. In addition, critical habitat shall not be designated in foreign countries (50 CFR 424.12 (h)).

Critical habitat receives protection under section 7 of the Act through the prohibition against destruction or adverse modification of critical habitat with regard to actions carried out, funded, or authorized by a Federal agency. Section 7 also requires conferences on Federal actions that are likely to result in the destruction or adverse modification of proposed critical habitat. In our regulations at 50 CFR 402.02, we define destruction or

adverse modification as “* * * the direct or indirect alteration that appreciably diminishes the value of critical habitat for both the survival and recovery of a listed species. Such alterations include, but are not limited to, alterations adversely modifying any of those physical or biological features that were the basis for determining the habitat to be critical.” Aside from the added protection that may be provided under section 7, the Act does not provide other forms of protection to lands designated as critical habitat. Because consultation under section 7 of the Act does not apply to activities on private or other non-Federal lands that do not involve a Federal nexus, critical habitat designation would not afford any additional protections under the Act against such activities.

In order to be included in a critical habitat designation, the habitat must first be “essential to the conservation of the species.” Critical habitat designations identify, to the extent known using the best scientific and commercial data available, habitat areas that provide essential life cycle needs of the species (*i.e.*, areas on which are found the primary constituent elements, as defined at 50 CFR 424.12(b)).

Section 4 requires that we designate critical habitat at the time of listing and based on what we know at the time of the designation. When we designate critical habitat at the time of listing or under short, court-ordered deadlines, we will often not have sufficient information to identify all areas of critical habitat. We are required, nevertheless, to make a decision and thus must base our designations on what we know, at the time of designation, to be essential to the conservation of the species.

Within the geographic area occupied by the species, we will designate only areas currently known to be essential. Essential areas should already have the features and habitat characteristics that are necessary to sustain the species. We will not speculate about what areas might be found to be essential if better information became available, or what areas may become essential over time. If the information available at the time of designation does not show that an area provides essential life cycle needs of the species, then the area should not be included in the critical habitat designation. Within the geographic area occupied by the species, we will not designate areas that do not now have the primary constituent elements, as defined at 50 CFR 424.12(b), that provide essential life cycle needs of the species.

Our regulations state that the "Secretary shall designate as critical habitat areas outside the geographic area presently occupied by the species only when a designation limited to its present range would be inadequate to ensure the conservation of the species" (50 CFR 424.12(e)). Accordingly, when the best available scientific and commercial data do not demonstrate that the conservation needs of the species require designation outside of occupied areas, we will not designate critical habitat in areas outside the geographic area occupied by the species.

The Service's Policy on Information Standards Under the Act, published in the **Federal Register** on July 1, 1994 (Vol. 59, p. 34271), provides criteria, establishes procedures, and provides guidance to ensure that decisions made by the Service represent the best scientific and commercial data available. It requires Service biologists, to the extent consistent with the Act and with the use of the best scientific and commercial data available, to use primary and original sources of information as the basis for recommendations to designate critical habitat. When determining which areas are critical habitat, a primary source of information should be the listing package for the species. Additional information may be obtained from a recovery plan, articles in peer-reviewed journals, conservation plans developed by States and counties, scientific status surveys and studies, and biological assessments or other unpublished materials (*i.e.*, "gray literature").

Habitat is often dynamic, and species may move from one area to another over time. Furthermore, we recognize that designation of critical habitat may not include all of the habitat areas that may eventually be determined to be necessary for the recovery of the species. For these reasons, all should understand that critical habitat designations *do not* signal that habitat outside the designation is unimportant or may not be required for recovery. Areas outside the critical habitat designation will continue to be subject to conservation actions that may be implemented under section 7(a)(1) and to the regulatory protections afforded by the section 7(a)(2) jeopardy standard and the section 9 take prohibition. We specifically anticipate that federally funded or assisted projects affecting listed species outside their designated critical habitat areas may still result in jeopardy findings in some cases. Similarly, critical habitat designations made on the basis of the best information available at the time of the designation will not control the

direction and substance of future recovery plans, habitat conservation plans, or other species conservation planning efforts if new information available to these planning efforts calls for a different outcome.

As part of a court decision of August 30, 2000, in *Center for Biological Diversity v. Bruce Babbitt, Secretary of the Department of the Interior, and the United States Fish and Wildlife Service*, C99-3202 SC, we have entered into a court approved settlement agreement to submit a proposed rule for designation of critical habitat for the Kootenai River population of white sturgeon to the **Federal Register** by December 15, 2000.

Although the Service, in cooperation with other agencies, has gained important life history information during the 6 years since listing the species, considerable uncertainty remains in accurately delineating critical habitat for the Kootenai River population of white sturgeon. However, we rely on the best currently available information, including our 1999 recovery plan for the species, to designate critical habitat; we will now summarize the recent findings and remaining areas of uncertainty. Information being gathered now and in the future may require substantially amending this rule, the associated analyses of impacts, and any recommendations under section 7 of the Act.

In 1997, Paragamian *et al.* (1997) estimated that there may be 1,468 adult sturgeon remaining in the Kootenai River population, with a male-to-female ratio of 1.7:1, or about 539 females. With 7 percent of these females reproductively active in a given year (Apperson 1992), and an assumed average of 100,000 eggs per female, there may be as many as 3.8 million eggs released on average annually. To increase the probability of survival of fertilized eggs, the U.S. Army Corps of Engineers has provided various augmentation flows from Libby Dam. However, during the last 10 years of intensive monitoring, only one hatching fry has been found, and no free swimming larvae or young-of-the-year have been captured. To date, only 17 juvenile sturgeon have been captured that can be associated with the experimental augmentation flows between 1991 and 1997. Because of sampling gear limitations, the success of sturgeon recruitment during the 1998 and 1999 augmentation flows cannot be assessed at this time. Considering the extent of occupied habitat in the United States and Canada, we believe that we have not yet accounted for other naturally recruited sturgeon from these

same year classes that are present in the system. However, because of the high incidence of recapture of marked juvenile sturgeon in this system, the number of additional juvenile sturgeon is believed to be small.

There is evidence that very high levels of mortality of sturgeon eggs and sac fry are occurring annually. While we anticipate high levels of mortality at early life stages of a highly fecund species such as the Kootenai River white sturgeon, during 10 years of intensive monitoring we have never captured a free swimming larvae or young-of-the-year sturgeon, and have captured a total of only 17 juveniles. Thus, exceptionally high levels of mortality are likely occurring at the sites now being used for spawning, egg incubation, and yolk sac fry development.

White sturgeon are broadcast spawners that release adhesive eggs which then sink to the river bottom (Stockley 1981, Brannon *et al.* 1984). In the lower Columbia River, most sturgeon eggs are sheltered by attaching themselves and incubating on rocky substrate near the spawning site (Parsley *et al.* 1993). Rocky substrates also provide cover for yolk sac larvae before they become free swimming. However, in the Kootenai River, most of the current sturgeon spawning sites are over sandy substrate, and most eggs are found drifting along the river bottom covered with fine sand particles (Paragamian *et al.* in press).

When significant sturgeon recruitment last occurred in 1974, the Kootenai River recorded the preferred spawning temperatures, near 10 degrees Celsius (50 degrees Fahrenheit); base flows of 40,000 cubic feet per second (cfs) (1,120 cubic meters per second (cms)); peak flows of 55,000 cfs (1,540 cms); and a water surface elevation at Bonners Ferry of 1,765.5 feet (538.5 meters) above sea level. We do not know the locations or the substrate composition of the spawning sites selected by adults under these 1974 conditions. The more extreme flow events common in the unregulated Kootenai River prior to impoundment may have caused gravel to be exposed within the spawning area. Rocky substrates are needed for attachment, and provide shelter for incubating eggs and cover for yolk sac larvae in inter-gravel spaces. For example, the flood of record at Bonners Ferry, Idaho, was estimated to have been 157,000 (4,396 cubic meters per second), and peak flows in the range of 70,000 cubic feet per second (1,960 cubic meters per second) were not unusual prior to construction of Libby Dam, which

became fully operational in 1975. These flow, water surface elevation, and temperature conditions have not all been replicated at one time since 1974.

In the Kootenai River, spawning has not resulted in significant levels of recruitment, and it is unclear whether this is due to: 1) the current spawning site selection is a behavioral response to changed river velocities and depths from the operations of Libby Dam, which may be causing the sturgeon to spawn primarily at new sites below Bonners Ferry with unsuitable sandy riverbed substrates; or 2) spawning sites have remained unchanged, but the operations of Libby Dam have reduced peak flood flows and associated stream energy, which may be causing rocky substrate, otherwise suitable for egg incubation and sac fry development, to be covered with sand.

Suitable water and sediment quality are necessary for viability of early life stages of Kootenai River white sturgeon, including both incubating eggs and yolk sac larvae, and normal breeding behavior. In 1992, Apperson documented elevated levels of copper in both Kootenai River sediments and sturgeon oocytes and found low levels of the PCB Arochlor 1260 in river water. Because offspring of wild sturgeon captured and spawned in the hatchery appeared to survive and develop normally on filtered hatchery water, the question regarding quality of the river habitat remains. Subsequent studies of biota and survival (egg and larvae) has continued the concern as to the role water and sediment quality is playing in the lack of recruitment to the KRWS population. Although most sturgeon eggs released in the Kootenai River are not believed to live long enough to begin feeding, various constituents nutrients trapped in Lake Koocanusa, above Libby Dam, including nutrients, nitrogen and phosphorus, may affect the food base of those larvae that do hatch. The operations of Libby Dam can effect water temperatures in the spawning reach, especially during intermediate and low water years. Water temperature may effect spawning behavior. Optimum spawning temperature is near 10 degrees Celsius, and sudden drops of 2 to 3 degrees Celsius cause males to become reproductively inactive. Water and sediment quality and the effects of contaminants on sturgeon recruitment remain an area of concern and uncertainty.

Researchers with the U.S. Geological Survey (USGS) are beginning a study of possible changes in riverbed substrate and water depths in the Kootenai River from Kootenay Lake, British Columbia, to above Bonners Ferry, Idaho, which

may have resulted from the last 26 years of operations at Libby Dam. Further, there is an ongoing study involving the releases of large numbers (over 100,000) of four-day-old, hatchery-reared, yolk sac larvae over both sandy and rocky substrates in the Kootenai River, which is also intended to address uncertainties involving the sturgeon population's riverbed substrate needs.

Primary Constituent Elements

Regulations in 50 CFR 424.12 provide that in identifying areas as critical habitat within the geographic area occupied by the species, we consider those physical and biological features which are essential to conservation of the species, and that may require special management considerations or protection. These physical and biological features, as outlined in 50 CFR 424.12, include but are not limited to the following:

- Space for individual and population growth, and for normal behavior;
- Food, water, or other nutritional or physiological requirements;
- Cover or shelter;
- Sites for breeding, reproduction, or rearing of offspring; and
- Habitats that are protected from disturbance or are representative of the historical geographical and ecological distributions of a species.

The important habitat features that provide for breeding and rearing of offspring through the free-swimming larvae stage include: water temperatures, depths, and flows sufficient to trigger sturgeon breeding, and water volumes and substrates sufficient to cover and shelter incubating eggs and yolk sac larvae.

We have determined the primary constituent elements of critical habitat for the Kootenai River population of white sturgeon from studies of their habitats, life history, and population biology described and referenced above. As noted, Kootenai River flows may affect the sturgeon in two ways and, based on the best available information, we recognize each for identification of the primary constituent elements. Flows may affect normal breeding behavior, including site selection, and/or alter the riverbed substrate, which may affect survival of eggs and cover for yolk sac larvae. Flows may also affect the efficiency of predators to locate eggs and sac fry larvae. The four primary constituent elements of Kootenai River sturgeon critical habitat are:

1. A flow regime that creates a hydrologic profile characterized by flow magnitude, timing, and velocity, and

water depth and quality (including temperatures) necessary for normal behavior involving breeding site selection, breeding and fertilization, and cover for egg incubation and yolk sac fry development.

2. A flow regime that creates a hydrologic profile characterized by water of sufficient duration and magnitude to restore or maintain riverbed substrate necessary for attachment and shelter of incubating eggs and cover for yolk sac fry in inter-gravel spaces.

3. A flow regime that creates a hydrologic profile characterized by flow magnitude, time, velocity, depth, and duration necessary for the normal behavior of adult and juvenile sturgeon.

4. Water and sediment quality necessary for normal behavior, including breeding behavior, and viability of all life stages of the Kootenai River white sturgeon, including incubating eggs and yolk sac larvae.

The area we are proposing for designation as critical habitat for the Kootenai River population of white sturgeon provides the above constituent elements and requires special management considerations or protection to ensure their contribution to the species' conservation.

Criteria Used to Identify Critical Habitat

Section 4(b)(2) of the Act requires us to designate critical habitat on the basis of the best scientific and commercial information available, and to consider the economic and other relevant impacts of designating a particular area as critical habitat. We may exclude areas from critical habitat upon a determination that the benefits of such exclusions outweigh the benefits of specifying such areas as critical habitat.

In an effort to map areas essential to the conservation of the species, we used data on known Kootenai River sturgeon spawning and early life stage rearing areas. In the lower Columbia River, where white sturgeon continue to spawn successfully, egg incubation sites and yolk sac fry development sites are at or slightly downstream of spawning sites (Parsley *et al.* 1993). In the Kootenai River, eggs at all stages of development and one hatching yolk sac fry have been found at or downstream of the spawning sites. Since 1991, sturgeon eggs have been recovered in the Kootenai River between river kilometer 228 (river mile 141.4), below Shorty's Island (Paramagian *et al.* 1995), and river kilometer 246 (river mile 152.6), above the Highway 95 bridge at Bonner's Ferry, Idaho (Paramagian *et al.* in press). Although many of the eggs

found were unattached and drifting along the river bottom, Paragamian *et al.* (in press) support the assumption that the Kootenai River sturgeon egg collection sites are in the vicinity of the spawning sites. Further, since no other spawning sites have been identified in 10 years of monitoring, we believe these are the same sites where at least some successful egg incubation and yolk sac fry development has occurred, as evidenced by the 17 wild juveniles captured and aged to year classes within this same 10 year study period.

Existing structures within the proposed critical habitat boundaries, such as highway and railroad bridges, do not contain one or more of the primary constituent elements, and therefore are not included in this critical habitat designation.

Proposed Critical Habitat Designation

We propose the following as critical habitat for the Kootenai River population of white sturgeon: that portion of the Kootenai River within Boundary County, Idaho, from river kilometer 228 (river mile 141.4) to river kilometer 246 (river mile 152.6). The lateral extent of proposed critical habitat is up to the ordinary high water line (as defined by the Corps in 33 CFR Part 329.11) on each bank of the Kootenai River within the 18 kilometer (11.2 mile) reach.

Land Ownership

The reach of the Kootenai River proposed as critical habitat lies within the ordinary high water lines as defined for regulatory purposes (33 CFR part 329.11). Upon statehood in 1890, the State of Idaho claimed ownership of the bed of the Kootenai River up to ordinary high water lines. Numerous private-, public-, and tribally-owned parcels abut this State-owned riverbed, including lands managed by the Service at the Kootenai National Wildlife Refuge and trust lands managed by the Kootenai Tribe of Idaho.

Based upon early U.S. Forest Service (USFS) maps from 1916, USGS maps from 1928, and the confining effects of the Corps' levees constructed in 1961, it appears that within this reach of the Kootenai River the ordinary high water lines originally delineating State lands are essentially unchanged. Because of the scales of the available maps, it is possible that minor river channel changes have occurred since statehood, and that some small portions of private lands now occur within the ordinary high water lines. However, we understand that most of the lands where these changes may have occurred lie within the flowage and seepage

easements purchased by the Federal government under Public Law 93-251, Section 56, passed in 1974. In addition, when the river meanders, the "government lot" or parcel owners abutting State-owned riverbed may request parcel boundary adjustments to the new ordinary high water line, and corresponding adjustments in taxable acreage. Although the elevations of ordinary high water have been lowered by the operations of Libby Dam since 1974, the lateral extent of the State-owned riverbed along the steep levees may be closely approximated today through the Corps' definition of ordinary high water line cited above. Thus, we believe the lands proposed here as critical habitat are within lands owned by the State of Idaho.

Effect of Critical Habitat Designation

Section 7(a) of the Act requires Federal agencies to ensure that actions they fund, authorize, or carry out do not destroy or adversely modify critical habitat to the extent that the action appreciably diminishes the value of the critical habitat for both the survival and recovery of the species. Individuals, organizations, State, Tribal, and local governments, and other non-Federal entities are affected by the designation of critical habitat only if their actions occur on Federal lands, require a Federal permit, license, or other authorization, or involve Federal funding. Thus, activities on Federal lands that may affect the Kootenai River white sturgeon or its critical habitat, if designated, will require section 7 consultation. Actions on private or State lands receiving funding or requiring a permit from a Federal agency also will be subject to the section 7 consultation process if the action may affect the species or its critical habitat, if designated. Federal actions not affecting the species or its critical habitat, as well as actions on non-Federal lands that are not federally funded or permitted, will not require section 7 consultation.

Federal agencies are required to evaluate their actions with respect to any species that is proposed or listed as endangered or threatened, and with respect to its proposed or designated critical habitat. Regulations implementing these interagency cooperation provisions of the Act are codified at 50 CFR part 402. Section 7(a)(4) of the Act and regulations at 50 CFR 402.10 require Federal agencies to confer with us on any action that is likely to jeopardize the continued existence of a proposed species, or to result in destruction or adverse modification of proposed critical habitat. A section 7 conference on

proposed critical habitat results in a report that may provide conservation recommendations to assist the action agency in eliminating or minimizing adverse effects to the proposed critical habitat that may be caused by the proposed agency action. The conservation recommendations in a conference report are advisory. We may issue a formal conference report, if requested by a Federal agency. Formal conference reports on proposed critical habitat contain a conference opinion as to whether the proposed action is likely to destroy or adversely modify proposed critical habitat. This conference opinion is prepared as if critical habitat were designated as final, in accordance with 50 CFR 402.13.

If we finalize this proposed critical habitat designation, section 7(a)(1) will require Federal agencies to enter into consultation with us on agency actions that may affect critical habitat. Consultations on agency actions that will likely adversely affect critical habitat will result in issuance of a biological opinion. We may adopt a formal conference report as the biological opinion if no significant new information or changes in the action alter the content or the opinion (see 50 CFR 402.10(d)).

If we find a proposed agency action is likely to destroy or adversely modify the critical habitat, our biological opinion may include reasonable and prudent alternatives to the action that are designed to avoid destruction or adverse modification of critical habitat. Reasonable and prudent alternatives are defined at 50 CFR 402.02 as alternative actions that can be implemented in a manner consistent with the intended purpose of the action, that are consistent with the scope of the Federal agency's legal authority and jurisdiction, that are economically and technologically feasible, and that we believe would avoid destruction or adverse modification of critical habitat. Reasonable and prudent alternatives can vary from slight project modifications to extensive redesign or relocation of the project. Costs associated with implementing a reasonable and prudent alternative vary accordingly.

Regulations at 50 CFR 402.16 also require Federal agencies to reinstate consultation in instances where we have already reviewed an action for its effects on listed species if critical habitat is subsequently designated and the Federal agency has retained discretionary involvement or control over the action or such discretionary involvement or control is authorized by law. Consequently, some Federal agencies may request reinitiation of

conferencing with us on actions likely to destroy or adversely modify proposed critical habitat, or consultation if their actions may affect designated critical habitat.

Section 4(b)(8) of the Act requires us to briefly evaluate and describe in any proposed or final regulation that designates critical habitat those activities involving a Federal action that may adversely modify such habitat, or that may be affected by such designation. Activities that may destroy or adversely modify critical habitat include those that alter the primary constituent elements to an extent that the value of critical habitat for both the survival and recovery of the Kootenai River population of white sturgeon is appreciably reduced. We note that such activities may also jeopardize the continued existence of the species. A wide range of Federal activities may include land and water management actions of Federal agencies (e.g., U.S. Army Corps of Engineers (COE), Bonneville Power Administration, Natural Resources Conservation Service, U.S. Forest Service, U.S. Environmental Protection Agency (EPA), Bureau of Indian Affairs, and U.S. Fish and Wildlife Service), and related or similar actions of other federally regulated projects (e.g., road and bridge construction or maintenance activities by the Federal Highway Administration; dredge and fill projects, sand and gravel mining, bank stabilization activities conducted by the COE; and National Pollutant Discharge Elimination System permits authorized by the EPA). These activities may destroy or adversely modify critical habitat if they alter the primary constituent elements (defined above) to an extent that the value of critical habitat for both the survival and recovery of the Kootenai River population of white sturgeon is appreciably reduced. Activities that, when carried out, funded, or authorized by a Federal agency, may destroy or adversely modify critical habitat include, but are not limited to:

(1) Altering the flow regime within the proposed critical habitat in ways that prevent the necessary conditions for breeding and fertilization. For example, flood control and hydroelectric operations and water release configuration limitations of Libby Dam may destroy or adversely modify proposed critical habitat by altering habitat for normal breeding behavior, shelter for incubating eggs, and cover for yolk sac larvae.

(2) Altering the flow regime within the proposed critical habitat in ways that prevent the necessary conditions for incubating eggs and developing yolk

sac larvae. Flood control and hydroelectric operations combined with the water release configuration limitations of Libby Dam may destroy or adversely modify proposed critical habitat necessary for incubation of eggs and development of yolk sac larvae by altering riverbed substrate composition, through reduced bed load transport energy and unnatural distribution of stream bed sand and silt. Land management activities accelerating sediment releases from watersheds entering the Kootenai River below Libby Dam, and above or within proposed critical habitat, may also destroy or adversely modify this proposed critical habitat through increased deposition of sand and silt in the stream bed. Other actions, including channelization, levee reconstruction, stream bank stabilization, gravel removal, and road and bridge construction, could also have this result.

(3) Altering water chemistry. Possible actions include the release of chemicals or biological pollutants into the waters passing through the proposed critical habitat from point sources or by dispersed releases (non-point sources).

These examples indicate the types of activities that will require consultation in the future and, therefore, that may be affected by critical habitat designation. These kinds of activities would also generally require consultation when they affect a listed species, irrespective of impacts to critical habitat. As discussed above, the standards for "jeopardy" and "adverse modification" are essentially identical. As a result, we do not expect that designation of critical habitat in this area, occupied by the Kootenai River population of white sturgeon, will result in a regulatory burden substantially above that already in place, due to the presence of the already-listed species.

Federal actions that are found likely to destroy or adversely modify critical habitat (or to jeopardize the continued existence of the species) may often be modified, through development of reasonable and prudent alternatives, in ways that will remove the likelihood of destruction or adverse modification of critical habitat (or jeopardy). Project modifications may include, but are not limited to, adjustment in timing of projects to avoid sensitive periods for the species and its habitat; minimization of work and vehicle use in the wetted channel; avoidance of pollution; use of alternative material sources; sediment barriers; and use of best land management and construction practices.

If you have questions regarding whether specific activities will likely constitute destruction or adverse

modification of critical habitat, contact the Field Supervisor, Upper Columbia River Fish and Wildlife Office (see **ADDRESSES** section). Requests for copies of the regulations on listed wildlife, and inquiries about prohibitions and permits may be addressed to the Division of Endangered Species, U.S. Fish and Wildlife Service, 911 NE 11th Avenue, Portland, Oregon 97232-4181 (telephone 503-231-6158; facsimile 503-231-6243).

Economic Analysis

Section 4(b)(2) of the Act requires we designate critical habitat on the basis of the best available scientific and commercial information available and that we consider the economic and other relevant impacts of designating a particular area as critical habitat. The economic impacts to be considered in critical habitat designation are the incremental effects of the designation over and above the economic impacts attributable to listing of the species.

We may exclude areas from critical habitat upon a determination that the benefits of such exclusions outweigh the benefits of specifying those areas as critical habitat; however, we cannot exclude areas from critical habitat when the exclusion will result in extinction of the species. A draft economic analysis will be made available for public review and comment (see **ADDRESSES** section). The availability of the draft economic analysis will be announced in the **Federal Register** and in local newspapers. We will utilize the economic analysis, and take into consideration all comments and information submitted during the public hearing and comment period, to determine whether areas should be excluded from final critical habitat designation.

American Indian Tribal Rights, Federal-Tribal Trust Responsibilities, and the Endangered Species Act

In accordance with the President's memorandum of April 29, 1994, "Government-to-Government Relations with Native American Tribal Governments" (59 FR 22951) and 512 DM 2, we understand that federally recognized Tribes must be related to on a government-to-government basis. We support tribal measures that preclude the need for conservation regulations, and we provide technical assistance to tribes who wish assistance in developing and expanding tribal programs for the management of healthy ecosystems so that Federal conservation regulations, such as designation of critical habitat, on tribal lands are unnecessary.

The Presidential Memorandum of April 29, 1994, also requires us to consult with the tribes on matters that affect them, and section 4(b)(2) of the Act requires us to gather information regarding the designation of critical habitat and the effects thereof from all relevant sources, including the tribes. Recognizing a government-to-government relationship with tribes and our Federal trust responsibilities, we consulted representatives of the Kootenai Tribe of Idaho with regard to trust resources, tribal lands, or tribal rights that might be affected by the designation of critical habitat.

In our deliberations over this critical habitat proposal, we identified possible effects to the Kootenai Tribe of Idaho or tribal resources. These include: (1) effects of designation of critical habitat on State lands adjacent to tribal lands; and (2) the effects on tribal resources, such as water deliveries and aquatic resources such as the Kootenai River white sturgeon. The Kootenai Tribe of Idaho is directly involved in the conservation of the Kootenai River white sturgeon, and conducts a conservation aquaculture program. To do this, the Tribe diverts a small amount of water directly from the Kootenai River within the area of proposed critical habitat. We do not anticipate any indirect adverse effects to Tribal lands through management actions intended to enhance or maintain proposed critical habitat on adjacent State of Idaho lands. However, we do anticipate beneficial effects to Tribal resources, including water quality and the sturgeon, from the designation of critical habitat on adjacent non-tribal lands.

In complying with our tribal trust responsibilities, we must communicate with all tribes potentially affected by the designation. Therefore, we are soliciting information during the comment period on potential effects to tribes or tribal resources that may result from critical habitat designation.

Public Comments Solicited

We intend for any final action resulting from this proposal to be as accurate and as effective as possible. Therefore, we are soliciting comments or suggestions from the public, other concerned governmental agencies, the scientific community, industry, or any other interested party concerning this proposed rule. We particularly seek comments concerning:

(1) The reasons why any habitat should or should not be determined to be critical habitat as provided by section 4 of the Act, including whether the benefits of excluding areas will

outweigh the benefits of including areas as critical habitat;

(2) Specific information on any habitat changes which may have occurred in the Kootenai River since 1961;

(3) Areas that are essential to the conservation of the species and that may require special management considerations or protections;

(4) Land or water use practices and current or planned activities in the subject areas and their possible impacts on proposed critical habitat;

(5) Any foreseeable economic or other impacts resulting from proposed critical habitat; and

(6) Economic and other values associated with designating critical habitat for the Kootenai River white sturgeon, such as those derived from non-consumptive uses (e.g., enhanced watershed protection, "existence values", increased soil retention, water quality, and reductions in administrative costs).

If you wish to comment, you may submit your comments and materials concerning this proposal by any one of several methods.

(1) You may submit written comments and information to the Field Supervisor, U.S. Fish and Wildlife Service, Upper Columbia Fish and Wildlife Office, 11103 East Montgomery, Spokane, Washington 99206.

(2) You may send comments by electronic mail (e-mail) to FW1SPOK_crithab_stur@R1.fws.gov. If you submit comments by e-mail, please submit comments as an ASCII file format and avoid the use of special characters and encryption. Please include "Attn: [1018-AH06]" and your name and return address in your e-mail message. If you do not receive a confirmation from the system that we have received your e-mail message, contact us directly by calling our Upper Columbia Fish and Wildlife Office at phone number 509-891-6839. Please note that this e-mail address will be closed out at the termination of the public comment period.

(3) You may hand-deliver written comments to our Upper Columbia Fish and Wildlife Office, 11103 East Montgomery, Spokane, Washington.

(4) You may provide comments at the public hearing on January 18, 2001, at the Bonners Ferry Kootenai River Inn, 7160 Plaza Street, Bonners Ferry, Idaho.

Our practice is to make comments, including names and home addresses of respondents, available for public review during regular business hours. Respondents may request that we withhold their home address, which we will honor to the extent allowable by

law. There also may be circumstances in which we would withhold a respondent's identity, as allowable by law. If you wish us to withhold your name and/or address, you must state this request prominently at the beginning of your comment. However, we will not consider anonymous comments. To the extent consistent with applicable law, we will make all submissions from organizations or businesses, and from individuals identifying themselves as representatives or officials of organizations or businesses, available for public inspection in their entirety. Comments and materials received will be available for public inspection, by appointment, during normal business hours at the above address.

Peer Review

In accordance with our policy published on July 1, 1994 (59 FR 34270), we will seek expert opinions of at least three appropriate independent specialists regarding this proposed rule. The purpose of such review is to ensure listing decisions are based on scientifically sound data, assumptions, and analysis. We will send copies of this proposed rule immediately following publication in the **Federal Register** to these peer reviewers. We will invite these peer reviewers to comment, during the public comment period, on the specific assumptions and conclusions regarding the proposed designation of critical habitat.

We will consider all comments and information received during the comment period on this proposed rule during the preparation of a final rulemaking. Accordingly, the final decision may differ from this proposal.

Public Hearings

In anticipation of public interest in this issue, a public hearing has been scheduled for Thursday, January 18, 2001, from 6:00 p.m. until 8:00 p.m. at the Kootenai River Inn, 7160 Plaza Street, Bonners Ferry, Idaho.

Written comments submitted during the comment period receive equal consideration with those comments presented at a public hearing.

Clarity of the Rule

Executive Order 12866 requires each agency to write regulations that are easy to understand. We invite your comments on how to make this proposed rule easier to understand including answers to questions such as the following: (1) Are the requirements in the document clearly stated? (2) Does the proposed rule contain technical language or jargon that interferes with

clarity? (3) Does the format of the proposed rule (grouping and order of sections, use of headings, paragraphing, etc.) aid or reduce clarity? (4) Is the description of the proposed rule in the **SUPPLEMENTARY INFORMATION** section of the preamble helpful in understanding the document? (5) What else could we do to make the proposed rule easier to understand?

Send a copy of any comments that concern how we could make this notice easier to understand to: Office of Regulatory Affairs, Department of the Interior, Room 7229, 1849 C Street, NW, Washington, DC 20240. You may e-mail your comments to this address: Execsec@ios.doi.gov.

Required Determinations

Regulatory Planning and Review

In accordance with the criteria in Executive Order 12866, this rule is a significant regulatory action and has been reviewed by the Office of Management and Budget (OMB). We will prepare a draft economic analysis of this proposed action to determine the economic consequences of designating the specific area of critical habitat. The draft economic analysis will be available for public review and comment.

(a) This rule will not have an annual economic effect of \$100 million or more or adversely affect an economic sector, productivity, jobs, the environment, or other units of government. A cost-benefit analysis is not required for the purposes of executive Order 12866. The Kootenai River Population of white

sturgeon was listed as endangered in 1994. We are currently conducting one formal section 7 consultation with the Corps, Bonneville Power Administration, and the Bureau of Reclamation on operations of the Federal Columbia River Power System, in part, to ensure that their actions would not jeopardize the continued existence of the Kootenai River population of white sturgeon. Based on the proposed action, we have issued a draft non-jeopardy biological opinion on the sturgeon. We plan to finalize this biological opinion by December 2000.

Under the Act, critical habitat may not be destroyed or adversely modified by a Federal agency action; it does not impose any restrictions on non-Federal persons unless they are conducting activities funded or otherwise sponsored or permitted by a Federal agency (see Table 1 below). Section 7 requires Federal agencies to ensure that they do not jeopardize the continued existence of the species. Based upon our experience with the species and its needs, we conclude that any Federal action or authorized action that could potentially cause adverse modification of designated critical habitat would currently be considered as "jeopardy" under the Act. Accordingly, the designation of areas within the geographic range occupied by the Kootenai River population of white sturgeon does not have any incremental impacts on what actions may or may not be conducted by Federal agencies or non-Federal persons that receive Federal authorization or funding. Non-Federal persons that do not have a

Federal "sponsorship" of their actions are not restricted by the designation of critical habitat although they continue to be bound by the provisions of the Act concerning "take" of the species.

(b) This rule will not create inconsistencies with other agencies' actions. Federal agencies have been required to ensure that their actions do not jeopardize the continued existence of the Kootenai River white sturgeon since its listing in 1994. The prohibition against adverse modification of critical habitat is not expected to impose any additional restrictions to those that currently exist in occupied areas of proposed critical habitat. Because of the potential for impacts on other Federal agency activities, we will continue to review this proposed action for any inconsistencies with other Federal agency actions.

(c) This proposed rule, if made final, will not significantly impact entitlements, grants, user fees, loan programs, or the rights and obligations of recipients. Federal agencies are currently required to ensure that their activities do not jeopardize the continued existence of the species, and, as discussed above, we do not anticipate that the adverse modification prohibition (resulting from critical habitat designation) will have any incremental effects in areas of occupied habitat.

(d) This rule will not raise novel legal or policy issues. The proposed rule follows the requirements for determining critical habitat contained in the Endangered Species Act.

TABLE 1.—ACTIVITIES POTENTIALLY IMPACTED BY KOOTENAI RIVER POPULATION OF WHITE STURGEON LISTING AND CRITICAL HABITAT DESIGNATION

Categories of activities	Activities potentially affected by species listing only ¹	Additional activities potentially affected by critical habitat designation ²
Potentially Affected Activities that are Initiated by a Federal Agency.	Operation of dams, reservoirs, and other water control facilities in the Kootenai River watershed. Federal issuance of scientific permits, operation of captive propagation facilities, sturgeon habitat restoration.	None.
Potentially Affected Activities Initiated by a Private or Other Non-Federal Entity That May Need Federal Authorization or Funding.	Construction and/or operation of freshwater hatcheries, water withdrawal projects, approval of new or revised water quality standards, pesticide registration, streambank stabilization, gravel mining, road and bridge construction, pipeline streamcrossings, and sturgeon habitat restoration that require a Federal action (permit, authorization, or funding).	None.

¹ This column represents the activities potentially affected by listing the Kootenai River population of white sturgeon as an endangered species (September 6, 1994; 59 FR 45989) under the Endangered Species Act.

² This column represents the activities potentially affected by the critical habitat designation in addition to those activities potentially affected by listing the species.

Regulatory Flexibility Act (5 U.S.C. 601 et seq.)

In the draft economic analysis, we will determine if designation of critical habitat will have a significant effect on a substantial number of small entities. As discussed under Regulatory Planning and Review above, this rule is not expected to result in any restrictions in addition to those currently in existence for areas of occupied critical habitat.

Small Business Regulatory Enforcement Fairness Act (5 U.S.C. 804(2))

Under our draft economic analysis, we will determine whether designation of critical habitat will cause: (a) any increases in costs or prices for consumers; individual industries; Federal, State, Tribal, or local government agencies; or geographic regions; or (b) any significant adverse effects on competition, employment, investment, productivity, innovation, or the ability of U.S.-based enterprises to compete with foreign-based enterprises. As discussed above, we anticipate that the designation of critical habitat will not have any additional effects on these activities in areas of critical habitat occupied by the species.

Unfunded Mandates Reform Act (2 U.S.C. 1501 et seq.)

In accordance with the Unfunded Mandates Reform Act:

(a) This rule will not "significantly or uniquely" affect small governments. A Small Government Agency Plan will not be required. Small governments will be affected only to the extent that any programs involving Federal funds, permits, or other authorized activities must ensure that their actions will not destroy or adversely modify critical habitat. However, as discussed above, these actions are currently subject to equivalent restrictions through the listing protections of the species, and no further restrictions are anticipated in areas of occupied proposed critical habitat.

(b) This rule will not produce a Federal mandate on State, Tribal, or local governments or the private sector of \$100 million or greater in any year, *i.e.*, it is not a "significant regulatory action" under the Unfunded Mandates Reform Act. The designation of critical habitat imposes no obligations on State, Tribal, or local governments.

Takings

In accordance with Executive Order 12630, this rule does not have significant takings implications, and a takings implication assessment is not required. This proposed rule, if made final, will not "take" private property.

The designation of critical habitat affects only Federal agency actions. The rule will not increase or decrease the current restrictions on private property concerning take of the Kootenai River population of white sturgeon. Additionally, critical habitat designation does not preclude development of habitat conservation plans and issuance of incidental take permits. Non-Federal landowners in areas that are included in the designated critical habitat will continue to have opportunity to utilize their property in ways consistent with the survival of the Kootenai River population of white sturgeon.

Federalism

In accordance with Executive Order 13132, the rule does not have significant Federalism effects. A Federalism assessment is not required. The designation of critical habitat in areas currently occupied by the Kootenai River white sturgeon imposes no additional restrictions to those currently in place, and therefore has little incremental impact on State and local governments and their activities.

In keeping with Department of the Interior policy, we requested information from and coordinated development of this critical habitat designation with appropriate State resource agencies in Idaho. We also utilized information on critical habitat submitted by the State during the listing of the Kootenai River white sturgeon. The State now has representation on our recovery team for this species. Consequently, we will continue to coordinate this and any future designation of critical habitat with the appropriate State agency.

Civil Justice Reform

In accordance with Executive Order 12988, the Department of the Interior's Office of the Solicitor determined that this rule does not unduly burden the judicial system and meets the requirements of sections 3(a) and 3(b)(2) of the Order. The Office of the Solicitor will review the final determination for this proposal. We will make every effort to ensure that the final determination contains no drafting errors, provides clear standards, simplifies procedures, reduces burden, and is clearly written such that litigation risk is minimized.

Paperwork Reduction Act of 1995 (44 U.S.C. 3501 et seq.)

This proposed rule does not contain any information collection requirements for which OMB approval under the Paperwork Reduction Act is required.

National Environmental Policy Act

We have determined that we do not need to prepare an Environmental Assessment and/or an Environmental Impact Statement as defined by the National Environmental Policy Act of 1969 in connection with regulations adopted pursuant to section 4(a) of the Endangered Species Act, as amended. We published a notice outlining our reasons for this determination in the **Federal Register** on October 25, 1983 (48 FR 49244). This position was upheld by the U. S. Court of Appeals for the Ninth Circuit (*Douglas County v. Babbitt*, 48 F.3d 1495 (9th Cir.1995), *cert. denied* 116 S. Ct. 698 (1996)).

Government-to-Government Relationship with Tribes

In accordance with the President's memorandum of April 29, 1994, "Government-to-Government Relations with Native American Tribal Governments" (59 FR 22951) and the Department of the Interior's requirement at 512 DM 2, we understand that recognized Federal Tribes must be related to on a Government-to-Government basis.

References Cited

A complete list of all references cited in this proposed rule is available upon request from U.S. Fish and Wildlife Service, Upper Columbia Fish and Wildlife Office (see **ADDRESSES** section).

Author

The primary author of this notice is Bob Hallock, U.S. Fish and Wildlife Service (see **ADDRESSES** section).

List of Subjects in 50 CFR Part 17

Endangered and threatened species, Exports, Imports, Reporting and record keeping requirements, Transportation.

Proposed Regulation Promulgation

Accordingly, we propose to amend part 17, subchapter B of chapter 1, title 50 of the Code of Federal Regulations 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. Amend § 17.11 (h), by revising the entry for "sturgeon, white" under "FISHES" to read as follows:

§ 17.11 Endangered and threatened wildlife.

* * * * *

(h) * * *

Species		Historic range	Vertebrate population where endangered or threatened	Status	When listed	Critical habitat	Special rules
Common name	Scientific name						
FISHES							
*	*	*	*	*	*	*	*
Sturgeon, white	Acipenser transmontanus.	U.S.A. (ID, MT), Canada (B.C.).	U.S.A. (ID, MT), Canada (B.C.), (Kootenai R. system).	E	549	17.95(e)	NA
*	*	*	*	*	*	*	*

3. Amend § 17.95(e) by adding critical habitat for the Kootenai River population of white sturgeon (*Acipenser transmontanus*) in the same alphabetical order as this species occurs in § 17.11 (h) to read as follows:

§ 17.95 Critical habitat—fish and wildlife.

* * * * *

(e) *Fishes.*

* * * * *

Kootenai River population of white sturgeon (*Acipenser transmontanus*).

1. Critical habitat is depicted for Boundary County, Idaho on the map and as described below.

2. Critical habitat includes the Kootenai River from river kilometer 228 (river mile 141.4) to river kilometer 246 (river mile 152.6), as indicated on the map below, from ordinary high water line to opposite ordinary high water line as defined by the U.S. Army Corps of Engineers (33 CFR 329.11).

3. Within these areas, the primary constituent elements include, but are not limited to, those that are essential for the primary biological needs of

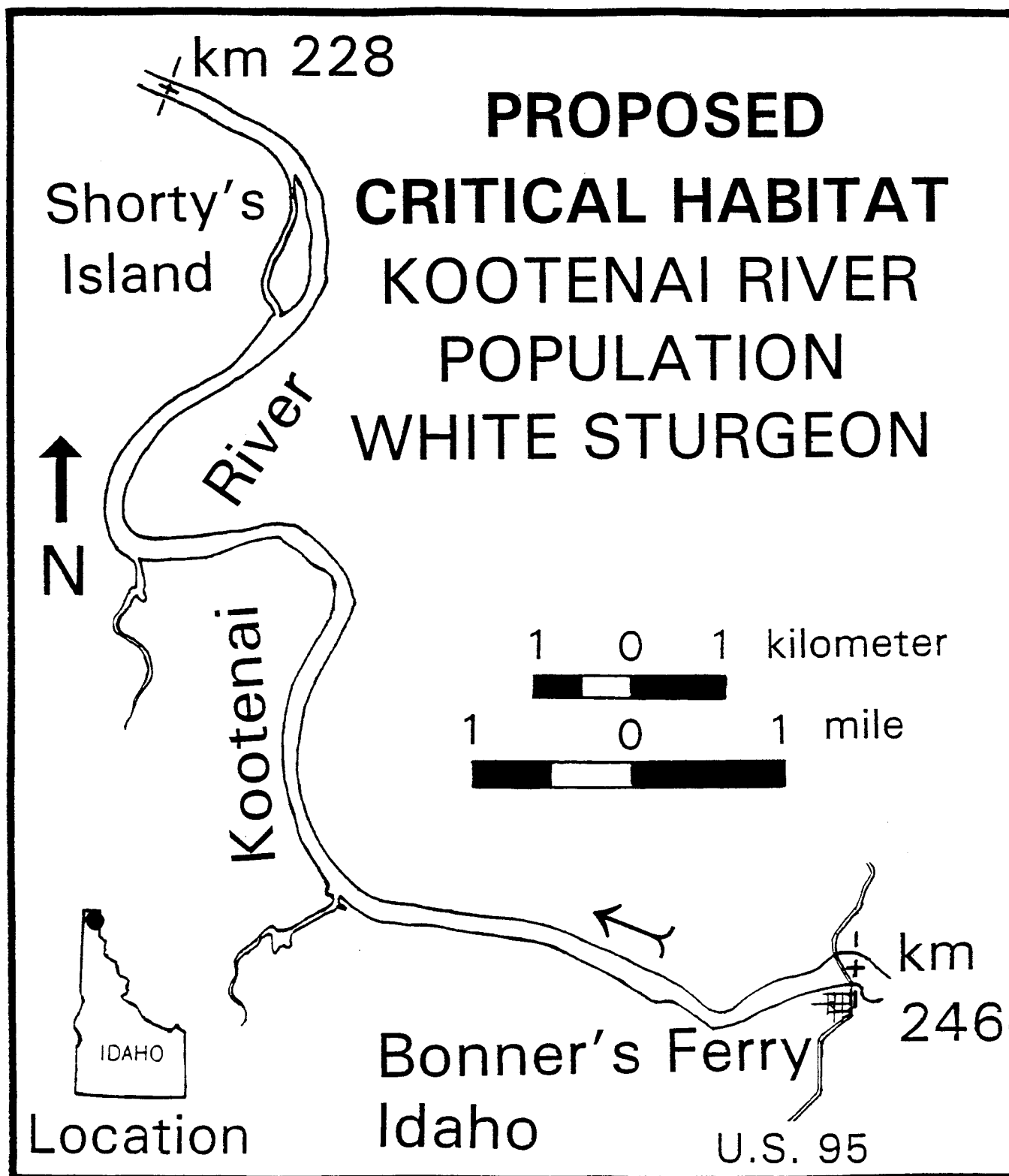
normal behavior, water requirements, cover, shelter, breeding, and rearing of offspring. These elements include the following: (1) A flow and hydrologic regime characterized by water magnitude, timing, depth and velocity; and water quality, including temperatures necessary for normal behavior involving breeding site selection, breeding and fertilization, and cover for egg incubation and yolk sac fry development; (2) a flow and hydrologic regime characterized by water of sufficient duration and magnitude to restore or maintain riverbed substrate necessary for cover and shelter for both incubating eggs and yolk sac larvae; (3) a flow and hydrologic regime characterized by flow magnitude, time, velocity, depth, and duration necessary for the normal behavior of adult and juvenile sturgeon; and (4) water and sediment quality necessary for normal behavior, including breeding behavior, and the viability of all life stages, including incubating eggs and yolk sac larvae.

4. Within this area, existing structures, such as buildings and roads, are not included in the critical habitat designation.

5. Idaho (Boise Meridian (BM)): Areas of land and water as follows: Physical features were identified using USGS 7.5' quadrangle maps for the downstream margin, and the Bonners Ferry Gage location information from USGS data (USGS 1997) for the upstream margin; river reach distances were initially provided in kilometers by Idaho Department of Fish and Game and converted to river miles with reference points found on USGS 7.5' quadrangles.

Proposed critical habitat in the Kootenai River within Boundary County, Idaho from river kilometer 228 (river mile 141.4) (SW¼, Sec. 25, T.63N., R.1W., BM), below "Shorty's Island", upstream to river kilometer 246 (river mile 152.6) (NE¼, Sec. 27, T.62N., R.1E., BM), above the Highway 95 bridge at Bonners Ferry.

BILLING CODE 4310-55-P



Dated: December 15, 2000.

Kenneth L. Smith,

*Acting Assistant Secretary for Fish and
Wildlife and Parks.*

[FR Doc. 00-32466 Filed 12-20-00; 8:45 am]

BILLING CODE 4310-55-C



Federal Register

**Thursday,
December 21, 2000**

Part VII

Department of Commerce

**National Telecommunications and
Information Administration**

**Public Telecommunications Facilities
Program: Closing Date; Notice**

DEPARTMENT OF COMMERCE**National Telecommunications and Information Administration****[Docket No. 001215353-0353-01]****RIN 0660-ZA14****Public Telecommunications Facilities Program: Closing Date****AGENCY:** National Telecommunications and Information Administration (NTIA), Commerce.**ACTION:** Notice of availability of funds.

SUMMARY: The National Telecommunications and Information Administration (NTIA), U.S. Department of Commerce, announces the solicitation of applications for planning and construction grants for public telecommunications facilities under the Public Telecommunications Facilities Program (PTFP).

DATES: Pursuant to 15 CFR 2301.8(b), the NTIA Administrator hereby establishes the closing date for the filing of applications for PTFP grants. The closing date selected for the submission of applications for FY 2001 is February 15, 2001. Applications must be received prior to 7 p.m. on or before February 15, 2001. Applications submitted by facsimile or electronic means are not acceptable.

ADDRESSES: To obtain an application package, submit completed applications, or send any other correspondence, write to: NTIA/PTFP, Room H-4625, U.S. Department of Commerce, 1401 Constitution Avenue, NW., Washington, DC 20230.

FOR FURTHER INFORMATION CONTACT: William Cooperman, Director, Public Broadcasting Division, telephone: (202) 482-5802; fax: (202) 482-2156. Information about the PTFP can also be obtained electronically via Internet (<http://www.ntia.doc.gov/otiahome/ptfp>).

SUPPLEMENTARY INFORMATION:**I. Closing Date**

Applicants for matching grants under the PTFP must file their applications on or before 7 p.m., Thursday, February 15, 2001. Approximately \$30 million is available for FY 2001 PTFP grants in response to this Notice.¹ In appropriating FY 2001 funds, the

¹ See the Conference Report (H. Rept. 106-1033) on H.R. 4577, Departments of Labor, Health and Human Services, and Education, and Related Agencies Appropriations Act, 2001. NTIA has allocated approximately \$10 million from the \$43.5 million appropriated for multi-year projects initially funded in FY 2000.

Congress directed that NTIA "maintain an appropriate balance between traditional grants and those to stations converting to digital broadcasting."² Information regarding digital television Broadcast Other projects is included in Section V of this document. Section V also describes revisions of the PTFP Rules which will be applicable only for the 2001 Grant Round for applications in the Broadcast Other category. The amount of a grant award by NTIA will vary, depending on the approved project. For fiscal year 2000, NTIA awarded \$25.8 million in funds to 103 projects. The awards ranged from \$4,054 to \$1,250,680.

II. Application Forms

PTFP has a new application form which all applicants must use for the FY 2001 grant cycle. This form expires on October 31, 2003, and no previous versions of the form may be used. Each page of the new application form has the expiration date of 10/31/2003 printed on the bottom line. (In accordance with the Paperwork Reduction Act, the current application form has been cleared under OMB control no. 0660-0003.) To apply for a PTFP grant, an applicant must file an original and five copies of a timely and complete application on the new application form. Applicants for television projects in the Broadcast Other category (15 CFR 2301.4(b)(6)) are requested to supply one additional copy of their application (an original and six copies), if this does not create a hardship on the applicant. The current application form will be provided to applicants as part of the application package.

III. Regulations

The applicable Rules for the PTFP were published on November 8, 1996 (61FR 57966). In accordance with provisions provided in 15 CFR part 2301, § 2301.26, certain requirements of the PTFP are modified in this Notice for FY 2001. Copies of the 1996 Rules will be posted on the NTIA Internet site and NTIA will make printed copies available to applicants. Parties interested in applying for financial assistance should refer to these rules and to the authorizing legislation (47 U.S.C. 390-393, 397-399b) for additional information on the program's goals and objectives, eligibility criteria, evaluation criteria, and other requirements.

² See The House Rep. 106-1005, the Conference report on H.R. 4942. Similar language regarding PTFP has appeared in conference reports accompanying appropriations for fiscal years 1999 and 2000.

Applicants sending applications by the United States Postal Service or commercial delivery services must ensure that the carrier will be able to guarantee delivery of the application by the Closing Date and Time. NTIA *will not* accept mail delivery of applications posted on the Closing Date or later and received after the above deadline. However, if an application is received after the Closing Date due to (1) carrier error, when the carrier accepted the package with a guarantee for delivery by the Closing Date, or (2) significant weather delays or natural disasters, NTIA will, upon receipt of proper documentation, consider the application as having been received by the deadline.

Applicants submitting applications by hand delivery are notified that, due to security procedures in the Department of Commerce, all packages must be cleared by the Department's security office. Entrance to the Department of Commerce Building for security clearance is on the 15th Street side of the building. Applicants whose applications are not received by the deadline are hereby notified that their applications will not be considered in the current grant round and will be returned to the applicant. See 15 CFR 2301.8(c); but see also 15 CFR 2301.26. NTIA will also return any application which is substantially incomplete, or when the Agency finds that either the applicant or project is ineligible for funding under 15 CFR 2301.3 or 2301.4. The Agency will inform the applicant of the reason for the return of any application.

All persons and organizations on the PTFP's mailing list will be sent a notification of the FY 2001 Grant round. Copies of the application forms, Final Rules, Closing Date notification and application guidelines will be available on the NTIA Internet site: www.ntia.doc.gov/otiahome/ptfp. Those not on the mailing list or who desire a printed copy of these materials may obtain copies by contacting the PTFP at the telephone and fax numbers, at the Internet site, or at mailing address listed above. Prospective applicants should read the Final Rules carefully before submitting applications. Applicants whose applications were deferred in FY 2000 will be mailed information regarding the reactivation of their applications. Applicants whose *television* projects were deferred from FY 2000 should carefully review Section V. Television Broadcasting and Digital Conversion, regarding policies which apply to the reactivation of their applications.

Indirect costs for *construction* applications are not supported by this

program. The total dollar amount of the indirect costs proposed in a *planning* application under this program must not exceed the indirect cost rate negotiated and approved by a cognizant Federal agency prior to the proposed effective date of the award.

Special Note: NTIA has established a policy which is intended to encourage stations to increase from 25 percent to 50 percent the matching percentage for those proposals that call for equipment replacement, improvement, or augmentation (PTFP Policy Statement, 56 FR 59168 (1991)). The presumption of 50 percent funding will be the general rule for the replacement, improvement or augmentation of equipment. (This 50 percent presumption, however, does not apply to television projects as explained in Section III. Television Broadcasting and Digital Conversion.) A showing of extraordinary need (*i.e.* small community-licensee stations or a station that is licensed to a large institution [*e.g.*, a college or university] documenting that it does not receive direct or in-kind support from the larger institution) or an emergency situation will be taken into consideration as justification for grants of up to 75 percent of the total project cost for such projects.

A point of clarification is in order: NTIA expects to continue funding projects to activate stations or to extend service at up to 75 percent of the total project cost. NTIA will do this because applicants proposing to provide first service to a geographic area ordinarily incur considerable costs that are not eligible for NTIA funding. The applicant must cover the ineligible costs including those for construction or renovation of buildings and other similar expenses.

Since NTIA has limited funds for the PTFP program, the PTFP Final Rules (published November 8, 1996) modified NTIA's policy regarding the funding of planning applications. Our policy now includes the general presumption to fund planning projects at no more than 75 percent of the project costs. NTIA notes that most of the planning grants awarded by PTFP in recent years include matching in-kind services and funds contributed by the grantee. The new NTIA policy, therefore, codifies what already has become PTFP practice. NTIA, however, is mindful that planning grants are sometimes the only resource that emerging community groups have with which to initiate the planning of new facilities in unserved areas. We, therefore, will continue to award up to 100 percent of total project costs in cases of extraordinary need (*e.g.* small community group proposing to initiate new public telecommunication service).

We take this opportunity to restate the policy published in the November 22, 1991, PTFP Policy Statement (56 FR

59168 (1991)), regarding applicants' use of funds from the Corporation for Public Broadcasting (CPB) to meet the local match requirements of the PTFP grant. NTIA continues to believe that the policies and purposes underlying the PTFP requirements could be significantly frustrated if applicants routinely relied upon another Federally supported grant program for local matching funds. Accordingly, NTIA has limited the use of CPB funds for the non-Federal share of PTFP projects to circumstances of "clear and compelling need" (15 CFR 2301.6(c)(2)). NTIA intends to maintain that standard and to apply it on a case-by-case basis.

IV. Radio Broadcasting

During the FY 2001 grant round, NTIA is proposing no changes from prior years in its support of radio applications. The changes outlined in the next section of this document on Television Broadcasting and Digital Conversion apply only to digital television applications. The eligibility or priority of radio projects, eligibility of radio equipment and the 50% presumption of funding for radio equipment replacement applications remain as they were in the FY 2000 grant round. NTIA will take great care to ensure that its funding of radio applications reflects its responsibilities under 47 U.S.C. 393(c) that "a substantial amount" of each year's PTFP funds should be awarded to public radio.

NTIA encourages the use of digital technologies for public radio facilities. NTIA has funded projects for digital STLs and audio production equipment which will assist public radio stations as they prepare for conversion to digital technologies. These digital projects are funded as equipment replacement, improvement or augmentation projects with the presumption of a 50 percent Federal share as discussed earlier in Section III of this document, Regulations, unless a showing of extraordinary need for a higher percentage has been made pursuant to § 2301.6(b)(ii) of the PTFP Rules.

For fiscal year 2000, NTIA awarded \$4.5 million in funds to 56 grants for public radio projects. The awards ranged from \$4,054 to \$414,334.

V. Television Broadcasting and Digital Conversion

The FCC's adoption of the Fifth Report and Order in April 1997 requires that all public television stations begin the broadcast of a digital signal by May 1, 2003. This deadline is so close that, last year, NTIA instituted several new policies that applied only to FY 2000

applications for projects to convert public television stations to digital transmission capability. NTIA requested comments on the policies instituted for the FY 2000 grant round but received no written comments. Informal comments received from applicants were favorable. NTIA believes that the policies worked well and resulted in receipt of 106 digital television conversion applications. These applications requested \$100 million in FY 2000 funds and an additional \$100 million for subsequent years of multi-year projects permitted by the new policies. Those policies are being continued for the FY 2001 Grant Round and are included in full in this document.

NTIA recognizes that meeting the FCC's deadline is one of the greatest challenges facing America's public television stations. Over 350 stations must overcome both technical and financial challenges in order to complete conversion to digital broadcasting within the FCC's timetable.

In February 1999, the Administration proposed a major expansion of the PTFP and recommended that \$355 million be appropriated to NTIA over a five-year period. These funds would primarily be used to assist public television stations in meeting the FCC's deadline. While these sums are significant, NTIA anticipates that the majority of funds required to convert all the nation's public television stations will actually come from non-Federal sources.

For fiscal year 2000, NTIA awarded \$18 million in funds to 34 projects which assisted public television stations in the conversion to digital technologies. The awards ranged from \$51,619 to \$1,250,680. NTIA awarded approximately \$14.4 million from the Broadcast Other category to assist in the digital conversion of thirty-eight public television stations. NTIA also awarded an additional \$3.6 million in equipment replacement funds to nine projects which purchased digital television equipment required for the orderly conversion of a station to digital broadcasting.

NTIA has considered how best to efficiently implement the distribution of digital conversion funds to public television stations through the PTFP. One of NTIA's goals during the FY 2001 grant round is to ensure that PTFP's administrative procedures as well as its funds can support public television's needs in meeting the FCC's 2003 deadline. Another of NTIA's goals is to maintain an acceptable balance between equipment replacement projects and digital television conversion projects. NTIA is continuing the following policies/procedures instituted during

the FY 2000 grant cycle which will assist public television stations in the application for and use of PTFP funds for digital conversion projects.

These policies/procedures are summarized here and then are discussed fully in parts A through G later in this section:

(A) Digital television conversion projects and digital equipment replacement. NTIA has established a "Digital TV List" which includes the equipment eligible for PTFP funding under the Broadcast Other category. NTIA will also use the "Digital TV List" for most television equipment replacement projects and modifies the way it views television replacement applications.

(B) Multi-year funding. NTIA will accept applications under the Broadcast Other category for phased projects requesting funding for up to three years and which are intended to enable all of the applicant's public television stations to meet the FCC's May 2003 digital broadcasting deadline.

(C) Effective date for expenditure of local matching funds. Applicants for digital conversion projects in the Broadcast Other category may include eligible equipment from the Digital TV List in their projects when that equipment is purchased with non-Federal funds after July 1, 1999.

(D) Subpriorities for digital conversion projects. NTIA is creating three Subpriorities to aid in the processing of digital conversion applications.

(E) Funding levels for television projects. NTIA has revised the presumption of funding from 50% Federal share for most television projects to 40%, has established simplified procedures so stations can qualify for hardship grants up to a 67% Federal share, and will provide incentives for applicants who request only 25% Federal funding.

(F) Use of CPB funds. Applicants may use CPB funds as part of their local non-Federal match in cases of clear and compelling need.

(G) Partnerships; urgency. NTIA encourages partnerships with commercial as well as noncommercial organizations and clarifies its consideration of urgency for digital conversion applications. NTIA believes that digital conversion applications should be afforded high urgency when they document time-sensitive partnerships, time-sensitive funding opportunities, or which include the replacement of equipment required to maintain existing service.

In implementing these policies for the FY 2001 grant round, NTIA intends to

remain responsive to the equipment replacement needs of public television stations. NTIA's balancing of equipment replacement and digital conversion applications is discussed in the following sections.

In order to assist public television stations in meeting the FCC's May 2003 deadline and to facilitate a station's raising non-Federal matching funds required for digital conversion projects, NTIA is modifying its application procedures in the following areas.

(A) Digital Television Conversion Projects and Digital Equipment Replacement. For FY 2001, NTIA will support the equipment necessary for a public television station to comply with the FCC's 2003 deadline. This includes equipment required for digital broadcast of programs produced locally in analog format as well as the broadcast of digital programming received from national sources. NTIA is posting on its Internet site a listing of transmission and distribution equipment (as contained in the "Digital TV List") which is eligible for PTFP digital television conversion funding. Printed copies of this list are also be available from PTFP at the address shown in the **ADDRESSES** section of this document. This list was developed in conjunction with the Public Broadcasting Service and is similar to equipment lists PTFP used during last year's grant round. The Digital TV List includes transmission equipment (transmitters, antennas, STLs, towers, etc.) as well as distribution equipment located in a station's master control (routing switchers, video servers, PSIP generators, digital encoders, etc.). Applications seeking funding for the equipment necessary to meet the FCC's 2003 deadline will, as in FY 98, FY 99, and FY 2000, be placed in the Broadcast Other category.

NTIA believes that many stations must replace obsolete equipment in order to complete their digital conversion projects. NTIA is now revising its policies to permit the replacement of obsolete equipment as part of digital conversion projects. If the conversion to digital transmission includes the urgent replacement of an existing item of equipment, the application will be considered as a Broadcast Other, rather than as replacement under Priorities 2 or 4. Replacement of existing equipment then is a normal part of a digital conversion application.

If the purpose of an application is just for replacement of urgently needed equipment, even though the equipment is drawn from the Digital TV List, the

application will be classified as a Priority 2 or 4, as appropriate.

Any application which includes equipment replacement as a justification for the urgency criterion should submit documentation of downtime or other evidence in support of the urgency evaluation criterion as contained in § 2301.17 of the PTFP Final Rules. The need to replace current equipment in order to maintain existing services will, in many cases, strengthen the urgency criterion of a digital conversion application.

Because of the requirement that all public television stations begin their digital broadcasts by May 2003, all public television applications, whether submitted for Priority 2, Priority 4 or the Broadcast Other category, should include the station's comprehensive plan for digital conversion to meet the FCC's deadline and explain how the requested equipment is consistent with that plan. If the applicant is still developing its plan for digital conversion, the application should address how the requested equipment will be consistent with the overall objective of converting the facility for digital broadcasting. Failure to provide detailed information on the applicant's proposed or existing digital conversion plan will place a television application at a competitive disadvantage during the evaluation of the technical qualification criterion as described in 15 CFR 2301.17 of the PTFP Rules.

NTIA calls applicants' attention to the fact that television production equipment is not included on the Digital TV List but will be found on other equipment lists posted on the NTIA Internet site or available from NTIA by mail. NTIA notes that while a television station must use digital transmission and distribution equipment to begin digital broadcasting, digital production equipment is not required to meet the FCC's May 2003 deadline. As the FCC deadline approaches, NTIA has reluctantly concluded that, with the funds available to it in FY 2001, it cannot fund television production equipment at the same level as it has in the past. Television production equipment will continue to be eligible for PTFP funding under Priority 2 and Priority 4, as appropriate. However, for the FY 2001 grant round NTIA will fund television production equipment replacement applications only for those projects that present a "clear and compelling" case for the urgency of such replacement. NTIA anticipates funding television production replacement projects in FY 2001, though fewer than in recent years.

When making the final selection of awards under the procedures of § 2301.17, NTIA will take care to ensure that there is an acceptable balance between projects awarded for equipment replacement projects and those awarded for digital conversion projects. Further, NTIA will consider as part of this balance those stations in the Broadcast Other category (1) which request digital conversion projects and (2) which also include elements of equipment replacement. NTIA will not fund applications in the Broadcast Other category requesting digital conversion to the exclusion of those Broadcast Other applications which include documentation supporting equipment replacement as part of their urgency justification. Further, in making funding decisions for FY 2001, NTIA will limit its support of television replacement applications for production equipment to those applications which present a "clear and compelling" justification for funding during the current grant round.

A complete listing of equipment eligible for funding during the FY 2001 grant round is posted on the NTIA Internet site and printed copies are available from PTFP.

(B) Multi-year funding. NTIA anticipates that it will take many public television licensees several years to complete their digital conversion projects. The time required to complete a digital conversion project will be determined by several factors. In some instances, it will take a station several years to raise the local funds required to complete the project. Even if a station has accumulated all the funds required for its digital conversion project, the technical complexity of some projects (such as the construction of a 1,000-foot tower) will probably require several years to complete. Finally, many public television licensees operate several stations and are, therefore, responsible for the conversion of multiple broadcast facilities.

NTIA recognizes that the construction period for many of these digital conversion projects must, of necessity, be longer than the typical one to two years of the usual PTFP grant. Further, NTIA acknowledges that, with the funds available for award, the PTFP would be unable to fully fund more than a few of the digital conversion applications it could receive in FY 2001.

Therefore, for FY 2001, the PTFP will accept construction applications within the Broadcast Other category for digital television conversion projects which propose multi-year funding.

Applicants may submit project plans and budgets for up to three years. A

multi-year application must contain the applicant's entire digital conversion plan. The plan must be divided into severable phases, with a budget request for each phase of the project. The application must identify the Federal funds requested for each phase. Only one phase of the project will be funded in any grant cycle. Once a project is approved, applicants will not be required to compete each year for funding of subsequent phases. Funding of subsequent phases will be at the sole discretion of the Department of Commerce and will depend on satisfactory performance by the recipient and the availability of funds to support the continuation of the project(s).

Projections based on previous experience indicate availability of between \$8 million and \$15 million to support multi-year digital television projects in FY 2001. The exact level of funding available for multi-year awards will be determined by NTIA after a review of applications submitted for multi-year awards and those radio, television and distance learning applications requesting a regular award.

NTIA believes that multi-year funding for digital television awards has significant benefits for both public television licensees and NTIA.

- Submission of a multi-year application particularly should help applicants which must convert multiple broadcast transmitters. NTIA understands that many stations have already begun to raise significant non-Federal funds with which they can begin to implement their digital conversion plans. Upon submission of a multi-year application, an applicant could begin spending its local match—at its own risk. An applicant, therefore, might be able to complete a portion of its digital conversion project using its local non-Federal funds for which Federal matching funds may not be available for several years. (For example, a future phase of a statewide project might be the conversion of two repeater stations; one might be constructed with available non-Federal funds, the second constructed if Federal funds are received). Applicants are cautioned, however, that while expenditure of the local match is permitted, PTFP Rules (§ 2301.6(d)) prohibit a grantee from obligating funds from the eventual Federal share of an award before a grant is actually awarded.

- NTIA believes that a multi-year award will reduce the administrative burden on both grantees and the PTFP. Grant recipients will submit only one application to cover the multiple years

of their award, saving both the grantee and the PTFP the administrative tasks required to process applications during the annual grant round.

- Multi-year applications and awards will also assist both NTIA and public broadcasting licensees in the advance planning required to complete the conversion of almost 350 television facilities by May 2003.

- By issuing multi-year grants, NTIA would be able to fund the initial phases of more digital conversion projects with the monies available in FY 2001 than if PTFP funded fewer entire digital conversion plans.

NTIA believes that multi-year funding through the Broadcast Other category also is appropriate for projects which include urgent replacement of equipment, since, as noted earlier, most television equipment replacement requests can be viewed as one phase of a station's conversion to digital broadcasting.

Applications which are reactivated for the FY 2001 grant round must comply with the guidelines included in this notice, including the funding levels for television projects discussed later in this document.

Applicants submitting projects for consideration under the Broadcast Other category have a choice and may request either multi-year funding or a single grant. However, applications submitted for consideration under Priority 2 or Priority 4 may only request a single grant for a project, as in the past. NTIA anticipates that a majority of the television grants funded in FY 2001 will include multi-year projects.

(C) Effective date for expenditure of local matching funds for digital conversion projects. NTIA recognizes that many public television stations have begun to raise significant non-Federal funds for their digital conversion projects. State or local governments may have appropriated funds to initiate digital conversion projects that, by local law, must be expended during the fiscal year in which they are awarded. Public television licensees that have raised significant non-Federal funds may desire to take advantage of unique opportunities (such as partnering with other stations to share broadcast antennas or towers). Some stations may be anxious to begin digital conversion projects with long lead times for completion, or may desire to begin digital broadcasting on the same timetable as commercial stations in their market. Within the limitations of Federal regulations, NTIA supports efforts undertaken by public television stations which bring the benefits of

digital television broadcasting to their communities as quickly as possible.

In order to facilitate the raising of non-Federal funds for digital television projects and to also permit stations to begin construction of their digital facilities as soon as possible, NTIA is revising section § 2301.6(b)(2) of the PTFP Final Rules. This section states that "Inclusion of equipment purchased prior to the closing date will be considered on a case-by-case basis only when clear and compelling justification is provided to PTFP."

For FY 2001, NTIA will modify this regulation. If eligible equipment for a Broadcast Other project was purchased with non-Federal funds after July 1, 1999, NTIA will permit the applicant to include this equipment in a PTFP application. This date was selected to coincide with the beginning of the 2000 fiscal year used by many state and local governments and was announced at the beginning of this digital television conversion initiative in the Notice of Availability of Funds for the FY 2000 PTFP grant cycle (64 FR 246, pp. 72225–72234). NTIA also anticipates that July 1, 1999 will be the effective date in the FY 2002 and FY 2003 grant rounds for the expenditure of non-Federal funds for projects in the Broadcast Other category. Applicants who desire to use equipment purchased prior to July 1, 1999 as part of their local match must submit a "clear and compelling justification" supporting their request.

Applicants who are reactivating applications originally submitted in FY 99 and deferred from the FY 99 and FY 2000 grant rounds will be permitted to use the closing date of their original applications.

(D) Subpriorities for Digital Conversion Projects. As almost 350 public television stations are required to convert to digital broadcasting by May 2003, NTIA anticipates a significant increase in the number of applications in the Broadcast Other category for digital conversion projects. In order to process these applications in an orderly manner and to provide guidance to potential applicants for the FY 2001 grant round, NTIA will divide the Broadcast Other category into three subpriorities; Broadcast Other-A; Broadcast Other-B, and Broadcast Other -C.

These three divisions are intended to reflect the priorities NTIA has used in the evaluation of traditional broadcast applications and to place a premium on projects either to assist stations providing sole service, to encourage cooperative efforts among different stations, or to support licensees facing the requirement to convert multiple

transmission facilities in several television markets. NTIA notes that in the past it has been able to fund applications each year in most if not all of the five traditional broadcast Priorities and anticipates that it will be able to fund applications in FY 2001 in most if not all of the subpriorities under the Broadcast Other category.

NTIA will assign the following applications for conversion of public broadcasting facilities to advanced digital technologies at the first subpriority level within the Broadcast Other category. These applications will receive equal consideration as subpriority A.

- A single applicant providing the sole service in an area unserved by a digital public television signal. This reflects PTFP's funding priority for equipment replacement projects for sole service stations (PTFP Priority 2).
- Cooperative applications by two or more licensees for the first digital public television service to an area. This is intended to encourage cooperation and efficiencies among stations in overlap markets (as listed by CPB) in constructing digital facilities. It would provide stations in overlap markets the opportunity, if they work collaboratively, to be eligible for the highest priority in funding within this category.
- A statewide staged plan for the conversion of multiple stations, whether a state network, or other appropriate statewide organization, or a staged plan from a licensee with stations in several markets. This is intended to encourage licensees that must convert multiple stations and also to encourage groups of stations to work collaboratively in developing a digital conversion project.

NTIA will assign the following applications for conversion of public broadcasting facilities to advanced digital technologies at the second subpriority level within the Broadcast Other category. These applications will receive equal consideration as subpriority B.

- An applicant in a multi-PTV station market providing first public television service in an area. An applicant in a multi-PTV station market who chooses to file separately, rather than in conjunction with another licensee in the same area, receives a second priority for funding.
- A cooperative application by two or more licensees in an area already served by a digital public television station. The application is given a priority over Broadcast Other—C to encourage efficiency and cooperation.

Since this is not the first service in the area, it is given a second priority.

NTIA will assign the following applications for conversion of public broadcasting facilities to advanced digital technologies at the third subpriority level within the Broadcast Other category. These applications will receive equal consideration as subpriority C.

- Individual applicants proposing a second digital public television service in an area already receiving a digital public television signal. This reflects PTFP's funding priority for equipment replacement applications in served areas (Priority 4).
- All other public television digital conversion applications.

(E) Funding Levels for Television Projects. As noted earlier in Section III of this document, NTIA has published several policies regarding the presumed Federal share of a requested project. These policies are intended to aid applicants in the planning of their applications. The policy for PTFP support of equipment replacement applications has long been the presumption of a 50 percent Federal share, although applicants are permitted to submit justification for a Federal grant of up to 75 percent of project costs. Those policies are also contained in § 2301.6(b) of the PTFP Final Rules.

In reviewing the projected costs to convert all the public television stations in the country, NTIA has concluded that it cannot continue its 50 percent presumption of Federal funding for television equipment replacement or digital conversion projects. Furthermore, NTIA believes that many public television facilities will be unable to raise 50 percent of the project costs. A significant number of stations may need Federal funding of 67 percent of a project's cost, or even up to the legal maximum of 75 percent of a project's cost, in order for them to meet the FCC's deadline.

In order to ensure that sufficient Federal funds are available to support the conversion of the nation's public television stations, NTIA is establishing a new policy regarding the presumed Federal funding level for television equipment. As noted earlier in this section, NTIA recognizes that equipment on the PTFP Digital TV List may be included in either Broadcast Other digital conversion applications or in Priority 2 or Priority 4 equipment replacement applications. In order to treat all applicants equitably, NTIA's new policy will be the presumption of a 40 percent Federal share of the eligible project costs for television equipment

for digital conversion or equipment replacement, improvement or augmentation projects. This 40 percent presumption will apply whether the application requests consideration under the two equipment replacement priorities (Priority 2 or 4) or under the digital conversion category (Broadcast Other). As noted earlier, NTIA will fund the replacement of production equipment upon a showing of clear and compelling need. However, since the deadline for digital conversion is rapidly approaching and Federal funds are limited, NTIA will fund replacement of production equipment at the same level of Federal support as digital conversion or equipment replacement projects. The presumption of a 40 percent Federal share will extend to all television projects to replace or upgrade equipment. However, because of the emphasis NTIA places on the extension of broadcast services to unserved areas, NTIA has retained the 75 percent level of Federal funding applications proposing new television facilities in Priority 1 (§ 2301.4(b)(1)).

Applicants who are reactivating applications deferred from the FY 99 grant round will be permitted to request the same percentage of Federal support as requested in the FY 99 application as long as the scope of their application remains the same. Applicants who wish to revise their deferred application to include their full digital conversion plans, however, will be subject to the new policies presented in this section.

As already noted, NTIA recognizes that many small stations, primarily in rural areas, will be unable to raise even a 50 percent local share of the funds required for their PTFP projects. NTIA has long permitted stations to request more than the standard level of Federal support upon a showing of "extraordinary need" per § 2301.6(b)(ii) of the PTFP Rules. NTIA will permit applicants to qualify for hardship funding and receive a 67 percent Federal share of their project costs. An applicant can qualify for 67% Federal funding by certifying that it is unable to match at least 60% of the eligible project costs, and either (a) by providing documentation that its average annual cash revenue for the previous four years is \$2 million or less, or (b) by providing documentation that the eligible project costs are greater than the applicant's average annual cash revenue for the previous four years.

In addition, NTIA will continue to permit any applicant to provide justification that it has an "extraordinary need" for Federal funding up to the legal limit of 75 percent of eligible project costs.

In order to gather additional funds to award to stations which qualify under the hardship criteria, NTIA encourages financially able applicants to request a smaller share of Federal funds for digital equipment projects than the standard 40 percent. NTIA will add three additional points to the application evaluations from the independent review panel for applicants who request no more than 25 percent Federal funding. This provision will give extra credit to applications already highly reviewed, and, based on NTIA's previous experience, is often sufficient to move applications into the range for funding.

However, when making the final selection of awards, NTIA will take care to ensure that there is an acceptable balance between projects awarded to stations requesting a 25 percent Federal share and those requesting a higher Federal share. NTIA will not fund applications requesting a 25 percent Federal share to the exclusion of applications meeting the hardship criteria or to the exclusion of those requesting the standard 40 percent Federal share.

(F) Use of CPB funds. As discussed earlier in this document at the conclusion of Section III. Regulations, NTIA has limited the use of CPB funds for the non-Federal share of PTFP projects to circumstances of "clear and compelling need" (15 CFR § 2301.6(c)(2)). NTIA recognizes that it will be difficult for many public television stations to raise the funds required to meet the FCC's digital broadcasting deadline. Therefore, NTIA continues its past policy that applicants may submit justification under this section for the use of CPB funds as part of their local match. Any request for the use of CPB funds must be accompanied by a statement regarding any limitations that CPB has placed on the expenditure of those funds.

(G) Miscellaneous Items. As discussed earlier in this section, part (D) on New Subpriorities, NTIA encourages efforts which promote efficiency within the public television system in order to save both current conversion costs and future operating costs. NTIA, therefore, also encourages public television stations to partner with commercial entities when this is in the best interests of the public station and the Federal government. In cases of public television partnerships with commercial entities, the PTFP project will be limited to the public television station's ownership share or use rights in the equipment. NTIA believes that such partnerships with commercial organizations comply with current PTFP regulations and PTFP has

funded several projects for joint use of towers and broadcast antennas.

The urgency of an application is one of the criteria under which all PTFP applications are evaluated. (The evaluation criteria are listed in § 2301.17 of the PTFP Rules). NTIA suggests that there are at least three situations in which Broadcast Other applications may present high degrees of urgency. As we have just noted, applications containing proposals for joint use/ownership partnerships with other organizations may demonstrate a high urgency due to a time-sensitive opportunity. NTIA encourages these applicants to document the time-sensitive nature of the partnership opportunity in their response to the urgency criterion.

NTIA also recognizes that some applicants may be presented with time-sensitive funding opportunities and, therefore, encourages these applicants to document the time sensitive nature of these funding opportunities in their response to the urgency criterion. Finally, as already noted, NTIA expects that some applications will request urgent replacement of existing equipment as part of a Broadcast Other application. NTIA encourages such applicants to provide documentation of their need to replace their equipment during the current grant round. This documentation might include maintenance logs, letters from manufacturers, reports from independent engineers, photos etc.

NTIA will instruct the panels evaluating the FY 2001 Broadcast Other applications that they should award the highest score under the urgency criterion to those applications which fully justify and document either (1) the time sensitive nature of partnerships, (2) the time sensitive nature of funding opportunities, or (3) the need for equipment replacements that must be accomplished during this grant round in order to maintain existing services.

VI. Distance Learning Projects

Since 1979, NTIA has funded nonbroadcast distance learning projects through the "Special Applications" category as established in § 2301.4(a) of the PTFP Rules. In 1996, NTIA established a similar category for broadcast projects, "Broadcast/other" in § 2301.4(b)(6). NTIA encourages applications in either category for innovative or unique distance learning projects which address demonstrated and substantial community needs. For fiscal year 2000, NTIA awarded \$1.14 million in funds to five grants for distance learning projects. The awards ranged from \$49,781 to \$368,440.

The growth of digital technologies provides new opportunities for distance learning projects using both broadcast or nonbroadcast facilities. NTIA encourages applicants to consider the use of digital technologies in proposing unique or innovative distance learning projects for funding in FY 2001. Examples of innovative digital applications might include projects (1) which use broadband technologies for distance learning, (2) which distribute educational or informational programming via Direct Broadcast Satellite technologies, or (3) which use the multi-channel capabilities of a digital public television station. All distance learning applications must address substantial and demonstrated needs of the communities being served. NTIA is particularly interested in distance learning projects which benefit traditionally underserved audiences, such as projects serving minorities or people living in rural areas.³

As discussed in Section V of this document, NTIA anticipates that, in FY 2001, it will receive numerous digital conversion applications in the Broadcast/ Other category. NTIA recognizes that, due to the multi-channel capability of digital television, distance learning components may well be a part of a digital conversion application. NTIA will, therefore, consider such distance learning proposals under the subpriorities established in Section V. If NTIA determines that a broadcast distance learning project is not part of a digital conversion application, NTIA will evaluate the application pursuant to §§ 2301.4(b)(6) and 2301.17.

The November 22, 1991, PTFP Policy Statement (56 FR 59168 (1991)) mentioned in the Application Forms and Regulations section discussed a number of issues of particular relevance to applicants proposing *nonbroadcast* educational and instructional projects and potential improvement of nonbroadcast facilities. These policies remain in effect and will be available to all PTFP applicants as part of the Guidelines for preparing FY 2001 PTFP applications.

VII. Eligible and Ineligible Costs

Eligible equipment for the FY 2001 grant round includes the apparatus necessary for the production, interconnection, captioning, broadcast, or other distribution of programming, including but not limited to studio

equipment; audio and video storage, processing, and switching equipment; terminal equipment; towers; antennas; transmitters; remote control equipment; transmission line; translators; microwave equipment; mobile equipment; satellite communications equipment; instructional television fixed service equipment; subsidiary communications authorization transmitting and receiving equipment; cable television equipment; and optical fiber communications equipment.

A complete listing of equipment eligible for funding during the FY 2001 grant round is posted on the NTIA Internet site and printed copies are available from PTFP.

Other Costs

(1) Construction Applications: NTIA generally will not fund salary expenses, including staff installation costs, and pre-application legal and engineering fees. Certain "pre-operational expenses" are eligible for funding. (See 15 CFR 2301.2.) Despite this provision, NTIA regards its primary mandate to be funding the acquisition of equipment and only secondarily funding of salaries. A discussion of this issue appears in the PTFP Final Rules under the heading *Support for Salary Expenses* in the introductory section of the document.

(2) Planning Applications. (a) Eligible: Salaries are eligible expenses for all planning grant applications, but should be fully described and justified within the application. Planning grant applicants may lease office equipment, furniture and space, and may purchase expendable supplies under the terms of 47 U.S.C. 392 (c). (b) Ineligible: Planning grant applications cannot include the cost of constructing or operating a telecommunications facility.

(3) Audit Costs. Audits shall be performed in accordance with audit requirements contained in Office of Management and Budget Circular A-133, Audits of States, Local Governments, and Non-Profit Organizations, revised June 30, 1997. OMB Circular A-133 requires that non-profit organizations, government agencies, Indian tribes and educational institutions expending \$300,000 or more in federal funds during a one-year period conduct a single audit in accordance with guidelines outlined in the circular. Applicants are reminded that other audits may be conducted by the Office of Inspector General.

NTIA recognizes that most of its grant recipients are divisions of state and local governments or are public broadcasting facilities, all of which routinely conduct annual audits. In

order to make the maximum amount of monies available for equipment purchases and planning activities, NTIA will, therefore, fund audit costs only in exceptional circumstances.

VIII. Notice of Applications Received

In accordance with 15 CFR 2301.13, NTIA will publish a notice in the **Federal Register** listing all applications received by the Agency. Listing an application merely acknowledges receipt of an application to compete for funding with other applications. This listing does not preclude subsequent return of the application for the reasons discussed under the Dates section above, or disapproval of the application, nor does it assure that the application will be funded. The notice will also include a request for comments on the applications from any interested party. NTIA will also publish more complete information about all the applications received by the Agency on the NTIA Internet site and will make this information available by mail. The address of the NTIA Internet site is: www.ntia.doc.gov/otiahome/ptfp.

IX. Evaluation Process

See 15 CFR 2301.16 for a description of the Technical Evaluation and 15 CFR 2301.17 for the Evaluation Criteria.

X. Selection Process

Based upon the above cited evaluation criteria, the PTFP program staff prepares summary recommendations for the PTFP Director. These recommendations incorporate outside reviewers rankings and recommendations, engineering assessments, and input from the National Advisory Panel, State Single Point of Contacts and state telecommunications agencies. Staff recommendations also consider project impact, the cost/benefit of a project and whether review panels have consistently applied the evaluation criteria. The PTFP Director will consider the summary recommendations prepared by program staff, will recommend the funding order of the applications, and will present recommendations to the OTIA (Office of Telecommunications and Information Applications) Associate Administrator for review and approval. The PTFP Director recommends the funding order for applications in three categories: "Recommended for Funding," "Recommended for Funding if Funds Available," and "Not Recommended for Funding." See 15 CFR 2301.18 for a description of the selection factors retained by the Director, OTIA Associate Administrator, and the Assistant

³ House Rep. 106-1005, the Conference report on H.R. 4942 directs that NTIA "place special emphasis on distance learning initiatives targeting rural areas."

Secretary for Telecommunications and Information.

Upon review and approval by the OTIA Associate Administrator, the Director's recommendations will then be presented to the Selection Official, the NTIA Administrator. The NTIA Administrator selects the applications for possible grant award taking into consideration the Director's recommendations and the degree to which the slate of applications, taken as a whole, satisfies the program's stated purposes set forth at 15 CFR 2301.1(a) and (c). Prior to award, applications may be negotiated between PTFP staff and the applicant to resolve whatever differences might exist between the original request and what PTFP proposes to fund. Some applications may be dropped from the proposed slate due to lack of FCC licensing authority, an applicant's inability to make adequate assurances or certifications, or other reasons. Negotiation of an application does not ensure that a final award will be made. The PTFP Director recommends final selections to the NTIA Administrator applying the same factors as listed in 15 CFR 2301.18. The Administrator then makes the final award selections taking into consideration the Director's recommendations and the degree to which the slate of applications, taken as a whole, satisfies the program's stated purposes in 15 CFR 2301.1(a) and (c).

XI. Project Period

Planning grant award periods customarily do not exceed one year, whereas construction grant award periods for grants in the five broadcast Priorities and nonbroadcast Special Applications category commonly range from one to two years. Construction projects funded in the Broadcast Other category would commonly be awarded for a one to two year period with the expectation that they would be extended annually in subsequent years dependent on the availability of Federal funds. Although these time frames are generally applied to the award of all PTFP grants, variances in project periods may be based on specific circumstances of an individual proposal.

XII. NTIA Policies on Procedural Matters

Based upon NTIA's experience during the PTFP 2000 grant round, NTIA has determined that it is in the best interest of NTIA and applicants to continue recent policies regarding three procedural matters. The following policies are applicable only to the FY

2001 PTFP grant round and resulting awards.

Applications Resulting From Catastrophic Damage or Emergency Situations

Section 2301.10 provides for submission of applications resulting from catastrophic damage or emergency situations. NTIA would like to clarify its implementation of this provision.

For FY 2001 PTFP applicants, when an eligible broadcast applicant suffers catastrophic damage to the basic equipment essential to its continued operation as a result of a natural or manmade disaster, or as the result of significant equipment failure, and is in dire need of assistance in funding replacement of the damaged equipment, it may file an emergency application for PTFP funding at any time. NTIA limits this request to equipment essential to a station's continued operation such as transmitters, towers, antennas, STLs or similar equipment which, if the equipment failed, would result in a complete loss of service to the community.

When submitting an emergency application, the applicant should describe the circumstances that prompt the request and should provide appropriate supporting documentation. NTIA requires that applicants claiming significant failure of equipment will document the circumstances of the equipment failure and demonstrate that the equipment has been maintained in accordance with standard broadcast engineering practices.

NTIA will grant an award only if it determines that (1) the emergency satisfies this policy, and (2) the applicant either carried adequate insurance or had acceptable self-insurance coverage.

Applications filed and accepted for emergency applications must contain all of the information required by the Agency application materials and must be submitted in the number of copies specified by the Agency.

NTIA will evaluate the application according to the evaluation criteria set forth in § 2301.17(b). The PTFP Director takes into account program staff evaluations (including the outside reviewers) the availability of funds, the type of project and broadcast priorities set forth at § 2301.4(b), and whether the applicant has any current NTIA grants. The Director presents recommendations to the Office of Telecommunications and Information Applications (OTIA) Associate Administrator for review and approval. Upon approval by the OTIA Associate Administrator, the Director's recommendation will be presented to

the Selecting Official, the NTIA Administrator. The Administrator makes final award selections taking into consideration the Director's recommendation and the degree to which the application fulfills the requirements for an emergency award and satisfies the program's stated purposes set forth at § 2301.1(a) and (c).

Service of Applications

FY 2001 PTFP applicants are not required to submit copies of their PTFP applications to the FCC, nor are they required to submit copies of the FCC transmittal cover letters as part of their PTFP applications. NTIA routinely notifies the FCC of projects submitted for funding which require FCC authorizations.

FY 2001 PTFP applicants for distance learning projects are not required to notify every state telecommunications agency in a potential service area. Many distance learning applications propose projects which are nationwide in nature. NTIA, therefore, believes that the requirement to provide a summary copy of the application in every state telecommunications agency in a potential service area is unduly burdensome to applicants. NTIA, however, does expect that distance learning applicants will notify the state telecommunications agencies in the states in which they are located.

Federal Communications Commission Authorizations

For the FY 2001 PTFP grant round, applicants may submit applications to the FCC after the closing date, but do so at their own risk. Applicants are urged to submit their FCC applications with as much time before the PTFP closing date as possible. No grant will be awarded for a project requiring FCC authorization until confirmation has been received by NTIA from the FCC that the necessary authorization will be issued.

For FY 2001 PTFP applications, since there is no potential for terrestrial interference with Ku-band satellite uplinks, grant applicants for Ku-band satellite uplinks may submit FCC applications after a PTFP award is made. Grant recipients for Ku-band satellite uplinks will be required to document receipt of FCC authorizations to operate the uplink prior to the release of Federal funds.

For FY 2001 PTFP applications, NTIA may accept FCC authorizations that are in the name of an organization other than the PTFP applicant in certain circumstances. Applicants requiring the use of FCC authorizations issued to another organization should discuss in the application Program Narrative why

the FCC authorization must be in the other organization's name. NTIA believes that such circumstances will be rare and, in its experience, are usually limited to authorizations such as those for microwave interconnections or satellite uplinks.

As noted above, for FY 2001 PTFP applications, NTIA does not require that the FCC applications be filed by the closing date. While NTIA is permitting submission of FCC applications after the closing date, applicants are reminded that they must continue to provide copies of FCC applications, as they were filed or will be filed, or equivalent engineering data, in the PTFP application so NTIA can properly evaluate the equipment request. These include applications for permits, construction permits and licenses already received for (1) construction of broadcast station, (including a digital broadcasting facility) or translator, (2) microwave facilities, (3) ITFS authorizations, (4) SCA authorizations, and (5) requests for extensions of time.

For those applicants whose projects require authorization by the Federal Communications Commission (FCC), NTIA reminds applicants that the mailing address for the Federal Communications Commission has changed to: 445 12th St., SW., Washington, DC 20554.

XIII. Department of Commerce Application Requirements

Applicants should note that they must continue to comply with the provisions of Executive Order 12372, "Intergovernmental Review of Federal Programs." The Executive Order requires applicants for financial assistance under this program to file a copy of their application with the Single Points of Contact (SPOC) of all states relevant to the project. Applicants are required to provide a copy of their completed application to the appropriate SPOC on or before February 15, 2001. Applicants are encouraged to contact the appropriate SPOC well before their PTFP closing date. A listing of the state SPOC offices may be found with the PTFP application materials at the NTIA Internet site. A list of the SPOC offices is available from NTIA (see the **ADDRESS** section above).

Notwithstanding any other provision of the law, no person is required to respond to, nor shall any person be subject to a penalty for failure to comply with, a collection of information subject to the requirements of the Paperwork Reduction Act (PRA), unless that collection displays a currently valid

Office of Management and Budget (OMB) control number.

All primary applicants must submit a completed Form CD-511, "Certifications Regarding Debarment, Suspension, and Other Responsibility Matters; Drug-Free Workplace Requirements and Lobbying," and the following explanations are hereby provided:

(1) *Nonprocurement Debarment and Suspension*. Prospective participants (as defined at 15 CFR Part 26, section 105) are subject to 15 CFR part 26, "Nonprocurement Debarment and Suspension" and the related section of the certification form prescribed above applies;

(2) *Drug Free Workplace*. Grantees (as defined at 15 CFR Part 26, section 605) are subject to 15 CFR part 26, Subpart F, "Government-wide Requirements for Drug-Free Workplace (Grants)" and the related section of the certification form prescribed above applies;

(3) *Anti-lobbying*. Persons (as defined at 15 CFR part 28, section 105) are subject to the lobbying provisions of 31 U.S.C. 1352, "Limitation on use of appropriated funds to influence certain Federal contracting and financial transactions," and the lobbying section of the certification form prescribed above applies to applicants/bidders for grants, cooperative agreements, and contracts for more than \$100,000, and loans and loan guarantees for more than \$150,000, or the single family maximum mortgage limit for affected programs, whichever is greater; and

(4) *Anti-lobbying Disclosures*. Any applicant that has paid or will pay for lobbying using any funds must submit an SF-LLL, "Disclosure of Lobbying Activities," (OMB Control Number 0348-0046) as required under 15 CFR part 28, Appendix B.

Recipients shall require applicants/bidders for subgrants, contracts, subcontracts, or other lower tier covered transactions at any tier under the grant award to submit, if applicable, a completed Form CD-512, "Certifications Regarding Debarment, Suspension, Ineligibility and Voluntary Exclusion-Lower Tier Covered Transactions and Lobbying" and disclosure form, SF-LLL, "Disclosure of Lobbying Activities." Form CD-512 is intended for the use of recipients and should not be transmitted to the Department. SF-LLL submitted by any tier recipient or subrecipient should be submitted to the Department in accordance with the instructions contained in the award document.

All non-profit applicants are subject to a name check review process. Name checks are intended to reveal whether key individuals associated with the applying organization have been convicted of, or are presently facing, such criminal charges as fraud, theft, perjury, or other matters that significantly reflect on the applicant's management, honesty, or financial integrity. Potential non-profit recipients may also be subject to reviews of Dun and Bradstreet data or other similar credit checks.

No award of Federal funds shall be made to an applicant who has an outstanding delinquent Federal debt until either: (1) The delinquent account is paid in full; (2) a negotiated repayment schedule is established and at least one payment is received, or (3) other arrangements satisfactory to the Department are made.

If an application is selected for funding, the Department of Commerce has no obligation to provide any additional future funding in connection with that award. Renewal of an award to increase funding or extend the period of performance is at the total discretion of the Department.

Recipients and subrecipients are subject to all Federal laws and Federal and DOC policies, regulations, and procedures applicable to Federal assistance awards. In addition, unsatisfactory performance by the applicant under prior Federal awards may result in the application not being considered for funding.

If applicants incur any costs prior to an award being made, they do so solely at their own risk of not being reimbursed by the Government. Notwithstanding any verbal or written assurance that they have received, there is no obligation on the part of the Department to cover preaward costs.

Applicants are reminded that a false statement on the application may be grounds for denial or termination of funds and grounds for possible punishment by a fine or imprisonment as provided in 18 U.S.C. 1001.

Authority: The Public Telecommunications Financing Act of 1978, as amended, 47 U.S.C. 390-393, 397-399(b). (Catalog of Federal Domestic Assistance No. 11.550)

Bernadette McGuire-Rivera,

Associate Administrator, Office of Telecommunications and Information Applications.

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Federal Register

**Thursday,
December 21, 2000**

Part VIII

The President

**Proclamation 7387—Wright Brothers Day,
2000**

**Proclamation 7388—To Modify Duty-Free
Treatment Under the Generalized System
of Preferences for Sub-Saharan African
Countries and for Other Purposes**

Presidential Documents

Title 3—

Proclamation 7387 of December 14, 2000

The President

Wright Brothers Day, 2000

By the President of the United States of America

A Proclamation

In 1903, Orville and Wilbur Wright were poised on the brink of one of history's most remarkable advances. For years, the two brothers had been mesmerized by the principle of flight and had studied birds to understand how these fascinating creatures rose, fell, and darted through the air. The Wright Brothers' studies affirmed what they had long believed: that powered, controlled human flight was possible. After much research and experimentation and many trials and failures, the brothers tested their prototype biplane on the windy dunes of Kitty Hawk, North Carolina. On December 17, their efforts were rewarded and their dream realized when the Wright Flyer rose through the air, soaring for 12 seconds and traveling 120 feet.

While it took humanity thousands of years to reach that pivotal moment, we have achieved stunning advances in aviation in the past century alone. Less than 25 years after the Wright Brothers' inaugural flight, Charles Lindbergh conquered the Atlantic Ocean flying nonstop aboard The Spirit of St. Louis; in less than 50 years, Chuck Yeager broke the sound barrier; and in less than 70 years, the United States reached the heavens and landed two men on the Moon. Today, we continue to explore the frontiers of space as the International Space Station orbits the Earth.

The creative vision, ingenuity, and indomitable spirit that sparked the Wright Brothers' achievement still power our Nation's aviation accomplishments today. Air travel is a vital part of life in America, and people across the country depend on our air transportation system to link them with one another and to sustain our growing economy. Last year alone, U.S. airlines safely transported almost 700 million passengers on 13 million flights.

The gift of flight has immeasurably strengthened our Nation and enriched the lives of people around the world. It is only fitting that we should remember on December 17 the two visionary Americans whose scientific curiosity, independent thinking, and technical genius began a new era that has taken us to the threshold of space and beyond.

The Congress, by a joint resolution approved December 17, 1963 (77 Stat. 402; 36 U.S.C. 143), has designated December 17 of each year as "Wright Brothers Day" and has authorized and requested the President to issue annually a proclamation inviting the people of the United States to observe that day with appropriate ceremonies and activities.

NOW, THEREFORE, I, WILLIAM J. CLINTON, President of the United States of America, do hereby proclaim December 17, 2000, as Wright Brothers Day.

IN WITNESS WHEREOF, I have hereunto set my hand this fourteenth day of December, in the year of our Lord two thousand, and of the Independence of the United States of America the two hundred and twenty-fifth.

William Clinton

[FR Doc. 00-32741

Filed 12-20-00; 8:45 am]

Billing code 3195-01-P

Presidential Documents

Proclamation 7388 of December 18, 2000

To Modify Duty-Free Treatment Under the Generalized System of Preferences for Sub-Saharan African Countries and for Other Purposes

By the President of the United States of America

A Proclamation

1. Section 506A(b)(1) of the Trade Act of 1974, as amended (the “1974 Act”) (19 U.S.C. 2466a(b)(1)), as added by section 111(a) of the African Growth and Opportunity Act (Title I of Public Law 106-200) (AGOA), authorizes the President to provide duty-free treatment under the Generalized System of Preferences (GSP) to any article described in section 503(b)(1)(B) through (G) of the 1974 Act (19 U.S.C. 2463(b)(1)(B)-(G)) that is the growth, product, or manufacture of a designated beneficiary sub-Saharan African country, if, after taking into account the advice of the United States International Trade Commission (USITC), the President determines that such article is not import-sensitive in the context of imports from beneficiary sub-Saharan African countries.

2. Proclamation 7350 of October 2, 2000, designated certain countries listed in section 107 of the AGOA as beneficiary sub-Saharan African countries.

3. Pursuant to section 506A(b)(1) of the 1974 Act, and having taken into account the advice of the USITC, I have determined that certain articles are not import-sensitive in the context of imports from beneficiary sub-Saharan African countries. I have determined to designate those articles as eligible for duty-free treatment under the GSP. I have decided to designate these articles by inserting the symbol “D” in the Rates of Duty 1-Special subcolumn of the Harmonized Tariff Schedule of the United States (HTS) for subheadings covering such articles.

4. Section 213(b)(3)(A) of the Caribbean Basin Economic Recovery Act (CBERA) (19 U.S.C. 2703(b)(3)(A)), as amended by section 211(a) of the United States-Caribbean Basin Trade Partnership Act (Title II of Public Law 106-200) (CBTPA), provides that the tariff treatment accorded at any time during the transition period defined in section 213(b)(5)(D) of the CBERA (19 U.S.C. 2703(b)(5)(D)), as amended by section 211(a) of the CBTPA, to certain articles that are originating goods of designated CBTPA beneficiary countries shall be identical to the tariff treatment that is accorded at such time under Annex 302.2 of the North American Free Trade Agreement (NAFTA) to an article described in the same 8-digit subheading of the HTS that is a good of Mexico and is imported into the United States. Such articles are described in section 213(b)(1)(B) through (F) of the CBERA (19 U.S.C. 2703(b)(1)(B)-(F)), as amended by section 211(a) of the CBTPA.

5. Proclamation 7351 of October 2, 2000, designated certain countries as CBTPA beneficiary countries and reflected in the HTS the tariff treatment provided under the CBTPA, which became effective on that date with respect to those CBTPA beneficiary countries enumerated in a **Federal Register** notice issued by the United States Trade Representative. The Annex to Proclamation 7351 designated certain HTS subheadings covering articles described in section 213(b)(1)(B) through (F) of the CBERA as eligible for the tariff treatment authorized by section 213(b)(3)(A) of the CBERA. Certain

HTS provisions covering watches and watch parts and footwear were inadvertently omitted. I have determined that these provisions should be designated as covering articles eligible for the tariff treatment authorized by section 213(b)(3)(A) of the CBERA.

6. Proclamation 7351 incorporated into the HTS the provisions of the CBTPA concerning the tariff treatment of certain textile and apparel articles imported into the United States from designated CBTPA beneficiary countries, pursuant to section 213(b)(2) of the CBERA (19 U.S.C. 2703(b)(2)), as amended by section 211(a) of the CBTPA. I have determined that a technical error in one of the legal notes to chapter 98 of the HTS created by the Annex to that proclamation should be corrected.

7. Section 604 of the 1974 Act (19 U.S.C. 2483) authorizes the President to embody in the HTS the substance of the relevant provisions of that Act, and of other acts affecting import treatment, and actions thereunder, including the removal, modification, continuance, or imposition of any rate of duty or other import restriction.

NOW, THEREFORE, I, WILLIAM J. CLINTON, President of the United States of America, acting under the authority vested in me by the Constitution and the laws of the United States of America, including title V and section 604 of the 1974 Act, section 111 of the AGOA, section 211 of the CBTPA, and section 213 of the CBERA, do proclaim that:

(1) In order to provide duty-free treatment under the GSP to certain articles when imported from designated beneficiary sub-Saharan African countries, the HTS is modified as provided in Annex I to this proclamation.

(2) In order to accord, at any time during the transition period, to certain watches and watch parts described in section 213(b)(1)(E) of the CBERA, when such watches and watch parts are CBTPA originating goods, the identical tariff treatment that is accorded at such time under Annex 302.2 of the NAFTA to an article described in the same 8-digit subheading of the HTS that is a good of Mexico and is imported into the United States, chapter 91 of the HTS is modified as provided in Annex II to this proclamation.

(3) In order to make a technical correction in U.S. note 2(c) to subchapter XX of chapter 98 of the HTS, such note is modified as provided in Annex II to this proclamation.

(4) Any provisions of previous proclamations and Executive orders that are inconsistent with this proclamation are superseded to the extent of such inconsistency.

(5)(a) The modifications made by Annex I to this proclamation shall be effective with respect to articles entered, or withdrawn from warehouse for consumption, on or after the date of publication of this proclamation in the **Federal Register**.

(b) The modifications made by Annex II to this proclamation shall be effective with respect to articles entered, or withdrawn from warehouse for consumption, on or after October 2, 2000.

IN WITNESS WHEREOF, I have hereunto set my hand this eighteenth day of December, in the year of our Lord two thousand, and of the Independence of the United States of America the two hundred and twenty-fifth.



Annex I

Section A. Effective with respect to goods entered, or withdrawn from warehouse for consumption, on or after the date of publication of this proclamation in the *Federal Register*, the Harmonized Tariff Schedule of the United States (HTS) is modified as set forth herein.

(1). General note 3(c)(i) to the tariff schedule is modified by inserting, immediately above the line reading "Caribbean Basin Economic Recovery Act...E or E*", a new line reading "African Growth and Opportunity Act....D".

(2). The following new general note 16 is inserted in numerical sequence:

"16. Products of Countries Designated as Beneficiary Countries under the African Growth and Opportunity Act (AGOA).

- (a) The following sub-Saharan African countries, having been designated as beneficiary sub-Saharan African countries for purposes of the African Growth and Opportunity Act (AGOA), have met the requirements of the AGOA and, therefore, are to be afforded the tariff treatment provided in this note, shall be treated as beneficiary sub-Saharan African countries for purposes of this note:

Republic of Benin	Republic of Mali
Republic of Botswana	Islamic Republic of Mauritania
Republic of Cape Verde	Republic of Mauritius
Republic of Cameroon	Republic of Mozambique
Central African Republic	Republic of Namibia
Republic of Chad	Republic of Niger
Republic of Congo	Federal Republic of Nigeria
Republic of Djibouti	Republic of Rwanda
State of Eritrea	Democratic Republic of Sao Tome and Principe
Ethiopia	Republic of Senegal
Gabonese Republic	Republic of Seychelles
Republic of Ghana	Republic of Sierra Leone
Republic of Guinea	Republic of South Africa
Republic of Guinea-Bissau	United Republic of Tanzania
Republic of Kenya	Republic of Uganda
Kingdom of Lesotho	Republic of Zambia
Republic of Madagascar	
Republic of Malawi	

- (b) Articles provided for in a provision for which a rate of duty appears in the "Special" subcolumn followed by the symbol "D" in chapters 1 through 97 of the tariff schedule are those designated by the President to be eligible articles pursuant to section 111(a) of the AGOA and section 506A of the Trade Act of 1974 ("the 1974 Act"). Whenever an eligible article which is a good of a designated beneficiary sub-Saharan African country enumerated in subdivision (a) of this note is imported directly into the customs territory of the United States, such article shall be entitled to receive the duty-free treatment provided for herein, without regard to the limitations on preferential treatment of eligible articles in section 503(c)(2)(A) of the 1974 Act, provided that such good—

- (i) is the growth, product or manufacture of a designated beneficiary sub-Saharan African country enumerated in subdivision (a) of this note, and
- (ii) the sum of—
- (A) the cost or value of the materials produced in one or more designated beneficiary sub-Saharan African countries, plus
- (B) the direct costs of processing operations performed in the designated beneficiary sub-Saharan African country or any two or more designated beneficiary sub-Saharan African countries that are members of the same association of countries which is treated as one country under section 507(a)(2) of the 1974 Act,

is not less than 35 per centum of the appraised value of such article at the time it is entered. If the cost or value of the materials produced in the customs territory of the United States is included with respect to an eligible article, an amount not to exceed 15 per centum of the appraised value of such article at the time it is entered that is attributed to such United States cost or value may be applied toward determining the percentage referred to in clause (ii)(B) above. No article or material of a designated beneficiary sub-Saharan African country enumerated in subdivision (a) of this note and receiving the tariff treatment specified in this note shall be eligible for such duty-free treatment by virtue of having merely undergone simple combining or packing operations, or mere dilution with water or mere dilution with another substance that does not materially alter the characteristics of the article.

Annex (con.)

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- (c) The duty-free treatment provided for in this note shall be effective with respect to eligible articles entered, or withdrawn from warehouse for consumption, as of the date proclaimed by the President and shall continue in effect through the close of September 30, 2008."

Conforming change: General note 4(b)(ii) is modified by deleting "section 502(a)(3)" and by inserting in lieu thereof "section 507(2)".

(3). For the following HTS provisions, the Rates of Duty 1-Special subcolumn is modified by inserting, in alphabetical order, the symbol "D" in the parentheses following the "Free" rate of duty in such subcolumn.

0101.20.20	0207.25.20	0403.90.72	0406.30.12	0406.90.86
0101.20.40	0207.25.40	0403.90.74	0406.30.14	0406.90.90
0102.90.40	0207.26.00	0403.90.85	0406.30.22	0406.90.93
0104.20.00	0207.27.00	0403.90.87	0406.30.24	0406.90.95
0105.11.00	0207.32.00	0403.90.90	0406.30.32	0406.90.99
0105.12.00	0207.34.00	0404.10.08	0406.30.34	0408.11.00
0105.19.00	0207.35.00	0404.10.11	0406.30.42	0408.19.00
0105.92.00	0207.36.00	0404.10.20	0406.30.44	0408.91.00
0105.93.00	0208.10.00	0404.10.48	0406.30.49	0408.99.00
0105.99.00	0208.90.40	0404.10.50	0406.30.51	0409.00.00
0106.00.30	0210.11.00	0404.90.28	0406.30.55	0509.00.00
0201.10.05	0210.19.00	0404.90.30	0406.30.56	0601.10.30
0201.10.10	0305.30.20	0404.90.70	0406.30.57	0601.10.85
0201.20.02	0305.30.40	0405.10.05	0406.30.61	0601.20.10
0201.20.04	0305.41.00	0405.10.10	0406.30.65	0602.90.50
0201.20.06	0305.61.20	0405.20.10	0406.30.69	0603.10.60
0201.20.10	0305.69.20	0405.20.20	0406.30.73	0701.10.00
0201.20.30	0305.69.40	0405.20.40	0406.30.77	0701.90.50
0201.20.50	0401.10.00	0405.20.50	0406.30.81	0702.00.20
0201.30.02	0401.20.20	0405.20.60	0406.30.85	0702.00.40
0201.30.04	0401.30.02	0405.90.05	0406.30.89	0703.90.00
0201.30.06	0401.30.05	0405.90.10	0406.30.95	0704.90.40
0201.30.10	0401.30.42	0406.10.12	0406.40.20	0706.10.05
0201.30.30	0401.30.50	0406.10.14	0406.40.40	0706.10.20
0201.30.50	0402.10.05	0406.10.24	0406.40.51	0706.90.40
0202.10.05	0402.10.10	0406.10.34	0406.40.52	0707.00.50
0202.10.10	0402.21.02	0406.10.44	0406.40.54	0708.20.90
0202.20.02	0402.21.05	0406.10.54	0406.40.58	0708.90.40
0202.20.04	0402.21.27	0406.10.64	0406.90.05	0709.20.90
0202.20.06	0402.21.30	0406.10.74	0406.90.06	0709.40.20
0202.20.10	0402.21.73	0406.10.84	0406.90.08	0709.40.60
0202.20.30	0402.21.75	0406.10.95	0406.90.14	0709.51.00
0202.20.50	0402.29.05	0406.20.10	0406.90.16	0709.70.00
0202.30.04	0402.29.10	0406.20.22	0406.90.20	0709.90.30
0202.30.06	0402.91.03	0406.20.24	0406.90.25	0709.90.35
0202.30.30	0402.91.06	0406.20.29	0406.90.28	0709.90.45
0202.30.50	0402.91.10	0406.20.31	0406.90.31	0709.90.90
0203.12.10	0402.91.30	0406.20.34	0406.90.33	0710.10.00
0203.19.20	0402.99.03	0406.20.36	0406.90.34	0710.22.37
0204.10.00	0402.99.06	0406.20.43	0406.90.36	0710.22.40
0204.21.00	0402.99.10	0406.20.44	0406.90.38	0710.29.40
0204.22.20	0402.99.30	0406.20.49	0406.90.39	0710.30.00
0204.22.40	0402.99.68	0406.20.51	0406.90.41	0710.40.00
0204.23.20	0402.99.70	0406.20.54	0406.90.43	0710.80.20
0204.23.40	0403.10.05	0406.20.55	0406.90.44	0710.80.40
0204.30.00	0403.10.10	0406.20.56	0406.90.46	0710.80.45
0204.41.00	0403.10.90	0406.20.57	0406.90.49	0710.80.60
0204.42.20	0403.90.02	0406.20.61	0406.90.51	0710.80.85
0204.42.40	0403.90.04	0406.20.65	0406.90.52	0710.80.97
0204.43.20	0403.90.20	0406.20.69	0406.90.59	0710.90.90
0204.43.40	0403.90.37	0406.20.73	0406.90.61	0711.20.38
0207.11.00	0403.90.41	0406.20.77	0406.90.63	0711.20.40
0207.12.00	0403.90.47	0406.20.81	0406.90.66	0711.90.40
0207.13.00	0403.90.51	0406.20.85	0406.90.72	0712.20.20
0207.14.00	0403.90.57	0406.20.89	0406.90.76	0712.20.40
0207.24.00	0403.90.61	0406.20.95	0406.90.82	0712.30.20

Annex (con.)

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0712.90.20	1008.20.00	1604.12.20	2006.00.20	2106.90.64
0712.90.78	1008.90.00	1604.13.20	2006.00.40	2106.90.78
0714.90.40	1101.00.00	1604.13.30	2006.00.50	2106.90.83
0802.11.00	1102.10.00	1604.14.10	2006.00.60	2106.90.85
0802.12.00	1103.11.00	1604.14.20	2007.10.00	2106.90.95
0802.21.00	1103.19.00	1604.14.30	2007.91.10	2202.90.10
0802.22.00	1104.11.00	1604.14.40	2007.99.15	2202.90.22
0802.32.00	1104.19.00	1604.14.70	2007.99.35	2202.90.24
0802.90.10	1104.21.00	1604.14.80	2007.99.55	2202.90.30
0802.90.98	1105.20.00	1604.19.10	2007.99.60	2202.90.35
0804.10.20	1107.10.00	1604.19.40	2007.99.65	2204.21.20
0804.10.40	1107.20.00	1604.19.50	2007.99.70	2204.21.50
0804.10.60	1108.13.00	1604.20.40	2008.11.22	2204.29.20
0804.10.80	1202.10.05	1604.20.50	2008.11.25	2204.29.40
0804.20.40	1202.10.40	1605.90.50	2008.11.42	2204.29.60
0804.20.80	1202.20.05	1702.11.00	2008.11.45	2204.29.80
0804.30.20	1202.20.40	1702.19.00	2008.19.20	2204.30.00
0804.30.40	1204.00.00	1702.50.00	2008.19.40	2205.90.40
0804.30.60	1205.00.00	1704.90.10	2008.19.50	2206.00.30
0804.40.00	1207.20.00	1704.90.52	2008.19.85	2206.00.60
0805.10.00	1208.10.00	1704.90.54	2008.20.00	2207.10.60
0805.20.00	1208.90.00	1704.90.74	2008.30.20	2207.20.00
0805.30.20	1209.22.20	1704.90.90	2008.30.30	2208.40.20
0805.40.40	1209.24.00	1806.20.79	2008.30.35	2208.40.40
0805.40.60	1209.25.00	1806.20.81	2008.30.40	2208.40.60
0805.40.80	1209.91.10	1806.20.85	2008.30.46	2208.40.80
0806.10.20	1209.91.50	1806.20.95	2008.30.55	2302.50.00
0806.10.60	1212.30.00	1806.20.99	2008.30.65	2303.10.00
0806.20.10	1212.91.00	1901.10.05	2008.30.70	2304.00.00
0806.20.20	1214.10.00	1901.10.15	2008.30.80	2306.10.00
0806.20.90	1302.13.00	1901.10.35	2008.30.85	2308.10.00
0807.11.40	1302.39.00	1901.10.45	2008.40.00	2308.90.80
0807.19.10	1401.90.20	1901.10.55	2008.60.00	2309.90.22
0807.19.80	1402.90.10	1901.10.60	2008.80.00	2309.90.24
0808.20.40	1403.10.00	1901.10.80	2008.92.10	2309.90.42
0809.10.00	1501.00.00	1901.10.95	2008.99.05	2309.90.44
0809.30.20	1502.00.00	1901.90.10	2008.99.10	2309.90.60
0809.40.40	1503.00.00	1901.90.20	2008.99.18	2309.90.95
0810.20.10	1504.10.40	1901.90.32	2008.99.25	2401.10.61
0811.90.22	1507.10.00	1901.90.33	2008.99.29	2401.10.63
0811.90.40	1507.90.40	1901.90.34	2008.99.42	2401.20.05
0812.10.00	1508.10.00	1901.90.38	2008.99.60	2401.20.31
0812.20.00	1508.90.00	1901.90.42	2009.11.00	2401.20.33
0812.90.10	1512.11.00	1901.90.44	2009.19.25	2401.20.83
0812.90.20	1512.19.00	1901.90.46	2009.19.45	2401.20.85
0812.90.30	1512.21.00	1901.90.48	2009.20.20	2401.30.25
0812.90.40	1512.29.00	1901.90.56	2009.20.40	2401.30.27
0812.90.90	1514.10.90	1901.90.70	2009.30.40	2401.30.35
0813.20.10	1514.90.50	1903.00.40	2009.30.60	2401.30.37
0813.20.20	1514.90.90	1904.20.10	2009.40.20	2402.10.30
0813.40.15	1515.11.00	1904.20.90	2009.40.40	2402.10.60
0813.40.30	1515.19.00	2001.90.20	2009.60.00	2402.20.80
0813.40.40	1515.21.00	2001.90.35	2009.80.40	2402.90.00
0813.40.90	1515.29.00	2001.90.60	2009.90.40	2403.10.20
0813.50.00	1516.20.10	2002.10.00	2101.30.00	2403.10.30
0814.00.80	1516.20.90	2002.90.80	2103.20.40	2403.10.60
0901.90.20	1517.10.00	2003.10.00	2105.00.05	2403.91.43
0904.20.40	1517.90.45	2004.10.80	2105.00.10	2403.91.45
0910.40.40	1517.90.50	2004.90.90	2105.00.25	2403.99.20
1001.10.00	1517.90.90	2005.51.20	2105.00.30	2403.99.30
1001.90.10	1518.00.20	2005.60.00	2105.00.50	2403.99.60
1001.90.20	1522.00.00	2005.70.50	2106.90.22	2613.10.00
1003.00.20	1602.10.00	2005.70.60	2106.90.24	2613.90.00
1003.00.40	1602.20.20	2005.70.70	2106.90.28	2616.10.00
1006.10.00	1602.41.90	2005.70.91	2106.90.32	2616.90.00
1006.20.20	1602.42.40	2005.70.97	2106.90.34	2709.00.10
1006.20.40	1602.50.60	2005.90.30	2106.90.38	2709.00.20
1006.30.90	1603.00.10	2005.90.50	2106.90.48	2710.00.05
1006.40.00	1604.11.20	2005.90.80	2106.90.62	2710.00.10

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2710.00.15	2908.90.40	2918.30.25	2922.50.35	2933.51.90
2710.00.18	2908.90.50	2918.30.30	2922.50.40	2933.59.21
2710.00.20	2909.30.05	2918.90.05	2924.10.80	2933.59.22
2710.00.25	2909.30.07	2918.90.43	2924.21.20	2933.59.36
2710.00.30	2909.30.09	2918.90.47	2924.21.45	2933.59.45
2710.00.45	2909.30.40	2919.00.30	2924.22.00	2933.59.53
2710.00.60	2909.30.60	2920.90.20	2924.29.05	2933.59.70
2801.30.20	2909.49.10	2921.22.10	2924.29.20	2933.59.80
2805.11.00	2909.49.15	2921.30.10	2924.29.31	2933.79.09
2805.19.00	2909.50.10	2921.30.30	2924.29.70	2933.79.15
2805.21.00	2909.50.45	2921.41.10	2924.29.75	2933.90.13
2805.30.00	2909.50.50	2921.41.20	2925.19.10	2933.90.26
2825.90.30	2909.60.10	2921.42.10	2925.19.40	2933.90.46
2827.39.40	2909.60.20	2921.42.18	2925.20.10	2933.90.53
2841.80.00	2910.90.20	2921.42.22	2925.20.20	2933.90.61
2842.10.00	2912.21.00	2921.42.65	2925.20.60	2933.90.65
2843.10.00	2912.30.10	2921.42.90	2926.90.05	2933.90.70
2844.10.50	2913.00.40	2921.43.08	2926.90.12	2933.90.75
2849.90.30	2914.11.10	2921.43.15	2926.90.44	2933.90.79
2850.00.10	2914.40.40	2921.43.40	2926.90.47	2933.90.82
2902.90.30	2914.50.30	2921.43.80	2927.00.06	2934.10.10
2902.90.90	2914.69.20	2921.44.10	2927.00.40	2934.10.20
2903.30.05	2914.69.90	2921.44.20	2927.00.50	2934.20.20
2903.59.05	2914.70.40	2921.44.70	2928.00.25	2934.20.30
2903.59.15	2915.39.30	2921.45.10	2929.10.10	2934.20.40
2903.59.20	2915.39.35	2921.45.20	2929.10.20	2934.20.80
2903.61.20	2915.40.20	2921.45.60	2929.10.35	2934.30.12
2903.62.00	2915.40.30	2921.45.90	2929.10.55	2934.30.23
2903.69.10	2915.90.18	2921.49.10	2929.10.80	2934.30.27
2903.69.20	2916.11.00	2921.49.37	2929.90.15	2934.30.43
2903.69.27	2916.13.00	2921.49.43	2929.90.20	2934.30.50
2903.69.70	2916.15.10	2921.49.45	2930.20.20	2934.90.05
2904.10.10	2916.19.30	2921.49.50	2930.90.29	2934.90.06
2904.10.15	2916.31.30	2921.51.10	2930.90.49	2934.90.39
2904.10.32	2916.31.50	2921.51.30	2931.00.10	2934.90.44
2904.10.37	2916.32.10	2921.51.50	2931.00.15	2935.00.10
2904.10.50	2916.32.20	2921.59.08	2931.00.22	2935.00.15
2904.20.10	2916.34.10	2921.59.30	2931.00.27	2935.00.48
2904.20.15	2916.34.25	2921.59.40	2931.00.30	2935.00.60
2904.20.35	2916.34.55	2921.59.80	2931.00.60	2935.00.75
2904.20.40	2916.35.25	2922.19.18	2932.19.10	2935.00.95
2904.20.45	2916.35.55	2922.19.20	2932.29.20	2942.00.05
2904.90.08	2916.39.03	2922.19.60	2932.29.30	2942.00.10
2904.90.20	2916.39.45	2922.19.70	2932.29.45	2942.00.35
2904.90.30	2916.39.75	2922.21.10	2932.91.00	3202.10.50
2904.90.40	2917.12.10	2922.21.40	2932.92.00	3204.11.10
2904.90.47	2917.12.50	2922.21.50	2932.93.00	3204.11.15
2905.17.00	2917.19.20	2922.22.10	2932.99.35	3204.11.35
2906.12.00	2917.19.27	2922.22.20	2932.99.39	3204.11.50
2906.21.00	2917.19.40	2922.22.50	2932.99.60	3204.12.17
2906.29.60	2917.20.00	2922.29.10	2932.99.70	3204.13.10
2907.13.00	2917.36.00	2922.29.15	2933.19.08	3204.13.20
2907.15.60	2917.39.04	2922.29.27	2933.19.37	3204.13.25
2907.19.10	2917.39.15	2922.29.60	2933.19.43	3204.13.60
2907.19.20	2917.39.17	2922.29.80	2933.29.10	3204.13.80
2907.19.80	2917.39.30	2922.30.10	2933.29.35	3204.14.10
2907.21.00	2917.39.70	2922.30.25	2933.29.43	3204.14.20
2907.22.50	2918.17.50	2922.30.45	2933.32.10	3204.14.25
2907.29.90	2918.19.10	2922.42.10	2933.32.50	3204.14.30
2907.30.00	2918.19.20	2922.43.10	2933.39.20	3204.14.50
2908.10.10	2918.19.30	2922.43.50	2933.39.30	3204.15.10
2908.10.25	2918.19.90	2922.49.10	2933.39.41	3204.15.20
2908.10.35	2918.23.30	2922.49.27	2933.39.61	3204.15.30
2908.10.60	2918.23.50	2922.49.30	2933.39.91	3204.15.35
2908.20.04	2918.29.04	2922.49.37	2933.40.15	3204.15.40
2908.20.20	2918.29.20	2922.50.10	2933.40.20	3204.15.80
2908.20.60	2918.29.65	2922.50.14	2933.40.26	3204.16.10
2908.90.08	2918.29.75	2922.50.17	2933.40.60	3204.16.20
2908.90.28	2918.30.10	2922.50.25	2933.40.70	3204.16.30

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3204.16.50	3824.90.45	4409.10.65	6404.11.40	7013.39.20
3204.17.04	3824.90.47	4409.20.65	6404.11.50	7013.39.30
3204.17.20	3824.90.90	4412.19.50	6404.11.60	7013.39.40
3204.17.60	3912.20.00	4421.10.00	6404.11.70	7013.39.50
3204.17.90	3916.90.30	4421.90.20	6404.11.80	7013.39.60
3204.19.11	3918.10.32	4421.90.40	6404.11.90	7013.91.10
3204.19.20	3918.10.40	4421.90.80	6404.19.15	7013.91.20
3204.19.25	3918.90.20	4421.90.85	6404.19.20	7013.91.30
3204.19.30	3918.90.30	4601.99.00	6404.19.25	7013.99.10
3204.19.40	3921.13.19	4602.10.21	6404.19.30	7013.99.20
3204.19.50	3921.90.19	4602.10.22	6404.19.35	7013.99.40
3205.00.40	3921.90.21	4602.10.25	6404.19.40	7013.99.50
3205.00.50	3921.90.29	4602.10.29	6404.19.50	7013.99.60
3206.49.20	3926.20.40	6401.10.00	6404.19.60	7013.99.70
3206.50.00	3926.30.50	6401.91.00	6404.19.70	7013.99.80
3207.40.50	3926.90.55	6401.92.60	6404.19.80	7013.99.90
3211.00.00	3926.90.59	6401.92.90	6404.19.90	7018.20.00
3214.90.50	3926.90.65	6401.99.30	6404.20.20	7019.19.90
3301.13.00	3926.90.77	6401.99.60	6404.20.40	7019.90.10
3403.11.20	3926.90.85	6401.99.90	6404.20.60	7104.20.00
3403.19.10	4010.12.90	6402.19.05	6405.10.00	7114.11.45
3403.91.50	4010.19.80	6402.19.15	6405.20.30	7202.11.50
3403.99.00	4010.21.30	6402.19.50	6405.20.90	7202.21.75
3502.11.00	4010.22.30	6402.19.70	6405.90.90	7202.21.90
3502.19.00	4010.23.50	6402.19.90	6406.10.05	7202.49.10
3503.00.20	4010.24.50	6402.30.30	6406.10.10	7202.70.00
3503.00.40	4010.29.10	6402.30.50	6406.10.20	7202.91.00
3506.10.10	4010.29.50	6402.30.60	6406.10.25	7202.93.00
3606.90.30	4015.19.50	6402.30.70	6406.10.30	7202.99.50
3804.00.50	4015.90.00	6402.30.80	6406.10.35	7206.10.00
3805.90.00	4104.10.60	6402.30.90	6406.10.40	7207.11.00
3806.90.00	4104.10.80	6402.91.40	6406.10.45	7207.12.00
3808.10.50	4105.12.00	6402.91.50	6406.10.50	7207.19.00
3808.20.50	4105.19.10	6402.91.60	6812.50.10	7207.20.00
3808.30.50	4105.19.20	6402.91.70	6907.10.00	7208.10.15
3808.90.95	4105.20.30	6402.91.80	6907.90.00	7208.10.30
3809.92.10	4107.10.20	6402.91.90	6908.10.10	7208.10.60
3809.92.50	4107.10.30	6402.99.05	6908.10.50	7208.25.30
3809.93.10	4107.90.30	6402.99.10	6908.90.00	7208.25.60
3809.93.50	4109.00.30	6402.99.14	6911.10.10	7208.26.00
3810.10.00	4109.00.40	6402.99.18	6911.10.52	7208.27.00
3810.90.10	4202.11.00	6402.99.20	6911.10.58	7208.36.00
3810.90.50	4202.12.20	6402.99.30	6911.10.80	7208.37.00
3811.19.00	4202.19.00	6402.99.60	6912.00.20	7208.38.00
3811.21.00	4202.21.30	6402.99.70	6912.00.39	7208.39.00
3811.29.00	4202.21.60	6402.99.80	6912.00.45	7208.40.60
3811.90.00	4202.21.90	6402.99.90	7002.10.10	7208.54.00
3812.10.50	4202.22.15	6403.19.10	7005.21.10	7209.15.00
3812.20.50	4202.22.70	6403.19.30	7005.21.20	7209.16.00
3812.30.90	4202.29.50	6403.19.40	7005.29.08	7209.17.00
3814.00.10	4202.29.90	6403.19.50	7005.29.18	7209.18.15
3814.00.50	4202.31.60	6403.40.30	7013.10.50	7209.18.25
3815.90.50	4202.32.85	6403.40.60	7013.21.10	7209.18.60
3817.10.10	4202.39.50	6403.51.30	7013.21.20	7209.25.00
3817.20.00	4202.91.00	6403.51.60	7013.21.30	7209.26.00
3819.00.00	4202.92.45	6403.51.90	7013.29.05	7209.27.00
3820.00.00	4202.99.50	6403.59.15	7013.29.10	7209.28.00
3821.00.00	4202.99.90	6403.59.30	7013.29.20	7209.90.00
3823.13.00	4203.10.40	6403.59.60	7013.29.30	7210.11.00
3823.19.40	4203.29.05	6403.59.90	7013.29.40	7210.12.00
3823.70.20	4203.29.08	6403.91.30	7013.29.50	7210.20.00
3823.70.40	4203.29.15	6403.91.60	7013.29.60	7210.30.00
3823.70.60	4203.29.18	6403.91.90	7013.31.10	7210.41.00
3824.10.00	4203.29.20	6403.99.20	7013.31.20	7210.49.00
3824.40.10	4203.29.30	6403.99.40	7013.32.10	7210.50.00
3824.40.50	4203.29.40	6403.99.60	7013.32.20	7210.61.00
3824.71.00	4203.29.50	6403.99.75	7013.32.30	7210.69.00
3824.79.00	4304.00.00	6403.99.90	7013.32.40	7210.70.60
3824.90.35	4405.00.00	6404.11.20	7013.39.10	7210.90.10

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7210.90.60	7222.20.00	7302.10.50	7318.14.10	8528.12.32
7211.19.15	7222.30.00	7302.20.00	7318.14.50	8528.12.40
7211.19.20	7222.40.30	7302.40.00	7320.10.60	8528.12.48
7211.19.30	7222.40.60	7304.21.30	7326.90.35	8528.12.56
7211.19.45	7223.00.10	7304.21.60	7419.99.15	8528.12.72
7211.19.60	7223.00.50	7304.29.10	7601.10.30	8528.12.97
7211.19.75	7223.00.90	7304.29.20	7601.20.30	8528.13.00
7211.23.15	7224.10.00	7304.29.30	7601.20.60	8528.21.29
7211.23.20	7224.90.00	7304.29.40	7604.21.00	8528.21.39
7211.23.30	7225.11.00	7304.29.50	7614.10.10	8528.21.42
7211.23.45	7225.19.00	7304.29.60	7614.90.40	8528.21.49
7211.23.60	7225.20.00	7304.41.30	7901.12.10	8528.21.52
7211.29.20	7225.30.10	7304.41.60	8101.10.00	8528.21.70
7211.29.45	7225.30.30	7304.49.00	8101.91.50	8528.21.90
7211.29.60	7225.30.50	7304.51.10	8101.92.00	8528.22.00
7212.10.00	7225.30.70	7304.59.10	8101.93.00	8528.30.40
7212.20.00	7225.40.10	7304.59.20	8102.10.00	8528.30.60
7212.30.10	7225.40.30	7304.90.10	8102.91.10	8528.30.68
7212.30.30	7225.40.50	7304.90.30	8104.19.00	8528.30.78
7212.30.50	7225.40.70	7304.90.50	8105.10.30	8528.30.90
7212.60.00	7225.50.10	7304.90.70	8108.10.50	8529.10.20
7213.10.00	7225.50.60	7305.11.10	8109.10.60	8529.90.03
7213.20.00	7225.50.70	7305.11.50	8112.40.60	8529.90.13
7214.10.00	7225.50.80	7305.12.10	8112.91.40	8529.90.33
7214.20.00	7226.11.10	7305.12.50	8112.91.60	8529.90.39
7214.30.00	7226.11.90	7305.19.10	8203.20.40	8529.90.43
7214.91.00	7226.19.10	7305.19.50	8205.90.00	8529.90.49
7214.99.00	7226.19.90	7305.20.20	8206.00.00	8529.90.53
7215.10.00	7226.20.00	7305.20.40	8211.10.00	8529.90.69
7215.50.00	7226.91.15	7305.20.60	8211.91.20	8529.90.83
7215.90.10	7226.91.25	7305.20.80	8211.91.25	8529.90.88
7215.90.30	7226.91.50	7305.31.40	8211.91.30	8529.90.93
7216.10.00	7226.91.70	7305.31.60	8211.91.40	8540.11.10
7216.21.00	7226.91.80	7305.39.10	8213.00.90	8540.11.24
7216.22.00	7226.92.10	7305.39.50	8214.90.30	8540.11.28
7216.31.00	7226.92.30	7305.90.10	8215.10.00	8540.11.30
7216.32.00	7226.92.50	7305.90.50	8215.20.00	8540.11.44
7216.33.00	7226.92.70	7306.20.10	8215.99.01	8540.11.48
7216.40.00	7226.92.80	7306.20.20	8215.99.05	8540.11.50
7216.50.00	7226.93.00	7306.20.30	8215.99.10	8540.12.50
7216.91.00	7226.94.00	7306.20.40	8215.99.15	8540.12.70
7216.99.00	7226.99.00	7306.20.60	8215.99.26	8540.20.20
7217.10.10	7227.10.00	7306.20.80	8215.99.30	8540.20.40
7217.10.20	7227.90.10	7306.30.10	8215.99.35	8540.40.00
7217.10.30	7227.90.20	7306.30.50	8301.10.20	8540.50.00
7217.10.40	7228.10.00	7306.40.10	8301.10.40	8540.60.00
7217.10.50	7228.20.10	7306.40.50	8301.10.80	8540.71.40
7217.10.60	7228.20.50	7306.50.10	8302.30.60	8540.72.00
7217.10.70	7228.30.20	7306.50.50	8482.10.10	8540.79.00
7217.10.80	7228.30.60	7306.60.10	8482.10.50	8540.81.00
7217.10.90	7228.30.80	7306.60.30	8482.20.00	8540.89.00
7217.20.15	7228.40.00	7306.60.50	8482.91.00	8540.91.15
7217.20.30	7228.50.10	7306.60.70	8482.99.05	8540.91.50
7217.20.45	7228.50.50	7306.90.10	8482.99.15	8607.19.06
7217.20.60	7228.60.10	7306.90.50	8482.99.25	8701.20.00
7217.20.75	7228.60.60	7307.19.90	8482.99.35	8703.10.10
7217.30.15	7228.60.80	7307.93.30	8482.99.45	8703.21.00
7217.30.30	7228.70.30	7308.90.30	8482.99.65	8703.22.00
7217.30.45	7228.70.60	7308.90.60	8483.20.80	8703.23.00
7217.30.60	7228.80.00	7312.10.30	8483.30.80	8703.24.00
7217.30.75	7229.10.00	7312.10.50	8483.60.80	8703.31.00
7217.90.10	7229.20.00	7312.10.60	8483.90.30	8703.32.00
7217.90.50	7229.90.10	7312.10.70	8483.90.70	8703.33.00
7218.10.00	7229.90.50	7312.10.90	8483.90.80	8703.90.00
7218.91.00	7229.90.90	7314.31.10	8525.10.30	8704.21.00
7218.99.00	7301.10.00	7314.41.00	8527.29.80	8704.22.10
7221.00.00	7301.20.10	7314.42.00	8527.31.05	8704.22.50
7222.11.00	7301.20.50	7317.00.55	8527.31.50	8704.23.00
7222.19.00	7302.10.10	7318.11.00	8528.12.24	8704.31.00

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8704.32.00	9102.91.40	9105.91.40	9109.19.10	9114.40.40
8704.90.00	9102.91.80	9105.91.80	9109.19.20	9114.40.60
8706.00.03	9103.10.20	9105.99.50	9109.19.40	9114.40.80
8706.00.05	9103.10.40	9105.99.60	9109.19.60	9114.90.15
8706.00.15	9103.10.80	9106.10.00	9109.90.20	9114.90.30
8706.00.25	9103.90.00	9106.20.00	9109.90.40	9114.90.40
8707.10.00	9104.00.05	9106.90.75	9109.90.60	9114.90.50
8707.90.50	9104.00.10	9106.90.85	9110.11.00	9209.91.80
8708.92.50	9104.00.20	9107.00.80	9110.12.00	9302.00.00
8712.00.15	9104.00.25	9108.11.40	9110.19.00	9305.10.20
8712.00.25	9104.00.30	9108.11.80	9110.90.20	9404.29.10
8712.00.35	9104.00.40	9108.12.00	9110.90.40	9506.99.08
8712.00.44	9104.00.45	9108.19.40	9110.90.60	9507.10.00
8712.00.48	9104.00.50	9108.19.80	9111.10.00	9507.30.20
8714.91.30	9104.00.60	9108.91.10	9111.20.20	9507.30.40
8714.91.50	9105.11.40	9108.91.20	9111.20.40	9507.90.70
8714.92.10	9105.11.80	9108.91.30	9111.80.00	9603.10.05
8714.93.28	9105.19.20	9108.91.40	9111.90.40	9603.10.15
8714.93.35	9105.19.30	9108.91.50	9111.90.50	9603.10.35
8714.94.90	9105.19.50	9108.91.60	9111.90.70	9603.10.40
8714.95.00	9105.21.40	9108.99.20	9112.10.00	9603.10.50
8714.96.10	9105.21.80	9108.99.40	9113.20.40	9603.10.60
8714.96.90	9105.29.10	9108.99.80	9114.10.40	9608.31.00
8714.99.80	9105.29.20	9109.11.10	9114.10.80	9608.39.00
9029.20.20	9105.29.30	9109.11.20	9114.30.40	9608.50.00
9029.90.40	9105.29.40	9109.11.40	9114.30.80	9612.20.00
9101.11.40	9105.29.50	9109.11.60	9114.40.20	9616.20.00
9101.11.80				
9101.19.40				
9101.19.80				
9101.21.10				
9101.21.80				
9101.29.10				
9101.29.20				
9101.29.30				
9101.29.40				
9101.29.50				
9101.29.70				
9102.11.10				
9102.11.25				
9102.11.30				
9102.11.45				
9102.11.50				
9102.11.65				
9102.11.70				
9102.11.95				
9102.19.20				
9102.19.40				
9102.19.60				
9102.19.80				
9102.21.10				
9102.21.25				
9102.21.30				
9102.21.50				
9102.21.70				
9102.21.90				
9102.29.02				
9102.29.15				
9102.29.20				
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9102.29.60				

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Annex II

Section A. Effective with respect to goods entered, or withdrawn from warehouse for consumption, on or after October 2, 2000, the Rates of Duty 1-Special subcolumn in the HTS is modified for each of the following HTS subheadings by inserting the symbol "R" in alphabetical order in the parentheses following the "Free" rate of duty.

9101.11.40	9102.11.50	9102.29.25	9108.19.80	9111.90.70
9101.11.80	9102.11.65	9102.29.30	9108.91.10	9113.10.00
9101.19.40	9102.11.70	9102.29.35	9108.91.20	9113.20.20
9101.19.80	9102.11.95	9102.29.40	9108.91.30	9113.20.40
9101.21.10	9102.19.20	9102.29.45	9108.91.40	9113.20.60
9101.21.30	9102.19.40	9102.29.50	9108.91.50	9113.20.90
9101.21.80	9102.19.60	9102.29.55	9108.91.60	9113.90.40
9101.29.10	9102.19.80	9102.29.60	9108.99.20	9113.90.80
9101.29.20	9102.21.10	9102.91.20	9108.99.40	9114.10.40
9101.29.30	9102.21.25	9102.91.40	9108.99.80	9114.30.40
9101.29.40	9102.21.30	9102.91.80	9110.11.00	9114.30.80
9101.29.50	9102.21.50	9102.99.20	9110.12.00	9114.40.20
9101.29.70	9102.21.70	9102.99.40	9110.19.00	9114.40.60
9101.29.80	9102.21.90	9102.99.60	9111.10.00	9114.90.15
9101.99.40	9102.29.02	9102.99.80	9111.20.20	9114.90.40
9102.11.10	9102.29.04	9108.11.40	9111.20.40	
9102.11.25	9102.29.10	9108.11.80	9111.80.00	
9102.11.30	9102.29.15	9108.12.00	9111.90.40	
9102.11.45	9102.29.20	9108.19.40	9111.90.50	

Section B. Effective on October 2, 2000, U.S. note 2(c) to subchapter XX of chapter 98 of the HTS is modified by striking "October 1, 2004 through September 30, 2005 and subsequent 12-month periods.....7,604,685" and by inserting the phrase "and subsequent 12-month periods" immediately after the date "September 30, 2004" in such note.

Section C. Effective with respect to articles entered, or withdrawn from warehouse for consumption, on or after October 2, 2000, HTS subheading 6402.99.70 is modified by inserting in the Rates of Duty 1-Special subcolumn the symbol "R" in the parenthetical expression reading "(MX)". Effective with respect to articles entered, or withdrawn from warehouse for consumption, on or after each of the dates set forth in this table, such subheading shall be further modified by deleting the special rate of duty in the HTS that is followed by the symbol "R" in parentheses and by inserting in lieu thereof the following new rate of duty:

January 1, 2001.....18¢/pr. + 11.2%
 January 1, 2002..... 9¢/pr. + 3%
 January 1, 2003..... Free

14	75822
19	77250
208	75822, 75856
225	75856
325	75856
331	78899
343	75822
506	78900
509	78900
536	75822
560	78900
705	80298
Proposed Rules:	
3	76180
5	75870, 75872
8	75196
9	75872
203	78656
208	76180
225	76180, 80384
325	76180
567	76180
584	77528
907	78994
908	78994

13 CFR**Proposed Rules:**

112	76480
117	76480
121	76184

14 CFR

25	76147, 77252, 79706
39	75582, 75585, 75588, 75590, 75592, 75595, 75597, 75599, 75601, 75603, 75605, 75608, 75610, 75611, 75613, 75615, 75617, 75618, 75620, 75624, 75625, 76149, 77259, 77261, 77263, 77774, 77776, 77778, 77780, 77782, 77783, 77785, 78083, 78902, 78905, 78913, 80300, 80301
71	76150, 77282, 77497, 77811, 80302
73	76151, 78915
95	78916
97	78085, 78086, 78089
1214	80302

Proposed Rules:

25	79278, 79294
27	79786
39	75198, 75877, 75879, 75881, 75883, 75887, 76185, 76187, 76950, 76953, 77528, 77530, 78122, 79323, 80388, 80390, 80392
73	79013
91	79284
1250	76460
1251	76460
1252	76460

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736	76561
744	76561
801	77282, 77812
806	78919, 78920
902	77450
930	77124

Proposed Rules:

8	76460
8b	76460
20	76460

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0	78407
23	78738
300	75154
303	75154

17 CFR

1	77962, 77993, 80497
3	77993
4	77993
5	77962
15	77962
35	78030
36	77962
37	77962
38	77962
39	78020
100	77962
140	77993
155	77993
166	77993
170	77962
180	77962
210	76012
240	75414, 75439, 76012
242	76562
270	76189

Proposed Rules:

32	77838

18 CFR

11	76916
33	76009
260	80306
284	75628, 77285
342	79711

Proposed Rules:

1302	76460
1307	76460
1309	76460

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12	77813, 80497
113	77813, 80497
132	77816
162	78091
163	77813, 77816
171	78091
178	77813, 78091

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24	78430

20 CFR

404	80307
416	80307
655	80110
656	80110
718	79920
722	79920
725	79920
726	79920
727	79920

21 CFR

16	76096
73	75158
101	76096
115	76096
172	79718
179	76096
510	76924
514	76924
556	76930
558	76924
660	77497

876	76930
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101	75887
660	77532
1271	77838
1308	77328

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22	78094
42	78094, 78095
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143	76460
209	76460
217	76460
218	76460

23 CFR

655	78923
Proposed Rules:	
945	77534

24 CFR

5	77230
200	77230
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30	76520

25 CFR

20	76563
1000	78688
Proposed Rules:	
580	75888

26 CFR

1	76932, 79719
26	79735
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301	78409
602	77818

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1	76194, 79015, 79788
31	76194
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9	78097

28 CFR

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4007	75160, 77429
4011	75164
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32	76460
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42	77292

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77	77292
250	76933
701	79582
724	79582
750	79582
773	79582
774	79582
775	79582
778	79582
785	79582
795	79582
817	79582
840	79582
842	79582
843	79582
846	79582
847	79582
874	79582
875	79582
903	79582
905	79582
910	79582
912	79582
920	78416
921	79582
922	79582
933	79582
937	79582
939	79582
941	79582
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203	78431
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948	75889

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29	77500

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100	76153, 77512, 77513
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373	77432
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607	79309
608	79309

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1194	80500

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7	79024
18	77538

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1	76756, 78958

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 253.....75167
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 3240.....78440
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 3470.....78440
 3500.....78440
 3510.....78440
 3520.....78440
 3530.....78440
 3540.....78440
 3550.....78440
 3560.....78440
 3570.....78440
 3580.....78440
 3590.....78440
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 3800.....78440
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REMINDERS

The items in this list were editorially compiled as an aid to Federal Register users. Inclusion or exclusion from this list has no legal significance.

RULES GOING INTO EFFECT DECEMBER 21, 2000**AGRICULTURE DEPARTMENT**

Donation of excess research equipment; priorities and administrative guidelines; published 11-21-00

ENVIRONMENTAL PROTECTION AGENCY

Pesticides; tolerances in food, animal feeds, and raw agricultural commodities:

Avermectin; published 12-21-00

Avermectin B1; published 12-21-00

Clomazone; published 12-21-00

Thiamethoxam; published 12-21-00

FEDERAL RESERVE SYSTEM

Depository institutions; reserve requirements (Regulation D):

Low reserve tranche annual indexing and 2001 reserve requirement exemption; published 11-21-00

GENERAL ACCOUNTING OFFICE

Personnel Appeals Board; procedural rules:

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LIST OF PUBLIC LAWS

This is a continuing list of public bills from the current session of Congress which have become Federal laws. It may be used in conjunction with "PLUS" (Public Laws Update Service) on 202-523-6641. This list is also available online at <http://www.nara.gov/fedreg>.

The text of laws is not published in the **Federal Register** but may be ordered in "slip law" (individual pamphlet) form from the Superintendent of Documents, U.S. Government Printing Office, Washington, DC 20402 (phone, 202-512-1808). The text will also be made available on the Internet from GPO Access at <http://www.access.gpo.gov/nara/index.html>. Some laws may not yet be available.

H.J. Res. 133/P.L. 106-543

Making further continuing appropriations for the fiscal year 2001, and for other purposes. (Dec. 15, 2000; 114 Stat. 2714)

Last List December 19, 2000

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