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# federal register

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## DEPARTMENT OF AGRICULTURE

### Federal Crop Insurance Corporation

### 7 CFR Part 457

### Pea Crop Insurance Regulations; and Common Crop Insurance Regulations, Dry Pea Crop Insurance Provisions

**AGENCY:** Federal Crop Insurance Corporation, USDA.

**ACTION:** Final rule.

**SUMMARY:** The Federal Crop Insurance Corporation (FCIC) finalizes specific crop provisions for the insurance of dry peas. The provisions will be used in conjunction with the Common Crop Insurance Policy, Basic Provisions, which contain standard terms and conditions common to most crops. The intended effect of this action is to provide policy changes to better meet the needs of the insured, separate dry peas and green peas into separate crop insurance provisions, include the current pea crop insurance regulations with the Common Crop Insurance Policy for ease of use and consistency of terms, and to restrict the effect of the current pea crop insurance regulations to the 1997 and prior crop years.

**EFFECTIVE DATE:** December 16, 1997.

**FOR FURTHER INFORMATION CONTACT:** Arden Routh, Insurance Management Specialist, Research and Development, Product Development Division, Federal Crop Insurance Corporation, United States Department of Agriculture, 9435 Holmes Road, Kansas City, MO 64131, telephone (816) 926–7730.

**SUPPLEMENTARY INFORMATION:**

#### Executive Order No. 12866

The Office of Management and Budget (OMB) has determined this rule to be exempt for the purposes of Executive Order No. 12866, and, therefore, has not been reviewed by OMB.

#### Paperwork Reduction Act of 1995

Pursuant to the Paperwork Reduction Act of 1995 (44 U.S.C. 3507), those collections of information have been approved by the Office of Management and Budget (OMB) under control number 0563–0053.

#### Unfunded Mandates Reform Act of 1995

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. 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. Therefore, this rule is not subject to the requirements of sections 202 and 205 of the UMRA.

#### Executive Order No. 12612

It has been determined under section 6(a) of Executive Order No. 12612, Federalism, that this rule does not have sufficient federalism implications to warrant the preparation of a Federalism Assessment. The provisions contained in this rule will not have a substantial direct effect on States or their political subdivisions, or on the distribution of power and responsibilities among various levels of government.

#### Regulatory Flexibility Act

This regulation will not have a significant economic impact on a substantial number of small entities. New provisions included in this rule will not impact small entities to a greater extent than on large entities. Under the current regulations, a producer is required to complete an application and acreage report. If the crop is damaged or destroyed, the insured is required to give notice of loss and provide the necessary information to complete a claim for indemnity.

The insured must also annually certify to the previous years production if adequate records are available to support the certification. The producer must maintain the production records to support the certified information for at least three years. This regulation does not alter those requirements.

The amount of work required of the insurance companies delivering and servicing these policies will not increase significantly from the amount of work currently required. Therefore, this action is determined to be exempt from the provisions of the Regulatory Flexibility Act (5 U.S.C. 605), and no Regulatory Flexibility Analysis was prepared.

#### Federal Assistance Program

This program is listed in the Catalog of Federal Domestic Assistance under No. 10.450.

#### Executive Order No. 12372

This program is not subject to the provisions of Executive Order No. 12372, which require intergovernmental consultation with State and local officials. See the Notice related to 7 CFR part 3015, subpart V, published at 48 FR 29115, June 24, 1983.

#### Executive Order No. 12998

This final rule has been reviewed in accordance with Executive Order No. 12998 on civil justice reform. The provisions of this rule will not have a retroactive effect prior to the effective date. The provisions of this rule will preempt State and local laws to the extent such State and local laws are inconsistent herewith. The administrative appeal provisions published at 7 CFR part 11 must be exhausted before any action for judicial review may be brought.

#### Environmental Evaluation

This action is not expected to have a significant impact on the quality of the human environment, health, and safety. Therefore, neither an Environmental Assessment nor an Environmental Impact Statement is needed.

#### National Performance Review

This regulatory action is being taken as part of the National Performance Review Initiative to eliminate unnecessary or duplicative regulations and improve those that remain in force.

#### Background

On Thursday, May 15, 1997, FCIC published a proposed rule in the **Federal Register** at 62 FR 26750 to add to the Common Crop Insurance Regulations (7 CFR part 457) a new section, 7 CFR 457.140, Dry Pea Crop Insurance Provisions. The new provisions will be effective for the 1998 and succeeding crop years. These provisions will replace and supersede

the current provisions for insuring dry peas found at 7 CFR part 416 (Pea Crop Insurance Regulations).

Following publication of the proposed rule, the public was afforded 30 days to submit written comments, data, and opinions. A total of 42 comments were received from an insurance service organization and reinsured companies. The comments received, and FCIC's responses, are as follows:

*Comment:* An insurance service organization recommended that FCIC consider combining contract seed peas and contract seed beans into one crop provision.

*Response:* FCIC will consider combining insurance provisions for these two crop types in the future.

*Comment:* An insurance service organization was concerned about late and prevented planting coverage for dry peas if revisions to the Basic Provisions are not finalized in time to be effective for the 1998 crop year.

*Response:* The late and prevented planting provisions in the Basic Provisions, will be applicable to this policy.

*Comment:* An insurance service organization questioned if the plant population is determined per unit or per acre within the unit in the definition of ''adequate stand.''

*Response:* FCIC has clarified the definition of ''adequate stand'' to specify that the plant population is determined on a per acre basis.

*Comment:* An insurance service organization questioned if the term ''contract seed peas'' had replaced ''wrinkled varieties of dry peas'' in the 1986–CHIAA 713 policy.

*Response:* The term ''contract seed peas'' has replaced ''wrinkled varieties of dry peas'' in those crop provisions.

*Comment:* An insurance service organization questioned if item (1) in the definition of ''dry peas'' includes peas grown for seed that do not qualify as contract seed for the purpose of the policy, and if this allows such peas to be included in the same unit as the dry edible types.

*Response:* Peas grown for seed that do not qualify as contract seed peas under the policy terms are treated the same as dry edible peas for purposes of the policy. Therefore, the peas grown for seed could be included in the same unit.

*Comment:* A reinsured company and an insurance service organization indicated that cultural practices may exist that are not recognized (or possibly known) by the Cooperative State Research, Education and Extension Service (CSREES). The comments indicated that the definition of ''Good farming practices'' is too restrictive since it limits acceptable farming practices to those recognized by the CSREES. The comments also suggested changing the last word of the definition from ''county'' to ''area.''

*Response:* CSREES recognizes farming practices that are considered acceptable for producing dry peas. If a producer is following practices currently not recognized as acceptable by CSREES, such recognition can be sought by interested parties. The actuarial documents are on a county basis. No changes have been made.

*Comment:* A reinsured company recommended adding the words ''and quality'' after the word ''quantity'' in the definition of ''Irrigated practice.''

*Response:* Water quality is an important issue. However, since no standards or procedures have been developed to measure water quality for insurance purposes, quality cannot be included in the definition. No change has been made.

*Comment:* An insurance service organization questioned the definition of ''local market price'' which refers to grades and prices for ''dry peas or lentils.'' The definition of ''dry peas'' includes lentils as one dry pea type. It seems unnecessary to specify ''or lentils'' if the language in the definition of ''local market price'' is intended to exclude contract seed peas. The commenter recommended changing the words ''dry peas or lentils'' to ''dry edible peas or lentils,'' but if there is no change, ''lentils'' should be defined separately from the ''dry peas.''

*Response:* Under the definition of ''dry peas,'' peas grown for seed may be insured as dry edible peas. FCIC has amended the definition of local market price by deleting the words ''and lentils.''

*Comment:* A reinsured company questioned whether the reference to ''late planting period'' in the definition of ''practical to replant'' is still appropriate since there is not a section in these provisions for late and prevented planting. The commenter also asked if late planting period will be defined in the late and prevented planting provisions of the proposed Basic Provisions.

*Response:* Since the late planting period is no longer defined in these Crop Provisions, the words ''late planting period'' have been changed to ''25 days.'' The Basic Provisions contain a definition for ''late planting period'' as well as sections with provisions for late and prevented planting.

*Comment:* An insurance service organization stated that a nurse crop is not always intended to be harvested separately, but may be removed with a herbicide or other means. The commenter recommended deleting the phrase ''that is intended to be harvested separately,'' in the definition of ''nurse crop.''

*Response:* The primary reason that a nurse crop is planted is to improve the growing conditions of the crop with which it is grown. The definition has been revised to specify that the nurse crop is not intended to be harvested with the insured crop.

*Comment:* An insurance service organization questioned if the phrase ''marketing window'' in the definition of ''practical to replant'' applies to dry peas.

*Response:* The Federal Agriculture Improvement and Reform Act of 1996 requires FCIC to consider marketing window when determining whether it is practical to replant. No change has been made.

*Comment:* A reinsured company and an insurance service organization are concerned with the definition of ''replanting.'' The reinsured company indicated that the phrase replace the pea seed and then replacing the pea seed is awkward and cumbersome. The insurance service organization recommended clarifying the definition of ''replanting'' by specifying the crop name as follows: ''with the expectation of growing a successful pea crop.''

*Response:* The definition of ''replanting'' clearly describes the steps required to replant the crop. The producer must first perform the cultural practices needed to replant the seed before replanting the seed. FCIC has revised the definition to specify that the crop be replanted with or expectation of producing at least the guarantee. No change has been made.

*Comment:* An insurance service organization stated that the definition of ''salvage value'' appears to be unnecessary as the term is not used elsewhere in these provisions.

*Response:* FCIC has deleted the phrase ''salvage value'' from these Crop Provisions.

*Comment:* An insurance service organization questioned whether the defined dry pea types are the same as the varietal groups of dry peas that qualify for basic units in the current 1986–CHIAA 713 provisions.

*Response:* The dry pea types defined in these Crop Provisions are the same as the varietal groups of dry peas that qualify for basic units in the current 1986–CHIAA 713 provisions, except that Austrian Winter Peas are added under these Crop Provisions. A basic unit may be divided into optional units by type.

*Comment:* An insurance service organization stated that section 2 allows basic units to be divided into optional units by type (varietal group). The proposed change would require an insured to keep separate production records to qualify for optional units by type and the insured would no longer qualify for the basic unit discount. The commenter asked whether there would be any corresponding rate adjustment?

*Response:* Insureds have the option of selecting optional units by type. It is not required. To qualify for optional units, the insured must maintain separate production records by type. The premium rate charged will depend on the unit structure selected by the insured.

*Comment:* An insurance service organization recommended removal of the opening phrase in section 2(e)(4)(iii) of the proposed rule that states ''In addition to, or instead of, establishing optional units by section, section equivalent or FSA Farm Serial Number since section 2(e)(4) of the proposed rule specifies that ''Each optional unit must meet one or more of the following criteria.

*Response:* FCIC has revised this provision in the Basic Provisions.

*Comment:* An insurance service organization questioned if the various types of peas listed in the ''dry pea'' definition have similar growing seasons and harvest dates.

*Response:* With the exception of Austrian Winter Peas, the various types of peas listed in the ''dry pea'' definition have similar growing seasons and harvest dates. Austrian Winter Peas have a different growing season since they are normally planted in the fall. This difference should be no more complex than is the case for winter and spring wheats that also are grown in the Pacific Northwest.

*Comment:* A reinsured company and an insurance service organization questioned why the provisions in section 3 allow different price election percentages by dry pea type. This is not consistent with most other Crop Provisions unless each type is treated as a separate crop. They stated that this inconsistency may lead to confusion on the part of the insureds and agents.

*Response:* Producer groups have requested the flexibility to select a different percentage of the maximum price election for each type. The economic significance of different types of dry peas can vary considerably to a producer. Insurance providers have already programmed computer systems to allow variation in price election percentages for dry beans. There should be no significant costs if the same system is used for dry peas. No changes have been made.

*Comment:* An insurance service organization questioned why peas would be excluded from the seed contract ''during'' the crop year.

*Response:* The processor may modify the terms of the contract to exclude acreage or production because of over-production. If, for any reason, peas are excluded, they may not be covered under these Crop Provisions.

*Comment:* An insurance service organization questioned whether, under section 7(a)(3), interplanting would be limited to certain acres and whether this practice would require a growing season inspection.

*Response:* If the Special Provisions allow for interplanted dry peas, insurance coverage for this practice would apply to all acreage in a county. If a written agreement provides coverage for interplanted dry peas, the agreement itself would specify any limitations. In neither case, would a growing season inspection be required.

*Comment:* An insurance service organization stated that the term ''lease'' in section 7(b) is confusing. It questioned if this section should be moved to the definition of ''seed company.''

*Response:* FCIC agrees that the provisions are confusing and has revised section 7(b) to specify that the insured must retain control of the leased acreage.

*Comment:* An insurance service organization questioned the provisions in section 7(c) that reference an adequate stand as one capable of producing ''at least the production guarantee'' which conflicts with the definition of ''adequate stand.''

*Response:* Section 7(c) has been revised to refer to adequate stand.

*Comment:* An insurance service organization questioned the provisions of section 7(c), which permit insurance for Austrian Winter Peas, if provided for on the Special Provisions, the insured requests insurance on or before the sales closing date, and if the insurance provider agrees in writing that there is an adequate stand in the spring to produce the yield used to establish the production guarantee. The commenter asked if a growing season inspection would be required.

*Response:* A preliminary inspection will be required to determine if there is an adequate stand for insurance coverage. Once it is determined that there is an adequate stand, and insurance has attached, it will be up to the insurance provider to determine if a growing season inspection should be performed.

*Comment:* An insurance service organization recommended clarifying the provisions of section 7(d) to specify that coverage for replanted acreage will be based on the originally planted type, and to move this provision to section 8(b).

*Response:* To be consistent with other Crop Provisions, FCIC has added a provision to specify that the guarantee and premium for acreage replanted to a different insurable type will be based on the replanted type. Since this provision describes the insured crop, it will remain in section 7.

*Comment:* A reinsured company and an insurance service organization recommended deleting the phrase in section 8(b) to the extent that the majority of producers in the area would normally not further care for the crop as this phrase is subjective and meaningless, and causes problems if acreage of the crop is damaged after the final planting date, but other producers in the area are still replanting.

*Response:* FCIC has revised this provision to require replanting when most producers of the crop on acreage with similar characteristics are replanting.

*Comment:* A reinsured company questioned whether the phrase at the beginning of section 9 should be ''In addition to'' instead of ''In accordance with.''

*Response:* FCIC has amended the beginning of section 9 accordingly.

*Comment:* A reinsured company and an insurance service organization questioned if the provisions of section 9(b) applied only to Austrian Winter Peas or to all dry pea types.

*Response:* Section 9(b) has been clarified to indicate that the provisions apply to all dry pea types unless otherwise specified in the Special Provisions.

*Comment:* An insurance service organization indicated that the calculation sequence in section 12(b)(1)–(13) is difficult to follow because it is so wordy. They stated that it seems unnecessary to refer to the previous item by number as if it were on another page.

*Response:* Since some of the calculations involved are not performed in sequential order, it is necessary to refer to specific section numbers. Removal of the references would make the provisions less clear. FCIC will add an example for clarity.

*Comment:* An insurance service organization questioned if the reference to ''each contract seed pea type,'' in section 12(b)(4), meant the same as each type that qualifies for a separate optional unit according to section

2(e)(4)(i), or if the optional unit division is applicable to only the ''types'' listed in the definition or ''dry peas.'' If this is the case, the commenter recommended that another term should be used in this section as well as section 12(c).

*Response:* The provisions in sections 12(b)(4) and 12(c) should have referred to contract seed pea varieties. This section has been clarified accordingly.

*Comment:* A reinsured company questioned if the terms ''value'' and ''actual value'' in section 12(c) should be defined. The commenter also wanted to know how cull value is incorporated into the calculations to determine the value of production to count.

*Response:* FCIC has revised section 12(c) to refer to the ''highest local market price'' instead of ''actual value'' in order to set an objective standard for determining the value of damaged production. The provisions clearly indicate that the value of production to count is based on the new term local market price. The local market price of any ''cull'' production will be included when determining the amount of any indemnity.

*Comment:* An insurance service organization questioned how the ''actual value'' is determined for mature production that does not meet the minimum quality requirements contained in the seed pea contract. The commenter asked if the value of production that does not meet the minimum quality requirements contained in the seed pea contract would be considered to be the ''salvage value.''

*Response:* The ''local market price'' for contract seed pea production not meeting the minimum quality requirements contained in the seed pea contract will be the highest price obtainable for the production regardless of its ultimate disposition. If a salvage use proves to provide the highest value obtainable, then that ''salvage value'' will be used to determine the value of the production to count.

*Comment:* An insurance service organization received one comment stating that the policy should not allow the insured to defer settlement and wait for a later, generally lower appraisal.

*Response:* A later appraisal will only be necessary if the insurance provider and the insured do not agree on the appraisal or if the insurance provider believes that the crop needs to be carried farther to make a more accurate appraisal. If the insured does not provide sufficient care for the remaining crop, the insurance provider may use the original appraisal or assess an appraisal for an uninsured cause of loss. Therefore, no change has been made.

*Comment:* A reinsured company questioned if the term ''condition'' should be defined as this term is used in section 12(e)(3)(i)(C).

*Response:* FCIC has defined ''conditioning'' in section 1 of these Crop Provisions.

*Comment:* The crop insurance industry recommended that the requirement for a written agreement to be renewed each year be removed. Terms of the agreement should be stated in the agreement to fit the particular situation for the policy, or if no substantive changes occur from one year to the next, allow the written agreement to be continuous.

*Response:* Written agreements are intended to change policy terms or permit insurance in unusual situations where such changes will not increase risk. If such practices continue year to year, they should be incorporated into the policy or Special Provisions. It is important to minimize exceptions to assure that the insured is well aware of the specific terms of the policy. The written agreement provisions are deleted and moved to the Basic Provisions.

In addition to the changes described above, FCIC has made the following editorial changes to the Dry Pea Crop Insurance Provisions:

1. Amended the paragraph preceding section 1 (Definitions) to include the Catastrophic Risk Protection Endorsement.

2. Section 1—Amended the definition of ''combining,'' ''contract seed peas,'' ''local market price,'' ''practical to replant,'' and ''seed company contract'' for clarification. Deleted the definition of ''contract price'' since this term is not used in these provisions. Deleted the definition of ''days,'' ''FSA,'' ''final planting date,'' ''good farming practices,'' ''interplanted,'' ''irrigated practice,'' ''production guarantee (per acre),'' ''replanting,'' ''USDA,'' ''timely planting,'' and ''written agreement'' because these definitions were moved to the Basic Provisions. Revised the definition of ''planted acreage'' and ''practical to replant'' to delete those provisions moved to the Basic Provisions.

3. Section 2—Deleted those provisions moved to the Basic Provisions.

4. Section 3—Removed the provision in section 3 regarding administrative fees because it is duplicative of provisions contained in 7 CFR part 400, subpart T.

5. Section 6—Deleted the requirements of ''spring-planted'' and ''grown under contract with a seed company'' since they are included in the definition of ''contract seed peas.''

6. Section 7(c)—Clarified that Austrian Winter Peas will be insured if authorized by the Special Provisions, if the insured requests insurance in writing for such dry peas, and if the insurance provider agrees in writing to provide coverage.

7. Section 12(d)(1)(iv)(B)—Clarified language to indicate that if the producer continues to care for the crop, the amount of production to count will be the harvested production or the reappraised amount if the crop is not harvested.

In general, FCIC has clarified some language to make these provisions easier to read.

Good cause is shown to make this rule effective upon publication in the **Federal Register**. This rule improves the dry pea insurance coverage and brings it under the Common Crop Insurance Policy Basic Provisions for consistency among policies. The earliest contract change date that can be met for the 1998 crop year is December 31, 1997. It is therefore imperative that these provisions be made final before that date so that the reinsured companies and insureds may have sufficient time to implement these changes. Therefore, public interest requires the agency to act immediately to make these provisions available for the 1998 crop year.

### List of Subjects in 7 CFR Part 457

Crop insurance, Dry pea, Pea crop insurance regulations.

### Final Rule

Accordingly, for the reasons set forth in the preamble, the Federal Crop Insurance Corporation, hereby amends 7 CFR part 457, as follows:

## PART 457—COMMON CROP INSURANCE REGULATIONS; REGULATIONS FOR THE 1994 AND SUBSEQUENT CONTRACT YEARS

1. The authority citation for 7 CFR part 457 continues to read as follows:

**Authority:** 7 U.S.C. 1506(l), 1506(p).

2. Section 457.140 is added to read as follows:

### § 457.140 Dry pea crop insurance provisions.

The Dry Pea Crop Insurance Provisions for the 1998 and succeeding crop years are as follows:

FCIC policies:

DEPARTMENT OF AGRICULTURE

Federal Crop Insurance Corporation

Reinsured policies:

(Appropriate title for insurance provider)

Both FCIC and reinsured policies:

Dry Pea Crop Provisions

If a conflict exists among the policy provisions, the order of priority is as follows: (1) The Catastrophic Risk Protection Endorsement, if applicable; (2) the Special Provisions; (3) these Crop Provisions; and (4) the Basic Provisions with (1) controlling (2), etc.

1. Definitions.

*Adequate stand.* A population of live plants per acre that will produce at least the yield used to establish your production guarantee.

*Base price.* The price per pound stipulated in the processor contract without regard to discounts or incentives that may apply, and that will be paid to the producer for at least 50 percent of the total production under contract with the seed company.

*Combining.* A mechanical process that separates the peas from the pods and other vegetative matter and place the peas into a temporary storage receptacle.

*Conditioning.* A process that improves the quality of production by screening or any other operation commonly used in the dry pea industry to remove dry peas that are deficient in quality.

*Contract seed peas.* Dry peas produced for seed to be planted at a future date and that:

(a) Are grown on acreage enrolled in the seed certification program administered by the state in which the peas are produced;

(b) Are grown on acreage planted in the spring; and

(c) Are under a seed company contract.

*Dry peas.* Peas of the following types:

(a) All spring-planted smooth green and yellow varieties of commercial dry edible peas, and peas grown to produce seed to be planted at a future date that do not meet the requirements contained in the seed company contract;

(b) All fall-planted varieties of Austrian Winter Peas only if provided for in the Special Provisions;

(c) All spring-planted varieties of lentils; and

(d) All varieties of contract seed peas.

*Harvest.* Combining of dry peas.

*Local market price.* The cash price per pound for the U.S. No. 2 grade of dry peas as determined by us. Such price will be the prevailing dollar amount these buyers are willing to pay for dry peas containing the maximum limits of quality deficiencies allowable for the U.S. No. 2 grade. Factors not associated with grading under the United States Standards for Whole Dry Peas, Split Peas and Lentils will not be considered.

*Nurse crop (companion crop).* A crop planted into the same acreage as another crop, that is intended to improve the growing conditions for the crop with which it is grown and that is not intended to be harvested with the insured crop.

*Planted acreage.* In addition to the definition contained in the Basic Provisions, dry peas must initially be planted in rows to be considered planted. Acreage planted in any other manner will not be insurable unless otherwise provided by the Special Provisions or by written agreement.

*Practical to replant.* In addition to the definition contained in the Basic Provisions, it will not be considered practical to replant dry peas, except for seed peas, more than 25 days after the final planting date unless replanting is generally occurring in the area. For seed peas, it will not be considered practical to replant unless production from the replanted acreage can be delivered under the terms of the seed pea processor contract or the seed company agrees in writing to accept such production.

*Price election.* In addition to the provisions of the definition contained in the Basic Provisions, the price election for contract seed peas will be a percentage (not to exceed 100 percent) of the base price that you elect.

*Seed company.* Any business enterprise regularly engaged in the processing of contract seed peas, that possesses all licenses and permits for marketing contract seed peas required by the state in which it operates, and that owns, or has contracted, sufficient drying, screening, and bagging or packaging equipment to accept and process the contract seed peas within a reasonable amount of time after harvest.

*Seed company contract.* A written agreement between the producer and the seed company, executed by the acreage reporting date, containing at a minimum:

(a) The producer's promise to plant and grow one or more specific varieties of contract seed peas, and deliver the production from those varieties to the seed company;

(b) The seed company's promise to purchase all the production stated in the contract; and

(c) A fixed price, or a method to determine such price based on published information compiled by a third party, that will be paid to the producer for at least 50 percent of the production stated in the contract.

2. Unit Division.

(a) In addition to, or instead of, establishing optional units by section, section equivalent, or FSA farm serial number and by irrigated and non-irrigated acreage as provided in the unit division provisions contained in the Basic Provisions, a separate optional unit may be established for each pea type listed in section 1 of these Crop Provisions.

(b) Contract seed peas may qualify for optional units only if the seed company contract specifies the number of acres under contract. Contract seed peas produced under a seed company contract that specifies only an amount of production or a combination of acreage and production, are not eligible for optional units.

3. Insurance Guarantees, Coverage Levels, and Prices for Determining Indemnities.

In addition to the requirements of section 3 of the Basic Provisions, you may select only one price election for all the dry peas, including contract seed peas, in the county insured under this policy unless the Special Provisions provide different price elections by type, in which case you may select one price election for each dry pea type so designated in the Special Provisions. The price elections you choose for each type are not required to have the same percentage relationship to the maximum price offered by us for each type. For example, if you choose 100 percent of the maximum price election for one type, you may choose 80 percent of the maximum price election for another type. However, if you elect the Catastrophic Risk Protection level of insurance for any dry pea type, the same level of coverage will be applicable to all insured acreage in the county.

4. Contract Changes.

In accordance with section 4 of the Basic Provisions, the contract change date is November 30 preceding the cancellation date.

5. Cancellation and Termination Dates.

In accordance with section 2 of the Basic Provisions, the cancellation and termination dates are March 15.

6. Report of Acreage.

In addition to the provisions of section 6 of the Basic Provisions, you must submit a copy of the seed company contract to us on or before the acreage reporting date if you are insuring contract seed peas.

7. Insured Crop.

(a) In accordance with section 8 of the Basic Provisions, the crop insured will be all the dry pea types in the county (including Austrian Winter Peas if you request insurance for such peas in accordance with section 7(c)) for which a premium rate is provided by the actuarial documents:

(1) In which you have a share;

(2) That are planted for harvest as dry peas and which, if grown under a seed company contract, are not excluded from such contract during the crop year;

(3) That are grown in accordance with the requirements of the seed company contract, if applicable;

(4) That are not (unless allowed by the Special Provisions or by written agreement):

(i) Interplanted with another crop;

(ii) Planted into an established grass or legume; or

(iii) Planted as a nurse crop.

(b) You will be considered to have a share in the insured crop if, under the processor contract, you retain control of the acreage on which the contract seed peas are grown, you are at risk of loss, and the processor contract is in effect.

(c) Austrian Winter Peas are only insurable if you request insurance in writing for such dry peas, and we agree in writing to provide coverage. Your request to insure Austrian Winter Peas must be submitted to us not later than the sales closing date. We will not agree to insure Austrian Winter Peas unless an adequate stand exists in the spring.

(d) Any acreage of dry peas that is destroyed and replanted to a different insurable type of dry peas will be considered insured acreage. The guarantee and premium for acreage replanted to a different insurable type will be based on the replanted type and will be calculated in accordance with sections 3 and 7 of the Basic Provisions and section 3 of these Crop Provisions.

8. Insurable Acreage.

In addition to the provisions of section 9 of the Basic Provisions:

(a) We will not insure any acreage that does not meet the rotation requirements, if applicable, contained in the Special Provisions; or

(b) Any acreage of the insured crop damaged before the final planting date, to the extent that most producers of the crop or acreage with similar characteristics in the area would normally not further care for the crop, must be replanted unless we agree that it is not practical to replant. We will not require you to replant if it is not practical to replant the type of dry peas originally planted.

9. Insurance Period.

In addition to the provisions of section 11 of the Basic Provisions:

(a) Coverage for Austrian Winter Peas, will begin on the earlier of March 16 or the date we agree to accept the acreage for insurance, but not before March 1; and

(b) The calendar date for the end of the insurance period for all insurable types of dry peas in the county is September 30 of the crop year in which the crop normally is harvested unless otherwise specified in the Special Provisions.

10. Causes of Loss.

In accordance with the provisions of section 12 of the Basic Provisions, insurance is provided only against the following causes of loss that occur during the insurance period:

(a) Adverse weather conditions;

(b) Fire;

(c) Insects, but not damage due to insufficient or improper application of pest control measures;

(d) Plant disease, but not damage due to insufficient or improper application of disease control measures;

(e) Wildlife;

(f) Earthquake;

(g) Volcanic eruption; or

(h) Failure of the irrigation water supply, if due to a cause of loss contained in section 10(a) through (g) that occurs during the insurance period.

11. Duties In The Event of Damage or Loss.

In accordance with the requirements of section 14 of the Basic Provisions, the representative samples of the unharvested crop must be at least 10 feet wide and extend the entire length of each field in the unit. If you intend to destroy the crop prior to harvest, the samples must not be destroyed until after our inspection.

12. Settlement of Claim.

(a) We will determine your loss on a unit basis. In the event you are unable to provide separate acceptable production records:

(1) For any optional units, we will combine all optional units for which such production records were not provided; or

(2) For any basic units, we will allocate any commingled production to such units in proportion to our liability on the harvested acreage for the units.

(b) In the event of loss or damage to your pea crop covered by this policy, we will settle your claim by:

(1) Multiplying the insured acreage of each dry pea type, if applicable, excluding contract seed peas, by its respective production guarantee;

(2) Multiplying each result of section 12(b)(1) by the respective price election;

(3) Totaling the results of section 12(b)(2);

(4) Multiplying the insured acreage of each contract seed pea variety by its respective production guarantee;

(5) Multiplying each result of section 12(b)(4) by the applicable base price;

(6) Multiplying each result of section 12(b)(5) by your selected price election percentage;

(7) Totaling the results of section 12(b)(6);

(8) Totaling the results of section 12(b)(3) and section 12(b)(7);

(9) Multiplying the total production to be counted of each dry pea type, excluding contract seed peas, if applicable (see section 12(d)), by the respective price elections;

(10) Totaling the value of all contract seed pea production (see section 12(c));

(11) Totaling the results of section 12(b)(9) and section 12(b)(10);

(12) Subtracting the result of section 12(b)(11) from the result in section 12(b)(8); and

(13) Multiplying the result of section 12(b)12 by your share.

For example:

You have a 100 percent share in 100 acres of spring-planted smooth green dry edible peas in the unit, with a guarantee of 4,000 pounds per acre and a price election of $0.09 per pound. You are only able to harvest 200,000 pounds. Your indemnity would be calculated as follows:

(1) 100 acres × 4,000 pounds = 400,000 pounds guarantee;

(2) 400,000 pounds × $0.09 price election = $36,000.00 value of guarantee;

(9) 200,000 pounds × $0.09 price election = $18,000.00 value of production to count; $36,000.00 value of guarantee − $18,000.00 value of production to count = $18,000.00 loss; and

(13) $18,000.00 × 100 percent = $18,000.00 indemnity payment.

You also have a 100 percent share in 100 acres of contract seed peas in the same unit, with a guarantee of 5,000 pounds per acre and a base price of $0.40 per pound. Your selected price election percentage is 75 percent. You are only able to harvest 450,000 pounds. Your total indemnity for both spring-planted smooth green dry edible peas and contract seed peas would be calculated as follows:

(1) 100 acres × 4,000 pounds = 400,000 pounds guarantee for the spring-planted smooth green dry edible pea type, and

(4) 100 acres × 5,000 pounds = 500,000 pounds guarantee for the contract seed pea type;

(2) 400,000 pounds guarantee × $0.09 price election = $36,000.00 value of guarantee for the spring-planted smooth green dry edible pea type, and

(5) 500,000 pounds guarantee × $0.40 base price = $200,000.00 gross value of guarantee for the contract seed pea type;

(6) $200,000 × .75 price election percentage = $150,000 net value of guarantee for the contract seed pea type;

(8) $36,000.00+$150,000.00 = $186,000.00 total value of guarantee;

(9) 200,000 pounds × $0.09 price election = $18,000.00 value of production to count for the spring-planted smooth green dry edible pea type, and

(10) 450,000 pounds × $0.30 = $135,000.00 value of production to count for the contract seed pea type;

(11) $18,000.00+$135,000.00 = $153,000.00 total value of production to count;

(12) $186,000.00 − $153,000.00 = $33,000.00 loss; and

(13) $33,000.00 loss × 100 percent = $33,000.00 indemnity payment.

(c) The value of contract seed pea production to count for each variety in the unit will be determined as follows:

(1) For production meeting the minimum quality requirements contained in the seed company contract, and for production that does not meet such requirements due to uninsured causes:

(i) Multiplying the local market price or base price per pound, whichever is greater, by the price election percentage you selected; and

(ii) Multiplying the result by the number of pounds of such production.

(2) For mature production not meeting the minimum quality requirements contained in the seed pea processor contract due to insurable causes, and immature production that is appraised:

(i) Multiplying the highest local market price available for such dry peas by the price election percentage you selected; and

(ii) Multiplying the result by the number of pounds of such production.

(d) The total pea production to count (in pounds) from all insurable acreage on the unit will include:

(1) All appraised production as follows:

(i) Not less than the production guarantee per acre for acreage:

(A) That is abandoned;

(B) That is put to another use without our consent;

(C) That is damaged solely by uninsured causes; or

(D) For which you fail to provide production records that are acceptable to us;

(ii) Production lost due to uninsured causes;

(iii) Unharvested production (mature unharvested production of dry peas, excluding Austrian Winter Peas, may be adjusted for quality deficiencies in accordance with section 12 (c) or (e), if applicable); and

(iv) Potential production on insured acreage that you intend to put to another use or abandon, if you and we agree on the appraised amount of production. Upon such agreement, the insurance period for that acreage will end when you put the acreage to another use or abandon the crop. If agreement on the appraised amount of production is not reached:

(A) If you do not elect to continue to care for the crop, we may give you consent to put the acreage to another use if you agree to leave intact, and provide sufficient care for, representative samples of the crop in locations acceptable to us (The amount of production to count for such acreage will be based on the harvested production or appraisals from the samples at the time harvest should have occurred. If you do not leave the required samples intact, or fail to provide sufficient care for the samples, our appraisal made prior to giving you consent to put the acreage to another use will be used to determine the amount of production to count); or

(B) If you elect to continue to care for the crop, the amount of production to count for

the acreage will be the harvested production, or our reappraisal if the crop is not harvested; and

(2) All harvested production from the insurable acreage.

(e) Mature production of smooth green and yellow peas, lentils, and seed peas that do not qualify as contract seed peas under the policy terms, and that are not deliverable under the contract or are sold under the contract for less than the contract price, may be adjusted for quality deficiencies. No adjustment for quality deficiencies will be allowed for Austrian Winter Peas.

(1) Production will be eligible for quality adjustment if:

(i) Deficiencies in quality, in accordance with the United States Standards for Whole Dry Peas, Split Peas, and Lentils, result in production grading U.S. No. 2 or worse because of defects, color, skinned production (lentils only), odor, material weathering, or distinctly low quality; or

(ii) Substances or conditions are present that are identified by the Food and Drug Administration or other public health organizations of the United States as being injurious to human or animal health.

(2) Quality will be a factor in determining your loss only if:

(i) The deficiencies, substances, or conditions resulted from a cause of loss against which insurance is provided under these Crop Provisions and which occurs within the insurance period;

(ii) The deficiencies, substances, or conditions result in a net price for the damaged production that is less than the local market price;

(iii) All determinations of these deficiencies, substances, or conditions are made using samples of the production obtained by us or by a disinterested third party approved by us; and

(iv) The samples are analyzed by a grader licensed to grade dry peas under the authority of the United States Agricultural Marketing Act or the United States Warehouse Act with regard to deficiencies in quality, or by a laboratory approved by us with regard to substances or conditions injurious to human or animal health. Test weight for quality adjustment purposes may be determined by our loss adjuster.

(3) Dry Pea production that is eligible for quality adjustment, as specified in sections 12(e) (1) and (2), will be reduced as follows:

(i) The highest local market price for the qualifying damaged production will be determined on the earlier of the date such damaged production is sold or the date of final inspection for the unit. The highest local market price for the qualifying damaged production will be determined in the local area to the extent feasible. We may obtain prices from any buyer of our choice. If we obtain prices from one or more buyers located outside your local market area, we will reduce such prices by the additional costs required to deliver the dry peas to those buyers. Discounts used to establish the net value of the damaged production will be limited to those that are usual, customary, and reasonable.

The value will not be reduced for:

(A) Moisture content;

(B) Damage due to uninsured causes; or

(C) Drying, handling, processing, or any other costs associated with normal harvesting, handling, and marketing of the dry peas; except, if the value of the damaged production can be increased by conditioning, we may reduce the value of the production after it has been conditioned by the cost of conditioning but not lower than the value of the production before conditioning;

(ii) The value per pound of the damaged or conditioned production will be divided by the local market price to determine the quality adjustment factor;

(iii) The number of pounds of the damaged or conditioned production will then be multiplied by the quality adjustment factor to determine the production count to be included in section 12(d); and

(iv) Any production harvested from plants growing in the insured crop may be counted as production of the insured crop on a weight basis.

13. Prevented Planting.

Your prevented planting coverage will be 60 percent of your production guarantee for timely planted acreage. If you have limited or additional levels of coverage as specified in 7 CFR part 400, subpart T, and pay an additional premium, you may increase your prevented planting coverage to a level specified in the actuarial documents.

Signed in Washington, D.C., on December 9, 1997.

**Kenneth D. Ackerman,**

*Manager, Federal Crop Insurance Corporation.*

[FR Doc. 97–32619 Filed 12–15–97; 8:45 am]

BILLING CODE 3410–08–P

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## DEPARTMENT OF AGRICULTURE

## Animal and Plant Health Inspection Service

## 9 CFR Part 94

**[Docket No. 97–034–3]**

## Change in Disease Status of The Netherlands Because of BSE

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

**ACTION:** Affirmation of interim rule as final rule.

**SUMMARY:** We are adopting as a final rule, without change, an interim rule that added The Netherlands to the list of countries where bovine spongiform encephalopathy (BSE) exists. We took this action because BSE was detected in a cow in The Netherlands. The effect of the interim rule was to prohibit or restrict the importation of live ruminants and certain fresh, chilled, and frozen meat, and certain other animal products and animal byproducts from ruminants which have been in The Netherlands. The interim rule was necessary to reduce the risk that BSE could be introduced into the United States.

**EFFECTIVE DATE:** The interim rule was effective on March 21, 1997.

**FOR FURTHER INFORMATION CONTACT:** Dr. John Cougill, Staff Veterinarian, Animal Products Program, National Center for Import and Export, VS, APHIS, 4700 River Road Unit 40, Riverdale, MD 20737–1231, (301) 734–3399; or e-mail: jcougill@aphis.usda.gov.

**SUPPLEMENTARY INFORMATION:**

### Background

In an interim rule effective April 10, 1997, and published in the **Federal Register** on April 15, 1997 (62 FR 18263–18264, Docket No. 97–034–1), we amended our regulations by adding The Netherlands to the list of countries where BSE exists. We took this action because BSE was detected in a cow born in The Netherlands. We also published another interim rule in the **Federal Register** on May 7, 1997 (62 FR 24802, Docket No. 97–034–2), that changed the effective date of the April 1997 interim rule from April 10, 1997, to March 21, 1997. The change in effective date was necessary to ensure that the prohibitions and restrictions established by the April 1997 interim rule applied to animal products and byproducts that were shipped to the United States from The Netherlands between March 21, 1997, when BSE was detected in The Netherlands, and April 10, 1997, when the first interim rule was signed.

Comments on the interim rule were required to be received on or before June 16, 1997. We received two comments by that date. They were from a company that imports cattle semen and an importer of meat and meat byproducts. They are discussed below.

The commenters did not oppose adding The Netherlands to the list of countries where BSE exists. However, one comment expressed concerns about Animal and Plant Health Inspection Service regulations that restrict the importation of veal from countries where BSE is known to exist. The other comment concerned the trade protocols of the United States and other countries for importing cattle semen from countries where BSE exists. Both comments are outside the scope of the interim rule. However, we continually review and update our regulations to make them consistent with current scientific data. We will consider these comments as we review our regulations. If we decide to make any changes to our regulations in response to these comments, we will publish a proposed rule in the **Federal Register**.

Therefore, based on the rationale set forth in the April 1997 interim rule, we are affirming the provisions of the interim rule without change.

This action also affirms the information contained in the interim rule concerning Executive Orders 12866 and 12988 and the Paperwork Reduction Act.

Further, for this action, the Office of Management and Budget has waived the review process required by Executive Order 12866.

**Regulatory Flexibility Act**

This rule affirms an interim rule that amended our regulations by adding The Netherlands to the list of countries where BSE exists. We took this action because BSE was detected in a cow in that country. The effect of the interim rule was to prohibit or restrict the importation of certain fresh, chilled, and frozen meat, and certain other animal products and animal byproducts from ruminants which have been in The Netherlands. The interim rule was necessary to reduce the risk that BSE could be introduced into the United States.

BSE is a slowly progressing fatal degenerative disease that affects the central nervous system of cattle. The disease was first diagnosed in 1986 in Great Britain, where it is sometimes called ''mad cow disease.'' Infected animals may display changes in temperament, abnormal posture, incoordination and difficulty in rising, decreased milk production, and loss of body condition despite continued appetite. The causative agent of BSE is not completely characterized, and there is no treatment for the disease. At the current time, the disease is not known to exist in the United States. There is no vaccine to prevent BSE nor is there a test to detect the disease in live animals. Given those factors, the import restrictions imposed by the interim rule are the most effective means available for ensuring that BSE does not enter the United States from The Netherlands.

Preventing the introduction of BSE into the United States is critical. In addition to the potential threat to public health, BSE also has the potential to cause severe economic hardship for the U.S. livestock industry. Great Britain's experience with the disease provides an insight into how damaging BSE can be to livestock. Between November 1986 (when BSE was first diagnosed in Great Britain) and May 1996, an estimated 160,540 head of cattle in approximately 33,455 herds were diagnosed with BSE in Great Britain. The epidemic peaked there in January 1993, with almost 1,000 new cases per week. All of the animals in Great Britain showing signs of BSE, most of which were dairy cows between 3 and 5 years of age, were destroyed.

If BSE were introduced into the United States, livestock losses would likely be much greater than in Great Britain, because the United States raises more cattle. However, assuming the same number of cattle losses in the United States as in Great Britain (160,540), the introduction of BSE into the United States would cost U.S. livestock producers $177 million, based on the current price of $1,100 per head for dairy cows. The $177 million figure does not include higher production costs that would likely be incurred by U.S. producers, due to the presence of the disease.

U.S. export and consumer markets would also be affected. The United States currently restricts the importation of live ruminants and ruminant products from all countries where BSE is known to exist. Presumably, if BSE were introduced into the United States, other countries would adopt similar restrictions on the exportation of live ruminants and ruminant products from the United States. Such restrictions by other countries would be devastating economically. In 1993, for example, the dollar value of U.S. exports of both bovine animals and bovine animal meat totaled $2.1 billion. Those export sales could be lost in their entirety. Consumers would incur higher costs due to higher prices for ruminant products and increased prices for competitive products, such as poultry.

We expect that restricting the importation of live ruminants and ruminant products from The Netherlands will have little or no impact on U.S. consumers. This is because The Netherlands does not export live ruminants to the United States. Also, U.S. imports of ruminant products from The Netherlands are minimal when compared against total U.S. imports or overall U.S. supply (imported and domestically produced) of those commodities. In 1996, the volume of ruminant products imported from The Netherlands, categorized into seven broad product groups, was as follows: 149,906 kilograms (kg) of fresh or frozen beef with bone; 2,060 kg of prepared or preserved beef; 307,259 kg of variety meats; 458 cattle embryos; 3,016,847 kg of miscellaneous animal products; and 1,587,244 kg of animal feed. These seven product groups represent 40 subcategories of products imported from The Netherlands. For most subcategories, The Netherlands' share of the total U.S. imports of that product was 1 percent or less. The Netherlands' share exceeded 10 percent of the total U.S. imports in only 5 subcategories. However, even for those 5 product subcategories, The Netherlands' share of overall U.S. supply was not significant. Because The Netherlands is not a significant supply source for the U.S. market, restrictions on imports from The Netherlands should not have a significant effect on consumer prices in the United States.

The Regulatory Flexibility Act requires that agencies consider the economic impact of rule changes on small entities. We expect the interim rule will have little or no impact on small entities in the United States because imports of ruminants and ruminant products from The Netherlands affected by this interim rule have been minimal in the past. Small brokers, agents, and others in the United States who are directly involved in the importation and sale of ruminant products from The Netherlands should be able to obtain substitutes from alternative sources. We were unable to determine the number of small entities engaged in these activities.

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

**List of Subjects in 9 CFR Part 94**

Animal diseases, Imports, Livestock, Meat and meat products, Milk, Poultry and poultry products, Reporting and recordkeeping requirements.

## PART 94—RINDERPEST, FOOT-AND-MOUTH DISEASE, FOWL PEST (FOWL PLAGUE), EXOTIC NEWCASTLE DISEASE, AFRICAN SWINE FEVER, HOG CHOLERA, AND BOVINE SPONGIFORM ENCEPHALOPATHY: PROHIBITED AND RESTRICTED IMPORTATIONS

Accordingly, we are adopting as a final rule, without change, the interim rule that amended 9 CFR part 94 and that was published at 62 FR 18263–18264 on April 15, 1997.

**Authority:** 7 U.S.C. 147a, 150ee, 161, 162, and 450; 19 U.S.C. 1306, 21 U.S.C. 111, 114a, 134a, 134b, 134c, 134f, 136, and 136a; 31 U.S.C. 9701; 42 U.S.C. 4331 and 4332; 7 CFR 2.22, 2.80, and 371.2(d).

Done in Washington, DC, this 10th day of December 1997.

**Craig A. Reed,**

*Acting Administrator, Animal and Plant Health Inspection Service.*

[FR Doc. 97–32779 Filed 12–15–97; 8:45 am]

BILLING CODE 3410–34–P

**DEPARTMENT OF TRANSPORTATION**

**Federal Aviation Administration**

**14 CFR Part 39**

**[Docket No. 97–SW–44–AD; Amendment 39–10245; AD 97–26–02]**

**RIN 2120–AA64**

## Airworthiness Directives; Eurocopter Deutschland GmbH (ECD) Model BO–105A, BO–105C, BO–105S, BO–105LS A–1, and BO–105LS A–3 Helicopters and Eurocopter Canada Ltd. Model BO–105LS A–3 Helicopters

**AGENCY:** Federal Aviation Administration, DOT.

**ACTION:** Final rule; request for comments.

**SUMMARY:** This amendment adopts a new airworthiness directive (AD) that is applicable to Eurocopter Deutschland GmbH (ECD) (Eurocopter Deutschland) Model BO–105A, BO–105C, BO–105S, BO–105LS A–1, and BO–105LS A–3 helicopters; and Eurocopter Canada Ltd. Model BO–105LS A–3 helicopters. This action requires visual inspections for cracks in the ribbed area of the main rotor mast flange (flange). This amendment is prompted by a report of an operator discovering a crack in the flange after experiencing in-flight vibrations. The actions specified in this AD are intended to detect cracks in the flange, which, if not detected, could result in failure of the flange and subsequent loss of control of the helicopter.

**DATES:** Effective December 31, 1997.

The incorporation by reference of certain publications listed in the regulations is approved by the Director of the Federal Register as of December 31, 1997.

Comments for inclusion in the Rules Docket must be received on or before February 17, 1998.

**ADDRESSES:** Submit comments in triplicate to the Federal Aviation Administration (FAA), Office of Regional Counsel, Southwest Region, Attention: Rules Docket No. 97–SW–44–AD, 2601 Meacham Blvd., Room 663, Fort Worth, Texas 76137.

The service information referenced in this AD may be obtained from American Eurocopter Corporation, 2701 Forum Drive, Grand Prairie, Texas 75053–4005, telephone (972) 641–3460, fax (972) 641–3527. This information may be examined at the FAA, Office of Regional Counsel, Southwest Region, 2601 Meacham Blvd., Room 663, Fort Worth, Texas; or at the Office of the Federal Register, 800 North Capitol Street, NW., suite 700, Washington, DC.

**FOR FURTHER INFORMATION CONTACT:** Mr. Richard Monschke, Aerospace Engineer, FAA, Rotorcraft Directorate, Rotorcraft Standards Staff, 2601 Meacham Blvd., Fort Worth, Texas 76137, telephone (817) 222–5116, fax (817) 222–5961.

**SUPPLEMENTARY INFORMATION:** The Luftfahrt-Bundesamt (LBA), which is the airworthiness authority for the Federal Republic of Germany recently notified the FAA that an unsafe condition may exist on Eurocopter Deutschland Model BO–105A, BO–105C, BO–105S, BO–105LS A–1, and BO–105LS A–3 helicopters. The Federal Republic of Germany advises that a main rotor mast was found to have cracks of critical magnitude in the area of the flange. Additionally, Transport Canada, the airworthiness authority for Canada, recently notified the FAA that the same unsafe condition may exist on Eurocopter Canada Ltd. Model B0–105LS A–3 helicopters. The cause of the cracks is under investigation. Until the cause of the crack has been determined, the flange must be subjected to an immediate inspection and repetitive visual crack inspection at intervals not to exceed 100 hours time-in-service until further notice.

Eurocopter Deutschland has issued Eurocopter Deutschland GmbH Alert Service Bulletin No. ASB–BO 105–10–110, dated August 27, 1997, which specifies visually inspecting the area of the holes on the underside of the flange for cracks, especially in the ribbed area between the holes. The LBA classified this service bulletin as mandatory and issued AD 97–275, dated September 25, 1997, in order to assure the continued airworthiness of these helicopters in the Federal Republic of Germany. Eurocopter Canada Ltd. has issued Eurocopter Canada Ltd. Alert Service Bulletin No. ASB–BO 105 LS–10–9, dated September 11, 1997, for similar inspection. Transport Canada has classified this service bulletin mandatory and issued AD CF–97–18, dated September 30, 1997, in order to assure the continued airworthiness of these helicopters in Canada.

This helicopter model is manufactured in the Federal Republic of Germany and Canada and is type certificated for operation in the United States under the provisions of section 21.29 of the Federal Aviation Regulations (14 CFR 21.29) and the applicable bilateral airworthiness agreement. Pursuant to this bilateral airworthiness agreement, the LBA and Transport Canada have kept the FAA informed of the situation described above. The FAA has examined the findings of the LBA and Transport Canada, 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.

Since an unsafe condition has been identified that is likely to exist or develop on other Eurocopter Deutschland Model BO–105A, BO–105C, BO–105S, BO–105LS A–1, and BO–105LS A–3 helicopters and Eurocopter Canada Ltd. BO–105LS A–3 helicopters of the same type designs registered in the United States, this AD is being issued to detect cracks in the flange, which, if not detected, could result in failure of the flange and subsequent loss of control of the helicopter. The flange is a part of the main rotor mast assembly and therefore a critical component of the flight control system. Due to the criticality of the flange to the continued safe flight of the affected helicopters, and the required inspection before further flight, this rule must be issued immediately to correct an unsafe condition in the affected helicopters. This AD requires, before further flight, a visual inspection of the ribbed area of the flange for cracks using a 5-power or higher magnifying glass, and thereafter, repeated visual inspections at intervals not to exceed 100 hours time-in-service. The actions are required to be accomplished in accordance with the service bulletins described previously.

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

### Comments Invited

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

additional rulemaking action would be needed.

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

Commenters wishing the FAA to acknowledge receipt of their comments submitted in response to this rule must submit a self-addressed, stamped postcard on which the following statement is made: ''Comments to Docket No. 97–SW–44–AD.'' The postcard will be date stamped and returned to the commenter.

The regulations adopted herein will not have substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government. Therefore, in accordance with Executive Order 12612, it is determined that this final rule does not have sufficient federalism implications to warrant the preparation of a Federalism Assessment.

The FAA has determined that this regulation is an emergency regulation that must be issued immediately to correct an unsafe condition in aircraft, and that it is not a ''significant regulatory action'' under Executive Order 12866. It has been determined further that this action involves an emergency regulation under DOT Regulatory Policies and Procedures (44 FR 11034, February 26, 1979). If it is determined that this emergency regulation otherwise would be significant under DOT Regulatory Policies and Procedures, a final regulatory evaluation will be prepared and placed in the Rules Docket. A copy of it, if filed, may be obtained from the Rules Docket at the location provided under the caption **ADDRESSES**.

### List of Subjects in 14 CFR Part 39

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

### Adoption of the Amendment

Accordingly, pursuant to the authority delegated to me by the Administrator, the Federal Aviation Administration amends part 39 of the Federal Aviation Regulations (14 CFR part 39) as follows:

## PART 39—AIRWORTHINESS DIRECTIVES

1. The authority citation for part 39 continues to read as follows:

**Authority:** 49 U.S.C. 106(g), 40113, 44701.

**§ 39.13 [Amended]**

2. Section 39.13 is amended by adding a new airworthiness directive to read as follows:

**97–26–02 Eurocopter Deutschland GmbH (ECD) and Eurocopter Canada LTD.:** Amendment 39–10245. Docket No. 97–SW–44–AD.

*Applicability:* Eurocopter Deutschland GmbH Model BO–105A, BO–105C, BO–105S, BO–105LS A–1, and BO–105LS A–3 helicopters and Eurocopter Canada Ltd. BO–105LS A–3 helicopters, certificated in any category.

**Note 1:** This AD applies to each helicopter 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 helicopters that have been modified, altered, or repaired so that the performance of the requirements of this AD is affected, the owner/operator must use the authority provided in paragraph (c) to request approval from the FAA. This approval may address either no action, if the current configuration eliminates the unsafe condition, or different actions necessary to address the unsafe condition described in this AD. Such a request should include an assessment of the effect of the changed configuration on the unsafe condition addressed by this AD. In no case does the presence of any modification, alteration, or repair remove any helicopter from the applicability of this AD.

*Compliance:* Required as indicated, unless accomplished previously.

To detect cracks in the main rotor mast flange (flange), which, if not detected, could result in failure of the flange and subsequent loss of control of the helicopter, accomplish the following:

(a) Before further flight and thereafter at intervals not to exceed 100 hours time-in-service, visually inspect the flange in the ribbed area for cracks using a 5-power or higher magnifying glass in accordance with paragraphs 2.A.1. and 2.A.2. of the Accomplishment Instructions of Eurocopter Deutschland GmbH Alert Service Bulletin No. ASB–BO 105–10–110, dated August 27, 1997, or Eurocopter Canada Alert Service Bulletin No. ASB–BO 105 LS–10–9, dated September 11, 1997, as applicable.

(b) If a crack is found, remove the cracked main rotor mast and replace it with an airworthy main rotor mast.

(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, Rotorcraft Standards Staff, Rotorcraft Directorate, FAA. Operators shall submit their requests through an FAA Principal Maintenance Inspector, who may concur or comment and then send it to the Manager, Rotorcraft Standards Staff.

**Note 2:** Information concerning the existence of approved alternative methods of compliance with this AD, if any, may be obtained from the Rotorcraft Standards Staff.

(d) Special flight permits will not be issued.

(e) The inspection shall be done in accordance with Eurocopter Deutschland GmbH Alert Service Bulletin No. ASB–BO 105–10–110, dated August 27, 1997, or Eurocopter Canada Alert Service Bulletin No. ASB–BO 105 LS–10–9, dated September 11, 1997, as applicable. These incorporations by reference were 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 American Eurocopter Corporation, 2701 Forum Drive, Grand Prairie, Texas 75053–4005, telephone (972) 641–3460, fax (972) 641–3527. Copies may be inspected at the FAA, Office of Regional Counsel, Southwest Region, 2601 Meacham Blvd., Room 663, Fort Worth, Texas 76137; or at the Office of the Federal Register, 800 North Capitol Street, NW., suite 700, Washington, DC.

(f) This amendment becomes effective on December 31, 1997.

**Note 3:** The subject of this AD is addressed in Luftfahrt-Bundesamt (Germany) AD 97–275, dated September 25, 1997, and in Transport Canada AD CF–97–18, dated September 30, 1997.

Issued in Fort Worth, Texas, on December 5, 1997.

**Eric Bries,**

*Acting Manager, Rotorcraft Directorate, Aircraft Certification Service.*

[FR Doc. 97–32720 Filed 12–15–97; 8:45 am]

BILLING CODE 4910–13–U

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## DEPARTMENT OF TRANSPORTATION

## Federal Aviation Administration

## 14 CFR Part 39

**[Docket No. 97–SW–45–AD; Amendment 39–10246; AD 97–26–03]**

**RIN 2120–AA64**

## Airworthiness Directives; Eurocopter Deutschland GmbH (ECD) (Eurocopter Deutschland) Model MBB–BK 117 A–1, A–3, A–4, B–1, B–2, and C–1 Helicopters

**AGENCY:** Federal Aviation Administration, DOT.

**ACTION:** Final rule; request for comments.

**SUMMARY:** This amendment adopts a new airworthiness directive (AD) that is applicable to Eurocopter Deutschland Model MBB–BK 117 A–1, A–3, A–4, B–1, B–2, and C–1 helicopters. This action requires visual inspections for cracks in the ribbed area of the main rotor mast flange (flange). This amendment is prompted by one report of cracks in a flange. The actions specified in this AD are intended to detect cracks in the

flange, which, if not detected, could result in failure of the flange and subsequent loss of control of the helicopter.

**DATES:** Effective December 31, 1997.

The incorporation by reference of certain publications listed in the regulations is approved by the Director of the Federal Register as of December 31, 1997.

Comments for inclusion in the Rules Docket must be received on or before February 17, 1998.

**ADDRESSES:** Submit comments in triplicate to the Federal Aviation Administration (FAA), Office of Regional Counsel, Southwest Region, Attention: Rules Docket No. 97–SW–45–AD, 2601 Meacham Blvd., Room 663, Fort Worth, Texas 76137.

The service information referenced in this AD may be obtained from American Eurocopter Corporation, 2701 Forum Drive, Grand Prairie, Texas 75053–4005, telephone (972) 641–3460, fax (972) 641–3527. This information may be examined at the FAA, Office of Regional Counsel, Southwest Region, 2601 Meacham Blvd., Room 663, Fort Worth, Texas; or at the Office of the Federal Register, 800 North Capitol Street, NW., suite 700, Washington, DC.

**FOR FURTHER INFORMATION CONTACT:** Mr. Richard Monschke, Aerospace Engineer, FAA, Rotorcraft Directorate, Rotorcraft Standards Staff, 2601 Meacham Blvd., Fort Worth, Texas 76137, telephone (817) 222–5116, (817) 222–5961.

**SUPPLEMENTARY INFORMATION:** The Luftfahrt-Bundesamt (LBA), which is the airworthiness authority for the Federal Republic of Germany recently notified the FAA that an unsafe condition may exist on Eurocopter Deutschland Model MBB–BK 117 A–1, A–3, A–4, B–1, B–2, and C–1 helicopters. The LBA advises that a main rotor mast was found to have cracks of critical magnitude in the area of the flange. The cause of the cracks is under investigation. Until the cause of the cracks has been determined, the flange must be subjected to immediate and repetitive visual crack inspections until further notice.

Eurocopter Deutschland has issued Eurocopter Deutschland GmbH Alert Service Bulletin MBB–BK 117 No. ASB–MBB–BK 117–10–114, dated August 27, 1997, which specifies visually inspecting the area of the holes on the underside of the flange for cracks, especially in the ribbed area between the holes, and if cracks are found, contacting Eurocopter Deutschland before further flight for advice on how to proceed. The LBA classified this service bulletin as mandatory and issued LBA AD 97–276, effective September 25, 1997, in order to assure the continued airworthiness of these helicopters in the Federal Republic of Germany.

This helicopter model is manufactured in the Federal Republic of Germany and is type certificated for operation in the United States under the provisions of section 21.29 of the Federal Aviation Regulations (14 CFR 21.29) and the applicable bilateral airworthiness agreement. Pursuant to this bilateral airworthiness agreement, the LBA has kept the FAA informed of the situation described above. The FAA has examined the findings of the LBA, 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.

Since an unsafe condition has been identified that is likely to exist or develop on other Eurocopter Deutschland Model MBB–BK 117 A–1, A–3, A–4, B–1, B–2, and C–1 helicopters of the same type design registered in the United States, this AD is being issued to detect cracks in the flange, which, if not detected could result in failure of the flange and subsequent loss of control of the helicopter. This AD requires, before further flight, a visual inspection of the ribbed area of the flange for cracks using a 5-power or higher magnifying glass, and thereafter, repeated visual inspections at intervals not to exceed 100 hours time-in-service. The actions are required to be accomplished in accordance with the service bulletin described previously. This flange is a part of the main rotor mast assembly and therefore a critical component of the flight control system. Due to the criticality of the flange to the continued safe flight of the affected helicopters, and the required inspection before further flight, this rule must be issued immediately to correct an unsafe condition in the affected helicopters.

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

## Comments Invited

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

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

Commenters wishing the FAA to acknowledge receipt of their comments submitted in response to this rule must submit a self-addressed, stamped postcard on which the following statement is made: ''Comments to Docket No. 97–SW–45–AD.'' The postcard will be date stamped and returned to the commenter.

The regulations adopted herein will not have substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government. Therefore, in accordance with Executive Order 12612, it is determined that this final rule does not have sufficient federalism implications to warrant the preparation of a Federalism Assessment.

The FAA has determined that this regulation is an emergency regulation that must be issued immediately to correct an unsafe condition in aircraft, and that it is not a ''significant regulatory action'' under Executive Order 12866. It has been determined further that this action involves an emergency regulation under DOT Regulatory Policies and Procedures (44 FR 11034, February 26, 1979). If it is determined that this emergency regulation otherwise would be significant under DOT Regulatory Policies and Procedures, a final regulatory evaluation will be prepared and placed in the Rules Docket. A copy of it, if filed, may be obtained from the Rules Docket at the location provided under the caption **ADDRESSES**.

### List of Subjects in 14 CFR Part 39

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

### Adoption of the Amendment

Accordingly, pursuant to the authority delegated to me by the Administrator, the Federal Aviation Administration amends part 39 of the Federal Aviation Regulations (14 CFR part 39) as follows:

## PART 39—AIRWORTHINESS DIRECTIVES

1. The authority citation for part 39 continues to read as follows:

**Authority:** 49 U.S.C. 106(g), 40113, 44701.

### § 39.13 [Amended]

2. Section 39.13 is amended by adding a new airworthiness directive to read as follows:

**97–26–03 Eurocopter Deutschland:** Amendment 39–10246. Docket No. 97–SW–45–AD.

*Applicability:* Model MBB–BK 117 A–1, A–3, A–4, B–1, B–2, and C–1 helicopters, certificated in any category.

**Note 1:** This AD applies to each helicopter 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 helicopters that have been modified, altered, or repaired so that the performance of the requirements of this AD is affected, the owner/operator must use the authority provided in paragraph (c) to request approval from the FAA. This approval may address either no action, if the current configuration eliminates the unsafe condition, or different actions necessary to address the unsafe condition described in this AD. Such a request should include an assessment of the effect of the changed configuration on the unsafe condition addressed by this AD. In no case does the presence of any modification, alteration, or repair remove any helicopter from the applicability of this AD.

*Compliance:* Required as indicated, unless accomplished previously.

To detects cracks in the main rotor mast flange (flange), which, if not detected, could result in failure of the flange and subsequent loss of control of the helicopter, accomplish the following:

(a) Before further flight, and thereafter at intervals not to exceed 100 hours time-in-service, visually inspect the flange in the ribbed area for cracks using a 5-power or higher magnifying glass in accordance with paragraphs 2.A.1. and 2.A.2. of the Accomplishment Instructions in Eurocopter Deutschland GmbH Alert Service Bulletin MBB–BK 117 No. ASB–MBB–BK 117–10–114, dated August 27, 1997.

(b) If a crack is found as a result of the inspections specified in paragraph (a) of this AD, remove the cracked main rotor mast and replace it with an airworthy main rotor mast.

(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, Rotorcraft Standards Staff, Rotorcraft Directorate, FAA. Operators shall submit their requests through an FAA Principal Maintenance Inspector, who may concur or comment and then send it to the Manager, Rotorcraft Standards Staff.

**Note 2:** Information concerning the existence of approved alternative methods of compliance with this AD, if any, may be obtained from the Rotorcraft Standards Staff.

(d) Special flight permits will not be issued.

(e) The inspection shall be done in accordance with Eurocopter Deutschland GmbH Alert Service Bulletin MBB–BK 117 No. ASB–MBB–BK 117–10–114, dated August 27, 1997. 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 American Eurocopter Corporation, 2701 Forum Drive, Grand Prairie, Texas 75053–4005, telephone (972) 641–3460, fax (972) 641–3527. Copies may be inspected at the FAA, Office of Regional Counsel, Southwest Region, 2601 Meacham Blvd., Room 663, Fort Worth, Texas 76137; or at the Office of the Federal Register, 800 North Capitol Street, NW., suite 700, Washington, DC.

(f) This amendment becomes effective on December 31, 1997.

**Note 3:** The subject of this AD is addressed in Luftahrt-Bundesamt (Germany) AD 97–276, effective September 25, 1997.

Issued in Fort Worth, Texas, on December 5, 1997.

**Eric Bries,**

*Acting Manager, Rotorcraft Directorate, Aircraft Certification Service.*

[FR Doc. 97–32721 Filed 12–15–97; 8:45 am]

BILLING CODE 4910–13–U

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

## Food and Drug Administration

## 21 CFR Part 524

## Ophthalmic and Topical Dosage Form New Animal Drugs; Doramectin

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Final rule.

**SUMMARY:** The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect approval of a new animal drug application (NADA) filed by Pfizer, Inc. The NADA provides for topical use of doramectin for treatment and control of certain worm, grub, lice, and mite infections of cattle.

**EFFECTIVE DATE:** December 16, 1997.

**FOR FURTHER INFORMATION CONTACT:** Estella Z. Jones, Center for Veterinary Medicine (HFV–135), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–594–1643.

**SUPPLEMENTARY INFORMATION:** Pfizer, Inc., 235 East 42d St., New York, NY 10017–5755, is sponsor of NADA 141–095 that provides for the use of Dectomax® (doramectin) 0.5 percent pour-on solution for beef cattle and female dairy cattle less than 20 months of age for treatment and control of gastrointestinal roundworms, lungworms, eyeworms, grubs, biting and sucking lice, and mange mites, to control infections and protect from reinfection with *Cooperia oncophora* and *Dictyocaulus viviparus* for 21 days, and *Ostertagia ostertagia*, *C. punctata*, and *Oesophagostomum radiatum* for 28 days after treatment. The NADA is approved as of September 16, 1997, and the regulations are amended by adding new § 524.770 to reflect the approval. The basis of approval is discussed in the freedom of information summary.

In accordance with the freedom of information provisions of 21 CFR part 20 and 514.11(e)(2)(ii), a summary of safety and effectiveness data and information submitted to support approval of this application may be seen in the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857, between 9 a.m. and 4 p.m., Monday through Friday.

Under section 512(c)(2)(F)(ii) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b(c)(2)(F)(ii)), this approval for food-producing animals qualifies for 3 years of marketing exclusivity beginning September 16, 1997, because the NADA contains substantial evidence of the effectiveness of the drug involved, studies of animal safety or, in the case of food-producing animals, human food safety studies (other than bioequivalence or residue studies) required for approval and conducted or sponsored by the applicant.

The agency has carefully considered the potential environmental effects of this action. FDA has concluded that the action will not have a significant impact on the human environment, and that an environmental impact statement is not required. The agency's finding of no significant impact and the evidence supporting that finding, contained in an environmental assessment, may be seen in the Dockets Management Branch (address above) between 9 a.m. and 4 p.m., Monday through Friday.

### List of Subjects in 21 CFR Part 524

Animal drugs.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under

authority delegated to the Commissioner of Food and Drugs and redelegated to the Center for Veterinary Medicine, 21 CFR part 524 is amended as follows:

## PART 524—OPHTHALMIC OR TOPICAL DOSAGE FORM NEW ANIMAL DRUGS

1. The authority citation for 21 CFR part 524 continues to read as follows:

**Authority:** 21 U.S.C. 360b.

2. Section 524.770 is added to read as follows:

**§ 524.770 Doramectin.**

(a) *Specifications.* Each milliliter of solution contains 5 milligrams of doramectin.

(b) *Sponsor.* See 000069 in § 510.600(c) of this chapter.

(c) *Related tolerances.* See § 556.225 of this chapter.

(d) *Conditions of use—Cattle*—(1) *Amount.* 5 milligrams per 10 kilograms (5 milligrams per 22 pounds).

(2) *Indications for use.* For treatment and control of infections of gastrointestinal roundworms, lungworms, eyeworms, grubs, biting and sucking lice, and mange mites, and to control infections and to protect from reinfection with *Cooperia oncophora* and *Dictyocaulus viviparus* for 21 days, and *Ostertagia ostertagia*, *C. punctata*, and *Oesophagostomum radiatum* for 28 days after treatment.

(3) *Limitations.* Administer as a single dose. Do not slaughter cattle within 45 days of latest treatment. Not for use in female dairy cattle 20 months of age or older. Do not use in calves to be processed for veal. Consult your veterinarian for assistance in the diagnosis, treatment, and control of parasitism.

Dated: October 22, 1997.

**Stephen F. Sundlof,**

*Director, Center for Veterinary Medicine.*

[FR Doc. 97–32807 Filed 12–15–97; 8:45 am]

BILLING CODE 4160–01–F

## DEPARTMENT OF THE INTERIOR

## Minerals Management Service

## 30 CFR Part 206

**RIN 1010–AC06**

## Amendments to Transportation Allowance Regulations for Federal and Indian Leases to Specify Allowable Costs and Related Amendments To Gas Valuation Regulations

**AGENCY:** Minerals Management Service, Interior.

**ACTION:** Final rulemaking.

**SUMMARY:** The Minerals Management Service (MMS) is amending its regulations governing valuation for royalty purposes of gas produced from Federal and Indian leases. The rule primarily addresses allowances for transportation of gas. The amendments clarify the methods by which gas royalties and deductions for gas transportation are calculated.

**DATE:** Effective February 1, 1998.

**ADDRESSES:** David S. Guzy, Chief, Rules and Publications Staff, Royalty Management Program, Minerals Management Service, P.O. Box 25165, MS 3021, Denver, Colorado 80225–0165; courier delivery to Building 85, Denver Federal Center, Denver, Colorado 80225, telephone (303) 231–3432, FAX (303) 231–3385, e-Mail David__Guzy@mms.gov.

**FOR FURTHER INFORMATION CONTACT:** David S. Guzy, Chief, Rules and Publications Staff, Royalty Management Program, Minerals Management Service, phone (303) 231–3432, FAX (303) 231–3385, e-Mail David__Guzy@mms.gov.

**SUPPLEMENTARY INFORMATION:** The principal authors of this rule are Theresa Walsh Bayani and Susan Lupinski, from Royalty Valuation Division, MMS, Lakewood, Colorado.

### I. Background

MMS published a set of rules in 30 CFR part 206 governing gas valuation and gas transportation calculation methods to clarify and codify the departmental policy of granting deductions for the reasonable actual costs of transporting gas from a Federal or Indian lease when the gas is sold at a market away from the lease (53 FR 1272, January 15, 1988).

Since the 1988 rulemaking, Federal Energy Regulatory Commission (FERC) regulatory actions have significantly affected the gas transportation industry. Before these changes, gas pipeline companies served as the primary merchants in the natural gas industry. During that environment, pipelines:

- Bought gas at the wellhead,
- Transported the gas, and
- Sold the gas at the city gate to local distribution companies (LDC).

In the mid-1980's, FERC began establishing a competitive gas market, allowing shippers access to the pipeline transportation grid. These actions ensured that willing buyers and sellers could negotiate their own sales transactions.

Specifically, starting with the implementation of FERC Order 436, FERC began regulating pipelines as open access transporters and requiring nondiscriminatory transportation. This permitted downstream gas users (such as LDCs and industrial users) to buy gas directly from gas merchants in the production area and to ship that gas through interstate pipelines.

FERC Order 436 and amendments, plus the elimination of price controls, created a vigorous spot market. Producers and marketers, in competition for the sale of gas to end users, are now transporting substantial volumes of gas that they own through interstate pipelines.

In the early 1990's, FERC recognized that pipelines still held an advantage over competing sellers of gas. Pipelines held substantial market power and sold gas bundled with a transportation service. FERC remedied the inequities in the gas market by issuing FERC Order 636, effective May 18, 1992. Under the provisions of this order, FERC:

- Required the separation (unbundling) of sales and gas transportation services;
- Enabled the implementation of a capacity release program; and
- Allowed pipelines to assess shippers surcharges for services such as transition costs and FERC's annual charges (57 FR 13267, April 16, 1992).

The unbundled costs—previously embedded in a lump-sum charge—include:

- Transmission;
- Storage;
- Production; and
- Gathering costs.

*Necessity for This Rulemaking*

We reviewed our current gas transportation regulations (30 CFR 206.156 and 206.157 (for Federal leases), and 206.176 and 206.177 (for Indian leases) (1996)) and determined that they provide general authority to calculate transportation deductions for cost components resulting from implementing FERC Order 636 and previous FERC orders. However, we have determined that lessees and royalty payors need specific guidance and certainty on which components are deductible as transportation costs from royalty. This guidance is necessary because components previously aggregated and unidentifiable may now be separately identified in transportation contracts, and new costs unique to the FERC Order 636 environment are emerging.

Further, some of the components reflect non-deductible costs of marketing rather than transportation. We believe that without the clarification provided in this rule, lessees and payors

may claim improper deductions on their royalty reports and payments.

We issued a proposed rulemaking to clarify for the oil and gas industry which cost components or other charges are deductible (related to transportation) and which costs are not deductible (related to marketing) for Federal and Indian leases (61 FR 39931, July 31, 1996). The purpose of this rulemaking is also to clarify our existing policies. We received comments from 18 separate entities: Six responses from companies, six responses from industry trade associations, two responses from State representatives, one response from a State/Indian association, two responses from Indian tribes, and one response from an Indian tribal association.

This final rulemaking relates primarily to the effects of FERC Order 636 on interstate gas pipelines that FERC regulates. To the extent these same types of changes and issues are relevant for intrastate pipelines, our rule applies equally.

In conjunction with the changes to the transportation allowance regulations, we are also making certain changes to the gas valuation regulations. When FERC approves tariffs, they generally allow pipelines to include provisions ensuring that pipelines can maintain operational and financial control of their systems. These provisions may include requirements that shippers maintain pipeline receipts and deliveries within certain daily or monthly tolerances and that shippers cash-out accumulated imbalances. If a shipper over-delivers production to a pipeline, the pipeline may purchase the excess gas quantities from the shipper. If the gas quantity exceeds certain prescribed tolerances, the shipper may incur a penalty in the form of a substantially reduced price for that gas. We will not accept that penalty price as the value of production, and this rulemaking provides a method for valuing production sold under such circumstances.

Certain additions to revenues from the sale of natural gas may occur in the gas transportation environment. These issues are gas valuation issues beyond the scope of this rulemaking. However, these additions to revenues may be royalty bearing under existing regulations.

We also recognize that certain lessee gas transportation arrangements result in financial transactions not directly associated with the gas value. Such transactions may not have royalty consequences. If you are unsure whether your transactions result in additional royalty obligations, you may request valuation guidance from us.

The amendments discussed below apply to both arm's-length and non-arm's-length situations for valuing gas production and calculating transportation allowances.

## II. Comments on Proposed Rule

We published a proposed rule at 61 FR 39931, 7/31/96. The proposed rulemaking provided for a 60-day public comment period which ended September 30, 1996, and was extended to October 30, 1996 (61 FR 48872, 9/17/96).

### *General Comments*

The tribes believe that allowable deductions should be scrupulously examined and limited to the minimum amount for the economic best interest of the lessor tribe. They state that FERC-approved tariffs are not the actual, reasonable cost of transportation paid by the producer and should not be accepted. A few commenters stated that careful examination of tariffs is needed to assure revenue protection and accountability. These respondents claim that lessees believe tariffs are beyond our scrutiny once we permitted their use. They urge us to clearly state in this rulemaking that review of costs included in a tariff is not beyond audit review and that transportation allowances may be recalculated when the tariff does not reasonably reflect a lessee's actual costs.

One State commented that under no circumstances should the lessee be allowed to deduct transportation costs, including tariffs, in excess of the actual, reasonable costs incurred or paid, regardless of whether the transportation is arm's-length or non-arm's-length. One tribe and one Indian tribal association suggested that the preamble language should specify that allowances are limited to reasonable actual costs of transportation and are limited to no more than 50 percent of the value of the production. One tribe believes that this regulation changes the annual rent or royalty rate without the written consent of the tribe.

Several States and Indian commenters claim that clarifying the allowable charges under FERC Order 636 is important and pressing and urged us not to consider this rule an end to transportation allowance issues. They believe each cost must be evaluated against the lessees' duty to market production and that marketing costs are not a deductible expense. They also state that on each debatable cost, our proposal clearly benefits the lessees. Although they oppose several provisions of the rule, these commenters recognize that the FERC Order 636 environment raises difficult issues for royalty valuation, and they commend MMS for attempting a compromise proposal. In addition, one State commenter added that with modifications, they generally supported our efforts to amend the transportation allowance regulations.

In addition to the general comments, one tribe offered the following comments regarding the economic analysis of the rule. They believe that the Department has not complied with Department Manual, Chapter 2, Part 512 and that the economic analysis shows a deficiency of acting in the best economic interests of the tribe. They also believe that we have not taken seriously our obligation to ensure maximum revenue to the tribe. In the tribe's view, the statement that this proposal meets MMS's goal of certainty, clarity, and consistency is not an adequate basis to reduce Tribal royalties. The tribe asserts that MMS's statement in the July 31, 1996, proposed rulemaking that the rule will have a neutral or beneficial impact on Indian royalties is devoid of any real economic demonstration. Finally, the tribe stated that they are skeptical that the rule will have a neutral or beneficial impact or that it will enhance MMS's ability to fulfill its trust responsibility.

Six industry trade associations and three companies also offered general comments. Every respondent believes that this rulemaking is cumbersome and does not meet the goal of regulatory simplification or streamlining. They believe the proposal:

- Represents an extreme departure from current practice;
- Exceeds MMS's statutory authority;
- Is not supported by case law; and
- Illegally extends the lessee's obligations.

Several industry trade associations commented that the proposal will create heavy administrative expenses for producers to track gas molecules to the burnertip. In today's complex marketplace, these commenters believe the required tracking is impossible. One respondent stated that pipelines are not consistent in billing and frequently do not segregate costs, adding to the difficulty in compliance and likelihood of being second guessed by us in later audits. One industry trade association strongly urged us to withdraw this rule. If necessary, it believes that changes can be addressed in a negotiated rulemaking where all parties come to an equitable agreement. One industry trade association stated that this proposal:

- Fails to recognize the producer's lack of control over fees; and

• Penalizes and requires the producer to absorb all costs and risks of marketing downstream.

One industry trade association believes that the burdens and disincentives created by the rule dictate that we should allow producers to make royalty payments in kind.

*Response.* One of the main purposes of this rulemaking is to clarify the specific allowable and nonallowable costs of transportation. This rule is a continuation of our commitment to assure that lessees deduct only the actual, reasonable costs of transportation. We have carefully considered each cost component and are not allowing any costs of marketing as a deduction in the final rule.

Although one tribe believes that MMS did not comply with the economic analysis required by the Departmental Manual, Chapter 2, Part 512, we believe that the changes under FERC Order 636 will enable us to identify nonallowable costs of marketing. Prior to FERC Order 636, lessees deducted some bundled marketing costs. Under the FERC Order 636 environment, these costs are now separately identified. Consequently, this rulemaking limits the transportation allowance to the actual, reasonable costs of transportation. Our rulemaking will have a neutral or beneficial impact to the tribes, States, and Federal Treasury because lessees will not be able to deduct these previously bundled marketing costs.

We disagree with industry's statement that the Department does not have the authority to promulgate this rule. MMS is mandated by law to ensure that royalties are properly collected and distributed. See 30 U.S.C. 1701 *et. seq.* This responsibility includes providing clear guidance to the oil and gas industry regarding which costs are allowable transportation deductions and what are nonallowable marketing costs. The comment that pipelines are not consistent in billing and frequently do not segregate costs is contrary to FERC's requirement that every pipeline make rate filings publicly available. Under FERC's procedure, the pipeline must identify and justify the cost components. Any shipper can analyze these filings and protest any inequitable costs. Based on these reasons, MMS is publishing this rule as final.

MMS amends its regulations and deletes the existing sections 206.157(f) and 206.177(f) of 30 CFR part 206. (We retain the substance of these paragraphs in later revised paragraphs.) Further, we redesignate paragraph (g) of these sections as paragraph (h) and add two new paragraphs. New paragraph (f) describes the types of costs we will allow as part of a transportation allowance. A new paragraph (g) lists those costs that we expressly disallow. Because some of the nonallowable costs affect valuation, we also amend sections 206.152, 206.153, 206.172 and 206.173. These amendments address valuation of certain cash-out volumes and expressly reaffirm that marketing costs are not allowable deductions from royalty value.

*Specific Comments*

*Comments on §§ 206.152, 206.172, 206.153, and 206.173 (relating to paragraph (b)(1)(iv)) How to value over-delivered volumes under a cash-out program.*

We received comments from one State on the cash-out program. This State agrees with our amendments to the valuation regulations for cash-out programs.

Two industry trade associations and three companies commented on the cash-out program. All industry commenters disagree with our cash-out valuation proposal. They believe that we should accept the price specified in the FERC-approved tariff for valuation purposes. Many industry respondents stated that lessees cannot market production downstream of the lease without being subject to cash-out provisions under transportation contracts. These respondents also believe that:

• Our proposal ignores that imbalances are inevitable; and

• A cash-out provision is the best means to sell gas.

They also state that MMS is arbitrary and capricious if we do not first determine that the lessee acted imprudently before disallowing use of the cash-out provision outside the tolerance or using the benchmarks to value gas. One company disagrees with our assertion that volumes outside the tolerance (for over-delivery specified in the transportation contract) are a violation of the duty to market for the benefit of the lessee and lessor. This commenter believes that we should only disallow the FERC-approved cash-out value when we determine that the lessee is negligent.

*Response.* Pipelines developed tolerances in recognition of the fact that nominations never match actuals, and receipts never match deliveries. Because pipelines no longer own system supply gas to cover imbalances, they must maintain strict controls over shippers to assure system integrity. Pipelines developed the cash-out programs to penalize those shippers outside the tolerances while allowing for minor imbalances within tolerance. MMS also believes lessees must act diligently in scheduling shipments on pipelines. In the final rule, we retain the provision accepting the cash-out value within tolerance and not accepting the value outside the tolerance. We also retain the provision to value production under the benchmarks when the cash-out provision results in an unreasonable value for royalty purposes. This is consistent with the current valuation regulations requiring arm's-length contracts to meet total consideration and reasonable value criteria.

We amend paragraph (b)(1) of 30 CFR 206.152 and 206.172 (for unprocessed gas), and 30 CFR 206.153 and 206.173 (for processed gas) by adding another exception to the general rule that the gross proceeds under an arm's-length contract are acceptable as the royalty value. This exception adds new paragraph (iv) to these sections and provides that over-delivered volumes outside the pipeline tolerances are valued at the same price the pipeline purchases over-delivered volumes within the tolerances. We will not accept the penalty cash-out price as royalty value.

The rule also provides that if we determine that the cash-out price is unreasonably low, lessees must use the benchmarks to value the gas instead of the cash-out price. Lessees should also note that for production from Indian leases, other valuation provisions in the regulations still apply; *i.e.*, major portion and dual accounting.

*Comments on §§ 206.152(i), 206.172(i) (for unprocessed gas); and 206.153(i), and 206.173(i) (for processed gas).*

One Indian tribe responded that all marketing costs must be borne by the lessee and that the lessee must make every reasonable and prudent effort to market production for the benefit of the lessor. All other State and Indian respondents support this position but offered no specific comments.

Five industry trade association groups and four companies submitted responses regarding costs of placing production in marketable condition and marketing costs. The following paragraphs summarize industry specific responses.

*General Comments.* One industry trade association recommends deleting the language ''and to market the gas for the mutual benefit of the lessee and the lessor'' that we proposed adding to the existing regulations. Several industry commenters stated that this marketing language is beyond MMS's statutory authority and is bad public policy. One industry commenter also stated the marketing language was a thinly disguised attempt to increase revenue to

the government at the expense of lessees. Several industry commenters believe that the marketing language will impose royalty on marketing services long after production is saved, removed, or sold from the lease and that the point of royalty valuation is moved from the lease to the burnertip. These industry commenters also believe that even though the producer sold marketable gas under an arm's-length contract at the lease, lessees must trace gas all the way to the burnertip and pay royalty on the value at a ''new'' marketplace. A few industry commenters stated that we do not rely on a ''principled basis'' to determine what will or will not be a marketing cost, and it will be impossible for lessees to anticipate what downstream costs we will disallow. Commenters assert that this will create a loss of certainty for lessees. One company believes that the marketing language changes value determination from the current policy of accepting arm's-length gross proceeds to the highest-obtainable price anywhere from the lease to the resale at the burnertip.

*Duty to market/implied obligation to market.* Almost every industry trade association and company commenter stated that no obligation exists to market production away from the lease. They asserted that lessees are only obligated to market production at or near the lease. In addition, they claim that even if this obligation to market production is not new, the obligation to market production away from the lease is new. All industry commenters believe that the rule creates an unprecedented duty to market and imposes an elaborate new marketing standard. These commenters also believe that the creation of this new duty to market violates applicable statutes and lease terms. These industry commenters also state that the implied obligation to market for the mutual benefit of the lessee and the lessor never embodied the obligation to market *at no cost* to the lessor. Several commenters stated that this obligation is not implied simply because the agency says so and the rule leaps from the realities of past precedent by merely stating that the obligation to market production is implied. Several commenters claim that the implied obligation to market is not supported by *Walter Oil and Gas*, 111 IBLA 265 (1989) as cited by MMS.

*Production in marketable condition.* Several industry commenters claimed that we erroneously link the obligation to place production in marketable condition with the obligation to market that production. One industry trade association stated that in *Beartooth Oil and Gas Co.* v. *Lujan*, CV 92–99–BLG–RWA (D. Mont. Sept. 22, 1993, vacated and remanded) (*Beartooth*), the court determined that the marketable condition rule does not require the lessee to condition the gas so that it is suitable for secondary or retail markets. They further state that a series of markets exists between the lease and the burnertip but the lessee's obligation to place production in marketable condition refers only to the first market. Several industry commenters believe that the preamble to the March 1, 1988, regulations clearly shows that our intent was not to encompass any and all marketing costs but only those to place production in marketable condition. Most commenters state that the market for which production is conditioned is the market at or near the lease. They further claim that the definition of marketable condition in the March 1, 1988, rule focuses on gas that is sufficiently free from impurities and not on marketing that gas.

*Share in marketing costs.* Three companies and two industry trade associations claim that MMS is not entitled to a ''free ride'' on marketing costs. They believe that if we benefit from marketing activities then we should share in those costs. Two companies and one industry trade association state that the proposal shows that we are unwilling to share in costs to market but want to share in any higher price gained when the lessee performs marketing. This is not for mutual benefit of the lessee and lessor.

*Breach of duty.* Several industry trade associations and company commenters offered the following comments on the lessees' duty to market production. Because marketing costs are disallowed under the rule, if lessees don't incur marketing costs, these commenters are concerned that we will consider the lessee as breaching its duty to market production. They are also concerned that MMS will question all marketing decisions made by the lessee and make arbitrary determinations that producers failed to obtain the highest price.

*Response.* We recognize that the obligation to place production in marketable condition is legally distinct from the issue of marketing the gas. However, the implied covenant of the lease dictates that lessees must market production at no cost to the lessor. Both principles are expressly stated in the March 1, 1988, gas regulations; the definition for marketable condition at 30 CFR 206.151 discusses the physical treatment of gas for placing gas in marketable condition and 30 CFR 202.151 states that no allowance will be made for other expenses incidental to marketing. Based on these principles, MMS has consistently applied the concept that the lessee must market gas at no cost to the lessor and denied marketing costs as an allowable deduction. See *Arco Oil and Gas Co.*, 112 IBLA 8, 11 (1989); *Walter Oil and Gas Corp.*, 111 IBLA 260, 265 (1989). We have not changed the principle of accepting gross proceeds under arm's-length contracts and would not trace value beyond a true arm's-length transaction to the burner tip, as commented. The rule simply clarifies which cost components or other charges are deductible (transportation), and which costs are not deductible (marketing). This is consistent with the ruling in the *Beartooth* decision that addressed whether downstream compression was the cost of placing production in marketable condition or a transportation cost.

The final rule clarifies the principle that lessees cannot deduct from royalty value the costs of marketing production from Federal and Indian leases. The final rule adds specific language to paragraph (i) of 30 CFR 206.152, 206.153, 206.172, and 206.173 to expressly state lessees' obligation to incur all marketing costs. In all sections, we amend paragraph (i) to add the words ''and to market the gas for the mutual benefit of the lessee and the lessor'' after the words ''place gas in marketable condition'' and before the words ''at no cost to the Federal Government (or Indian lessor, as applicable).'' We also add the words ''or to market the gas'' at the end of the last sentence of that paragraph to accomplish this objective. We believe that the added language contains the concept embodied in the implied covenant to market for the mutual benefit of Federal and Indian oil and gas lessees and lessors. We further believe this imposes no additional marketing burden on the lessee than existing requirements.

*Comments on §§ 206.157(f)(1) and 206.177(f)(1) Firm demand charges paid to pipelines.*

One Indian tribal association, one State/Indian association, two tribes, and two States offered comments on firm demand charges. One tribe stated that if we allow firm demand charges, we must timely review and audit the actual amount claimed. The tribe believes that situations exist where lessees claim FERC-allowed costs, but lessees do not actually pay these costs for transportation. The State commenter agrees with our proposal allowing firm demand charges—limited to the applicable rate per MMBtu multiplied by the actual volumes transported. The State believes that it should not be liable for the additional costs for two reasons.

First, the lessee has ways to mitigate costs for unused capacity. Second, the lessor should not be liable for marketing mistakes caused by overbuying capacity. One State/Indian association, one tribe, and one State debated whether these charges are transportation charges or marketing costs. However, these commenters agreed that MMS's position is a reasonable compromise with the following two caveats. First, we should review and adjust firm demand charges if they include otherwise nondeductible costs or do not represent a lessee's reasonable actual costs. Second, the lessee should reduce the claimed allowance if a purchaser reimburses, directly or indirectly (through reservation charges or fees) all or some of the producer's demand charges.

Three trade associations and four companies offered the following comments on firm demand charges. All industry commenters believe that we should allow the entire demand charge actually paid by the lessee. One industry trade association and four companies believe that the demand charge is a legitimate cost that often enables the gas to be sold at a higher price. They believe the lessor should share in the entire demand charge even if only a portion is used because the royalty share benefits. Several industry commenters stated that the firm demand charge is not allocated between used and unused capacity. They stated that firm demand charges are consideration for transportation irrespective of capacity used. Many of the industry commenters stated that allowances should be reduced only when the lessee releases capacity and receives a credit. Many commenters stated that factors beyond the lessees' control can prevent them from using all reserved capacity. By denying part of the firm demand, we imply lessees acted imprudently and failed to market gas for the mutual benefit of the lessee and the lessor. One company stated that we should allow the demand/reservation charge because the charge is a transportation cost that is indistinguishable from any other transportation service.

*Response.* Our valuation regulations require that we allow the reasonable, actual costs of transportation. However, only the firm demand rate per MMBtu is an actual cost of transportation. We do not consider the amount paid for unused capacity as a transportation cost. Therefore, in §§ 206.157(f)(1) and 206.177(f)(1), we are allowing firm demand charges—limited to the applicable rate per MMBtu multiplied by the actual volumes transported—as allowable costs in computing the transportation allowance.

*Capacity release program.* We also received comments on the capacity release program. One Indian tribal association responded that they agree with permitting allowances for those portions of both demand and commodity charges that reflect the costs paid for gas actually shipped, but not permitting allowances for the potential business costs associated with purchases of surplus or unused capacity.

One company commenter would support including capacity release gains and losses if all firm demand charges were allowed. Several companies stated that there are no gains under the capacity release program. One industry trade association and two companies recommend rewriting the third sentence under firm demand charges to clearly state that any gains or losses from the sale of unused firm charges are not royalty bearing. These commenters also recommended clarifying the fourth sentence which includes the term ''other reasons.'' These respondents suggest using the term ''other refunds'' and clarifying the sentence to state that any refunds received are not considered gross proceeds if no firm demand charge was claimed on Form MMS–2014, Report of Sales and Royalty Remittance (Form MMS–2014).

*Response.* We do not consider the gains and losses associated with release of firm transportation as part of the actual cost of transporting gas. In §§ 206.157(f)(1) and 206.177(f)(1), lessees with firm transportation may only claim the firm demand charge per MMBtu multiplied by actual volumes transported, regardless of whether they release part or all of their reserved capacity. If a lessee/shipper acquires released capacity on a pipeline, we allow the cost of buying that capacity to the extent that capacity is used. The final rule provides that we will not participate in gains or losses associated with released capacity.

We agree that the third sentence under firm demand charges should be clarified and have replaced this sentence in the final rule with the following sentence: ''The lessee also may not include any gains associated with releasing firm capacity.''

*Pipeline rate adjustments.* The last issue under firm demand is pipeline rate adjustments. We also requested comments on how to simplify reporting for these adjustments. One Indian tribal association agrees that any allowances taken that are later rebated are royalty bearing. However, monitoring will be complicated if the refund or rebate is credited against future charges.

Four industry trade associations and five companies responded to pipeline rate adjustments. Several companies and industry trade associations believe that the proposal is unfair because it disallows deductions for penalties paid by the shipper but requires lessees to pay their share of penalty monies refunded to other pipeline customers. However, one company agreed that penalty refunds and rate case payments should be subject to royalty. Individual companies responded that rate case refunds don't segregate individual components into the allowable/nonallowable items as defined by MMS. Therefore, differentiating disallowed components will be unduly burdensome to the lessee. Another company stated that the rule implies that penalty refunds are refunded to the party who paid the penalty which may not be the case.

Most companies agree that monthly adjustments would be unduly burdensome and that MMS should establish a distinct transaction code and/or adjustment reason code for pipeline rate adjustments. Several companies do not believe that a simplified reporting method for Indian leases is possible because of major portion requirements. One company suggested that lessees be allowed to assess a ''Royalty Administration Fee'' to offset the costs associated with tracking all the exceptions spelled out in this rule.

*Response.* Pipelines charge a specific rate for transportation services. When FERC later requires pipelines to adjust these charges through a pipeline rate refund, these adjustments reduce the transportation allowance already taken by the lessee on the Form MMS–2014. We considered several options for simplifying reporting, but concluded that any form of rolled-up reporting would prohibit us from determining royalty properly for both Federal onshore and offshore and Indian lands. We use data reported on Form MMS–2014 from both Federal and Indian leases to calculate major portion prices for Indian leases. Rolling up transportation allowances will skew these major portion calculations. We also use Form MMS–2014 data to monitor valuation reporting and for settlement negotiation purposes. Therefore, in the final rule, we have not modified reporting requirements for pipeline rate adjustments. To reflect the FERC-modified transportation charge, the lessee must adjust the allowance to account for the refund they receive by reducing the allowance originally taken.

*Comments on §§ 206.157(f)(2) and 206.177(f)(2) Gas supply realignment (GSR) costs.*

One State/Indian association, two States and one tribe oppose MMS's position that gas supply realignment (GSR) costs are transportation costs. These respondents state that GSR costs are transitory and are not related to a pipeline's transportation costs. Instead, these costs relate only to money paid by pipelines to reform or terminate contracts. They believe there is inherent inequity in industry's position that industry is not required to pay royalties on contract reformation payments but are entitled to deduct GSR costs when embedded in a tariff.

One Indian tribal association questioned why we allow only that portion of firm demand charges actually used, but allow recovery of GSR costs paid through demand charges. They believe this negates the initial objective of limiting firm demand to charges for actual volumes transported. They also believe that the GSR cost ''carries'' the royalty owner along on a myriad of business decisions by pipelines and producers that have nothing to do with actual transportation of gas.

One State/Indian association, one State, and one tribe claim that our position is inconsistent because contract reformation payments are both royalty bearing and deductible. These commenters are opposed to allowing GSR costs but as a compromise, suggest the following options:

- If lessees receive contract settlement money and agree to pay royalties on it, we could allow those lessees to deduct GSR costs;
- If lessees do not receive contract settlement money, we could allow those lessees to deduct GSR costs; and
- If all lessees are required to pay royalties on contract settlement money, we could allow GSR costs across the board.

One State commenter believes that allowing GSR costs violates the gross proceeds rule.

All industry respondents agree that GSR costs should be deductible and should not be tied to royalty consequences of gas contract settlements or the outcome of any pending litigation. Several commenters state that GSR costs are costs of transporting gas charged to all pipeline customers.

*Response.* GSR costs stemmed specifically from FERC's regulatory actions under FERC Order 636. FERC is mandated to recognize prudently incurred costs in establishing just and reasonable rates for transportation. We consider these costs as an actual cost of transportation under the existing regulations and will allow GSR costs as a transportation deduction in §§ 206.157(f)(2) and 206.177(f)(2).

*Comments on §§ 206.157(f)(3) and 206.177(f)(3) Commodity charges.*

One Indian tribal association responded to this issue, stating that they do not share MMS's assumption that demand and commodity charges permit pipelines to recover only their fixed and variable costs. The association claims that profit margins are built into both these components as return on equity.

We received no comments from industry on this issue.

*Response.* The actual volumes transported on a firm transportation contract are charged a firm transportation commodity charge in addition to the reservation fee. All interruptible transportation rates are billed at commodity charges only. These commodity charges represent the pipeline's transportation-related variable costs. These are actual costs incurred by lessees for transporting gas, and we will specifically allow the commodity charge as a deduction in the final rule. We recognize that valuation implications result from a lessee's choice of securing firm versus interruptible services. If the gas sales transaction is not arm's-length, the lessee would apply the comparability criteria in §§ 206.152, 206.153, 206.172, and 206.173 and compare values of gas transported under the same transportation arrangement—firm to firm and interruptible to interruptible. In §§ 206.157(f)(3) and 206.177(f)(3), we allow the commodity charges paid to pipelines as allowable costs in computing the transportation allowance.

*Comments on §§ 206.157(f)(4) and 206.177(f)(4) Wheeling costs.*

One Indian tribal association stated that wheeling is an incidental cost associated with shunting gas to a siding then back into the transportation system. This respondent believes that these costs should be treated like banking/parking fees and be disallowed. However, they stated that if we allow wheeling, those costs should be limited to actual reasonable costs.

We received no comments from industry on this issue.

*Response.* Wheeling is a physical transfer of gas from one pipeline through the hub to either the same or another pipeline. This service is directly related to transportation. We allow the costs of wheeling as a transportation deduction in §§ 206.157(f)(4) and 206.177(f)(4) of the final rule.

*Comments on §§ 206.157(f)(5) and (6) and 206.177(f)(5) and (6) Gas Research Institute (GRI) fees and Annual Charge Adjustment (ACA) fees.*

Two tribes, one Indian tribal association, and two State/Indian associations oppose allowing Gas Research Institute (GRI)/Annual Charge Adjustment (ACA) fees. All respondents believe that these fees are not transportation-related costs.

We received no specific comments from industry.

*Response.* FERC requires member pipelines of GRI to charge customers a fee for funding GRI programs. The GRI conducts research, development and commercialization programs on natural gas related topics for the benefit of the U.S. gas industry and gas customers. FERC allows pipelines to charge customers an ACA fee. This fee allows a pipeline to recover its allocated share of FERC's operating expenses. Because such fees are required transportation charges, we will allow GRI and ACA fees under §§ 206.157(f)(5) and (6), and 206.177(f)(5) and (6) of the final rule. However, MMS is aware that GRI funding may become completely voluntary. Therefore, we will allow GRI fees only as long as they are mandatory fees in FERC-approved tariffs.

*Comments on §§ 206.157(f)(7) and 206.177(f)(7) Payments (either volumetric or in value) for actual or theoretical losses.*

One Indian tribal association, one State/Indian association, one State, and one tribe believe that actual or theoretical losses are nondeductible costs and should not be allowed even if they appear in a tariff.

Four companies and three industry trade associations agree that actual or theoretical losses should be allowed as a deduction in arm's-length contracts and non-arm's-length transportation contracts if a FERC or State regulatory agency-approved tariff includes these costs. However, they believe that MMS's position on non-arm's-length situations where no tariff exists is a discriminatory treatment of non-arm's-length transportation situations. These respondents believe that actual and theoretical losses should be allowed in all cases.

In addition to comments on actual or theoretical losses, five industry respondents commented that MMS should clarify that gas supply to the transporter for fuel (whether provided in kind or cash reimbursement) will be an allowable transportation cost.

*Response.* We allow the cost of fuel as a deduction when it is used for gas transportation. This policy has not changed under this rule. We will continue to allow payments (either volumetric or in value) for actual or

theoretical losses for arm's-length transportation arrangements and for non-arm's-length transportation arrangements if based on a FERC or State-regulatory approved tariff. However, we clarified the wording in the new §§ 206.157(f)(7) and 206.177(f)(7). There is no substantive change from the existing rules.

*Comments on §§ 206.157(f)(8) and 206.177(f)(8) Temporary storage services.*

One Indian tribal association agreed that MMS should not allow storage fees as a deduction. They believe that MMS should treat temporary or short-term storage fees (commonly known as banking and parking fees) as well as wheeling costs as nonallowable costs that are incidental to marketing. The Indian tribal association believes that MMS makes an exception to the gross proceeds rule regarding long-term storage. This Indian tribal association also believes that if a lessee stores gas for later sale, the lessee should pay an estimated royalty and pay additional royalties due when production is actually sold.

Three industry trade associations and four companies disagree with MMS's position that banking and parking are storage fees and not deductible. They state that these fees are part of the transportation process similar to wheeling, and we should allow these fees as a deduction. Most respondents state that banking and parking are necessary services to ensure balancing at market centers and hubs. These commenters state that we have no justification to disallow these fees, especially if the lessee is charged these fees in the same month as a sale.

*Response.* After reviewing the comments, we agree that temporary storage costs are different than long-term storage. Banking and parking are short-term storage services that give pipelines and shippers flexibility to avoid penalties related to imbalances. We agree with industry, and we will change the final rule by adding new sections 206.157(f)(8) and 206.177(f)(8) titled ''Temporary storage services.'' These sections will allow short-term storage services as a transportation deduction but will retain the sections 206.157(g)(1) and 206.177(g)(1) disallowing long-term storage. We define short-term storage as temporary storage occurring at a hub or market center for a duration of 30 days or less.

*Comments on §§ 206.157(f)(9) and 206.177(f)(9) Supplemental costs for compression, dehydration, and treatment of gas.*

One Indian tribal association, one State/Indian association, one tribe, and one State believe these costs are part of the lessee's duty to place production in marketable condition at no cost to the lessor. They assert that they are not allowable no matter where they occur in the transportation process. They further maintain that this provision invites dispute and litigation over what is ''typical'' or ''unusual.'' One Indian/State association commented that the economic rationale for permitting transportation allowances is that economic value is added by transporting production away from the lease. That transportation cost is then deducted from the enhanced value to determine value at the lease. There is no indication that value is added by ''supplemental services.'' Therefore, these costs should not be allowed.

Most of the industry commenters oppose the use of the word ''supplemental'' and recommend that it be replaced with the word ''other.'' These commenters stated that these services are an integral part of the transportation process and not an activity to put gas in marketable condition. They believe that once gas is in marketable condition, all subsequent services should be deductible. Several commenters state that compression, dehydration, and treatment of gas are not supplemental to transportation, they are an integral part of the transportation process.

A few industry trade associations and companies maintain that gas entering mainline pipelines is already in marketable condition, and we should allow deduction of all these costs. One company suggested that we look at the intent of the services; are these costs to place gas in marketable condition or for transportation? This company stated that gas may be acceptable to the transporter without compression, however, compression is necessary to offset line pressure in order to maintain deliverability and effectively manage reservoirs. They assert that this indicates that costs are due to transportation, not marketing restraints.

*Response.* The supplemental services indicated in the rule are not costs for placing gas in marketable condition. It is clear that Federal and Indian lessees must put production in marketable condition at no cost to the lessor. The costs addressed in the rule are costs that may occur in unusual circumstances where the pipeline performs additional compression, dehydration, or other treatment of gas for transportation purposes. These costs exceed the services necessary to place production in marketable condition. We allow charges for these supplemental services as a deduction in the final rule by renumbering sections 206.157(f)(9) and 206.177(f)(9).

*Comments on §§ 206.157(g)(1) and 206.177(g)(1) Fees or costs incurred for storage.*

See comments under §§ 206.157(f)(8) and 206.177(f)(8) above for detailed discussion on short duration storage fees.

*Response.* The regulation at 30 CFR § 202.150 (1996), the language of the various mineral leasing statutes, and terms of Federal leases require that royalty be a percentage of the amount or value of the production *removed or sold* from the lease. We consider gas removed from a Federal or Indian lease and stored at a location off the lease for future sale subject to royalty at the time of removal from the lease. The final rule is consistent by not allowing any costs incurred for storing production in a storage facility, whether on or off the lease, for a duration of greater than 30 days.

*Comments on §§ 206.157(g)(2) and 206.177(g)(2) Aggregator/marketer fees.*

The State and Indian commenters support MMS's position of not allowing aggregator/marketer fees as a transportation deduction. They believe that aggregator/marketer fees are not transportation costs and should be disallowed.

Four industry trade associations and three company respondents objected to disallowing aggregator/marketer fees from the transportation deduction. These respondents believe that lessees have no duty to market production downstream of the lease and no obligation to do so free of charge after production is placed in marketable condition. Industry believes that aggregating production results in enhanced value. Because MMS benefits from this enhanced value, industry believes that we should also share in these costs.

One industry trade association stated that denying aggregator/marketer fees will adversely affect independents because they do not have the ability to aggregate large volumes of production and, therefore, receive an enhanced value for gas.

*Response.* Aggregator/marketer fees are fees a producer pays to another person or company including its affiliates to market its gas. As previously discussed, the implied covenant to market the production is the lessee's obligation and the lessor does not share in marketing costs. The final rule in sections 206.157(g)(2) and 206.177(g)(2) reflects this principle by not allowing aggregator/marketer fees as a transportation deduction.

*Comments on §§ 206.157(g)(3)(i)–(iv) and 206.177(g)(3)(i)–(iv) Penalties the lessee incurs as shipper.*

One Indian tribal association and one State agree that penalties for cash-out, scheduling, imbalance, and curtailment or operational flow orders should be borne by the lessee. They believe that these penalties are not associated with reasonable actual costs of transportation. The State commenter believes that the lessee should bear any unrecouped losses incurred by their own marketing mistakes.

Two industry trade associations and three companies responded to the penalty provision. They agree that, within reasonable tolerances, costs due to negligence or mismanagement by the lessee should not be borne by the lessor. However, MMS should not disallow costs based on an assumption of breach of duty to market. Instead, MMS should review penalties on a case-by-case basis to determine if they were unavoidable. These respondents believe that if penalties are unavoidable, they should be deductible.

One company believes that MMS should share in all imbalance cash-out penalties regardless of whether a portion of the imbalance exceeds the pipeline tolerance level. This company believes that this proposal is contrary to MMS's acceptance of arm's-length contract sales as the basis for royalty value. They claim that imbalances are inevitable.

*Response.* We recognize that some imbalances occur. In cash-out situations, we will allow lessees within tolerance to determine value using that pipeline's specified rate. However, cash-out imbalances outside the tolerance and scheduling, imbalance, and operational penalties are costs incurred as a result of the lessee breaching its duty to market the production to the mutual benefit of the lessee and the lessor. These costs are marketing expenses the lessee must bear because there are a variety of mitigating devices available to help the lessee balance production and nominations. These devices include:

- Swapping or transferring imbalances;
- Establishing debit/credit accounts;
- Using electronic bulletin boards to adjust for variations between deliveries and nominations;
- Using swing supply and flexible receipt point authority;
- Entering into predetermined allocation agreements; or
- Insisting upstream operators enter into operational balancing agreements with downstream transporters.

In the final rule, we disallow as a transportation deduction:

- Over-delivery cash-out penalties (§§ 206.157(g)(3)(i) and 206.177(g)(3)(i));
- Scheduling penalties (§§ 206.157(g)(3)(ii) and 206.177(g)(3)(ii));
- Imbalance penalties (§§ 206.157(g)(3)(iii) and 206.177(g)(3)(iii)); and
- Operational penalties (§§ 206.157(g)(3)(iv) and 206.177(g)(3)(iv)).

*Comments on §§ 206.157(g)(4) and 206.177(g)(4) Intra-hub transfer fees.*

We received no comments from any Indian tribes or associations or States regarding intra-hub transfer fees.

Four industry trade associations and three companies offered the following responses. Several industry respondents stated that these fees track the ownership of the gas through the pipeline and MMS should consider these fees as part of the transportation cost. One industry trade association stated that if these fees are not deductible because it is the duty of the lessee to perform these services at no cost to the lessor, then MMS is implying that the small producer that doesn't provide this service is breaching its duty. Most industry commenters believe MMS should allow these fees because they are essential to efficient management of transportation and are necessary to transport gas through a hub. These commenters state that disallowing intra-hub transfer fees unjustly punishes aggressive marketers seeking to get the highest price.

*Response.* Intra-hub transfer fees are administrative costs and not actual costs of gas transportation. We disallow these fees as part of the transportation allowance in §§ 206.157(g)(4) and 206.177(g)(4).

*Comments on §§ 206.157(g)(5) and 206.177(g)(5) Other nonallowable costs.*

One Indian tribal association emphatically agrees that marketing costs are solely the province and duty of the producer. They stated that no deductions against royalties should be permitted for marketing costs. One State/Indian association, one tribe, and one State particularly support MMS's proposal on other nonallowable costs.

Two industry trade associations and four companies responded to this issue. All respondents believe that these costs, previously bundled prior to FERC Order 636, should be allowed. Several respondents claim that all these charges were allowable transportation costs for decades and, while it may now be easier for us to examine pipeline tariffs, we always had the ability to do so. These respondents believe that disallowing such costs creates a new obligation. Several industry commenters claim that MMS's concern about lessees relabelling or restructuring nondeductible costs as transportation costs is unfounded and unfair. Most commenters believe that this section will make it difficult for the lessee to determine which costs are allowable and nonallowable and prevents a fair examination of a particular fee's acceptance as a transportation expense.

*Response.* MMS has never allowed marketing costs as deductions from royalty value and maintains this position in the final rule. The fact that these costs were embedded in a bundled charge does not mean that we allow such charges. In the FERC Order 636 environment, component costs previously aggregated are now separately identified in transportation contracts. Some of these component costs are clearly costs of marketing and we continue to consider these as nonallowable costs under §§ 206.157(g)(5) and 206.177(g)(5) as we have always done.

## III. Other Matters

*Retroactive Effective Date*

Six companies and six industry trade associations strongly disagree with the retroactive effective date of May 18, 1992. Industry believes that the rule is not merely a clarification but rather a substantive rule that creates a whole new duty to market. They state that without this rule we have no clear authority to collect royalties on several of the issues under this rule and that it is a radical departure from MMS's past practice and standards.

Industry maintains that we cannot legally apply the rule retroactively for the following reasons:

- We have not been delegated authority to retroactively apply rules;
- Retroactivity is against the Administrative Procedures Act,
- It is unlawful;
- Retroactivity is against MMS's policy of prospective rulemaking only; and
- We are barred from action without specific Congressional authority.

Finally, industry believes that they should not be penalized for MMS's 4-year lack of instruction and that retroactivity will be an excessive administrative burden. In addition, industry claims that data may not exist for prior periods or cannot be recreated and that retroactivity will require lessees to go to the burnertip to chase charges such as intra-hub title transfer fees and aggregator/marketer fees.

*Response.* Based on advice provided by the Department of the Interior's Office of the Solicitor, we have determined that MMS does not have express statutory authority to implement a retroactive effective date for this rule. However, we disagree that this is a substantive rule that changes or increases our existing authority and policies. This rule merely clarifies and codifies long standing MMS policies in terms of the revised FERC vernacular. Therefore, MMS is making this final rule effective February 1, 1998.

*Indian Leases*

One tribe and one Indian tribal association strongly recommend that separate transportation regulations should be adopted for Indian leases. Because Federal and Indian lease terms differ, these commenters believe that while excessive transportation deductions may be allowed for Federal leases, such deductions should not be allowed for Indian leases. They stated that this proposal does not recognize the narrower permissibility of deductions under Indian lease terms and that we should recognize the propriety of treating tribal leases different from Federal leases. In addition, one Indian tribal association stated that the Secretary's trust responsibility and duty to maximize revenues to Indian mineral owners compel us to protect Indian royalties from being subjected to transportation allowances that are not contemplated in the lease.

We received no specific comments from industry respondents on the subject of separate regulations for Indian gas.

*Response.* Although we recently separated existing valuation and transportation regulations into individual sections for Federal and Indian leases, the principles used to determine both value and transportation were not changed. This rule is written to insert pertinent individual paragraphs into the separate sections for Federal and Indian leases. We will not publish a separate rule for Indian leases. If we finalize new regulations for gas valuation on Indian leases, this rulemaking may be superseded for Indian lands.

## IV. Procedural Matters

*The Regulatory Flexibility Act*

The Department certifies that this rule will not have a significant economic effect on a substantial number of small entities under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*). Approximately 2,600 entities pay royalties to MMS on production from Federal and Indian lands and the majority of these entities are small businesses because they employ 500 or less employees. However, this rule will not significantly impact these small businesses because this rule does not add any reporting or valuation requirements. Likewise, this regulation will not significantly or uniquely affect small governments because the rule will not change the valuation principles embodied in existing regulations. The sole purpose of this rule is to clarify which costs are allowable transportation deductions or nonallowable marketing costs.

*Executive Order 12630*

The Department certifies that the rule does not represent a governmental action capable of interference with constitutionally protected property rights. Thus, there is no need to prepare a Takings Implication Assessment under Executive Order 12630, ''Governmental Actions and Interference with Constitutionally Protected Property Rights.''

*Executive Order 12866*

This rule has been reviewed under Executive Order 12866 and is not a significant regulatory action. MMS estimates that this rule may result in a maximum of $3.37 million in additional royalties collected annually. However, this maximum revenue impact is based on the assumption that all tariffs for all Federal and Indian leases contained a nonallowable deduction of $0.01/MMBtu for a fee such as a intra-hub transfer fee.

*Executive Order 12988*

The Department has certified to OMB that this regulation meets the applicable standards provided in Section 3(a) and 3(b)(2) of E.O. 12988.

*Unfunded Mandates Reform Act of 1995*

The Department of the Interior has determined and certifies according to the Unfunded Mandates Reform Act, 2 U.S.C. 1502 *et seq.*, that this rule will not impose a cost of $100 million or more in any given year on local, tribal, State governments, or the private sector. A mandate is a legal, statutory, or regulatory provision that imposes an enforceable duty. A mandate does not include duties arising from participation in a voluntary Federal program. MMS funds audits performed by State and Indian auditors under voluntary cooperative agreements. Since participation in these cooperative agreements is voluntary and this rule will not require additional monies to perform audits of FERC-approved tariffs, no Federal mandates will be imposed on State, local, or tribal governments.

*Paperwork Reduction Act*

This rule has been examined under the Paperwork Reduction Act of 1995 and has been found to contain no new reporting or information collection requirements.

*National Environmental Policy Act of 1969*

We have determined that this rulemaking is not a major Federal Action significantly affecting the quality of the human environment, and a detailed statement under section 102(2)(C) of the National Environmental Policy Act of 1969 (42 U.S.C. 4332(2)(C)) is not required.

**List of Subjects in 30 CFR 206**

Coal, Continental Shelf, Geothermal energy, Government contracts, Indian lands, Mineral royalties, Natural gas, Petroleum, Public lands—mineral resources, Reporting and recordkeeping requirements.

Dated: December 3, 1997.

**Bob Armstrong,**

*Assistant Secretary—Land and Minerals Management.*

For the reasons set out in the preamble, MMS amends 30 CFR part 206 as follows:

## PART 206—PRODUCT VALUATION

1. The authority citation for part 206 continues to read as follows:

**Authority:** 5 U.S.C. 301 *et seq.*; 25 U.S.C. 396 *et seq.*, 396a *et seq.*, 2101 *et seq.*; 30 U.S.C. 181 *et seq.*, 351 *et seq.*, 1001 *et seq.*, 1701 *et seq.*; 31 U.S.C. 9701; 43 U.S.C. 1301 *et seq.*, 1331 *et seq.*, and 1801 *et seq.*

## Subpart D—Federal Gas

2. Section 206.152 is amended by revising the first sentence of paragraph (b)(1)(i) and adding a new paragraph (b)(1)(iv) to read as follows:

**§ 206.152 Valuation standards—unprocessed gas.**

* * * * *

(b)(1)(i) The value of gas sold under an arm's-length contract is the gross proceeds accruing to the lessee except as provided in paragraphs (b)(1)(ii), (iii), and (iv) of this section. * * *

* * * * *

(iv) *How to value over-delivered volumes under a cash-out program.* This paragraph applies to situations where a pipeline purchases gas from a lessee according to a cash-out program under a transportation contract. For all over-delivered volumes, the royalty value is the price the pipeline is required to pay

for volumes within the tolerances for over-delivery specified in the transportation contract. Use the same value for volumes that exceed the over-delivery tolerances even if those volumes are subject to a lower price under the transportation contract. However, if MMS determines that the price specified in the transportation contract for over-delivered volumes is unreasonably low, the lessee must value all over-delivered volumes under paragraph (c)(2) or (c)(3) of this section.

* * * * *

5. Section 206.153, paragraph (i) is revised to read as follows:

**§ 206.152 Valuation standards—unprocessed gas.**

* * * * *

(i) The lessee must place gas in marketable condition and market the gas for the mutual benefit of the lessee and the lessor at no cost to the Federal Government. Where the value established under this section is determined by a lessee's gross proceeds, that value will be increased to the extent that the gross proceeds have been reduced because the purchaser, or any other person, is providing certain services the cost of which ordinarily is the responsibility of the lessee to place the gas in marketable condition or to market the gas.

* * * * *

4. Section 206.153 is amended by revising the first sentence of paragraph (b)(1)(i) and adding a new paragraph (b)(1)(iv) to read as follows:

**§ 206.153 Valuation standards—processed gas.**

* * * * *

(b)(1)(i) The value of residue gas or any gas plant product sold under an arm's-length contract is the gross proceeds accruing to the lessee, except as provided in paragraphs (b)(1)(ii), (iii), and (iv) of this section. * * *

* * * * *

(iv) *How to value over-delivered volumes under a cash-out program.* This paragraph applies to situations where a pipeline purchases gas from a lessee according to a cash-out program under a transportation contract. For all over-delivered volumes, the royalty value is the price the pipeline is required to pay for volumes within the tolerances for over-delivery specified in the transportation contract. Use the same value for volumes that exceed the over-delivery tolerances even if those volumes are subject to a lower price under the transportation contract. However, if MMS determines that the price specified in the transportation contract for over-delivered volumes is unreasonably low, the lessee must value all over-delivered volumes under paragraph (c)(2) or (c)(3) of this section.

* * * * *

5. Section 206.153, paragraph (i), is revised to read as follows:

**§ 206.153 Valuation standards—processed gas.**

* * * * *

(i) The lessee must place residue gas and gas plant products in marketable condition and market the residue gas and gas plant products for the mutual benefit of the lessee and the lessor at no cost to the Federal Government. Where the value established under this section is determined by a lessee's gross proceeds, that value will be increased to the extent that the gross proceeds have been reduced because the purchaser, or any other person, is providing certain services the cost of which ordinarily is the responsibility of the lessee to place the residue gas or gas plant products in marketable condition or to market the residue gas and gas plant products.

* * * * *

6. In § 206.157, paragraph (f) is removed; paragraph (g) is redesignated as paragraph (h) and revised; and new paragraphs (f) and (g) are added to read as follows:

**§ 206.157 Determination of transportation allowances.**

* * * * *

(f) *Allowable costs in determining transportation allowances.* Lessees may include, but are not limited to, the following costs in determining the arm's-length transportation allowance under paragraph (a) of this section or the non-arm's-length transportation allowance under paragraph (b) of this section:

(1) *Firm demand charges paid to pipelines.* You must limit the allowable costs for the firm demand charges to the applicable rate per MMBtu multiplied by the actual volumes transported. You may not include any losses incurred for previously purchased but unused firm capacity. You also may not include any gains associated with releasing firm capacity. If you receive a payment or credit from the pipeline for penalty refunds, rate case refunds, or other reasons, you must reduce the firm demand charge claimed on the Form MMS–2014. You must modify the Form MMS–2014 by the amount received or credited for the affected reporting period;

(2) *Gas supply realignment (GSR) costs.* The GSR costs result from a pipeline reforming or terminating supply contracts with producers to implement the restructuring requirements of FERC Orders in 18 CFR part 284;

(3) *Commodity charges.* The commodity charge allows the pipeline to recover the costs of providing service;

(4) *Wheeling costs.* Hub operators charge a wheeling cost for transporting gas from one pipeline to either the same or another pipeline through a market center or hub. A hub is a connected manifold of pipelines through which a series of incoming pipelines are interconnected to a series of outgoing pipelines;

(5) *Gas Research Institute (GRI) fees.* The GRI conducts research, development, and commercialization programs on natural gas related topics for the benefit of the U.S. gas industry and gas customers. GRI fees are allowable provided such fees are mandatory in FERC-approved tariffs;

(6) *Annual Charge Adjustment (ACA) fees.* FERC charges these fees to pipelines to pay for its operating expenses;

(7) *Payments (either volumetric or in value) for actual or theoretical losses.* This paragraph does not apply to non-arm's-length transportation arrangements unless the transportation allowance is based on a FERC or State regulatory-approved tariff;

(8) *Temporary storage services.* This includes short duration storage services offered by market centers or hubs (commonly referred to as ''parking'' or ''banking''), or other temporary storage services provided by pipeline transporters, whether actual or provided as a matter of accounting. Temporary storage is limited to 30 days or less; and

(9) *Supplemental costs for compression, dehydration, and treatment of gas.* MMS allows these costs only if such services are required for transportation and exceed the services necessary to place production into marketable condition required under §§ 206.152(i) and 206.153(i) of this part.

(g) *Nonallowable costs in determining transportation allowances.* Lessees may not include the following costs in determining the arm's-length transportation allowance under paragraph (a) of this section or the non-arm's-length transportation allowance under paragraph (b) of this section:

(1) *Fees or costs incurred for storage.* This includes storing production in a storage facility, whether on or off the lease, for more than 30 days;

(2) *Aggregator/marketer fees.* This includes fees you pay to another person (including your affiliates) to market your gas, including purchasing and reselling the gas, or finding or

maintaining a market for the gas production;

(3) *Penalties you incur as shipper.* These penalties include, but are not limited to:

(i) *Over-delivery cash-out penalties.* This includes the difference between the price the pipeline pays you for over-delivered volumes outside the tolerances and the price you receive for over-delivered volumes within the tolerances;

(ii) *Scheduling penalties.* This includes penalties you incur for differences between daily volumes delivered into the pipeline and volumes scheduled or nominated at a receipt or delivery point;

(iii) *Imbalance penalties.* This includes penalties you incur (generally on a monthly basis) for differences between volumes delivered into the pipeline and volumes scheduled or nominated at a receipt or delivery point; and

(iv) *Operational penalties.* This includes fees you incur for violation of the pipeline's curtailment or operational orders issued to protect the operational integrity of the pipeline;

(4) *Intra-hub transfer fees.* These are fees you pay to hub operators for administrative services (e.g., title transfer tracking) necessary to account for the sale of gas within a hub; and

(5) *Other nonallowable costs.* Any cost you incur for services you are required to provide at no cost to the lessor.

(h) *Other transportation cost determinations.* Use this section when calculating transportation costs to establish value using a netback procedure or any other procedure that requires deduction of transportation costs.

## Subpart E—Indian Gas

7. Section 206.172 is amended by revising the first sentence of paragraph (b)(1)(i) and adding a new paragraph (b)(1)(iv) to read as follows:

**§ 206.172 Valuation standards—unprocessed gas.**

* * * * *

(b)(1)(i) The value of gas sold under an arm's-length contract is the gross proceeds accruing to the lessee, except as provided in paragraphs (b)(1)(ii), (iii), and (iv) of this section. * * *

* * * * *

(iv) *How to value over-delivered volumes under a cash-out program.* This paragraph applies to situations where a pipeline purchases gas from a lessee according to a cash-out program under a transportation contract. For all over-delivered volumes, the royalty value is the price the pipeline is required to pay for volumes within the tolerances for over-delivery specified in the transportation contract. Use the same value for volumes that exceed the over-delivery tolerances even if those volumes are subject to a lower price under the transportation contract. However, if MMS determines that the price specified in the transportation contract for over-delivered volumes is unreasonably low, the lessee must value all over-delivered volumes under paragraph (c)(2) or (c)(3) of this section.

* * * * *

8. Section 206.172, paragraph (i), is revised to read as follows:

**§ 206.172 Valuation standards—unprocessed gas.**

* * * * *

(i) The lessee must place gas in marketable condition and market the gas for the mutual benefit of the lessee and the lessor at no cost to the Indian lessor. Where the value established under this section is determined by a lessee's gross proceeds, that value will be increased to the extent that the gross proceeds have been reduced because the purchaser, or any other person, is providing certain services the cost of which ordinarily is the responsibility of the lessee to place the gas in marketable condition or to market the gas.

* * * * *

9. Section 206.173 is amended by revising the first sentence of paragraph (b)(1)(i) and adding a new paragraph (b)(1)(iv) to read as follows:

**§ 206.173 Valuation standards-processed gas.**

* * * * *

(b)(1)(i) The value of residue gas or any gas plant product sold under an arm's-length contract is the gross proceeds accruing to the lessee, except as provided in paragraphs (b)(1)(ii), (iii), and (iv) of this section.

* * * * *

(iv) *How to value over-delivered volumes under a cash-out program.* This paragraph applies to situations where a pipeline purchases gas from a lessee according to a cash-out program under a transportation contract. For all over-delivered volumes, the royalty value is the price the pipeline is required to pay for volumes within the tolerances for over-delivery specified in the transportation contract. Use the same value for volumes that exceed the over-delivery tolerances even if those volumes are subject to a lower price under the transportation contract. However, if MMS determines that the price specified in the transportation contract for over-delivered volumes is unreasonably low, the lessee must value all over-delivered volumes under paragraph (c)(2) or (c)(3) of this section.

* * * * *

10. Section 206.173, paragraph (i), is revised to read as follows:

**§ 206.173 Valuation standards—processed gas.**

* * * * *

(i) The lessee must place residue gas and gas plant products in marketable condition and market the residue gas and gas plant products for the mutual benefit of the lessee and the lessor at no cost to the Indian lessor. Where the value established under this section is determined by a lessee's gross proceeds, that value will be increased to the extent that the gross proceeds have been reduced because the purchaser, or any other person, is providing certain services the cost of which ordinarily is the responsibility of the lessee to place the residue gas or gas plant products in marketable condition or to market the residue gas and gas plant products.

* * * * *

11. In § 206.177, paragraph (f) is removed; paragraph (g) is redesignated as paragraph (h) and revised; and new paragraphs (f) and (g) are added to read as follows:

**§ 206.177 Determination of transportation allowances.**

* * * * *

(f) *Allowable costs in determining transportation allowances.* Lessees may include, but are not limited to, the following costs in determining the arm's-length transportation allowance under paragraph (a) of this section or the non-arm's-length transportation allowance under paragraph (b) of this section:

(1) *Firm demand charges paid to pipelines.* You must limit the allowable costs for the firm demand charges to the applicable rate per MMBtu multiplied by the actual volumes transported. You may not include any losses incurred for previously purchased but unused firm capacity. You also may not include any gains associated with releasing firm capacity. If you receive a payment or credit from the pipeline for penalty refunds, rate case refunds, or other reasons, you must reduce the firm demand charge claimed on the Form MMS–2014. You must modify the Form MMS–2014 by the amount received or credited for the affected reporting period;

(2) *Gas supply realignment (GSR) costs.* The GSR costs result from a pipeline reforming or terminating supply contracts with producers to

implement the restructuring requirements of FERC Orders in 18 CFR part 284;

(3) *Commodity charges.* The commodity charge allows the pipeline to recover the costs of providing service;

(4) *Wheeling costs.* Hub operators charge a wheeling cost for transporting gas from one pipeline to either the same or another pipeline through a market center or hub. A hub is a connected manifold of pipelines through which a series of incoming pipelines are interconnected to a series of outgoing pipelines;

(5) *Gas Research Institute (GRI) fees.* The GRI conducts research, development, and commercialization programs on natural gas related topics for the benefit of the U.S. gas industry and gas customers. GRI fees are allowable provided such fees are mandatory in FERC-approved tariffs;

(6) *Annual Charge Adjustment (ACA) fees.* FERC charges these fees to pipelines to pay for its operating expenses;

(7) *Payments (either volumetric or in value) for actual or theoretical losses.* This paragraph does not apply to non-arm's-length transportation arrangements unless the transportation allowance is based on a FERC or State regulatory-approved tariff;

(8) *Temporary storage services.* This includes short duration storage services offered by market centers or hubs (commonly referred to as ''parking'' or ''banking''), or other temporary storage services provided by pipeline transporters, whether actual or provided as a matter of accounting. Temporary storage is limited to 30 days or less; and

(9) *Supplemental costs for compression, dehydration, and treatment of gas.* MMS allows these costs only if such services are required for transportation and exceed the services necessary to place production into marketable condition required under §§ 206.172(i) and 206.173(i) of this part.

(g) *Nonallowable costs in determining transportation allowances.* Lessees may not include the following costs in determining the arm's-length transportation allowance under paragraph (a) of this section or the non-arm's-length transportation allowance under paragraph (b) of this section:

(1) *Fees or costs incurred for storage.* This includes storing production in a storage facility, whether on or off the lease, for more than 30 days;

(2) *Aggregator/marketer fees.* This includes fees you pay to another person (including your affiliates) to market your gas, including purchasing and reselling the gas, or finding or maintaining a market for the gas production;

(3) *Penalties you incur as shipper.* These penalties include, but are not limited to:

(i) *Over-delivery cash-out penalties.* This includes the difference between the price the pipeline pays you for over-delivered volumes outside the tolerances and the price you receive for over-delivered volumes within the tolerances;

(ii) *Scheduling penalties.* This includes penalties you incur for differences between daily volumes delivered into the pipeline and volumes scheduled or nominated at a receipt or delivery point;

(iii) *Imbalance penalties.* This includes penalties you incur (generally on a monthly basis) for differences between volumes delivered into the pipeline and volumes scheduled or nominated at a receipt or delivery point; and

(iv) *Operational penalties.* This includes fees you incur for violation of the pipeline's curtailment or operational orders issued to protect the operational integrity of the pipeline;

(4) *Intra-hub transfer fees.* These are fees you pay to hub operators for administrative services (e.g., title transfer tracking) necessary to account for the sale of gas within a hub; and

(5) *Other nonallowable costs.* Any cost you incur for services you are required to provide at no cost to the lessor.

(h) *Other transportation cost determinations.* Use this section when calculating transportation costs to establish value using a netback procedure or any other procedure that requires deduction of transportation costs.

[FR Doc. 97–32802 Filed 12–15–97; 8:45 am]

BILLING CODE 4310–MR–P

## FEDERAL COMMUNICATIONS COMMISSION

### 47 CFR Part 73

**[MM Docket No. 97–162; RM–9112]**

### Radio Broadcasting Services; Hutchinson, KS

**AGENCY:** Federal Communications Commission.

**ACTION:** Final rule.

**SUMMARY:** The Commission, at the request of Gary L. Violet, allots Channel 240A at Hutchinson, Kansas. *See* 62 FR 41016, July 31,1997. Channel 240A can be allotted to Hutchinson in compliance with the Commission's minimum distance separation requirements without the imposition of a site restriction. The coordinates for Channel 240A at Hutchinson are 38–04–54 NL and 97–55–42 WL. With this action, this proceeding is terminated.

**DATES:** Effective January 20, 1998. A filing window for Channel 240A at Hutchinson, Kansas, will not be opened at this time. Instead, the issue of opening a filing window for this channel will be addressed by the Commission in a subsequent order.

**FOR FURTHER INFORMATION CONTACT:** Pam Blumenthal, Mass Media Bureau, (202) 418–2180.

**SUPPLEMENTARY INFORMATION:** This is a synopsis of the Commission's Report and Order, MM Docket No. 97–162, adopted November 5, 1997, and released December 5, 1997. The full text of this Commission decision is available for inspection and copying during normal business hours in the FCC Reference Center (Room 239), 1919 M Street, NW, Washington, DC. The complete text of this decision may also be purchased from the Commission's copy contractor, ITS, 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, 336.

**§ 73.202 [Amended]**

2. Section 73.202(b), the Table of FM Allotments under Kansas, is amended by adding Channel 240A at Hutchinson.

Federal Communications Commission.

**John A. Karousos,**

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

[FR Doc. 97–32702 Filed 12–15–97; 8:45 am]

BILLING CODE 6712–01–F

## FEDERAL COMMUNICATIONS COMMISSION

### 47 CFR Part 73

**[MM Docket No. 97–32; RM–8931; RM–9065]**

### Radio Broadcasting Services; Calico Rock and Leslie, AR

**AGENCY:** Federal Communications Commission.

**ACTION:** Final rule.

**SUMMARY:** This document allots FM Channel 246A to Calico Rock, Arkansas, as that community's first local aural transmission service in response to a petition filed on behalf of Sugarloaf Broadcasting. *See* 62 FR 04227, January 29, 1997. Coordinates used for Channel 246A at Calico Rock are 36–05–01 and 92–09–26. A counterproposal filed on behalf of Leslie Broadcasters, seeking the allotment of Channel 246C2 to Leslie, Arkansas, as that community's first local aural transmission service is denied (RM–9065).

Our determination was reached after comparatively evaluating each proposal. That analysis revealed that each community receives at least five full-time aural reception services. Therefore, Calico Rock was preferred as it is the larger community. With this action, the proceeding is terminated.

**DATES:** Effective January 20, 1998. A filing window for Channel 246A at Calico Rock, Arkansas, will not be opened at this time. Instead, the issue of opening a filing window for this channel will be addressed by the Commission in a subsequent Order.

**FOR FURTHER INFORMATION CONTACT:** Nancy Joyner, Mass Media Bureau, (202) 418–2180. Questions related to the window application filing process should be addressed to the Audio Services Division, (202) 418–2700.

**SUPPLEMENTARY INFORMATION:** This is a synopsis of the Commission's Report and Order, MM Docket No. 97–32, adopted November 5, 1997, and released December 5, 1997. The full text of this Commission decision is available for inspection and copying during normal business hours in the FCC's Reference Center (Room 239), 1919 M Street, NW., Washington, DC. The complete text of this decision may also be purchased from the Commission's copy contractor, International Transcription Service, Inc., 1231 20th Street, NW., Washington, DC 20036, (202) 857–3800.

### 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, 336.

### § 73.202 [Amended]

2. Section 73.202(b), the Table of FM Allotments under Arkansas, is amended by adding Calico Rock, Channel 246A.

Federal Communications Commission.

**John A. Karousos,**

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

[FR Doc. 97–32706 Filed 12–15–97; 8:45 am]

BILLING CODE 6712–01–F

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## FEDERAL COMMUNICATIONS COMMISSION

## 47 CFR Part 73

**[MM Docket No. 97–34; RM–8938]**

## Radio Broadcasting Services; Saint Paul, AR

**AGENCY:** Federal Communications Commission.

**ACTION:** Final rule.

**SUMMARY:** This document allots Channel 287A to Saint Paul, Arkansas, as that community's first local aural transmission service in response to a petition filed on behalf of Saint Paul Broadcasting. *See* 62 FR 4225, January 29, 1997. Coordinates used for Channel 287A at Saint Paul, Arkansas, are 35–48–14 and 93–37–00. With this action, the proceeding is terminated.

**DATES:** Effective January 20, 1998. A filing window for Channel 287A at Saint Paul, Arkansas, will not be opened at this time. Instead, the issue of opening a filing window for this channel will be addressed by the Commission in a subsequent Order.

**FOR FURTHER INFORMATION CONTACT:** Nancy Joyner, Mass Media Bureau, (202) 418–2180. Questions related to the window application filing process should be addressed to the Audio Services Division, (202) 418–2700.

**SUPPLEMENTARY INFORMATION:** This is a synopsis of the Commission's Report and Order, MM Docket No. 97–34, adopted November 5, 1997, and released December 5, 1997. The full text of this Commission decision is available for inspection and copying during normal business hours in the FCC's Reference Center (Room 239), 1919 M Street, NW., Washington, DC. The complete text of this decision may also be purchased from the Commission's copy contractor, International Transcription Service, Inc., 1231 20th Street, NW., Washington, DC 20036, (202) 857–3800.

### 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, 336.

### § 73.202 [Amended]

2. Section 73.202(b), the Table of FM Allotments under Arkansas, is amended by adding Saint Paul, Channel 287A.

Federal Communications Commission.

**John A. Karousos,**

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

[FR Doc. 97–32707 Filed 12–15–97; 8:45 am]

BILLING CODE 6712–01–F

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## FEDERAL COMMUNICATIONS COMMISSION

## 47 CFR Part 73

**[MM Docket No. 97–114; RM–9059]**

## Radio Broadcasting Services; Dassel and Hutchinson, MN

**AGENCY:** Federal Communications Commission.

**ACTION:** Final rule.

**SUMMARY:** Action in this document substitutes Channel 295C3 for Channel 296A at Hutchinson, Minnesota, reallots Channel 295C3 to Dassel, Minnesota, and modifies the license for Station KKJR to specify operation on Channel 295C3 at Dassel in response to a petition filed by North American Broadcasting Co., Inc. *See* 62 FR 18558, April 16, 1997. The coordinates for Channel 295C3 at Dassel are 45–08–30 and 94–26–00. With this action, this proceeding is terminated.

**DATES:** Effective January 20, 1998.

**FOR FURTHER INFORMATION CONTACT:** Kathleen Scheuerle, Mass Media Bureau, (202) 418–2180.

**SUPPLEMENTARY INFORMATION:** This is a summary of the Commission's Report and Order, MM Docket No. 97–114, adopted November 19, 1997, and released December 5, 1997. The full text of this Commission decision is available for inspection and copying during normal business hours in the Commission's Reference Center (Room 239), 1919 M Street, NW, Washington, DC. The complete text of this decision may also be purchased from the Commission's copy contractors, International Transcription Services, Inc., 2131 20th Street, NW., Washington, DC. 20036, (202) 857–3800, facsimile (202) 857–3805.

### 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, 336.

**§ 73.202 [Amended]**

2. Section 73.202(b), the Table of FM Allotments under Minnesota, is amended by removing Channel 296A and Hutchinson and adding Dassel and Channel 295C3.

Federal Communications Commission.

**John A. Karousos,**

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

[FR Doc. 97–32705 Filed 12–15–97; 8:45 am]

BILLING CODE 6712–01–F

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## FEDERAL COMMUNICATIONS COMMISSION

## 47 CFR Part 73

**[MM Docket No. 97–124; RM–9073]**

## Radio Broadcasting Services; Blue Lake, CA

**AGENCY:** Federal Communications Commission.

**ACTION:** Final rule.

**SUMMARY:** This document allots Channel 292A to Blue Lake, California, as that community's first local aural transmission service, in response to a petition for rule making filed by Vixon Valley Broadcasting. *See* 62 FR 23427, April 30, 1997. Coordinates used for Channel 292A at Blue Lake, California, are 40–52–54 and 123–59–12. With this action, the proceeding is terminated.

**DATES:** Effective January 20, 1998. A filing window for Channel 292A at Blue Lake, California, will not be opened at this time. Instead, the issue of opening a filing window for this channel will be addressed by the Commission in a separate Order.

**FOR FURTHER INFORMATION CONTACT:** Nancy Joyner, Mass Media Bureau, (202) 418–2180. Questions related to the window application filing process should be addressed to the Audio Services Division, (202) 418–2700.

**SUPPLEMENTARY INFORMATION:** This is a synopsis of the Commission's Report and Order, MM Docket No. 97–124, adopted October 8, 1997, and released December 5, 1997. The full text of this Commission decision is available for inspection and copying during normal business hours in the FCC's Reference Center (Room 239), 1919 M Street, NW., Washington, DC. The complete text of this decision may also be purchased from the Commission's copy contractor, International Transcription Service, Inc., 1231 20th Street, NW., Washington, DC 20036, (202) 857–3800.

**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 reads as follows:

**Authority:** 47 U.S.C. 154, 303, 334, 336.

**§ 73.202 [Amended]**

2. Section 73.202(b), the Table of FM Allotments under California, is amended by adding Blue Lake, Channel 292A.

Federal Communications Commission.

**John A. Karousos,**

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

[FR Doc. 97–32704 Filed 12–15–97; 8:45 am]

BILLING CODE 6712–01–F

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## FEDERAL COMMUNICATIONS COMMISSION

## 47 CFR Part 73

**[MM Docket No. 96–215; RM–8898, RM–8924]**

## Radio Broadcasting Services; Anamosa and Asbury, IA

**AGENCY:** Federal Communications Commission.

**ACTION:** Final rule.

**SUMMARY:** The Commission, at the request of Susan I. Coloff, allots Channel 239A at Anamosa as the community's first local aural transmission service. *See* 61 FR 57360, November 6, 1996. In response to a counterproposal (RM–8924) filed by Sports America Radio Network the Commission also allots Channel 238A at Asbury, Iowa. Channel 239A and Channel 238A can be allotted to Anamosa and Asbury, respectively, in compliance with the Commission's minimum distance separation requirements with site restrictions of 6 kilometers west for Channel 239A at Anamosa and 6 kilometers east for Channel 238A at Asbury. The coordinates for Channel 239A at Anamosa are 42–05–40 NL and 91–21–18 WL. The coordinates for Channel 238A at Asbury are 42–30–18 NL and 90–40–46 WL. With this action, this proceeding is terminated.

**DATES:** Effective January 20, 1998. The filing window for Channel 239A at Anamosa and Channel 238A at Asbury will not be opened at this time. Instead, the issue of opening a filing window for these channels will be addressed by the Commission in a subsequent order.

**FOR FURTHER INFORMATION CONTACT:** Pam Blumenthal, Mass Media Bureau, (202) 418–2180.

**SUPPLEMENTARY INFORMATION:** This is a synopsis of the Commission's Report and Order, MM Docket No. 96–215, adopted November 26, 1997, and released December 5, 1997. The full text of this Commission decision is available for inspection and copying during normal business hours in the FCC Reference Center (Room 239), 1919 M Street, NW, Washington, DC. The complete text of this decision may also be purchased from the Commission's copy contractor, ITS, 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, 336.

**§ 73.202 [Amended]**

2. Section 73.202(b), the Table of FM Allotments under Iowa, is amended by adding Anamosa, Channel 239A and by adding Channel 238A at Asbury.

Federal Communications Commission.

**John A. Karousos,**

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

[FR Doc. 97–32703 Filed 12–15–97; 8:45 am]

BILLING CODE 6712–01–F

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## FEDERAL COMMUNICATIONS COMMISSION

## 47 CFR Part 73

**[MM Docket No. 97–109; RM–9018]**

## Radio Broadcasting Services; Eckley, CO

**AGENCY:** Federal Communications Commission.

**ACTION:** Final rule.

**SUMMARY:** This document allots Channel 237C1 to Eckley, Colorado, as that community's first local aural

transmission service, in response to a petition for rule making filed by KRDZ Broadcasters, Inc.. *See* 62 FR 17773, April 11, 1997. Coordinates used for Channel 237C1 at Eckley, Colorado, are 40–06–48 and 102–29–18. With this action, the proceeding is terminated.

**DATES:** Effective January 20, 1998. A filing window for Channel 237C1 at Eckley, Colorado, will not be opened at this time. Instead, the issue of opening a filing window for this channel will be addressed by the Commission in a subsequent Order.

**FOR FURTHER INFORMATION CONTACT:** Nancy Joyner, Mass Media Bureau, (202) 418–2180. Questions related to the window application filing process should be addressed to the Audio Services Division, (202) 418–2700.

**SUPPLEMENTARY INFORMATION:** This is a synopsis of the Commission's Report and Order, MM Docket No. 97–109, adopted November 5, 1997, and released December 5, 1997. The full text of this Commission decision is available for inspection and copying during normal business hours in the FCC's Reference Center (Room 239), 1919 M Street, NW., Washington, DC. The complete text of this decision may also be purchased from the Commission's copy contractor, International Transcription Service, Inc., 1231 20th Street, NW., Washington, DC 20036, (202) 857–3800.

## 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 reads as follows:

**Authority:** 47 U.S.C. 154, 303, 334, 336.

### § 73.202 [Amended]

2. Section 73.202(b), the Table of FM Allotments under Colorado, is amended by adding Eckley, Channel 237C1.

Federal Communications Commission.

**John A. Karousos,**

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

[FR Doc. 97–32700 Filed 12–15–97; 8:45 am]

BILLING CODE 6712–01–F

# Proposed Rules

Federal Register
Vol. 62, No. 241
Tuesday, December 16, 1997

This section of the FEDERAL REGISTER contains notices to the public of the proposed issuance of rules and regulations. The purpose of these notices is to give interested persons an opportunity to participate in the rule making prior to the adoption of the final rules.

## DEPARTMENT OF TRANSPORTATION

### Federal Aviation Administration

### 14 CFR Part 39

**[Docket No. 95–CE–71–AD]**

**RIN 2120–AA64**

## Airworthiness Directives; SOCATA-Groupe AEROSPATIALE Models TB10 and TB200 Airplanes

**AGENCY:** Federal Aviation Administration, DOT.

**ACTION:** Notice of proposed rulemaking (NPRM).

**SUMMARY:** This document proposes to adopt a new airworthiness directive (AD) that would apply to certain SOCATA-Groupe AEROSPATIALE (Socata) Models TB10 and TB200 airplanes. The proposed AD would require inspecting the wing rear attachment fittings for cracks, replacing any cracked fitting, and incorporating wing rear attachment fitting reinforcement kits. The proposed AD is the result of mandatory continued airworthiness information (MCAI) issued by the airworthiness authority for France. The actions specified by the proposed AD are intended to prevent structural failure of the wing rear attachment fittings caused by cracks in this area, which could result in a wing separating from the airplane with consequent loss of control of the airplane.

**DATES:** Comments must be received on or before January 11, 1998.

**ADDRESSES:** Submit comments in triplicate to the Federal Aviation Administration (FAA), Central Region, Office of the Regional Counsel, Attention: Rules Docket No. 95–CE–71–AD, Room 1558, 601 E. 12th Street, Kansas City, Missouri 64106. Comments may be inspected at this location between 8 a.m. and 4 p.m., Monday through Friday, holidays excepted. Service information that applies to the proposed AD may be obtained from the Socata-Groupe Aerospatiale, Socata Product Support, Aeroport Tarbes-Ossun-Lourdes, B P 930, 65009 Tarbes Cedex, France; telephone 62.41.74.26; facsimile 62.41.74.32; or the Product Support Manager, Socata-Groupe Aerospatiale, North Perry Airport, 7501 Pembroke Road, Pembroke Pines, Florida 33023; telephone (954) 964–6877; facsimile (954) 964–1668. This information also may be examined at the Rules Docket at the address above.

**FOR FURTHER INFORMATION CONTACT:** Mr. Karl Schletzbaum, Aerospace Engineer, FAA, Small Airplane Directorate, 1201 Walnut Street, suite 900, Kansas City, Missouri 64106; telephone (816) 426–6934; facsimile (816) 426–2169.

**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 should 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 notice may be changed in light of the comments received.

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 that summarizes 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 notice must submit a self-addressed, stamped postcard on which the following statement is made: ''Comments to Docket No. 95–CE–71–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, Central Region, Office of the Regional Counsel, Attention: Rules Docket No. 95–CE–71–AD, Room 1558, 601 E. 12th Street, Kansas City, Missouri 64106.

### Discussion

The Direction Generale de l'Aviation Civile (DGAC), which is the airworthiness authority for France, recently notified the FAA that an unsafe condition may exist on certain Socata Models TB10 and TB200 airplanes. The DGAC reports three incidents of cracks on the wing rear attachment fittings and one incident of rear wing attachment fitting deformation. These conditions, if not detected and corrected, could result in a wing separating from the airplane with consequent loss of control of the airplane.

### Relevant Service Information

Socata has issued Service Bulletin No. SB 10–082, Amdt. 1, dated April 1996, which specifies procedures for inspecting the wing rear attachment fittings for cracks. Also included in this service bulletin is reference to wing rear attachment fitting reinforcement kits that should be incorporated on the Socata Models TB10 and TB200 airplanes. The procedures for incorporating these reinforcement kits are in the technical instructions included with each kit.

The DGAC classified this service bulletin as mandatory and issued French AD 94–249(A)R1, dated June 19, 1996, in order to assure the continued airworthiness of these airplanes in France.

### The FAA's Determination

This airplane model is manufactured in France and is type certificated for operation in the United States under the provisions of section 21.29 of the Federal Aviation Regulations (14 CFR 21.29) and the applicable bilateral airworthiness agreement. Pursuant to this bilateral airworthiness agreement, the DGAC has kept the FAA informed of the situation described above.

The FAA has examined the findings of the DGAC; reviewed all available information, including the service information referenced above; and determined that AD action is necessary for products of this type design that are certificated for operation in the United States.

## Explanation of the Provisions of the Proposed AD

Since an unsafe condition has been identified that is likely to exist or develop in other Socata Models TB10 and TB200 airplanes of the same type design registered in the United States, the FAA is proposing AD action. The proposed AD would require inspecting the wing rear attachment fittings for cracks, replacing any cracked fitting, and incorporating wing rear attachment fitting reinforcement kits. Accomplishment of the proposed inspections would be in accordance with Socata Service Bulletin No. SB 10–082, Amdt. 1, dated April 1996. Accomplishment of the proposed reinforcement kits would be in accordance with the technical instructions included with each kit.

## Differences Between the French AD, the Service Bulletin, and This Proposed AD

French AD 94–249(A)R1, dated June 19, 1996, and Socata Service Bulletin No. SB 10–082, Amdt. 1, dated April 1996, both give the owners/operators of certain Models TB10 and TB200 airplanes the option of accomplishing one of the following if no cracks are found during the inspections:

—Incorporating the wing rear attachment fitting reinforcement kit No. OPT10 920300; or

—Reinspecting at certain intervals until cracks are found at which time the incorporation of a wing rear attachment fitting reinforcement kit would be mandatory.

The FAA's policy is to provide corrective action that will eliminate the need for repetitive inspections. The FAA has determined that long-term operational safety will be better assured by design changes that remove the source of the problem, rather than by repetitive inspections or other special procedures.

Because the incorporation of wing rear attachment fitting reinforcement kit No. OPT10 920300 on the affected airplanes eliminates the need for repetitive inspections, the proposed AD differs from the service bulletin and French AD in that it would mandate incorporation of two of these kits on each wing.

## Cost Impact

The FAA estimates that 71 airplanes in the U.S. registry would be affected by the proposed AD.

Accomplishing the actions of the proposed AD (both the inspection and incorporation of the reinforcement kits) would take approximately 11 workhours per airplane (3 workhours for the inspection of all four wing rear attachment fitting areas, and 2 workhours to incorporate the reinforcement kit at each of the four wing rear attachment fitting areas), at an average labor rate of approximately $60 an hour. Parts to accomplish the proposed AD cost approximately $200 per airplane ($50 per kit × 4 kits). Based on these figures, the total cost impact of the proposed initial inspection on U.S. operators is estimated to be $61,060 or $860 per airplane.

## Regulatory Impact

The regulations proposed herein would not have substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government. Therefore, in accordance with Executive Order 12612, it is determined that this proposal would not have sufficient federalism implications to warrant the preparation of a Federalism Assessment.

For the reasons discussed above, I certify that this action (1) is not a ''significant regulatory action'' under Executive Order 12866; (2) is not a ''significant rule'' under DOT Regulatory Policies and Procedures (44 FR 11034, February 26, 1979); and (3) 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 has been placed 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 USC 106(g), 40113, 44701.

### § 39.13 [Amended]

2. Section 39.13 is amended by adding a new airworthiness directive (AD) to read as follows:

**Socata-Groupe Aerospatiale:** Docket No. 95–CE–71–AD.

*Applicability:* Models TB10 and TB200 airplanes, serial numbers 804; 807; 808; 816 through 819; 823 through 1701; 1707 through 1733; and 1737 through 1761, 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 in the body of this AD, unless already accomplished.

To prevent structural failure of the rear wing attachment fittings caused by cracks in this area, which could result in a wing separating from the airplane with consequent loss of control of the airplane, accomplish the following:

**Note 2:** The compliance times of this AD are presented in landings instead of hours time-in-service (TIS). If the number of landings is unknown, hours TIS may be used by multiplying the number of hours TIS by 0.67.

**Note 3:** The paragraph structure of this AD is as follows:

Level 1: (a), (b), (c), etc.
Level 2: (1), (2), (3), etc.
Level 3: (i), (ii), (iii), etc.

Level 2 and Level 3 structures are designations of the Level 1 paragraph they immediately follow.

(a) Upon accumulating 3,000 landings on each wing rear attachment fitting (total of four; two per wing) or within the next 75 landings after the effective date of this AD, whichever occurs later, inspect the wing rear attachment fittings for cracks in accordance with the accomplishment instructions section of Socata Service Bulletin (SB) No. SB 10–082, mdt. 1, dated April 1996.

(1) If any fitting is found cracked on the wing side, prior to further flight, replace the cracked fitting and incorporate wing rear attachment fitting reinforcement kit No. OPT10 920300 in accordance with the Technical Instruction of Modification, OPT10 9203-57, Wing Rear Attachment Bracket, dated April 1996.

(2) If any fitting is found cracked on the fuselage side, prior to further flight, accomplish the following:

(i) Incorporate wing rear attachment fitting reinforcement kit No. OPT10 920500 in accordance with the Technical Instruction of

Modification, OPT10 9205–57, Wing Rear Attachment Bracket, dated April 1996; and

(ii) Incorporate wing rear attachment fitting reinforcement kit No. OPT10 920300 in accordance with the Technical Instruction of Modification, OPT109203–57, Wing Rear Attachment Bracket, dated April 1996.

(3) If any fitting is not found cracked, prior to further flight, incorporate wing rear attachment fitting reinforcement kit No. OPT10 920300 in accordance with the Technical Instruction of Modification, OPT109203–57, Wing Rear Attachment Bracket, dated April 1996.

(b) 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.

(c) An alternative method of compliance or adjustment of the compliance time that provides an equivalent level of safety may be approved by the Manager, Small Airplane Directorate, FAA, 1201 Walnut, suite 900, Kansas City, Missouri 64106. The request shall be forwarded through an appropriate FAA Maintenance Inspector, who may add comments and then send it to the Manager, Small Airplane Directorate.

**Note 4:** Information concerning the existence of approved alternative methods of compliance with this AD, if any, may be obtained from the Small Airplane Directorate.

(d) All persons affected by this directive may obtain copies of the documents referred to herein upon request to Socata—Groupe Aerospatiale, Socata Product Support, Aeroport Tarbes-Ossun-Lourdes, B P 930, 65009 Tarbes Cedex, France; or Perry Airport, 7501 Pembroke Road, Pembroke Pines, Florida 33023. These documents may also be examined at the FAA, Central Region, Office of the Regional Counsel, Room 1558, 601 E. 12th Street, Kansas City, Missouri 64106.

**Note 5:** The subject of this AD is addressed in French AD 94–249(A)R1, dated June 19, 1996.

Issued in Kansas City, Missouri, on December 10, 1997.

**Michael Gallagher,**

*Manager, Small Airplane Directorate, Aircraft Certification Service.*

[FR Doc. 97–32727 Filed 12–15–97; 8:45 am]

BILLING CODE 4910–13–U

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

## Food and Drug Administration

## 21 CFR Part 876

**[Docket No. 97N–0481]**

## Gastroenterology-Urology Devices: Reclassification of the Penile Rigidity Implant

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Proposed rule.

**SUMMARY:** The Food and Drug Administration (FDA) is proposing to reclassify the penile rigidity implant, a medical device intended to provide penile rigidity in men diagnosed as having erectile dysfunction, from class III to class II. The special controls identified in this proposed rule are the physician and patient labeling, biocompatibility testing, mechanical reliability performance testing, clinical testing, and sterilization requirements described in FDA's guidance document entitled ''Guidance for the Content of Premarket Notifications for Penile Rigidity Implants.'' This reclassification is being proposed on the agency's own initiative based on new information. This action is being taken under the Federal Food, Drug, and Cosmetic Act (the act), as amended by the Medical Device Amendments of 1976 (the 1976 amendments) and the Safe Medical Devices Act of 1990 (the SMDA).

**DATES:** Written comments by March 16, 1998. FDA proposes that any final regulation based on this proposal become effective 30 days after its date of publication in the **Federal Register**.

**ADDRESSES:** Submit written comments to the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857.

**FOR FURTHER INFORMATION CONTACT:** John H. Baxley, Center for Devices and Radiological Health (HFZ–470), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–594–2194.

**SUPPLEMENTARY INFORMATION:**

### I. Regulatory Authorities

The act, as amended by the 1976 amendments (Pub. L. 94–295) and the SMDA (Pub. L. 101–629), established a comprehensive system for the regulation of medical devices intended for human use. Section 513 of the act (21 U.S.C. 360c) established three categories (classes) of devices, depending on the regulatory controls needed to provide reasonable assurance of their safety and effectiveness. The three categories of devices are class I (general controls), class II (special controls), and class III (premarket approval).

Under section 513 of the act, devices that were in commercial distribution before May 28, 1976 (the date of enactment of the amendments), generally referred to as preamendments devices, are classified after FDA has: (1) Received a recommendation from a device classification panel (an FDA advisory committee); (2) published the panel's recommendation for comment, along with a proposed regulation classifying the device; and (3) published a final regulation classifying the device. FDA has classified most preamendments devices under these procedures.

Devices that were not in commercial distribution prior to May 28, 1976, generally referred to as post amendment devices, are classified automatically by statute (section 513(f) of the act) into class III without any FDA rulemaking process. Those devices remain in class III and require premarket approval, unless and until FDA issues an order finding the device to be substantially equivalent, under section 513(i) of the act, to a predicate device that does not require premarket approval. The agency determines whether new devices are substantially equivalent to previously offered devices by means of premarket notification procedures in section 510(k) of the act (21 U.S.C. 360(k)) and 21 CFR part 807 of the regulations.

A preamendments device that has been classified into class III may be marketed, by means of premarket notification procedures, without submission of a premarket approval application (PMA) until FDA issues a final regulation under section 515(b) of the act (21 U.S.C. 360e(b)) requiring premarket approval. Section 515(b) of the act describes a two step regulatory process. A notice of proposed rulemaking in the Federal Register, which includes the proposed regulation, proposed findings of risks and benefits of the device, an opportunity for the submission of comments and an opportunity to request reclassification, is followed by the final rule which issues the regulation.

In 1990, the SMDA added section 515(i) to the act. This section requires FDA to issue an order to manufacturers of preamendment class III devices for which no final regulation requiring the submission of PMA's has been issued to submit to the agency a summary of, and a citation to any information known or otherwise available to them respecting such devices, including adverse safety and effectiveness information which has not been submitted under section 519 of the act (21 U.S.C. 360i). Section 519 of the act requires manufacturers, importers, distributors and device user facilities to submit adverse event reports of certain device-related events. Section 515(i) of the act also directs FDA to either revise the classification of the device into class I or class II or require the device to remain in class III and establish a schedule for the issuance of a rule requiring the submission of PMA's for those devices remaining in class III.

In the **Federal Register** of May 6, 1994 (59 FR 23731), FDA announced its strategy and made available a document setting forth its strategy for implementing the provisions of the SMDA that require FDA to review the classification of preamendment class III devices. In accordance to this plan, the agency divided preamendment class III devices into the following three groups: Group 1 devices are devices that FDA believes raise significant questions of safety and/or effectiveness, but are no longer used or are in very limited use. Group 2 devices are devices that FDA believes have a high potential for being reclassified into class II. Group 3 devices are devices that FDA believes are currently in commercial distribution and are not likely candidates for reclassification. FDA also announced its intent to call for submission of PMA's for the 15 highest priority devices in Group 3, and for all Group 1 devices. The agency also announced its intent to issue an order under section 515(i) of the act for the remaining Group 3 devices and for all of the Group 2 devices.

In the **Federal Register** of August 14, 1995 (60 FR 41984), FDA published two orders for Certain Class III Devices; requiring the submission of safety and effectiveness information in accordance with the Preamendments Class III Strategy for implementing section 515(i) of the act. Each of the orders described in detail the format for submitting the type of information required by section 515(i) of the act so that the information submitted would clearly support reclassification or indicate that a device should be retained in class III. The orders also scheduled the required submissions in groups of nine devices at 6-month intervals beginning with August 14, 1996. The device proposed in this regulation for reclassification was included in the August 14, 1995, order on Group 2 devices (Docket No. 94N–0417).

Reclassification of classified preamendments devices is governed by section 513(e) of the act. This section provides that FDA may, by rulemaking, reclassify a device (in a proceeding that parallels the initial classification proceeding) based upon ''new information.'' The reclassification can be initiated by FDA or by the petition of an interested person. The term ''new information,'' as used in section 513(e) of the act, includes information developed as a result of a reevaluation of the data before the agency when the device was originally classified, as well as information not presented, not available, or not developed at that time. (See, e.g., *Holland Rantos* v. *United States Department of Health, Education, and Welfare*, 587 F.2d 1173, 1174 n.1 (D.C. Cir. 1978); *Upjohn* v. *Finch*, 422 F.2d 944 (6th Cir. 1970); *Bell* v. *Goddard*, 366 F.2d 177 (7th Cir. 1966).)

Reevaluation of the data previously before the agency is an appropriate basis for subsequent regulatory action where the reevaluation is made in light of changes in ''medical science.'' (See *Upjohn* v. *Finch*, supra, 422 F.2d at 951.) However, regardless of whether data before the agency are past or new data, the ''new information'' on which any reclassification is based is required to consist of ''valid scientific evidence'' as defined in section 513(a)(3) of the act and 21 CFR 860.7(c)(2). FDA relies upon ''valid scientific evidence'' in the classification process to determine the level of regulation for devices. For the purpose of reclassification, the valid scientific evidence upon which the agency relies must be publicly available. Publicly available information excludes trade secret and/or confidential commercial information, e.g., the contents of PMA's. (See section 520(c) of the act (21 U.S.C. 360j(c)).)

## II. Regulatory History of the Device

In the **Federal Register** of November 23, 1983 (48 FR 53012 at 53023), FDA issued a final rule classifying the penile rigidity implant into class III (21 CFR 876.3630). The preamble to the proposal to classify the device (46 FR 7578, January 23, 1981) included the recommendations of the Gastroenterology and Urology Devices Advisory Panel and the General and Plastic Surgery Devices Advisory Panel (the Panels), FDA advisory committees, which met regarding the classification of the device. The Panels both recommended that the device be classified in class II, listing poor tissue compatibility, tissue trauma, and device structural problems as potential risks of the device and citing that general controls and performance standards would provide reasonable assurance of the safety and effectiveness of the device.

FDA disagreed with the Panels' recommendations and proposed that the penile rigidity implant be classified into class III. The proposal stated that the agency believed that insufficient information existed to determine that general controls would provide reasonable assurance of safety and effectiveness of the device, or to establish a performance standard to provide this assurance. The proposal stated that premarket approval is necessary for this device because it presents a potential unreasonable risk of injury due to: (1) Adverse tissue reaction if the materials used in the construction of the device are not biocompatible; (2) infection resulting from defects in the design, construction, packaging, or processing of the device; (3) urinary retention if the prosthesis compresses the urethra; and (4) erosion or malfunction if the implant is improperly sized or mechanically breaks. In support of its proposal to strengthen regulatory surveillance of the device, FDA cited references supporting the proposed classification.

In the **Federal Register** of April 7, 1981 (46 FR 20687), FDA reopened the comment period for the proposed regulation classifying this device for an additional 60 days. This addition 60-day comment period was established because the proposed classification regulation for the penile rigidity implant stated incorrectly that the Gastroenterology and Urology Devices Advisory Panel recommended that the device be classified into class III, rather than class II. In the April 7, 1981 notice, FDA announced that on April 13, 1981, a meeting of the Panel would be held. During this meeting, the Panel reviewed all comments, and again recommended that the penile rigidity implant be classified into class II. No other comments were received during the remainder of the comment period. Again, FDA disagreed with the Panel's recommendation and proposed that the penile rigidity implant be classified into class III. FDA searched the published literature and further documented the potential risks to health resulting from silicone implants, such as silicone particle migration and allergic or adverse tissue reaction.

The preamble to the November 23, 1983 (48 FR 53012), final rule classifying the device into class III advised that the earliest date by which PMA's for the device could be required was June 30, 1986, or 90 days after issuance of a rule requiring premarket approval for the device, whichever occurs later.

In the **Federal Register** of May 6, 1994, FDA categorized the penile rigidity implant as a Group 2 device, which FDA believes has a high potential for being reclassified into class II. The agency also announced its intent to issue an order under section 515(i) of the act for Group 2 devices.

In the **Federal Register** of August 14, 1995 (60 FR 41984 at 41986), FDA published an order requiring manufacturers of penile rigidity implants to submit safety and effectiveness information in accordance with the Preamendments Class III Strategy for implementing section 515(i) of the act. On August 14, 1996, two

summaries of safety and effectiveness information were submitted to the agency (Refs. 39 and 40). These summaries recommended that the penile rigidity implant be reclassified into class II and provide information to assist FDA in reclassifying this device.

In accordance with sections 513(e) of the act and 21 CFR 860.130, based on new information with respect to the device, FDA, on its own initiative, is proposing to reclassify this device from class III to class II when intended to provide penile rigidity in men diagnosed as having erectile dysfunction.

Consistent with the act and the regulation, FDA did not refer, because of the reasons stated herein, the proposed reclassification to the Panel for its recommendation on the requested change in classification.

## III. Device Description

A penile rigidity implant is a device that consists of a pair of semi-rigid rods implanted in the corpora cavernosa of the penis to provide rigidity. It is intended to be used in men diagnosed as having erectile dysfunction.

The proposed rule to reclassify the penile rigidity implant applies to legally marketed penile rigidity implants identified above that were commercially distributed before May 28, 1976, and to devices introduced into commercial distribution since that date that have been found to be substantially equivalent to such penile rigidity implants.

## IV. Proposed Reclassification

FDA is proposing that the penile rigidity implant be reclassified from class III to class II. FDA believes that class II with special controls (specifically, the physician and patient labeling, biocompatibility testing, mechanical reliability performance testing, clinical testing, and sterilization requirements described in FDA's guidance document entitled ''Guidance for the Content of Premarket Notifications for Penile Rigidity Implants'') would provide a reasonable assurance of safety and effectiveness.

## V. Risks to Health

After considering the information discussed by the Panels during the classification proceedings, as well as the published literature, Medical Device Reports, and 515(i) submissions of safety and effectiveness information, FDA has evaluated the risks associated with the penile rigidity implant. FDA now believes that the following are risks associated with the use of the penile rigidity implant:

### *A. Infection*

Infection is a risk common to all surgical procedures and implants. For penile rigidity implants, infection is typically reported to occur in 1 to 8 percent of cases (average of 3 percent) (Refs. 3, 5, 7, 9, 13, 23, and 26). In most cases, these infections result from seeding at the time of surgery and are reported as early post-operative complications (Refs. 5 and 23). However, late occurring prosthetic infections have been noted, and they are believed to be hematogenous in nature as the result of dental or other surgical procedures (Refs. 5, 6, 13, 17, and 23).

The best defense against infections is prophylaxis, particularly the selection of patients who are free of infection, the administration of an intraoperative shave and scrub, the use of perioperative antibiotics, and adherence to strict surgical technique (Refs. 5, 6, 18, 23, 26, and 32). However, even with these preventive measures, certain patients, such as those with a history of urinary tract infection, are still at risk for penile prosthesis infection (Refs. 5, 23, and 32).

The treatment of an infected penile prosthesis is removal of the device combined with appropriate antibiotic medications (Refs. 21, 23, and 26). A new device can either be placed at the time of removal, or 3 to 12 months later (Refs. 5, 7, 23, and 26). Sequela to penile prosthesis infections include scarring/fibrosis at the site of the prior implant, which could make reimplantation of a penile rigidity implant difficult (Refs. 21 and 30). Serious sequela are rare (Ref. 11).

### *B. Erosion, Migration, and Extrusion*

Erosion refers to the breakdown of tissue adjacent to the device. Migration refers to the movement of the implant within the body. In some cases, erosion may result in the external migration of the device, which is called extrusion. Erosion, migration, and extrusion of a penile rigidity implant are uncommon (<3 percent) complications (Ref. 28). Erosion and/or extrusion usually occur distally through either the urethra or the glans penis (Ref. 26). Proximal migration of the device without erosion or extrusion can result in inadequate support of the glans penis (often called ''floppy glans'' or ''SST deformity'') (Refs. 28 and 31).

Factors contributing to erosion, migration, or extrusion include implantation of a device that is too large, iatrogenic injury to the surrounding tissues (i.e., urethra, corpora, etc.), and infection (Refs. 26, 27, and 28). Additionally, it is possible that malfunction of the implant could lead to erosion, migration, or extrusion if rough or sharp edges are created or front/rear tips extenders become detached. Other risk factors include previous pelvic surgery, pelvic radiation, and spinal cord injury (Refs. 28 and 35).

Treatment of an eroded, migrated, or extruded device consists of removal of the device, antibiotic treatment, and supportive care (Refs. 21, 26, and 28). If the condition is not treated in a timely manner, the condition may worsen, leading to infection and loss of tissue (Ref. 21).

### *C. Mechanical Malfunction*

As with other prosthetic devices intended to restore a physiologic function, penile rigidity implants may malfunction mechanically. Rates for mechanical malfunction vary with the type and model of penile rigidity implant, and are believed to be significantly lower now than they were with previous models due to improvements in design (Refs. 14, 17, and 27). Mechanical malfunction may be caused by improper device handling or surgical technique, or problems with the device's design or manufacturing process (Ref. 27).

Mechanical malfunctions may affect device effectiveness in terms of decreases in device positionability, implant rigidity or column strength, or length of the prosthesis (Refs. 1, 14, 19, 24, 25, and 36). Surgical intervention to remove and replace the device is required if the patient desires a working prosthesis (Refs. 1, 33, and 36).

### *D. Patient Dissatisfaction*

If patients are not provided information and counseled about the risks and benefits of the penile rigidity implant prior to implantation, they may not have realistic expectations of the physical, psychological, and functional outcomes of the implant (Refs. 15, 26, and 30). Uninformed patients may be dissatisfied with the outcome in terms of size, shape, and rigidity of the prosthetic erection; concealability of the penis; penile scarring; penile sensation; the chance that any latent erectile capability will be lost following surgery; or other performance characteristics (Refs. 17, 21, 26, and 34). Some dissatisfied patients have requested removal of a device that was functioning according to the manufacturer's specifications because the implant did not meet their expectations (Refs. 9 and 22). With proper counseling, however, patient satisfaction with penile rigidity implants is typically in the range of 85

to 91 percent (Refs. 8, 12, 14, 16, 17, and 37).

*E. Adverse Tissue Reaction*

If the materials used in the construction of the device are not biocompatible, the patient may have an adverse tissue reaction. This risk is not unique to penile rigidity implants, as patients may have an adverse tissue or sensitivity reaction to any implanted device. Since the time that the penile rigidity implant was originally classified, few reports of adverse tissue reaction have been reported (Ref. 19). Surgical removal of the implant is generally indicated in patients experiencing prolonged discomfort or pain due to biocompatibility issues associated with device materials.

*F. Prolonged or Intractable Pain*

As would be expected for any implant, surgical placement of a penile rigidity implant results in temporary pain at the operative sites during the recovery period. Infrequently, however, cases of prolonged or intractable post-operative pain associated with device implantation have also been reported (Ref. 22). Persistent or worsening pain beyond the 4 to 6-week-post-operative healing period is symptomatic of possible infection (Refs. 23 and 29). However, studies have noted cases with persistent pain and subsequent device removal for which culture results were negative (Ref. 14). It is possible that pain can also be symptomatic of adverse tissue reaction, mechanical malfunction, or incorrect sizing of the device. Prolonged or intractable pain may lead to surgical intervention with device removal.

*G. Urinary Obstruction*

If the prosthesis compresses the urethra, urine flow could be impeded (Ref. 8). However, since the time that the penile rigidity implant was originally classified, reports of urinary obstruction secondary to implantation of a penile rigidity implant have been rare (Ref. 19). This complication may occur if the implant is improperly sized or malpositioned by the implanting physician. Surgical intervention may be indicated in patients experiencing urinary obstruction associated with the presence of the device.

*H. Silicone Particle Migration*

The patient-contacting surfaces of penile rigidity implants consist primarily of silicone elastomers. Neither silicone gel nor liquid are used in the construction of these devices. The migration of silicone particles from the solid elastomer exterior of various penile prostheses has been described by Barrett et al. (Ref. 2). Although particles of silicone were found in the tissues adjacent to the device and in draining lymph nodes in some patients, no deleterious effects have been associated with this finding to date. In a related study by Fishman et al., patients with pre-existing penile implants underwent pelvic lymph node dissection for reasons unrelated to the implant (Ref. 10). Microscopic examination of the lymph nodes showed no evidence of silicone elastomer migration.

Since the time that the reasons for placing penile rigidity implants into class III were first summarized, no adverse reactions related to silicone particle migration have been documented. Therefore, it appears that this theoretical risk may not be an actual risk of penile rigidity implants.

*I. Other Complications*

Other infrequently reported complications of the penile rigidity implant include post-operative bleeding, hematoma, penile edema, and penile necrosis/gangrene (Refs. 3, 19, 20, 26, and 36). Intraoperative complications have also been noted, which include perforation of the corpora or the urethra, inability to adequately dilate the corpora, incorrect sizing of the implant, and tearing or ripping the device during implantation (Refs. 5, 19, 26, 30, and 36). All of these complications can be reduced by good patient selection and careful surgical technique.

## VI. Summary of Reasons for Reclassification

FDA believes the penile rigidity implant should be classified into class II because special controls, in addition to general controls, provide reasonable assurance of the safety and effectiveness of the device, and there is sufficient information to establish special controls to provide such assurance.

## VII. Summary of Data Upon Which the Reclassification is Based

In addition to the potential risks of the penile rigidity implant described in section V of this document, there is reasonable knowledge of the benefits of the device. Specifically, placement of the penile rigidity implant in men with erectile dysfunction typically provides sufficient penile rigidity for vaginal intercourse. Furthermore, satisfaction rates in excess of 90 percent have been reported among penile rigidity implant recipients (Refs. 8, 12, 14, 16, 17, and 37).

Based on the available information, FDA believes that the special controls discussed in section VIII of this document are capable of providing reasonable assurance of the safety and effectiveness of the penile rigidity implant with regard to the identified risks to health of this device.

## VIII. Special Controls

In addition to general controls, FDA believes that the guidance document entitled, ''Guidance for the Content of Premarket Notifications for Penile Rigidity Implants'' (Ref. 38) is an adequate special control to address the risks to health described in section V of this document.

This guidance document addresses the following: (1) Physician labeling, (2) patient labeling, (3) biocompatibility testing, (4) mechanical testing, (5) clinical data requirements, and (6) sterilization procedures and labeling.

*A. Physician labeling*

The physician labeling section of the guidance document can help control the risks of infection, erosion, migration, extrusion, mechanical malfunction, patient dissatisfaction, prolonged or intractable pain, urinary obstruction, silicone particle migration, and other miscellaneous clinical complications by having the manufacturer provide information on: (1) The proper handling of the device prior to implantation, (2) selection and preparation of the patient, (3) surgical and sterile technique, (4) implant sizing, (5) care of the implant site during and after the recovery period, (6) post-operative use of the device, (7) how to recognize and minimize these potential complications, (8) the normal healing process, and (9) the realistic outcomes of the penile rigidity implant.

*B. Patient labeling*

The patient labeling section of the guidance document can help control the risks of infection, erosion, migration, extrusion, mechanical malfunction, patient dissatisfaction, prolonged or intractable pain, urinary obstruction, silicone particle migration, and other miscellaneous clinical complications by having the manufacturer provide prospective patients information on: (1) Care of the implant site during and after the recovery period, (2) post-operative use of the device, (3) how to recognize and minimize these potential complications, (4) the normal healing process, and (5) the realistic outcomes of the penile rigidity implant.

*C. Biocompatibility testing*

Adherence to the biocompatibility testing section of the guidance document can control the risk of

adverse tissue reaction by having the manufacturer demonstrate that the patient contacting materials of the penile rigidity implant are safe for long-term implantation.

*D. Mechanical testing*

Adherence to the mechanical testing section of the guidance document can help control the risks of erosion, migration, extrusion, and mechanical malfunction by demonstrating the reliability of the device.

*E. Clinical data requirements*

For penile rigidity implants that are significantly different from devices already on the market, the clinical data requirements section of the guidance document can help control the risks of infection, erosion, migration, extrusion, mechanical malfunction, and prolonged or intractable pain by determining whether these risks are within the limits established by existing devices.

*F. Sterilization procedures and labeling*

Adherence to the sterilization procedures and labeling section of the guidance document can help control the risk of infection by guarding against the implantation of an unsterile device.

## IX. References

The following references have been placed on display in the Dockets Management Branch (address above) and may be seen by interested persons between 9 am. and 4 pm., Monday through Friday.

1. Agatstein, E. H., J. H. Farrer, and S. Raz, ''Fracture of Semirigid Penile Prosthesis: A Rare Complication,'' *The Journal of Urology*, 135:376–377, 1986.

2. Barrett, D. M., D. C. O'Sullivan, A. A. Malizia, H. M. Reiman, and P. C. Abell-Aleff, ''Particle Shedding and Migration from Silicone Genitourinary Prosthetic Devices,'' *The Journal of Urology*, 146:319–322, 1991.

3. Benjany, D. E., P. E. Perito, M. Lustgarten, and R. K. Rhamy, ''Gangrene of the Penis after Implantation of Penile Prosthesis: Case Reports, Treatment Recommendations and Review of the Literature,'' *The Journal of Urology*, 150:190–192, 1993.

4. Blue book memorandum #G95–1, ''Use of International Standard ISO–10993, 'Biological Evaluation of Medical Devices Part 1: Evaluation and Testing,'" FDA.

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## X. Environmental Impact

The agency has determined under 21 CFR 25.24(e)(2) that this proposed classification action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

## XI. Analysis of Impacts

FDA has examined the impacts of the proposed rule under Executive Order 12866 and the Regulatory Flexibility Act (5 U.S.C. 601–612) (as amended by subtitle D of the Small Business

Regulatory Fairness Act of 1996 (Pub. L. 104–121), and the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4). Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety and other advantages distributive impacts and equity). The agency believes that this proposed rule is consistent with the regulatory philosophy and principles identified in the Executive Order. In addition, the proposed rule is not a significant regulatory action as defined by the Executive Order and so is not subject to review under the Executive Order.

The Regulatory Flexibility Act requires agencies to analyze regulatory options that would minimize any significant impact of a rule on small entities. Reclassification of this device from class III to class II will relieve all manufacturers of the device of the cost of complying with the premarket approval requirements in section 515 of the act. Because reclassification will reduce regulatory costs with respect to this device, it will impose no significant economic impact on any small entities, and it may permit small potential competitors to enter the marketplace by lowering their costs. The agency therefore certifies that the final rule will not have a significant economic impact on a substantial number of small entities. The rule also does not trigger the requirement for a written statement under section 202(a) of the Unfunded Mandates Reform Act because it does not impose a mandate that results in an expenditure of $100 million or more by State, local, or tribal governments in the aggregate, or by the private sector, in any 1 year.

## XII. Comments

Interested persons may, on or before March 16, 1998 submit to the Dockets Management Branch (address above) written comments regarding this proposal. Two copies of any comments are to be submitted except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

## List of Subjects in 21 CFR Part 876

Medical devices.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, it is proposed that 21 CFR part 876 be amended as follows:

## PART 876—GASTROENTEROLOGY-UROLOGY DEVICES

1. The authority citation for 21 CFR part 876 continues to read as follows:

**Authority:** 21 U.S.C. 351, 360, 360c, 360e, 360j, 360l, 371.

2. Section 876.3630 is revised to read as follows:

### § 876.3630 Penile rigidity implant.

(a) *Identification*. A penile rigidity implant is a device that consists of a pair of semi-rigid rods implanted in the corpora cavernosa of the penis to provide rigidity. It is intended to be used in men diagnosed as having erectile dysfunction. (b) *Classification*. Class II (special controls) (premarket notification guidance).

Dated: November 11, 1997.

**Joseph A. Levitt,**

*Deputy Director for Regulations Policy, Center for Devices and Radiological Health.*

[FR Doc. 97–32809 Filed 12-15-97; 8:45 am]

BILLING CODE 4160–01–F

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## NATIONAL INDIAN GAMING COMMISSION

## 25 CFR Part 514

## Annual Fees Payable By Indian Gaming Operations

**AGENCY:** National Indian Gaming Commission.

**ACTION:** Proposed rule.

**SUMMARY:** The National Indian Gaming Commission is proposing to amend its fee regulations to add class III gaming revenues to the assessable gross revenue base, increase the total amount of fees that can be imposed, and provide for an exemption for self-regulated tribes such as the Mississippi Band of Choctaw. This action is being taken pursuant to recent amendments to the Indian Gaming Regulatory Act. The primary effect of this action is to increase the funding for the National Indian Gaming Commission.

**DATES:** Comments must be submitted on or before January 15, 1998.

**ADDRESSES:** Comments may be mailed to: Fee Regulation Comments, National Indian Gaming Commission, 1441 L Street, N.W., Suite 9100, Washington, DC 20005, delivered to that address between 8:30 a.m. and 5:30 p.m., Monday through Friday, or faxed to 202/632–7066 (this is not a toll-free number). Comments received may be inspected between 9 a.m. and noon, and between 2 p.m. and 5 p.m.

**FOR FURTHER INFORMATION CONTACT:** Fred W. Stuckwisch at 202/632–7003; fax 202/632–7066 (these are not toll-free numbers).

**SUPPLEMENTARY INFORMATION:** The Indian Gaming Regulatory Act (IGRA), enacted on October 17, 1988, established the National Indian Gaming Commission (Commission). The Commission is charged with, among other things, regulating gaming on Indian lands. Pursuant to recent amendments to the IGRA, these fee regulations are being amended to:

(1) Add class III gaming revenues to the assessable gross revenue base,

(2) Increase the total amount of fees that can be imposed, and

(3) Provide an exemption for self-regulated tribes such as the Mississippi Band of Choctaw.

As a result, gaming operations offering only class III games must begin reporting and paying fees, and gaming operations offering both class II and III games must begin reporting and paying fees on their class III revenues.

The Commission has adopted a 30 day comment period for this proposed rule because (1) the basic rule has been in effect for six (6) years, (2) comments were received and considered before the basic rule was adopted, and (3) it is important that the increased funding for the Commission as enacted by Congress be implemented as soon as possible.

The purpose of these regulations is to implement those portions of IGRA that provide for the payment of fees by gaming operations and for the collection and use of such fees by the Commission. Gaming operations are the economic entities that are licensed by a tribe, operate the games, receive the revenues, issue the prizes, and pay the expenses. Gaming operations may be operated by a tribe directly, by a management contractor, or in the case of certain grandfathered class II gaming operations, by an individual owner/operator.

These regulations provide for a system of fee assessment and payment that is self-administered by the gaming operations. Briefly, the Commission adopts and communicates the assessment rates; the gaming operations apply those rates to their revenues, compute the fees to be paid, and report and remit the fees to the Commission on a quarterly basis.

Annual fees are payable quarterly each calendar year based on the previous calendar year's class II and III assessable gross revenues from the gaming operations.

The Commission will adopt preliminary annual fee rate(s) during the first quarter of each calendar year and final annual fee rate(s) for that year during the fourth quarter. Separate rates may be established for assessable gross revenue amounts under $1,500,000 (1st tier) and amounts over $1,500,000 (2nd tier). The rates when adopted will be published in the **Federal Register**.

Under the proposed rule, self-regulated tribes such as the Mississippi Band of Choctaw will be exempt from the payment of fees pursuant to the fiscal year 1998 Interior Appropriations Act. The definitions of self-regulation and self-regulated and the requirements for obtaining a certificate of self-regulation and designation as self-regulated will be developed and added to the regulations in later rulemakings.

Gaming operations are to apply the rates adopted to their assessable gross revenues from the preceding calendar year to determine to amount of fees to be paid. The gaming operations are to report the amounts of assessable gross revenues, the fees to be paid, and their calculations to the Commission when they remit their quarterly payments. Remittances and reports are due no later than March 31, June 30, September 30, and December 31, of each calendar year.

Examples of computations are included in the regulations.

By passing the fees on the previous year's assessable gross revenues, sufficient time is provided to the gaming operations to finalize and submit adjusted numbers before the end of the third quarter of the calendar year. Furthermore, by providing for the adoption of preliminary and final rates by the Commission, it is intended that sufficient time be provided the Commission to ascertain the assessable gross revenue base before finalizing the rates for each calendar year.

These regulations are applicable to all gaming operations under the jurisdiction of the Commission. New gaming operations (with no gaming revenues generated in the previous calendar year) must file reports quarterly even though no fees will be due.

Penalties and interest may be assessed for failures to file quarterly statements and to pay fees when due, and required approvals may be withheld, denied or revoked for failures to pay fees, penalties and interest.

## Regulatory Flexibility Act

This proposed rule will not have a significant economic impact on a substantial number of small business entities under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*). The additional entities becoming subject to these regulations as a result of the changes now being made are generally larger than those entities presently covered. Furthermore, the fees that will be paid by the entities presently covered will be less than the fees they are presently paying.

## National Environmental Policy Act

The Commission has determined that this proposed rule does not constitute a major Federal action significantly affecting the quality of the human environment and that no detailed statement is required pursuant to the National Environmental Policy Act of 1969.

**Tadd M. Johnson,**

*Chairman, National Indian Gaming Commission.*

## List of Subjects in 25 CFR Part 514

Gambling, Indians-lands, Reporting and recordkeeping requirements.

Accordingly, 25 CFR Part 514 is proposed to be amended as follows:

## PART 514—FEES

1. The authority for Part 514 continues to read as follows:

**Authority:** 25 U.S.C. 2706, 2708, 2710, 2717, 2717a.

2. Section 514.1 is amended by revising paragraphs (a) introductory text, (a)(4), (b) introductory text, (b)(4), (c) introductory text, (c)(1), (c)(2), (c)(5) introductory text, (c)(8), (d) introductory text, and (g) and by adding paragraph (a)(6), to read as follows:

### § 514.1 Annual Fees.

(a) Each gaming operation under the jurisdiction of the Commission shall pay to the Commission annual fees as established by the Commission. The Commission, by a vote of not less than two of its members, shall adopt the rates of fees to be paid.

* * * * *

(4) The rates of fees imposed shall be—

(i) No more than 2.5 percent of the first $1,500,000 (1st tier), and

(ii) No more than 5 percent of amounts in excess of the first $1,500,000 (2nd tier) of the assessable gross revenues from each gaming operation regulated by the Commission.

* * * * *

(6) If a tribe is determined to be self-regulated pursuant to the provisions of 25 U.S.C. 2717(a)(2)(C), no fees shall be imposed.

(b) For purposes of computing fees, assessable gross revenues for each gaming operation are the annual total amount of money wagered on class II and III games, admission fees (including table or card fees), less any amounts paid out as prizes or paid for prizes awarded, and less an allowance for amortization of capital expenditures for structures.

* * * * *

(4) All class II and III revenues from gaming operations are to be included.

(c) Each gaming operation regulated by the Commission shall file with the Commission quarterly a statement showing its assessable gross revenues for the previous calendar year.

(1) These quarterly statements shall show the amounts derived from each type of game, the amounts deducted for prizes, and the amounts deducted for the amortization of structures;

(2) These quarterly statements shall be filed no later than March 31, June 30, September 30, and December 31, of each calendar year the gaming operation is subject to the jurisdiction of the Commission, beginning in September 1991. Any changes or adjustments to the previous year's assessable gross revenue amounts from one quarter to the next shall be explained.

* * * * *

(5) Each gaming operation shall determine the amount of fees to be paid and remit them with the statement required in paragraph (c) of this section. The fees payable shall be computed using—

* * * * *

(8) Quarterly statements, remittances and communications about fees shall be transmitted to the Commission at the following address: Office of Finance, National Indian Gaming Commission, 1441 L Street, N.W., Suite 9100, Washington, DC 20005. Checks should be made payable to the National Indian Gaming Commission (do not remit cash).

* * * * *

(d) The total amount of all fees imposed during any fiscal year shall not exceed $8,000,000. The Commission shall credit pro-rata any fees collected in excess of this amount against amounts otherwise due at the end of the quarter following the quarter during which the Commission makes such determination.

* * * * *

(g) The information collection requirements contained in paragraph (c) of this section have been approved by the Office of Management and Budget under 44 U.S.C. 3501 *et seq.* and assigned clearance number 3200–0011. The information is being collected to determine the assessable gross revenues of each gaming operation and the

aggregate assessable gross revenues of all gaming operations. The information will be used to set and adjust fee rates and to verify the computations of fees paid by each gaming operation. Response is mandatory.

[FR Doc. 97–32662 Filed 12–15–97; 8:45 am]

BILLING CODE 7565–01–M

## DEPARTMENT OF LABOR

## Mine Safety and Health Administration

## 30 CFR Parts 56, 57, 62, 70, and 71

**RIN–AA53**

## Health Standards for Occupational Noise Exposure in Coal, Metal and Nonmetal Mines

**AGENCY:** Mine Safety and Health Administration (MSHA), Labor.

**ACTION:** Proposed rule; Availability of report.

**SUMMARY:** This notice announces the availability of a report from the National Institute for Occupational Safety and Health (NIOSH) entitled ''Prevalence of Hearing Loss For Noise-Exposed Metal/Nonmetal Miners.'' The report, which MSHA received on October 15, 1997, is cumulative evidence concerning the risk to metal and nonmetal miners of noise induced hearing loss (NIHL). The report is relevant to the magnitude of the risk of NIHL among miners. The Agency, therefore, will supplement the rulemaking record with this report and make it available to interested parties upon request.

**ADDRESSES:** Copies of the report are available from the Office of Standards, Regulations, and Variances, 703–235–1910.

**FOR FURTHER INFORMATION CONTACT:** Patricia W. Silvey, Director, MSHA, Office of Standards, Regulations, and Variances, 703–235–1910.

**SUPPLEMENTARY INFORMATION:** On December 17, 1996, MSHA published a proposed rule in the **Federal Register** (61 FR 66348) revising its health standards for occupational noise exposure in coal and metal and nonmetal mines. In this proposal, MSHA stated that current scientific evidence demonstrates that NIHL constitutes a serious hazard, that evidence exists of continuing harm to miners, and that MSHA standards no longer reflect experience and expert advice. The Agency concluded that regulatory action was necessary to address the continued excess risk of NIHL resulting from mining employment.

MSHA evaluated evidence related to the risk to miners from exposure to harmful levels of noise, and evidence on the level of that risk. MSHA determined that with respect to mine safety and health, any definition of material impairment of hearing should relate to a permanent, measurable loss of hearing which, unchecked, will limit the ability to understand speech, as it is spoken in everyday social (noisy) conditions. This is because speech comprehension is essential for mine safety.

The Agency reviewed the major studies on the level of risk at different noise exposures. The studies consistently indicated that the risk of developing a material impairment became significant over a working lifetime when workplace exposure exceeded average sound levels of 85 dBA. The data further indicated that while lowering exposure from an eight-hour time-weighted average ($TWA_8$) of 90 dBA to one of 85 dBA did not eliminate the risk, it did reduce the risk by approximately half. MSHA also reviewed a large body of data on the effects of varying industrial sound levels on worker hearing. These studies were supportive of the same conclusion. The Agency also focused on the harm that can occur at lower sound levels by reviewing studies of workers in other countries.

To confirm the magnitude of the risks of NIHL among miners, MSHA examined evidence of reported hearing loss among miners from a variety of sources audiometric data bases tracking hearing acuity among coal miners, individual commenter data, hearing loss data reported to MSHA, and workers' compensation data. MSHA also asked NIOSH to examine a body of audiometric data which tracked hearing acuity among coal miners and one which tracked hearing acuity among metal and nonmetal miners. NIOSH completed its analysis of the audiometric data on coal miners and issued a report to MSHA entitled ''Analysis of Audiograms for a Large Cohort of Noise-Exposed Miners,'' (Franks, 1996) which is a part of the existing rulemaking record.

NIOSH has now issued its report to MSHA which analyzes audiometric data on metal and nonmetal miners. This report is entitled ''Prevalence of Hearing Loss For Noise-Exposed Metal/Nonmetal Miners.'' The NIOSH analysis supports the conclusion from earlier scientific studies that miners are losing their hearing sensitivity faster than the general population. It indicates that 49% of the male population of metal and nonmetal miners have a hearing impairment by age 50 as compared with only 9% of the general population.

The report is available to interested members of the public and may be obtained upon request by electronic mail, fax, phone, or mail as follows: (1) Electronic mail: psilvey@msha.gov, (2) Fax: MSHA, Office of Standards, Regulations, and Variances, 703–235–5551, (3) Phone: Patricia W. Silvey, 703–235–1910, and (4) Mail: Mine Safety and Health Administration, Office of Standards, Regulations, and Variances, 4015 Wilson Boulevard, Room 631, Arlington, VA 22203–1984.

Dated: December 9, 1997.

**J. Davitt McAteer,**

*Assistant Secretary for Mine Safety and Health.*

[FR Doc. 97–32709 Filed 12–15–97; 8:45 am]

BILLING CODE 4510–43–P

## LIBRARY OF CONGRESS

## Copyright Office

## 37 CFR Part 253

**[Docket No. 96–6 CARP NCBRA]**

## Noncommercial Educational Broadcasting Compulsory License

**AGENCY:** Copyright Office, Library of Congress.

**ACTION:** Notice of proposed rulemaking; correction.

**SUMMARY:** This document clarifies the dates for filing comments and Notices of Intent to Participate published in the **Federal Register** notice of December 1, 1997, announcing the proposed rulemaking for adjusting the royalty rates for the noncommercial educational broadcasting compulsory license.

**FOR FURTHER INFORMATION CONTACT:** Tanya M. Sandros, Attorney Advisor, Copyright Arbitration Royalty Panel (CARP), P.O. Box 70977, Southwest Station, Washington, D.C. 20024. Telephone (202) 707–8380. Telefax: (202) 707–8366.

**SUPPLEMENTARY INFORMATION:** The notice of proposed rulemaking concerning the adjustment of royalty rates for compulsory license governing the use of certain copyrighted works in connection with noncommercial broadcasting contains two dates for filing comments and Notices of Intent to Participate. The correct date, December 29, 1997, is announced in the date caption. The second date, December 31, 1997, stated in the section entitled, Comments and Notices of Intent to Participate, page 63504, second column, first paragraph,

first sentence, is incorrect and should also read December 29, 1997.

The notice also contains an error in the regulatory text which requires correction.

**List of Subjects in 37 CFR Part 253**

Copyright, Music, Radio, Television.

Accordingly, 37 CFR part 253 is corrected by making the following correcting amendments:

## PART 253—USE OF CERTAIN COPYRIGHTED WORKS IN CONNECTION WITH NONCOMMERCIAL EDUCATIONAL BROADCASTING

1. The authority citation for part 253 continues to read as follows:

**Authority:** 17 U.S.C. 118, 801(b)(1) and 803.

**§ 253.7 Recording rights, rates and terms.**

2. In § 253.7, paragraph (b)(4), correct the parenthetical ''(per half'' to read ''(per half hour)''.

Dated: December 11, 1997.

**Marilyn J. Kretsinger,**

*Assistant General Counsel.*

[FR Doc. 97–32792 Filed 12–15–97; 8:45 am]

BILLING CODE 1410–33–P

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## LIBRARY OF CONGRESS

## Copyright Office

## 37 CFR Part 255

**[Docket No. 96–4 CARP DPRA]**

## Mechanical and Digital Phonorecord Delivery Rate Adjustment Proceeding

**AGENCY:** Copyright Office, Library of Congress.

**ACTION:** Notice of proposed rulemaking; correction.

**SUMMARY:** This document clarifies the dates for filing comments and Notices of Intent to Participate published in the **Federal Register** notice of December 1, 1997, announcing a proposed rulemaking concerning the adjustment of the physical phonorecord and digital phonorecord delivery royalty rates.

**FOR FURTHER INFORMATION CONTACT:** Tanya M. Sandros, Attorney Advisor, Copyright Arbitration Royalty Panel (CARP), P.O. Box 70977, Southwest Station, Washington, D.C. 20024. Telephone (202) 707–8380. Telefax: (202) 707–8366.

**SUPPLEMENTARY INFORMATION:** The notice of proposed rulemaking concerning the adjustment of royalty rates for the making and distribution of a physical phonorecord and a digital phonorecord delivery contains two dates for filing comments and Notices of Intent to Participate. The correct date, December 29, 1997, is announced in the date caption. The second date, December 31, 1997, stated in the section entitled, Comments and Notices of Intent to Participate, page 63507, third column, is incorrect and should also read December 29, 1997.

Dated: December 11, 1997.

**Marilyn J. Kretsinger,**

*Assistant General Counsel.*

[FR Doc. 97–32791 Filed 12–15–97; 8:45 am]

BILLING CODE 1410–33–P

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

## Administration for Children and Families

## 45 CFR Part 1302

**RIN 0970–AB52**

## Head Start Program

**AGENCY:** Administration on Children, Youth and Families (ACYF), Administration for Children and Families (ACF), HHS.

**ACTION:** Notice of proposed rulemaking.

**SUMMARY:** The Administration on Children, Youth and Families is issuing this notice of proposed rulemaking to amend its procedures regarding replacement of Indian tribal grantees. The proposed change would add provisions to implement a new statutory provision that allows Indian tribes which are Head Start grantees to identify an agency, and request that the agency be designated by the Department as an alternative grantee, when the grantee is terminated or denied refunding.

**DATES:** In order to be considered, comments on this proposed rule must be received on or before February 17, 1998.

**ADDRESSES:** Please address comments to the Associate Commissioner, Head Start Bureau, Administration for Children, Youth and Families, P.O. Box 1182, Washington, D.C. 20013. Beginning 14 days after close of the comment period, comments will be available for public inspection in Room 2217, 330 C Street, S.W., Washington, D.C. 20201, Monday through Friday between the hours of 9:00 a.m. and 4:00 p.m.

**FOR FURTHER INFORMATION CONTACT:** Douglas Klafehn, Deputy Associate Commissioner, Head Start Bureau, Administration for Children, Youth and Families, P.O. Box 1182, Washington, D.C. 20013; (202) 205–8572.

**SUPPLEMENTARY INFORMATION:**

### I. Program Purpose

Head Start is authorized under the Head Start Act (42 U.S.C. 9801 *et seq.*). It is a national program providing comprehensive developmental services primarily to low-income preschool children, age three to the age of compulsory school attendance, and their families. In addition, Section 645A of the Head Start Act provides authority to fund programs for families with infants and toddlers, known as Early Head Start programs. To help enrolled children achieve their full potential, Head Start programs provide comprehensive health, nutritional, educational, social and other services. Additionally, Head Start programs are required to provide for the direct participation of the parents of enrolled children in the development, conduct, and direction of local programs. Parents also receive training and education to foster their understanding of and involvement in the development of their children. In fiscal year 1996, Head Start served 752,000 children through a network of over 2,000 grantees and delegate agencies.

While Head Start is intended to serve primarily children whose families have incomes at or below the poverty line, or who receive public assistance, the Head Start Act and implementing regulations permit up to 10 percent (and more for Indian tribes under certain circumstances) of the children in local programs to be from families who do not meet these low-income criteria. The Act also requires that a minimum of 10 percent of the enrollment opportunities in each program be made available to children with disabilities. Such children are expected to participate in the full range of Head Start services and activities with their non-disabled peers and to receive needed special education and related services.

### II. Summary of the Proposed Regulation

The authority for this Notice of Proposed Rulemaking (NPRM) is section 646 of the Head Start Act (42 U.S.C. 9841), as amended by Public Law 103–252, Title I of the Human Service Amendments of 1994. Section 646(e) directs the Secretary to specify a process by which an Indian tribe may identify an agency, and request that the agency identified be designated as the Head Start agency providing services to the tribe, if (a) financial assistance to the tribal grantee is terminated, and (b) the

tribe would otherwise be precluded from providing Head Start services to its members because of the termination. The Act specifies that the regulation must prohibit the designation as Head Start grantee of an agency that includes an employee who served on the administrative or program staff of the terminated agency when that employee was responsible for a deficiency that was the basis for the termination.

The proposed rule:

- Adds a new definition for Indian tribe;
- Provides that an Indian tribe may identify an agency to serve as the alternative grantee at the time that it receives a notice of termination or a notice of denial of refunding;
- Allows the tribe to participate in the selection of the replacement grantee;
- Allows the tribe a second opportunity to identify an alternative agency if the Department finds the first agency identified by the tribe is not an eligible agency capable of operating a Head Start program. If the second agency identified by the tribe is not selected as a Head Start grantee, a replacement grantee will be designated under 45 CFR Part 1302.

## III. Section by Section Discussion of the NPRM

*Section 1302.2 Definitions*

We propose to add to this section a definition for the phrase ''Indian tribe,'' which is the same definition that appears in Section 637(10) (42 U.S.C. § 9832(10)) of the Head Start Act.

*Section 1302.30 Procedure for Identification of Alternative Agency*

Section 1302.30 outlines the procedures by which an Indian tribe may identify an agency to the Department as an alternative grantee and request that the agency be designated as a grantee in the event that the tribe has been terminated or denied refunding as Head Start grantee. While section 646(e)(1)(A) of the Head Start Act refers only to the ''termination'' of financial assistance, we have interpreted ''termination'' in this section to mean either termination of a grant or denial of refunding of the grantee, as there is no substantive difference between these two actions in terms of their impact on a grantee's Head Start program.

Section 1302.30(a) states that a grantee may take advantage of this procedure only if it was the sole agency that was receiving funding to provide Head Start services to the tribe, and if the members of the tribe would otherwise be precluded from receiving Head Start services because of the termination or denial of refunding. These basic qualifying criteria are found in Section 646(e)(1) of the Head Start Act.

Under section 1302.30(b) of the proposed procedures the Department, if it moves to terminate or deny refunding to a tribal grantee, must notify the grantee that it may propose an alternative agency to the Department, in writing, within the time limits established for appealing the Department's decision to deny refunding or terminate the grant at 45 CFR § 1303.14(c) and 45 CFR § 1303.15(b)(2).

If the Department finds that the alternative agency identified by the tribe is not an agency that is both eligible and capable of operating a Head Start program, the Department will, under section 1302.30(b)(3), so notify the tribe, and the tribe will have another opportunity to identify an alternative agency and request the designation of that agency as the alternative agency. This must be done within 15 days of the Department's sending notification to the grantee that the agency identified is unsuitable. Section 1302.30(b)(4) specifies that if the Department finds this second agency also not capable of operating a Head Start program, a replacement grantee will be selected by the Department according to the regulations under 45 CFR part 1302. Funding of the grantee will continue during any appeal, as provided under section 1302.30(c). The steps outlined in this proposed regulation for designation of an alternative agency identified by the tribe will be carried out during the appeal process.

Section 1302.30(d) provides that if the tribe does not identify an agency and request that it be appointed as alternative agency, the Department will seek a permanent replacement grantee under 45 CFR part 1302.

*Section 1302.31 Requirements of Alternative Agency*

The purpose of this section is to make clear that any agency designated by the Secretary to replace the grantee serving the Indian tribe must meet the minimum requirements for Head Start agencies as established by the Head Start Act. These are minimum requirements, which no agency designated a Head Start agency may fail to meet. However, merely satisfying these requirements does not qualify an agency to be a Head Start grantee. The Department will analyze the capabilities and experience of the agency identified by the tribe to determine whether that agency is capable of operating a Head Start program. This analysis will be guided by the criteria for agency designation found in section 641(d) of the Head Start Act and sections 1302.10 (b) (1) to (5) and 1302.11 (a) to (c) of this Part.

*Section 1302.32 Alternative Agency—Prohibition*

This section states that the tribe may not designate as an alternative agency an agency which includes an employee who served on the administrative or program staff of the Indian tribal grantee, and who was responsible for a deficiency that was the basis of the termination or denial of refunding described in section 1302.30. It also specifies that the Department, not the tribe, reserves the right to determine whether an employee was responsible for a deficiency within the meaning and context of this section.

## IV. Impact Analysis

*Executive Order 12866*

Executive Order 12866 requires that regulations be drafted to ensure that they are consistent with the priorities and principles set forth in the Executive Order. The Department has determined that this proposed rule is consistent with these priorities and principles. This Notice of Proposed Rulemaking sets forth a process whereby an Indian tribe that is being terminated as a Head Start grantee may identify an alternative agency and request that the alternative agency be designated as the Head Start agency providing services to the tribe. The costs of implementing this rule are not significant.

### Regulatory Flexibility Act of 1980

The Regulatory Act (5 U.S.C. Ch. 6) requires the Federal Government to anticipate and reduce the impact of rules and paperwork requirements on small businesses. For each rule with a ''significant economic impact on a substantial number of small entities'' an analysis must be prepared describing the rule's impact on small entities. Small entities are defined by the Act to include small businesses, small non-profit organizations and small governmental entities. While these regulations would affect small entities, they would not affect a substantial number. For this reason, the Secretary certifies that this rule will not have a significant impact on substantial numbers of small entities.

### Paperwork Reduction Act

Under the Paperwork Reduction Act of 1995, Pub. L. 104–13, all Departments are required to submit collections of information contained in proposed rules published for public comment in the

**Federal Register** to the Office of Management and Budget for review and approval. This NPRM does not contain collection of information as defined in the Paperwork Reduction Act and implementing regulations.

**List of Subjects in 45 CFR Part 1302**

Education of disadvantaged, Grant programs—social programs, Selection of grantees.

(Catalog of Federal Domestic Assistance Program Number 93.600, Project Head Start)

Dated: November 24, 1997.

**Olivia A. Golden,**

*Assistant Secretary for Children and Families.*

For the reasons set forth in the Preamble, 45 CFR Part 1302 is proposed to be amended as follows:

1. The Authority citation for Part 1302 continues to read as follows:

**Authority:** 42 U.S.C. 9801 *et seq.*

## PART 1302—POLICIES AND PROCEDURES FOR SELECTION, INITIAL FUNDING, AND REFUNDING OF HEAD START GRANTEES, AND FOR SELECTION OF REPLACEMENT GRANTEES

2. Section 1302.2 is amended by adding a definition for ''Indian Tribe'' to read as follows:

### § 1302.2 Definitions.

* * * * *

*Indian tribe* means any tribe, band, nation, pueblo, or other organized group or community of Indians, including any Native village described in section 3(c) of the Alaska Native Claims Settlement Act (43 U.S.C. 1602(c)) or established pursuant to such Act (43 U.S.C. 1601 *et seq.*) that is recognized as eligible for special programs and services provided by the United States to Indians because of their status as Indians.

* * * * *

3. A new Subpart D, containing new sections 1302.30, 1302.31, and 1302.32, is added to read as follows:

## Subpart D—Replacement of Indian Tribal Grantees

### § 1302.30 Procedure for identification of alternative agency.

(a) An Indian tribe whose Head Start grant has been terminated, or which has been denied refunding as a Head Start grantee, may identify an agency and request the responsible HHS official to designate such agency as an alternative agency to provide Head Start services to the tribe if:

(1) The tribe was the only agency that was receiving federal financial assistance to provide Head Start services to members of the tribe; and

(2) The tribe would be otherwise precluded from providing such services to its members because of the termination or denial of refunding.

(b)(1) The responsible HHS official, when notifying a tribal grantee of the intent to terminate financial assistance or deny its application for refunding, must notify the grantee that it may identify an agency and request that the agency serve as the alternative agency in the event that the grant is terminated or refunding denied.

(2) The tribe must identify the alternate agency to the responsible HHS official, in writing, within the time for filing an appeal under 45 CFR Part 1303.

(3) The responsible HHS official will notify the tribe, in writing, whether the alternative agency proposed by the tribe is found to be eligible for Head Start funding and capable of operating a Head Start program. If the alternative agency identified by the tribe is not an eligible agency capable of operating a Head Start program, the tribe will have 15 days from the date of the sending of the notification to that effect from the responsible HHS official to identify another agency and request that the agency be designated. The responsible HHS official will notify the tribe in writing whether the second proposed alternate agency is found to be an eligible agency capable of operating the Head Start program.

(4) If the tribe does not identify a suitable alternative agency, a replacement grantee will be designated under these regulations.

(c) If the tribe appeals a termination of financial assistance or a denial of refunding, it will, consistent with the terms of 45 CFR Part 1303, continue to be funded pending resolution of the appeal. However, the responsible HHS official and the grantee will proceed with the steps outlined in this regulation during the appeal process.

(d) If the tribe does not identify an agency and request that the agency be appointed as the alternative agency, the responsible HHS official will seek a permanent replacement grantee under these regulations.

### § 1302.31 Requirements of alternative agency.

The agency identified by the Indian tribe must establish that it meets all requirements established by the Head Start Act and these requirements for designation as a Head Start grantee and that it is capable of conducting a Head Start program. The responsible HHS official, in deciding whether to designate the proposed agency, will analyze the capacity and experience of the agency according to the criteria found in section 641(d) of the Head Start Act and §§ 1302.10(b) (1) through (b)(5) and 1302.11 of this part.

### § 1302.32 Alternative agency—prohibition.

(a) No agency will be designated as the alternative agency pursuant to this Subpart if the agency includes an employee who:

(1) Served on the administrative or program staff of the Indian tribal grantee, and

(2) Was responsible for a deficiency that:

(i) Relates to the performance standards or financial management standards described in the Head Start Act; and

(ii) Was the basis for the termination or denial of refunding described in § 1302.30 of this part.

(b) The responsible HHS official shall determine whether an employee was responsible for a deficiency within the meaning and context of this section.

[FR Doc. 97–32748 Filed 12–15–97; 8:45 am]

BILLING CODE 4184–01–P

## FEDERAL COMMUNICATIONS COMMISSION

## 47 CFR Parts 1, 21 and 74

**[MM Docket No. 97–217; DA 97–2547]**

## MDS and ITFS Two-Way Transmissions

**AGENCY:** Federal Communications Commission.

**ACTION:** Proposed rule; extension of comment period.

**SUMMARY:** In this Order Extending Time for Filing Comments and Reply Comments (''*Order*''), comment is sought on additional proposals for amendment of the Commission's rules to enable Multipoint Distribution Service (''MDS'') and Instructional Television Fixed Service (''ITFS'') licensees to engage in fixed two-way transmissions. In addition, the comment period in this docket is extended in order to allow for proper consideration of the proposals.

**DATES:** Comments must be filed on or before January 8, 1998, and reply comments on or before February 9, 1998. Written comments by the public on the Initial Regulatory Flexibility Analysis are due January 8, 1998.

**ADDRESSES:** Office of the Secretary, Federal Communications Commission, 1919 M Street, N.W., Washington, D.C. 20554.

**FOR FURTHER INFORMATION CONTACT:** Michael J. Jacobs, (202) 418–7066 or

Dave Roberts, (202) 418–1600, Video Services Division, Mass Media Bureau.

**SUPPLEMENTARY INFORMATION:** This is a synopsis of the Commission's *Order Extending Time for Filing Comments and Reply Comments*, MM Docket No. 97–217, adopted and released December 5, 1997. The full text of this *Order* is available for inspection and copying during normal business hours in the FCC Reference Center (Room 239), 1919 M Street, N.W., Washington, D.C., and also may be purchased from the Commission's copy contractor, International Transcription Services, Inc., (202) 857–3800, 1231 20th Street, N.W., Washington, D.C. 20036.

**Synopsis of Order Extending Time for Filing Comments and Reply Comments**

1. This *Order* was issued in response to a request filed by the Catholic Television Network (''CTN'') for a supplemental period to comment on the Commission's Notice of Proposed Rulemaking in this docket. *MDS and ITFS Two-Way Transmissions*, 62 FR 60025 (Nov. 6, 1997), *as corrected*, 62 FR 60750 (Nov. 12, 1997). Expressing concern that the proposed rules would create a potential for ''brute force overload'' interference from response stations to nearby non-co- nor adjacent channel ITFS receive sites, CTN argued that a two-way system should be implemented only if sufficient frequency separation is provided between ''downstream'' and ''upstream'' transmissions. CTN proposed to ''refarm'' the E, F, G and H channel groups to create a band of contiguous ITFS spectrum at 2500–2620 MHz and a band of contiguous spectrum for response transmissions at 2644–2690 MHz, making available up to 24 MHz for downstream MDS operations as a guard band. ITFS G channel licensees would be allowed to (i) consent to their channels being used as response channels, so long as they satisfy ITFS programming requirements on other system channels; (ii) request relocation of some or all of their channels to vacant or vacated ITFS frequencies, or to MDS Channels E1–2 and F1–2; or (iii) enter into a shared-time agreement with another ITFS licensee, under which both licensees could use the G channels as response channels and the partner's channels for ITFS programming requirements. CTN added that the 125 KHz channels should be reallocated to ITFS and used only as response channels. CTN suggested that its proposal would reduce harmful interference potential, encourage efficient spectrum usage, and preserve the spectrum reservation for ITFS.

2. The parties who commenced this proceeding (''Petitioners'') filed a response countering that other solutions to brute force interference may be more efficient, such as rendering the response hub licensee responsible to either cure any brute force interference to protected ITFS receive sites or to cease operating the offending transceiver. Regarding CTN's proposal, Petitioners disagreed with its limits on the location of response channels, and further disagreed that refarming only should occur where the ITFS G channels licensee voluntarily agrees.

3. Given the recent submission of CTN's proposal and its potential importance to this proceeding, and the complexity of CTN's proposal and of the other issues involved in this proceeding, interested parties are afforded an additional 30 days in which to file comments and reply comments.

4. *Authority.* This *Order* is issued pursuant to authority contained in Sections 4(i) and 303(r) of the Communications Act of 1934, as amended, 47 USC §§ 154(i) and 303(r), and §§ 0.204(b), 0.283, and 1.45 of the Commission's rules, 47 CFR 0.204(b), 0.283, and 1.45.

Federal Communications Commission.

**Roy J. Stewart,**

*Chief, Mass Media Bureau.*

[FR Doc. 97–32800 Filed 12–15–97; 8:45 am]

BILLING CODE 6712–01–P

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## FEDERAL COMMUNICATIONS COMMISSION

## 47 CFR Part 73

**[MM Docket No. 97–180; RM–9104]**

## Radio Broadcasting Services; Hawthorne, WI

**AGENCY:** Federal Communications Commission.

**ACTION:** Proposed rule.

**SUMMARY:** This document denies the petition filed by Burce F. Elving proposing the allotment of Channel 293A to Hawthorne, Wisconsin, as that community's first local service. *See* 62 FR 44434, August 21, 1997. Petitioner failed to provide sufficient information showing that Hawthorne meets the Commission's requirements with respect to community status for allotment purposes. The Commission also dismissed a counterproposal filed by WTRW, Incorporated seeking the allotment of Channel 293A at Superior, Wisconsin, as being technically deficient. With this action, this proceeding is terminated.

**FOR FURTHER INFORMATION CONTACT:** Kathleen Scheuerle, Mass Media Bureau, (202) 418–2180.

**SUPPLEMENTARY INFORMATION:** This is a summary of the Commission's Report and Order, MM Docket No. 97–180, adopted November 19, 1997, and released December 5, 1997. The full text of this Commission decision is available for inspection and copying during normal business hours in the Commission's Reference Center (Room 239), 1919 M Street, NW, Washington, DC. The complete text of this decision may also be purchased from the Commission's copy contractors, International Transcription Services, Inc., 1231 20th Street, NW., Washington, DC. 20036, (202) 857–3800; facsimile (202) 857–3805.

**List of Subjects in 47 CFR Part 73**

Radio broadcasting.

Federal Communications Commission.

**John A. Karousos,**

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

[FR Doc. 97–32708 Filed 12–15–97; 8:45 am]

BILLING CODE 6712–01–F

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## FEDERAL COMMUNICATIONS COMMISSION

## 47 CFR Part 73

**[MM Docket No. 97–235, RM–9187]**

## Radio Broadcasting Services; Pecos and Wink, TX

**AGENCY:** Federal Communications Commission.

**ACTION:** Proposed rule.

**SUMMARY:** The Commission requests comments on a petition filed by Ronald W. Latimer requesting the reallotment of Channel 247C1 from Pecos to Wink, Texas, and the modification of Station KKLY(FM)'s construction permit to specify Wink as its community of license. Channel 247C1 can be allotted to Wink in compliance with the Commission's minimum distance separation requirements with a site restriction of 36.7 kilometers (22.8 miles) southeast. The coordinates for Channel 247C1 at Wink are 31–28–16 NL and 102–57–28 WL. Since Wink is located within 230 kilometers (199 miles) of the U.S.-Mexican border, concurrence by the Mexican government has been requested. In accordance with the provision of Section 1.420(i) of the Commission's Rules, we will not accept competing expressions of interest in use of Channel 247C1 at Wink.

**DATES:** Comments must be filed on or before January 26, 1998, and reply comments on or before February 10, 1998.

**ADDRESSES:** Federal Communications Commission, Washington, DC 20554. In addition to filing comments with the FCC, interested parties should serve the petitioner, or its counsel or consultant, as follows: Barry A. Friedman, Thompson, Hine & Flory LLP, 1920 North Street, NW, Suite 800, Washington, DC 20036 (Counsel for petitioner).

**FOR FURTHER INFORMATION CONTACT:** Pam Blumenthal, Mass Media Bureau, (202) 418–2180.

**SUPPLEMENTARY INFORMATION:** This is a synopsis of the Commission's Notice of Proposed Rule Making, MM Docket No. 97–235, adopted November 19, 1997, and released December 5, 1997. The full text of this Commission decision is available for inspection and copying during normal business hours in the FCC's Reference Center (Room 239), 1919 M Street, NW, Washington, DC. The complete text of this decision may also be purchased from the Commission's copy contractor, ITS, Inc., (202) 857–3800, 1231 20th Street, NW, Washington, DC 20036.

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

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

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

### List of Subjects in 47 CFR Part 73

Radio broadcasting.

Federal Communications Commission.

**John A. Karousos,**

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

[FR Doc. 97–32701 Filed 12–15–97; 8:45 am]

BILLING CODE 6712–01–F

## FEDERAL COMMUNICATIONS COMMISSION

## 47 CFR Part 73

**[MM Docket No. 97–236, RM–9186]**

## Radio Broadcasting Services; Point Arena, CA

**AGENCY:** Federal Communications Commission.

**ACTION:** Proposed rule.

**SUMMARY:** This document requests comments on a petition for rule making filed on behalf of Point Broadcasting, one of two mutually exclusive applicants for Channel 272B1 at Point Arena, California, proposing the allotment of Channel 296B1 to Point Arena to resolve the mutual exclusivity while providing a second local FM service to that community. If the channel is allotted with cut-off protection, petitioner also seeks to amend its pending application for Channel 272B1 at Point Arena to reflect operation on Channel 296B1. Coordinates used for Channel 296B1 at Point Arena are 39–01–22 and 123–31–17.

**DATES:** Comments must be filed on or before January 26, 1998, and reply comments on or before February 10, 1998.

**ADDRESSES:** Secretary, Federal Communications Commission, Washington, DC 20554. In addition to filing comments with the FCC, interested parties should serve the petitioner's counsel, as follows: Jerrold Miller, Esq., Miller & Miller, P.C., P.O. Box 33003, Washington, DC 20033.

**FOR FURTHER INFORMATION CONTACT:** Nancy Joyner, Mass Media Bureau, (202) 418–2180.

**SUPPLEMENTARY INFORMATION:** This is a synopsis of the Commission's Notice of Proposed Rule Making, MM Docket No. 97–236, adopted November 19, 1997, and released December 5, 1997. The full text of this Commission decision is available for inspection and copying during normal business hours in the FCC's Reference Center (Room 239), 1919 M Street, NW., Washington, DC. The complete text of this decision may also be purchased from the Commission's copy contractor, International Transcription Service, Inc., 1231 20th Street, NW., Washington, DC 20036, (202) 857–3800.

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

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

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

### List of Subjects in 47 CFR Part 73

Radio broadcasting.

Federal Communications Commission.

**John A. Karousos,**

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

[FR Doc. 97–32771 Filed 12–15–97; 8:45 am]

BILLING CODE 6712–01–P

## DEPARTMENT OF DEFENSE

## 48 CFR Part 204

**[DFARS Case 97–D033]**

## Defense Federal Acquisition Regulation Supplement; Uniform Procurement Instrument Identification

**AGENCY:** Department of Defense (DoD).

**ACTION:** Advance notice of proposed rulemaking.

**SUMMARY:** Comments are solicited from Government and industry personnel on the contemplated revision of Defense Federal Acquisition Regulation Supplement (DFARS) guidance pertaining to uniform procurement instrument identification numbers. DoD has a need to address modifications to its system for numbering contracts, modifications, and orders.

**DATES:** Comments should be submitted in writing to the address shown below on or before February 17, 1998.

**ADDRESSES:** Interested parties should submit written comments to: Defense Acquisition Regulations Council, Attn: Ms. Melissa Rider, DAR Council, IMD 3D139, PDUSD(A&T)DP/DAR, 3062 Defense Pentagon, Washington, D.C. 20301–3062. Telefax number (703) 602–0350.

E-mail comments submitted over the Internet should be addressed to: dfars@acq.osd.mil.

Please cite DFARS Case 97–D033 in all correspondence related to this issue. E-mail comments should cite DFARS Case 97–D033 in the subject line.

**FOR FURTHER INFORMATION CONTACT:** Ms. Melissa Rider, telephone (703) 602–0131.

**SUPPLEMENTARY INFORMATION:** The Defense Acquisition Regulations (DAR)

Council has opened DFARS Case 97–D033 to revise DFARS Subpart 204.70, Uniform Procurement Instrument Identification Numbers, to address various issues associated with the use of Procurement Instrument Identification Numbers (PIINs) and Supplemental Procurement Instrument Identification Numbers (SPIINs).

a. Among the revisions under consideration is one to increase the length of SPIINs used to identify call or order numbers under contracts awarded by another activity from 4 characters to 13, or possibly 15, characters. This revision is similar to a revision included in an earlier proposed rule, DFARS Case 92–D044, that was published in the **Federal Register** on August 18, 1994 (59 FR 42566), and that was withdrawn on December 28, 1994 (59 FR 66884), in response to public comments addressing the significant cost impact it would have on existing automated systems. The notice withdrawing the proposed rule stated that ''. . . both industry and Government should ensure that these proposed revisions can be accommodated in any future automated systems.'' The DAR Council is interested in hearing from industry and Government activities with respect to their ability to accommodate such a change at this time. The Council asks that respondents specifically address whether assignment of a unique 13 (or possibly 15) character SPIIN for every order (i.e., every call or order would have a completely unique SPIIN, and, therefore, could be tracked by reference to its SPIIN only) would improve the potential benefits of the contemplated revision.

b. Other issues under consideration include:

1. To ensure compatibility with automated systems that use contract numbers, should there be a uniform contract numbering system, or an agreed upon maximum number of characters, for basic contract numbers assigned to all contracts subject to the Federal Acquisition Regulation or, at least, to any such contracts that may have calls or orders issued under them by other agencies?

2. Is there a need to use more than two digits to designate the fiscal year within PIINs, and possibly SPIINs, to avoid potential Year 2000 problems in automated systems?

**Michele P. Peterson,**

*Executive Edtior, Defense Acquisition Regulations Council.*

[FR Doc. 97–32757 Filed 12–15–97; 8:45 am]

BILLING CODE 5000–04–M

**DEPARTMENT OF THE INTERIOR**

**Fish and Wildlife Service**

**50 CFR Part 17**

**RIN 1018–AE48**

## Endangered and Threatened Wildlife and Plants; Proposed Endangered Status for Catesbaea Melanocarpa

**AGENCY:** Fish and Wildlife Service, Interior.

**ACTION:** Proposed rule.

**SUMMARY:** The Service proposes to determine *Catesbaea melanocarpa* (no common name) to be an endangered species pursuant to the Endangered Species Act of 1973, as amended (Act). *Catesbaea melanocarpa* is known from Puerto Rico, St. Croix in the U.S. Virgin Islands, Barbuda, Antigua, and Guadeloupe. In Puerto Rico, it is currently known from only one location in Cabo Rojo, and in the U.S. Virgin Islands, it is known from one location near Christiansted, St. Croix. Both populations are located on privately owned land subject to intense pressure for development for residential, tourism and industrial purposes. This proposal, if made final, would implement the Federal protection and recovery provisions afforded by the Act for *C. melanocarpa.* The Service seeks data and comments from the public on this proposal.

**DATES:** Comments from all interested parties must be received by February 17, 1998. Public hearing requests must be received by January 30, 1998.

**ADDRESSES:** Comments and materials concerning this proposal should be sent to the Field Supervisor, Boquerón Field Office, U.S. Fish and Wildlife Service, P.O. Box 491, Boquerón, Puerto Rico 00622. Comments and materials received will be available for public inspection, by appointment, during normal business hours at this office.

**FOR FURTHER INFORMATION CONTACT:** Ms. Susan Silander, Botanist, at the Boquerón Field Office (see **ADDRESSES** section) (787/851–7297, facsimile 787/851–7440).

**SUPPLEMENTARY INFORMATION:**

### Background

*Catesbaea melanocarpa* (no common name) was first discovered in the mid-nineteenth century on the British island of Antigua by the German collector Hienrich Rudolph Wullschlaegel. It was found in St. Croix, U.S. Virgin Islands, in about 1881 by the Danish collector Baron H. F. A. von Eggers and in Guánica, Puerto Rico, by the German collector Paul Sintenis in 1886. Although duplicate specimens are maintained at other herbariums, the original collections were in the herbarium at Berlin-Dahlem and were destroyed by the bombing during World War II.

The species has also been reported from Barbuda and Guadeloupe, islands of the Lesser Antilles (Howard 1989, Proctor 1991). While little is known about the plant's status on these islands, the Center for Plant Conservation (1992) describes it as rare on Antigua. It was not rediscovered in St. Croix until 1988 and to date, it has not been relocated in the Guánica, Puerto Rico, area. The St. Croix population, located near Christiansted, consists of about 24 individual plants (Breckon and Kolterman 1993). In 1995, a small population, consisting of one individual, was located in Cabo Rojo, Puerto Rico (Puerto Rico Planning Board 1995). One specimen, collected in 1974, located in the herbarium in San Juan apparently originated from the Susúa Commonwealth Forest. However, this specimen is sterile and in depauperate condition; therefore, its identification cannot be confirmed.

*Catesbaea melanocarpa,* of the family Rubiaceae, belongs to a genus which consists of ten or more species of spiny shrubs. Most are confined to the Antilles but some may extend into the Bahamas and the Florida Keys. In Puerto Rico, two species are known—*C. melanocarpa* and *C. parviflora.* These two species are differentiated by the size and color of the fruits, black and larger, 5 to 6 millimeters (mm) (.19 to .23 inches (in)) in diameter, in the former and white and smaller 2 to 4 mm (.07 to .15 in) in diameter, in the latter (Breckon and Kolterman 1993, Britton and Wilson 1925). Some authors note that *C. melanocarpa* may be a synonym or variant of *C. parviflora* (Howard 1989, Proctor 1991) and recommend further review. However, Breckon and Kolterman (1993) and the Center for Plant Conservation (1992) recommend its protection due to the extremely small number of individuals currently known, the intense pressure for development in these areas, and the potential for an appreciable loss of the species' genetic diversity.

*Catesbaea melanocarpa* is a branching shrub which may reach approximately 3 meters (9.8 feet) in height. Spines are borne at every internode and are from 1 to 2 centimeters (.39 to .78 in) long. Leaves are small, from 5 to 25 mm (.19 to 1.0 in) long and 2 to 15 mm (.07 to .58 in) wide, often fascicled (clustered), and the small stipules are deciduous. The

flowers are white, solitary or paired, and almost sessile in the axils. The corolla is funnelform and from 8 to 10 mm (.31 to .39 in) long. The fruit is globose, 5 to 6 mm (.19 to .23 in) in diameter, and black with a crustaceous pericarp. The two-celled fruit contains five to seven seeds in each cell (Proctor 1991).

**Previous Federal Action**

*Catesbaea melanocarpa* was identified as a category 2 candidate species in Notices of Review published in the **Federal Register** on February 21, 1990 (55 FR 6184), and September 30, 1993 (58 FR 51144). Prior to 1996, a category 2 species was one that was being considered for possible addition to the Federal List of Endangered and Threatened Plants, but for which conclusive data on biological vulnerability and threats were not available to support a proposed rule. Designation of category 2 species was discontinued in the February 28, 1996, Notice of Review (61 FR 7956). *Catesbaea melanocarpa* was approved as a candidate by the Service on September 6, 1995, and identified as a candidate in the 1996 Notice of Review. A candidate species is a species for which the Service has sufficient information to propose it for protection under the Act. This small shrub is considered a ''critical'' plant species by the Natural Heritage Program of the Puerto Rico Department of Natural and Environmental Resources. The Center for Plant Conservation (1992) has assigned the species a Priority Status of A (a species which could possibly go extinct in the wild in the next 5 years).

Because of budgetary constraints and the lasting effects of a congressionally imposed listing moratorium, the Service is processing listing actions according to the listing priority guidance published in the **Federal Register** on December 5, 1996 (61 FR 64475). The guidance clarifies the order in which the Service will process listing actions during fiscal year (FY) 1997. The guidance calls for giving highest priority to handling emergency situations (Tier 1) and second highest priority (Tier 2) to resolving the status of outstanding proposed listings. Third priority (Tier 3) is given to resolving the conservation status of candidate species and processing administrative findings on petitions to add species to the lists or reclassify threatened species to endangered status. The processing of this proposed rule falls under Tier 3. At this time, the Southeast Region has no pending Tier 1 actions and is near completion of its pending Tier 2 actions. Additionally, the guidance states that ''effective April 1, 1997, the Service will concurrently undertake all of the activities included in Tiers 1, 2, and 3'' (61 FR 64480). The Service announced an extension on October 23, 1997, (62 FR 55268) of the guidance for FY 1997. The guidance will remain in effect until the FY 1998 appropriations bill for the Department of the Interior becomes law and new final guidance is published in the **Federal Register**.

**Summary of Factors Affecting the Species**

Section 4 of the Act and regulations (50 CFR part 424) promulgated to implement the listing provisions of the Act set forth the procedures for adding species to the Federal lists. A species may be determined to be endangered or threatened due to one or more of the five factors described in section 4(a)(1). These factors and their application to *Catesbaea melanocarpa* (Krug and Urban) are as follows:

A. *The present or threatened destruction, modification, or curtailment of its habitat or range.* *Catesbaea melanocarpa* is known only from Puerto Rico, St. Croix, Barbuda, Antigua, and Guadeloupe. Available information indicates that it is rare on Antigua (Center for Plant Conservation 1992). In Puerto Rico, it is known from a single individual on privately owned land. In St. Croix it is known from only one population consisting of about 24 individuals, also on privately owned land. The known individual from Cabo Rojo, Puerto Rico, is located on land currently proposed for a residential/tourism development consisting of a hotel, condo-hotel, residential villas and lots, a golf course, and other associated facilities. In St. Croix, the population is located near Christiansted on land also subject to pressure for development.

B. *Overutilization for commercial, recreational, scientific, or educational purposes.* The use of the species for such purposes has not been documented as a factor in its decline.

C. *Disease or predation.* Disease and predation have not been documented as factors in the decline of this species.

D. *The inadequacy of existing regulatory mechanisms.* The Commonwealth of Puerto Rico has adopted a regulation that recognizes and provides protection for certain Commonwealth listed species. However, *Catesbaea melanocarpa* is not yet on the Commonwealth list. Federal listing would provide immediate protection under the Act and, by virtue of an existing section 6 agreement with the Commonwealth, listing will also assure the addition of this species to the Commonwealth list and enhance possibilities for funding needed research. The Territory of the U.S. Virgin Islands has amended an existing regulation to provide for protection of endangered and threatened wildlife and plants. *Catesbaea melanocarpa* is considered by the U.S. Virgin Islands to be endangered (see ''Available Conservation Measures'' for discussion of prohibitions). As with the Commonwealth, the existence of a section 6 Cooperative Agreement with the Service will increase possibilities for funding needed research with this plant.

E. *Other natural or manmade factors affecting its continued existence.* One of the most important factors affecting the continued survival of this species is its limited distribution. Because so few individuals are known to occur, the risk of extinction is extremely high. Catastrophic natural events, such as hurricanes, may dramatically affect forest species composition and structure by felling large trees and creating numerous canopy gaps. Breckon and Kolterman (1993) documented the loss of individuals in St. Croix following the passing of hurricane Hugo in 1989.

The Service has carefully assessed the best scientific and commercial information available regarding the past, present, and future threats faced by this species in determining to propose this rule. Based on this evaluation, the preferred action is to list *Catesbaea melanocarpa* as endangered. Within the United States, the species is known from only one locality in Puerto Rico and one in St. Croix, U.S. Virgin Islands. Deforestation for residential and tourism development are imminent threats to the survival of the species. Therefore, endangered rather than threatened status more accurately describes the species' condition. The reasons for not proposing critical habitat for this species are discussed below in the ''Critical Habitat'' section.

**Critical Habitat**

Critical habitat is defined in section 3 of the Act as: (i) the specific areas within the geographical area occupied by a 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 a determination that such areas are essential for the conservation of the species. ''Conservation'' means the use of all methods and procedures needed to bring the species to the point at which listing under the Act is no longer necessary.

Section 4(a)(3) of the Act, as amended, and implementing regulations (50 CFR 424.12) require that, to the maximum extent prudent and determinable, the Secretary shall propose critical habitat at the time the species is proposed to be endangered or threatened. Service regulations (50 CFR 424.12(a)(1)) state that the 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. The Service finds that designation of critical habitat for *Catesbaea melanocarpa* is not prudent because such designation would not be beneficial to the species.

Critical habitat designation, by definition, directly affects only Federal agency actions through consultation under section 7(a)(2) of the Act. Section 7(a)(2) requires Federal agencies to ensure that activities they authorize, fund, or carry out are not likely to jeopardize the continued existence of a listed species or destroy or adversely modify its critical habitat. Neither of the two known populations of *Catesbaea melanocarpa* occur on Federal land. However, Federal involvement with this species may occur through the use of Federal funding for rural housing and development on non-Federal lands. The use of such funding for projects affecting occupied habitat for this species would be subject to review under section 7(a)(2), whether or not critical habitat was designated. The precarious status of *C. melanocarpa* is such that any adverse modification or destruction of its occupied habitat would also jeopardize its continued existence. This would also hold true as the species recovers and its numbers increase. In addition, the Service believes that notification of Federal agencies of the areas where these plants occur can be accomplished without the designation of critical habitat. All involved parties and landowners have been notified of the location and importance of protecting this species' habitat. For these reasons, the Service believes that designation of currently occupied habitat of this species as critical habitat would not result in any additional benefit to the species and that such designation is not prudent.

Potential introduction sites within unoccupied lands occur on lands under Federal management (Cabo Rojo, Laguna Cartagena and Sandy Point National Wildlife Refuges) and Commonwealth management (Guánica Commonwealth Forest). As managers of these subtropical dry forest lands, the Service and the Puerto Rico Department of Natural and Environmental Resources are actively involved in conservation activities. Both agencies are committed to the protection of these forested areas and would minimize or avoid any impacts to such habitat. Any introduction would be closely coordinated with the area's managers. Introduction of this species onto unoccupied private lands likely would not be pursued because suitable habitat under private ownership occurs only in very small patches which are interspersed among developed areas and are too small for introduction. For these reasons, the Service believes that designation of currently unoccupied habitat of this species as critical habitat would not result in any additional benefit to the species and, therefore, such designation is not prudent.

**Available Conservation Measures**

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

Section 7(a) of the Act, as amended, requires Federal agencies to evaluate their actions with respect to any species that is proposed or listed as endangered or threatened and with respect to its critical habitat, if any is being designated. Regulations implementing this interagency cooperation provision of the Act are codified at 50 CFR part 402. Section 7(a)(4) requires Federal agencies to confer with the Service on any action that is likely to jeopardize the continued existence of a proposed species or result in destruction or adverse modification of proposed critical habitat. If a species is subsequently listed, section 7(a)(2) requires Federal agencies to ensure that activities they authorize, fund, or carry out are not likely to jeopardize the continued existence of the species or to destroy or adversely modify its critical habitat. If a Federal action may affect a listed species or its critical habitat, the responsible Federal agency must enter into formal consultation with the Service. No critical habitat is being proposed for this species, as discussed above. Federal involvement may include Federal funding for rural housing and development (for example, funding by agencies such as the Rural Development or Housing and Urban Development).

The Act and its implementing regulations set forth a series of general trade prohibitions and exceptions that apply to all endangered plants. All prohibitions of section 9(a)(2) of the Act, implemented by 50 CFR 17.61, apply. These prohibitions, in part, make it illegal for any person subject to the jurisdiction of the United States to import or export any endangered plant, transport it in interstate or foreign commerce in the course of a commercial activity, sell or offer it for sale in interstate or foreign commerce, or remove and reduce to possession the species from areas under Federal jurisdiction. In addition, for plants listed as endangered, the Act prohibits the malicious damage or destruction on areas under Federal jurisdiction and the removal, cutting, digging up, or damaging or destroying of endangered plants in knowing violation of any Commonwealth or Territorial law or regulation, including Commonwealth or Territorial criminal trespass law. Certain exceptions can apply to agents of the Service and Commonwealth and Territorial conservation agencies.

The Act and 50 CFR 17.62 and 17.63 also provide for the issuance of permits to carry out otherwise prohibited activities involving endangered plants under certain circumstances. Such permits are available for scientific purposes and to enhance the propagation and survival of the species. It is anticipated that few trade permits for this species will ever be sought or issued, since the species is not known to be in cultivation and is uncommon in the wild.

It is the policy of the Service, published in the **Federal Register** on July 1, 1994 (59 FR 34272), to identify to the maximum extent practicable those activities that would or would not constitute a violation of section 9 of the Act at the time of listing. The intent of this policy is to increase public awareness of the effect of listing on proposed or ongoing activities. The only known populations of *Catesbaea melanocarpa* are located on privately owned land. Since there is no Federal ownership, and the species is not currently in trade, the only potential

section 9 involvement would relate to removing or damaging the plant in knowing violation of Commonwealth or Territorial law, or in knowing violation of Commonwealth or Territorial criminal trespass law. Section 15.01(b) of the Commonwealth ''Regulation to Govern the Management of Threatened and Endangered Species in the Commonwealth of Puerto Rico'' states: ''It is illegal to take, cut, mutilate, uproot, burn or excavate any endangered plant species or part thereof within the jurisdiction of the Commonwealth of Puerto Rico.'' The U.S. Virgin Island regulation states that ''no person may harass, injure or kill, or attempt to do the same, or sell or offer for sale any specimen, or parts or produce of such specimen, of an endangered or threatened species.'' The Service is not aware of any otherwise lawful activities being conducted or proposed by the public that will be affected by this listing and result in a violation of section 9.

Questions regarding whether specific activities will constitute a violation of section 9 should be directed to the Field Supervisor of the Service's Caribbean Field Office (see **ADDRESSES** section). Requests for copies of the regulations on listed species and inquiries regarding prohibitions and permits should be addressed to the U.S. Fish and Wildlife Service, Ecological Services, 1875 Century Boulevard, Atlanta, Georgia 30345–3301 (404/679–7313).

## Public Comments Solicited

The Service intends that any final action resulting from this proposal will be as accurate and as effective as possible. Therefore, comments or suggestions from the public, other concerned governmental agencies, the scientific community, industry, or any other interested party concerning any aspect of this proposed rule are hereby solicited. Comments particularly are sought concerning:

(1) Biological, commercial trade, or other relevant data concerning any threat (or lack thereof) to *Catesbaea melanocarpa*;

(2) The location of any additional populations of this species and the reasons why any habitat should or should not be determined to be critical habitat pursuant to section 4 of the Act;

(3) Additional information concerning the range, distribution, and population size of this species; and

(4) Current or planned activities in the subject areas and their possible impacts on this species.

Final promulgation of the regulation on *Catesbaea melanocarpa* will take into consideration the comments and any additional information received by the Service, and such communications may lead to a final regulation that differs from this proposal.

The Act provides for one or more public hearings on this proposal, if requested. Requests must be filed within 45 days of the proposal. Such requests must be made in writing and addressed to the Supervisor, Boquerón Field Office (see **ADDRESSES** section).

## National Environmental Policy Act

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

## Required Determinations

The Service has examined this regulation under the Paperwork Reduction Act of 1995 and found it to contain no information collection requirements.

## References Cited


Breckon, G. and D. Kolterman. 1993. *Catesbaea melanocarpa* Krug & Urban [Rubiaceae]. Final Report under Cooperative Agreement No. 14–16–0004–92–970 between the U.S. Fish and Wildlife Service and the University of Puerto Rico, Mayaguez Campus.

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Center for Plant Conservation. 1992. Report on the Rare Plants of Puerto Rico. Missouri Botanical Garden, St. Louis, Missouri.

Howard, R.A. 1989. Flora of the Lesser Antilles. Leeward and Windward Islands. Volume 6. Dicotyledoneae—Part 3. Arnold Arboretum, Harvard University, Jamaica Plain, Massachusetts. 658 pp.

Liogier, H.L. and L.F. Martorell. 1982. Flora of Puerto Rico and Adjacent Islands: a systematic synopsis. Editorial de la Universidad de Puerto Rico, Río Piedras, Puerto Rico. 342 pp.

Proctor, G. R. 1991. Puerto Rican plant species of special concern. Status and recommendations. Publicacion Cientifica Miscelanea No. 2. Departamento de Recursos Naturales de Puerto Rico. San Juan, Puerto Rico. 197 pp.

Puerto Rico Planning Board. 1995. Draft Environmental Impact Statement for Monte Carlo Resort and Boqueron Bay Site. San Juan, Puerto Rico. 88 pp.


Author. The primary author of this proposed rule is Ms. Susan Silander, Boquerón Field Office (see **ADDRESSES** section).

## List of Subjects in 50 CFR Part 17

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

## Proposed Regulation Promulgation

Accordingly, the Service hereby proposes to amend part 17, subchapter B of chapter I, 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 section 17.12(h) by adding the following, in alphabetical order under FLOWERING PLANTS, to the list of Endangered and Threatened Plants:

**§ 17.12 Endangered and threatened plants.**

* * * * *

(h) * * *

| Species | | Historic range | Family | Status | When listed | Critical habitat | Special rules |
|---|---|---|---|---|---|---|---|
| Scientific name | Common name | | | | | | |
| FLOWERING PLANTS | | | | | | | |
| * | * | * | * | * | * | * | |
| *Catesbaea melanocarpa.* | None | U.S.A. (PR, VI) Antigua, Barbuda, Guadeloupe. | Rubiaceae | E | | NA | NA |
| * | * | * | * | * | * | * | |

Dated: November 25, 1997.

*Director, Fish and Wildlife Service,*

**Jamie Rappaport Clark,**

[FR Doc. 97–32738 Filed 12–15–97; 8:45 am]

BILLING CODE 4310–55–P

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## DEPARTMENT OF THE INTERIOR

## Fish and Wildlife Service

## 50 CFR Part 17

**RIN 1018–AE38**

## Endangered and Threatened Wildlife and Plants; Proposed Rule to List the Flatwoods Salamander as Threatened

**AGENCY:** Fish and Wildlife Service, Interior.

**ACTION:** Proposed rule and notice of petition finding.

**SUMMARY:** The U.S. Fish and Wildlife Service (Service) proposes to list the flatwoods salamander (*Ambystoma cingulatum*) as a threatened species under the authority of the Endangered Species Act of 1973, as amended (Act). This salamander occurs in isolated populations scattered across the lower southeastern Coastal Plain in Florida, Georgia, and South Carolina. Habitat loss and degradation from agriculture, urbanization, and silvicultural practices have resulted in the loss of over 80 percent of its pine flatwoods habitat. Surviving populations are currently threatened by the continued destruction and degradation of their habitat. This proposed rule, if made final, would extend the Act's protection to this species.

**DATES:** Comments from all interested parties must be received by February 17, 1998. Public hearing requests must be received by January 30, 1998.

**ADDRESSES:** Comments and materials concerning this proposal should be sent to the Field Supervisor, U.S. Fish and Wildlife Service, 6578 Dogwood View Parkway, Jackson, Mississippi 39213. Comments and materials received will be available for public inspection, by appointment, during normal business hours at the above address.

**FOR FURTHER INFORMATION CONTACT:** Ms. Linda LaClaire at the above address, or telephone 601/965–4900, Ext. 26; facsimile 601/965–4340.

**SUPPLEMENTARY INFORMATION:**

### Background

The earliest reference to the flatwoods salamander, *Ambystoma cingulatum*, was by Cope in 1867 from specimens he collected in Jasper County, South Carolina (referenced in Martof 1968). This salamander is a member of the family Ambystomatidae, the mole salamanders, which contains 15 North American species. A phylogenetic analysis of ambystomatid salamanders was used to determine that the flatwoods salamander is most closely related to the ringed salamander (*A. annulatum*), which occurs in portions of Arkansas, Missouri, and Oklahoma (Shaffer *et al.* 1991).

The flatwoods salamander is a slender, small-headed mole salamander that rarely exceeds 13 centimeters (cm) (approximately 5 inches (in)) in length when fully mature (Means 1986, Conant and Collins 1991, Ashton 1992). Adult dorsal color ranges from black to chocolate-black with highly variable fine, light gray lines forming a netlike or cross-banded pattern across the back (Palis 1996). Undersurfaces are plain gray to black with a few creamy or pearl-gray blotches or spots. Sexual dimorphism is only apparent in breeding males (swollen cloacal region) or in gravid females. Adults most closely resemble Mabee's salamander, *A. mabeei*, with which it shares part of its range in South Carolina (Martof 1968). Mabee's salamanders are often more brownish; have light flecking concentrated on their sides rather than the overall pattern of the flatwoods salamander; and have a single row of jaw teeth as opposed to multiple rows in the flatwoods salamander (Conant and Collins 1991).

Flatwoods salamander larvae are long and slender, broad-headed and bushy-gilled, with white bellies and striped sides (Means 1986, Ashton 1992, Palis 1995d). They have distinctive color patterns, typically a tan mid-dorsal stripe followed by a grayish black dorsolateral stripe, a pale cream mid-lateral stripe, a blue-black lower lateral stripe and a pale yellow ventrolateral stripe (Palis 1995d). The head has a dark brown stripe passing through the eye from the nostril to the gills (Means 1986).

Optimum habitat for the flatwoods salamander is an open, mesic woodland of longleaf/slash pine (*Pinus palustris/P. elliottii*) flatwoods maintained by frequent fires. Pine flatwoods are typically flat, low-lying open woodlands that lie between the drier sandhill community upslope and wetlands down slope (Wolfe *et al.* 1988). An organic hardpan, 0.3 to 0.7 meters (m)(1 to 2 feet) into the soil profile, inhibits subsurface water penetration and results in moist soils with water often at or near the surface (Wolfe *et al.* 1988). Historically, longleaf pine generally dominated the flatwoods with slash pine restricted to the wetter areas (Wolfe *et al.* 1988). Wiregrasses (*Aristida* sp.), especially *A. beyrichiana*, are often the dominant grasses in the herbaceous ground cover (Wolfe *et al.* 1988). The ground cover supports a rich herbivorous invertebrate community which serves as a food source for the flatwoods salamander.

Adult and subadult flatwoods salamanders are fossorial (adapted for living underground) (Mount 1975). They enlarge crayfish burrows (Ashton 1992) or build their own. Captive flatwoods salamanders have been observed digging burrows and resting at night with just the tip of their heads exposed (Goin 1950). Preliminary data indicate that flatwoods salamander males first breed at 1 year of age and females at 2 years of age (Palis 1996). There are no data on survivorship by age class for the species. The longevity record for their close relative, *A. annulatum*, is 4 years, 11 months; however, many Ambystomatidae live 10 years or longer (Snider and Bowler 1992).

Adult flatwoods salamanders move to their wetland breeding sites during rainy weather, in association with cold fronts, from October to December (Palis 1997). Breeding sites are isolated (not connected to any other water body) pond cypress (*Taxodium ascendens*), blackgum (*Nyssa sylvatica* var. *biflora*), or slash pine dominated depressions which dry completely on a cyclic basis. They are generally shallow and relatively small. Breeding sites in Florida have a mean size of 1.49 hectares (ha) (3.68 acres (ac)) and a mean depth of less than 39.2 cm (15.4 in) (Palis, in press). These wetlands have a marsh-like appearance with sedges often growing throughout and wiregrasses (*Aristida* sp.), panic grasses (*Panicum* spp.), and other herbaceous species concentrated in the shallow water edges. Trees and shrubs grow both in and around the ponds. A relatively open canopy is necessary to maintain the herbaceous component which serves as cover for flatwoods salamander larvae and their aquatic invertebrate prey. Flatwoods salamander larvae were not captured in sample plots with a high proportion of detritus or open water in a study on the Apalachicola National Forest in Florida (Sekerak *et al.*, in press). Ponds typically have a burrowing crayfish fauna (genus *Procambarus*) and a diverse macroinvertebrate fauna, but lack large predatory fish (e.g., *Lepomis* (sunfish), *Macropterus* (bass), *Amia calva* (bowfin)).

Before the breeding sites become flooded, the males and females court and the females lay their eggs (singly or in clumps) beneath leaf litter, under logs

and sphagnum moss mats, or at bases of bushes, small trees, or clumps of grass (Anderson and Williamson 1976, Means 1986). Egg masses have also been found at the entrances of and within crayfish burrows (Anderson and Williamson 1976). Embryos begin development immediately, but the egg must be inundated before it will hatch. Depending on when eggs are inundated, the larvae usually metamorphose in March or April; the length of the larval period varies from 11 to 18 weeks (Palis 1995d).

The timing and frequency of rainfall is critical to the successful reproduction and recruitment of flatwoods salamanders. Fall rains are required to facilitate movements to the pond and winter rains are needed to ensure that ponds are filled sufficiently to allow hatching, development, and metamorphosis of larvae. In contrast, too much rainfall in the summer will keep pond levels from dropping below the grassy pond edge, as needed to provide dry substrate for egg deposition. This reliance on specific weather conditions results in unpredictable breeding events and reduces the likelihood that recruitment will occur every year.

Adult flatwoods salamanders leave the pond site after breeding. Studies have suggested a homing ability, based on data that salamanders exit the breeding pond near the point of their arrival (Palis 1997). Movements greater than 1,700 m (1,859 yards (yd)) from the breeding pond have been recorded (Ashton 1992). Preliminary studies indicate that the activity range of some individuals (encompassing both terrestrial habitat, breeding sites, and the areas through which they migrate) exceeds 1,500 square m (1,640 square yd) (Ashton 1992). Refugia are needed within this activity range as individuals travel from their breeding sites to the subterranean habitats where they spend the majority of their lives. Thus, a flatwoods salamander population has been defined as those salamanders using breeding sites within 3.2 kilometers (km) (2 miles (mi)) of each other, barring an impassable barrier such as a perennial stream (Palis, in press).

High quality habitat for the flatwoods salamander includes a number of isolated wetland breeding sites within a landscape of longleaf pine/slash pine flatwoods with an abundant herbaceous ground cover (Sekerak 1994). A mosaic of ponds with varying hydrologies is needed to provide appropriate breeding conditions under different climatic regimes.

The historical range of the flatwoods salamander included parts of the States of Alabama, Florida, Georgia, and South Carolina located in the lower Coastal Plain of the southeastern United States. A museum record from Mississippi previously thought to be a flatwoods salamander has been discounted by knowledgeable researchers (Moler, pers. comm., 1988). However, it is possible that flatwoods salamanders once occurred in extreme southeastern Mississippi due to similarities in habitat to historical sites in adjacent Alabama. Recent surveys (Kuss 1988; L. LaClaire, U.S. Fish and Wildlife Service, pers. obs., 1995) have not documented the occurrence of flatwoods salamanders in Mississippi.

Historical records for the flatwoods salamander are limited. Longleaf pine/slash pine flatwoods historically occurred in a broad band across the lower southeastern Coastal Plain. The flatwoods salamander likely occurred in appropriate habitat throughout this area (Means, pers. comm., 1995). The present distribution of the flatwoods salamander consists of isolated populations scattered across the remaining longleaf pine/slash pine flatwoods. The Service has compiled 110 historical records for the flatwoods salamander. Historical records are defined as those localities found prior to 1990. Localities consist of collections made either by sampling breeding sites or collections made of individuals crossing highways on their way to or from breeding sites. During surveys of these localities over the last 7 years, the exact site was located for 52 records (47 percent) and the general area (within several miles) was determined for 45 others (41 percent). Thirteen sites could not be located due to limited information in the record. Of the 97 historical records that were visited, flatwoods salamanders were relocated at only 12 localities (12 percent).

Range-wide surveys of available habitat in Alabama, Florida, Georgia, and South Carolina have been ongoing since 1990 in an effort to locate new populations. A total of at least 1,189 wetlands, which had a minimum of marginal suitability for the flatwoods salamander, were sampled, most of them multiple times. Of these, flatwoods salamanders were found at 102 sites (9 percent success rate). Most surveys were presence/absence searches for larvae, thus no estimates of population size or viability can be inferred from these data.

Information on the current status of the flatwoods salamander by State can be briefly summarized as follows:

In Alabama, there are five historical localities for the flatwoods salamander, all in the extreme southern portion of the State. Surveys conducted from 1992 to 1995 at the historical breeding ponds and other potential breeding sites were not successful at locating any flatwoods salamander populations (Godwin 1994, pers. comm., 1997). The salamander was last observed in Alabama in 1981 (Jones *et al.* 1982).

A total of 33 historical records in 19 counties have been reported for Georgia (Goin 1950, Seyle 1994, Williamson and Moulis 1994); however, flatwoods salamanders have not been relocated at any of these sites in recent years. Surveys over the last 7 years of at least 451 wetlands with potential habitat for the flatwoods salamander have resulted in the location of 27 new breeding sites (6 percent success rate). These 27 breeding sites comprise 10 populations (sites within a 3.2 km (2 mi) radius of one another are considered the same population) (Seyle 1994; Jensen 1995; Moulis 1995a, 1995b; K. Lutz, The Nature Conservancy of Georgia, pers. comm., 1994; D. Stevenson, The Nature Conservancy of Georgia, pers. comm., 1996; L. LaClaire, pers. obs., 1995, 1997). Most extant breeding sites occur on Fort Stewart Military Installation.

In South Carolina, there are 29 historical records for the flatwoods salamander. Despite annual surveys since 1990, flatwoods salamanders have been found at only three of these sites (all sites represent a different population). One site is located on the Francis Marion National Forest and the other two are on private land. No new flatwoods salamander populations have been found, although surveys have been conducted at 57 additional wetlands considered to be potential habitat for this species.

In Florida, 39 of the 43 historical sites were relocated (or the general area thought to be the location). Nine (23 percent) contained flatwoods salamanders. Additional survey work over the past 7 years of at least 500 potential sites over a 22 county area resulted in the location of 75 new breeding sites (15 percent of total sites surveyed). The total number of extant flatwoods salamander populations known to occur in Florida is 34 with most occurring on the Apalachicola National Forest and Eglin Air Force Base (Palis 1993, 1994, 1995a, 1995b, 1995c; Printiss and Means 1996).

The combined State data from all survey work completed since 1990 indicate that 47 populations of flatwoods salamanders are known from across the historical range. Most of these occur in Florida (34 populations or 72 percent). Ten populations have been found in Georgia, three in South Carolina, and none have been found in Alabama. Some of these populations are

inferred from the capture of a single individual. Approximately half of the known populations for the flatwoods salamander occur on public land (25 of 47, or 53 percent). Federal landholdings that harbor flatwoods salamanders include the Apalachicola National Forest, Osceola National Forest, St. Marks National Wildlife Refuge, and Eglin Air Force Base in Florida; Fort Stewart Military Installation and Townsend Bombing Range in Georgia; and Francis Marion National Forest in South Carolina. An additional population is located on property managed by the State of Florida in the Pine Log State Forest. The remaining sites are on private land.

**Previous Federal Action**

The flatwoods salamander was identified as a Category 2 species in the Service's notices of review for animals published in the **Federal Register** on December 30, 1982 (47 FR 58454), September 18, 1985 (50 FR 37958), January 6, 1989 (54 FR 554), November 21, 1991 (56 FR 58804), and November 15, 1994 (59 FR 58982). Prior to 1996, a Category 2 species was one that was being considered for possible addition to the Federal List of Endangered and Threatened Wildlife, but for which conclusive data on biological vulnerability and threat were not currently available to support a proposed rule. Designation of Category 2 species was discontinued in the February 28, 1996, notice of review (61 FR 7956).

On May 18, 1992, the Service received a petition dated May 8, 1992, from the Biodiversity Legal Foundation, Boulder, Colorado, and Elizabeth Carlton, Gainesville, Florida, to list the flatwoods salamander as an endangered or threatened species throughout its historic range and to designate critical habitat. The petition stated that available evidence indicated that the flatwoods salamander had declined precipitously, that it was on the threshold of extirpation in many locations, and that it had been extirpated from a large portion of its historic range.

A 90-day finding that the petition did not present substantial information that the requested action may be warranted was announced in the **Federal Register** on May 12, 1993 (58 FR 27986). On August 23, 1993, attorneys representing the Biodiversity Legal Foundation, Jasper Carlton, the Director of the Biodiversity Legal Foundation, and Elizabeth Carlton notified the Service of their intent to sue the Service for violation of the Act. The petitioners felt a determination of ''may be warranted'' had, in effect, already been made by the Service through the inclusion of the flatwoods salamander as a Category 2 species on the comprehensive notices of review for animals published prior to 1993. On April 25, 1994, the suit was filed. In response to the agreed settlement, and based upon the Service's 1994 draft guidance relating to petitions for listing former Category 2 species, the 90-day finding announced on May 12, 1993, was rescinded, and replaced by a finding that the petitioned action may be warranted. This finding was announced in the **Federal Register** on September 21, 1994 (59 FR 48406), and included a request for comments and biological data on the status of the flatwoods salamander.

Section 4(b)(3)(B) of the Act and implementing regulations at 50 CFR 424.14, require the Secretary of the Interior, to the extent practicable, within 12 months of receipt of a petition, to make a finding as to whether the action requested in the petition is (a) not warranted, (b) warranted, or (c) warranted but precluded. Because of budgetary constraints and the lasting effects of a congressionally imposed listing moratorium, the Service is processing petitions and other listing actions according to the listing priority guidance published in the **Federal Register** on December 5, 1996 (61 FR 64475). In a **Federal Register** notice published on October 23, 1997 (62 FR 55628), the guidance was extended beyond fiscal year 1997 until such time as the fiscal year 1998 appropriations bill for the Department of the Interior becomes law and new final guidance is published. The fiscal year 1997 guidance clarifies the order in which the Service will process rulemakings following two related events: (1) the lifting on April 26, 1996, of the moratorium on final listings imposed on April 10, 1995 (Pub. L. 104–6), and (2) the restoration of significant funding for listing through passage of the Omnibus Budget Reconciliation Act passed on April 26, 1996, following severe funding constraints imposed by a number of continuing resolutions between November 1995 and April 1996. The guidance calls for giving highest priority to handling emergency situations (Tier 1) and second highest priority (Tier 2) to resolving the status of outstanding proposed listings. Third priority (Tier 3) is given to resolving the conservation status of candidate species and processing administrative findings on petitions to add species to the lists or reclassify threatened species to endangered status. The processing of this petition and proposed rule falls under Tier 3. At this time, the Southeast Region has no pending Tier 1 actions and no overdue Tier 2 actions. Additionally, the guidance states that ''effective April 1, 1997, the Service will concurrently undertake all of the activities presently included in Tiers 1, 2, and 3'' (61 FR 64480). This proposed rule constitutes the Service's 12-month finding on the petitioned action.

**Summary of Factors Affecting the Species**

Section 4(a) of the Endangered Species Act and regulations (50 CFR part 424) promulgated to implement the listing provisions of the Act set forth the procedures for adding species to the Federal lists. A species may be determined to be an endangered or threatened species due to one or more of the five factors described in section 4(a)(1). These factors and their application to the flatwoods salamander (*Ambystoma cingulatum* Cope) are as follows:

A. *The present or threatened destruction, modification, or curtailment of its habitat or range.* The major threat to the flatwoods salamander is loss of both its longleaf pine/slash pine flatwoods terrestrial habitat and its isolated, seasonally ponded breeding habitat. The combined pine flatwoods (longleaf pine-wiregrass flatwoods and slash pine flatwoods) historical acreage was approximately 12.8 million ha (32 million ac) (Wolfe *et al.* 1988, Outcalt 1997). Today, the combined flatwoods acreage has been reduced to 2.3 million ha (5.6 million ac) or approximately 18 percent of its original extent. These remaining pine flatwoods (non-plantation forests) areas are typically fragmented, degraded, second-growth forests.

Large acreages of pine flatwoods have been eliminated through land use conversions, primarily urban development and conversion to agriculture and pine plantations (Schultz 1983, Stout and Marion 1993, Outcalt and Sheffield 1996, Outcalt 1997). Surveys of historical flatwoods salamander localities documented the destruction of nine sites from urban development or agriculture and loss of three additional sites due to their conversion to pine plantations. State forest inventories completed between 1989 and 1995 indicate that flatwoods losses through land use conversion are still occurring (Outcalt 1997). In Florida and Georgia, the States where flatwoods habitat is concentrated and where most flatwoods salamander populations occur, 52,600 ha (130,000 ac) were lost to urban and agricultural use during the survey cycle of 8 years (Outcalt 1997).

Conversion of existing pine flatwoods second-growth forests to managed plantations is also continuing. In Georgia and Florida, there was a yearly loss of this habitat to pine plantations of nearly 20,200 ha (50,000 ac) in each State with a loss of 24 percent and 20 percent respectively during the 8 year survey interval (Outcalt 1997). Most of the remaining second-growth pine flatwoods (56 percent) occur on private non-industrial lands which are continuing to be converted to pine plantations after harvest (Outcalt 1997). Urban development is expanding into forested areas, especially in rapidly developing areas of Florida and Georgia. If present rates of loss continue, in 25 years nearly all natural pine flatwoods stands could be destroyed in these two States (Outcalt 1997).

Flatwoods salamander wetland breeding sites have also been degraded and destroyed. The number and diversity of these small wetlands have been reduced by alterations in hydrology, agricultural and urban development, silvicultural practices (described in more detail below), dumping in or filling of ponds, conversion of wetlands to fish ponds, domestic animal grazing, and soil disturbance (Vickers *et al.* 1985, Ashton 1992). Hydrological alterations represent the primary threat to flatwoods salamander breeding sites. Size and suitability of wetlands as breeding sites depend on subsoil moisture, the permeability of the hardpan, the pond's drainage area, and other factors. Alterations to any of these factors can affect the pond's ability to hold water and function as a breeding site.

Forest management strategies commonly used on pine plantations contribute to degradation of flatwoods salamander forested and wetland habitat. These include soil-disturbing site preparation techniques, lowered fire frequencies and reductions in average area burned per fire event (see Factor E), high seedling stocking rates, and herbicide use which reduces plant diversity in the understory. The result of these strategies is a forest that approaches even-age structure, has a dense understory, and low herbaceous cover. Forestry practices that directly affect wetland breeding sites include ditching ponds or low areas to drain water from a site, converting second-growth pine forests to bedded pine plantations, harvesting cypress from the ponds, disposing of slash in wetlands during timber operations, using ponds as part of ditched fire breaks, using fertilizers near wetlands which can result in eutrophication, and disturbing the soil at a wetland (Vickers *et al.* 1985; Ashton 1992; Means *et al.* 1996; Palis, in press).

Clear-cut harvesting of forested sites appears to be an additional threat. Studies on this type of harvest have demonstrated negative short-term impacts on local amphibian populations, especially salamanders (deMaynadier and Hunter 1995). Raymond and Hardy (1991) monitored the mole salamander (A. talpodieum) at a breeding site adjacent to a recent clear-cut. They found that salamanders were displaced from the cut side of the pond and that there was lowered survivorship in individuals of the breeding population that immigrated to the breeding pond from the clear-cut. Flatwoods salamanders may be vulnerable to the microhabitat drying from clear-cuts due to their moist permeable skin which acts as a respiratory organ and must remain moist to function properly (Duellman and Trueb 1986).

Silvicultural practices affecting both upland and breeding habitats have been implicated in the decline of a flatwoods salamander population located in the panhandle of western Florida and monitored for over 20 years (Means *et al.* 1996). The observed decline at this site was attributed to habitat modifications resulting from clear-cutting, conversion of the site to a pine plantation, and fire suppression. Habitat modifications included soil disturbance, hydrologic changes, canopy closure, and loss of herbaceous ground cover.

Habitat quality data were collected during recent surveys of historical sites where flatwoods salamanders were not relocated. Habitat quality at these sites was characterized as none (site destroyed), low (flatwoods salamanders unlikely), moderate (salamanders possible but habitat degraded), or high (habitat appears suitable for flatwoods salamanders). Three historical flatwoods salamander localities (assigned a quality of none) were altered so greatly by their conversion to slash pine plantations that they were no longer even marginally suitable for the flatwoods salamander. Forty-one historical sites (41 of 97, or 42 percent) were of low or moderate habitat quality. Most of these sites had been converted to slash pine plantations and had a subsequent loss of habitat suitability (L. LaClaire, pers. obs., 1997).

The habitat quality surrounding historical flatwoods salamander breeding ponds in Florida, where flatwoods salamanders have been found in recent surveys, was characterized by Palis (in press). Each site was assigned a score based on pine species dominance and disturbance (second-growth flatwoods versus plantation sites) and the relative abundance of wiregrass (*Aristida* sp.) ground cover. Wiregrass was chosen as a factor of habitat quality because its loss has been used as an indicator of site degradation from fire suppression and/or soil disturbance (Clewell 1989). In Palis' study, approximately 70 percent of the active breeding sites were surrounded by second-growth longleaf or slash pine flatwoods with nearly undisturbed wiregrass ground cover. In general, Palis found that the extant populations of the flatwoods salamander principally occurred on forest lands managed for long rotation, saw-timber production, rather than on short rotation pine plantations managed for pulp production.

Road construction plays a part in habitat degradation and destruction. At least one historical flatwoods breeding site was filled in association with the construction of a road (Palis 1993). Roads increase the accessibility of breeding ponds to off-road vehicle enthusiasts that use pond basins for ''mud bogging'' which disturbs the soil and vegetation and degrades the quality of a site for flatwoods salamander breeding. Roads may also alter the quality of isolated wetlands by draining, damming, or redirecting the water in a basin and contributing hydrocarbons and other chemical pollution via runoff and sedimentation.

A number of habitat degradation factors are implicated in the decline of one South Carolina flatwoods salamander population monitored for over 20 years (Moulis 1987, Bennett pers. comm. 1997). This site is bisected by a road that flatwoods salamanders have to cross to reach their breeding site. Much of the upland area, in which the salamanders dwell as adults, has undergone urban development (Bennett pers. comm. 1997). In addition, fire suppression has resulted in the loss of the open, grassy edge associated with quality breeding sites. Habitat quality at this site has degraded to the point where successful reproduction and recruitment are infrequent and the population is at risk.

Extensive surveys have been conducted over the past 7 years in Alabama, Georgia, Florida, South Carolina and Mississippi to search for flatwoods salamanders at historical localities and at other potential sites. The low level of success of these surveys is believed to be a reflection of both the loss of upland and isolated wetland breeding habitat and the reduction in the quality of these habitats.

B. *Overutilization for commercial, recreational, scientific, or educational purposes.* Overcollecting for scientific purposes may have contributed to the decline of a South Carolina population which was also impacted by habitat degradation. Between 1970 and 1976, a minimum of 84 adults and 870 larvae were collected in this area. Only two flatwoods salamanders have been captured at this locality since 1990, in spite of annual monitoring.

Overcollecting does not presently appear to be a significant threat to populations; however, it may become a problem if the specific locations become available to the general public. The rarity, uniqueness, and attractiveness of the species make the flatwoods salamander a candidate for the pet trade, should it become easy to obtain.

At some sites, larval flatwoods salamanders have been killed in association with bait harvesting for crayfish (Palis 1996). However, while this practice has caused the loss of some individuals, it is not currently thought to be a significant threat to the species as a whole.

C. *Disease or predation.* Disease is currently unknown in the flatwoods salamander.

Exposure to increased predation from fish is a potential threat to the flatwoods salamander when isolated, seasonally ponded breeding sites are changed to more permanent wetlands and become inhabited by fish. Ponds may be modified specifically to serve as fish ponds or sites may be altered due to the construction of drainage ditches or firebreaks which provide avenues for fish to enter the wetlands. Studies of other ambystomatid species have demonstrated a decline in larval survival in the presence of predatory fish (Semlitsch 1987, 1988).

D. *The inadequacy of existing regulatory mechanisms.* Regulatory mechanisms currently in effect do not provide adequate protection for the flatwoods salamander and its habitat. There are no existing regulatory mechanisms for the protection of the upland habitats where flatwoods salamanders spend most of their lives. Section 404 of the Clean Water Act is the primary Federal law that has the potential to provide some protection for the wetland breeding sites of the flatwoods salamander. Under section 404, nationwide permit 26 allows these wetlands to be filled with no review process if wetlands are less than 0.13 ha (⅓ ac) and with only minimal review if they are between 0.13 ha and 1.2 ha (3 ac) in size. Nationwide permit 26 cannot be used if there is a potential negative effect on a listed species.

Some populations on Federal lands have benefitted where prescribed burning has been used as a regular management tool. However, multiple use priorities on public lands, such as timber production, and military and recreational use, make protection of the flatwoods salamander secondary. The National Environmental Policy Act (NEPA) requires an intensive environmental review of projects that may adversely affect a federally listed species, but project proponents are not required to avoid impacts to non-listed species.

At the State and local levels, regulatory mechanisms are also limited. The flatwoods salamander is listed as a rare protected species in the State of Georgia (Seyle 1994). This designation protects the species by prohibiting actions that cause direct mortality or the destruction of its habitat on lands owned by the State of Georgia and by preventing its sale, purchase, or possession (Jensen, pers. comm., 1997). At present, there are no known flatwoods salamander populations on lands owned by the State of Georgia. In South Carolina, the flatwoods salamander is listed as endangered (Bennett 1995). Prohibitions extend only to the direct take of the flatwoods salamander (Bennett, pers. comm., 1997). These regulations offer no protection against the most significant threat to the flatwoods salamander, which is loss of its habitat. The flatwoods salamander is considered rare in Florida by the Florida Committee on Rare and Endangered Plants and Animals (Ashton 1992); however, there are no protective regulations for this species or its habitat in the State (Moler 1990).

E. *Other natural or manmade factors affecting its continued existence.* Fire is needed to maintain the natural pine flatwoods community. Fire suppression has been considered the primary reason for the degradation of remaining longleaf pine forest acreage (Means 1996b). Wolfe *et al.* (1988) reported that pine flatwoods naturally burn every 3 to 4 years, probably most commonly in the summer months. Sampling of longleaf pine flatwoods sites in Florida indicated that less than 30 percent of sites on private lands were being prescribed burned to mimic the effects of natural fire (Outcalt 1997). The disruption of the natural fire cycle has resulted in an increase in slash pine on sites formerly dominated by longleaf pine, an increase in hardwood understory, and a decrease in herbaceous ground cover (Wolfe *et al.* 1988; Means, pers. comm., 1995). Ponds surrounded by pine plantations and protected from the natural fire regime become unsuitable flatwoods salamander breeding sites due to canopy closure and the resultant reduction in emergent herbaceous vegetation needed for egg deposition and larval development sites (Palis 1993). Of the 13 historical flatwoods salamander localities altered to the point where the habitat was no longer suitable, fire suppression was a contributing factor in at least 5 (38 percent). Current forest management is moving away from burning as a management tool due to liability considerations and concerns that fire will damage the quality of the timber. When burning is used as a management tool, winter fires are commonly employed. Winter fires may not be optimal for the flatwoods salamander.

Habitat fragmentation of the longleaf pine ecosystem, resulting from habitat conversion, threatens the survival of the remaining flatwoods salamander populations. Forty-seven populations occur across four States. Fifty-three percent (25 of 47) of these populations are widely separated from each other by unsuitable habitat. Research conducted in Florida documented that 25 percent of remaining longleaf pine flatwoods sites were isolated fragments imbedded in agricultural and urban-dominated landscapes (Outcalt 1997). Studies have shown that the loss of fragmented populations is common, and recolonization is critical for their regional survival (Fahrig and Merriam 1994, Burkey 1995). As patches of available habitat become separated beyond the dispersal range of a species, populations are more sensitive to genetic, demographic, and environmental variability and may be unable to recover (Gilpin 1987, Sjogren 1991). Amphibian populations may be unable to recolonize areas after local extinctions due to their physiological constraints, relatively low mobility, and site fidelity (Blaustein *et al.* 1994).

Roads contribute to habitat fragmentation by isolating blocks of remaining contiguous habitat. Migration routes and dispersal of individuals to and from breeding sites may be disrupted. In addition, flatwoods salamanders may be killed by vehicles when attempting to cross roads (Means 1996a).

Pesticides and herbicides may pose a threat to amphibians such as the flatwoods salamander, because their permeable eggs and skin readily absorb substances from the surrounding aquatic or terrestrial environment (Duellman and Trueb 1986). They may be exposed to pesticides and herbicides accumulated in their invertebrate prey or their prey may be reduced through

the use of pesticides. In frogs, use of agricultural pesticides has resulted in lower survival rates, deformities, and lethal effects on tadpoles (Sanders 1970, FROGLOG 1993). Other negative effects of commonly used pesticides and herbicides on amphibians include delayed metamorphosis, paralysis, reduced growth rates, and mortality (Bishop 1992). Herbicides also alter the density and species composition of vegetation surrounding a breeding site and may reduce the number of potential sites for egg deposition, larval development, or shelter for migrating salamanders.

Long-lasting droughts or frequent floods may affect local flatwoods salamander populations. Although these are natural processes, other threats such as habitat fragmentation and habitat degradation may stress a population to the point that it cannot recover or recolonize other sites.

The Service has carefully assessed the best scientific and commercial information available regarding the past, present, and future threats faced by this species in determining to propose this rule. Based on this evaluation, the preferred action is to list the flatwoods salamander as threatened. The range and habitat of this species has been significantly reduced by activities associated with conversion of forests to agriculture and urban development, silvicultural practices, and the disruption of natural fire cycles. Remaining populations are vulnerable as suitable habitat continues to be lost or degraded by these activities. While not in immediate danger of extinction, the flatwoods salamander is likely to become an endangered species in the foreseeable future if the present trend continues.

**Critical Habitat**

Critical habitat is defined in section 3 of the Act as: (i) The specific areas within the geographical area occupied by a 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 consideration or protection and; (ii) specific areas outside the geographical area occupied by a species at the time it is listed, upon a determination that such areas are essential for the conservation of the species. ''Conservation'' means the use of all methods and procedures needed to bring the species to the point at which listing under the Act is no longer necessary.

Section 4(a)(3) of the Act, as amended, and 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. Service regulations (50 CFR 424.12(a)(1)) 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 activity and the 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. The Service finds that designation of critical habitat is not prudent for the flatwoods salamander.

Critical habitat designation, by definition, directly affects only Federal agency actions. Activities that might affect the flatwoods salamander on Federal lands include forestry management, military activities, and Federal actions that would impact the hydrology of the wetlands used by the flatwoods salamander for reproduction. Such activities would be subject to review under section 7(a)(2) of the Act, whether or not critical habitat was designated. Federal permit issuance on private lands would also be subject to review; however, the primary activities affecting habitat for the flatwoods salamander on private lands are silvicultural, and are not subject to the Federal review process under section 7.

Section 7(a)(2) requires Federal agencies to ensure that activities they authorize, fund, or carry out are not likely to jeopardize the continued existence of a listed species or to destroy or adversely modify its critical habitat. Common to definitions of the ''jeopardy'' and ''adverse modification'' standards is an appreciable detrimental effect on both survival and recovery of the species. The Service currently believes that any significant adverse modification or destruction of flatwoods salamander habitat to the extent that survival and recovery is appreciably diminished would likely jeopardize this species' continued existence. Therefore, habitat protection from Federal actions can be accomplished for the flatwoods salamander through the section 7 jeopardy standard. The Service is currently working with the appropriate Federal land managing agencies to identify, protect, and manage flatwoods salamander habitat.

On private lands, industrial timber landowners are cooperating with the Service to conduct surveys for the flatwoods salamander and to develop management strategies to protect its habitat. Should this rule become final, the Service will continue to coordinate with State and Federal agencies, as well as private property owners and other affected parties through the recovery process to manage habitat for the flatwoods salamander.

The Service believes that any potential benefits to critical habitat designation are outweighed by additional threats to the species that would result from such designation. Collecting for scientific and recreational purposes is a potential threat to the survival of the flatwoods salamander (see Factor B). Flatwoods salamanders are a rare and attractive species, and these characteristics make them potentially valuable in the pet trade. The collection of amphibians and reptiles for the pet trade has increased in recent years. For example, all box turtles have been placed on Appendix II of the Convention on International Trade in Endangered Species of Wild Fauna and Flora due to the increased commercialization of these species. Collection of amphibians and reptiles for personal use and the pet trade is common in the vicinity of the most viable flatwoods salamander populations (K. Enge, Florida Game and Fresh Water Fish Commission, pers. comm., 1997). Permits are required for commercial collecting; however, collection regulations are difficult to monitor and enforce. Flatwoods salamanders concentrate for breeding and reproduction around breeding ponds, where they are most vulnerable to collecting. Publication of specific localities of breeding ponds would be required in the critical habitat designation process in order to obtain the notification benefit provided by such designation. The publication of breeding pond sites would increase the flatwoods salamander's level of vulnerability to illegal collecting.

Based on the above analysis, the Service has concluded that critical habitat designation would provide little additional benefit for the flatwoods salamander beyond that which would result from listing under the Act. The Service also concludes that any potential benefit from such a designation would be offset by an increased level of vulnerability to collecting.

**Available Conservation Measures**

Conservation measures provided to species listed as endangered or threatened under the Act include recognition, recovery actions, requirements for Federal protection, and prohibitions against certain activities. Recognition through listing results in public awareness and conservation actions by Federal, State, and local

agencies, private organizations, and individuals. The Act provides for possible land acquisition and cooperation with the States and requires that recovery actions be carried out for all listed species. The protection required of Federal agencies and the prohibitions against taking and harm are discussed, in part, below.

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

The flatwoods salamander occurs on Federal lands administered by the Department of Defense, Fish and Wildlife Service, and U.S. Forest Service. These land management agencies would be required to evaluate the potential adverse impacts to the flatwoods salamander from their activities. Federal activities that could impact the flatwoods salamander through destruction or modification of suitable habitat include, but are not limited to, forest management, military operations, and road construction. Other Federal agencies that may be involved in authorizing, funding, or permitting activities that may affect the flatwoods salamander include the Army Corps of Engineers, due to their review of dredge and fill of isolated wetlands under section 404 of the Clean Water Act, nationwide permit 26; the Federal Energy Regulatory Commission, due to their oversight of gas pipeline and power line rights-of-way; and the Federal Highway Administration when Federal funds are involved in road construction. It has been the experience of the Service, however, that nearly all section 7 consultations have been resolved so that the species have been protected and the project objectives have been met.

The Act and its implementing regulations set forth a series of general prohibitions and exceptions that apply to all threatened wildlife. The prohibitions, codified at 50 CFR 17.21 and 17.31 for threatened wildlife, in part, make it illegal for any person subject to the jurisdiction of the United States to take (includes harass, harm, pursue, hunt, shoot, wound, kill, trap, capture, or collect; or to attempt any of these), import, export, ship in interstate commerce in the course of commercial activity, or sell or offer for sale in interstate or foreign commerce any listed species. It is also illegal to possess, sell, deliver, carry, transport, or ship any such wildlife that has been taken illegally. Certain exceptions apply to agents of the Service and State conservation agencies.

Permits may be issued to carry out otherwise prohibited activities involving threatened wildlife species under certain circumstances. Regulations governing permits are codified at 50 CFR 17.32 for threatened species. Such permits are available for scientific purposes, to enhance the propagation or survival of the species, and/or for incidental take in connection with otherwise lawful activities. For threatened species, permits also are available for zoological exhibition, educational purposes, or special purposes consistent with the purposes of the Act. In some instances, permits may be issued for a specified time to relieve undue economic hardship that would be suffered if such relief were not available. However, since this species is not currently in trade, such permit requests are not expected.

It is the policy of the Service, published in the **Federal Register** on July 1, 1994 (59 FR 34272), to identify, to the maximum extent practicable, those activities that would or would not constitute a violation of section 9 of the Act if the species is listed. The intent of this policy is to increase public awareness of the effects of the proposed listing on future and ongoing activities within a species' range. Activities which the Service believes are unlikely to result in a violation of section 9 for the flatwoods salamander are:

(1) Possession of legally acquired flatwoods salamanders;

(2) Lawful hunting activities;

(3) Lawful burning of habitat where the flatwoods salamander is known to occur, when used as a forest or wildlife management technique, including winter burning;

(4) Federally approved projects that involve activities such as discharge of fill material, draining, ditching, tiling, bedding, diversion or alteration of surface or ground water flow into or out of a wetland (i.e., due to roads, impoundments, discharge pipes, etc.), when such activity is conducted in accordance with any reasonable and prudent measures given by the Service in accordance with section 7 of the Act;

(5) Conversion of pine flatwoods habitat where the flatwoods salamander does not occur;

(6) Timber harvesting (including clear-cutting) in pine flatwoods habitat where the flatwoods salamander does not occur; and

(7) Crayfish bait collecting operations that do not harm flatwoods salamanders.

Activities that the Service believes would be likely to result in a violation of section 9, if the species is listed, include, but are not limited to:

(1) Unauthorized collecting or handling of individual flatwoods salamanders;

(2) Possessing, selling, transporting, or shipping illegally taken flatwoods salamanders;

(3) Unauthorized destruction or alteration of wetlands used as breeding sites by flatwoods salamanders. These actions would include discharge of fill material, draining, ditching, tiling, bedding, diversion or alteration of surface or ground water flow into or out of a wetland (i.e., due to roads, impoundments, discharge pipes, etc.), and operation of any vehicles within the wetland;

(4) Discharge or dumping of toxic chemicals, silt, or other pollutants (i.e., sewage, oil, and gasoline) into isolated wetlands or upland habitats supporting the species; and

(5) Unlawful destruction or alteration of suitable pine flatwoods habitat within a 1.6-km (1-mi) radius surrounding a known flatwoods salamander breeding pond. These actions would include, but are not limited to, destruction of the herbaceous ground cover or alteration of a site's existing hydrology, such as might result from conversion of habitat to agricultural or urban use, conversion of habitat to intensively managed pine plantations, or ditching and draining a site.

Other activities not identified above will be reviewed on a case-by-case basis to determine whether a violation of section 9 of the Act may be likely to result from such activities should the flatwoods salamander become listed. The Service does not consider these lists to be exhaustive and provides them as information to the public.

Questions regarding whether specific activities may constitute a future violation of section 9, should this species be listed, should be directed to

the Field Supervisor of the Service's Jackson Field Office (see **ADDRESSES** section). Requests for copies of the regulations regarding listed wildlife and inquiries about prohibitions and permits may be addressed to the U.S. Fish and Wildlife Service, 1875 Century Blvd., Suite 200, Atlanta, Georgia 30345, or telephone 404/679–7319; facsimile 404/679–7081.

Section 10(a)(1)(B) authorizes the Service to issue permits for the taking of listed species incidental to otherwise lawful activities such as agriculture, forestry, and urban development. Take permits authorized under section 10 must be supported by a habitat conservation plan (HCP) that identifies conservation measures that the permittee agrees to implement to conserve the species. A key element of the Service's review of a HCP is a determination of the plan's effect upon the long-term conservation of the species. The Service would approve a HCP, and issue a section 10(a)(1)(B) permit if the plan would minimize and mitigate the impacts of the taking and would not appreciably reduce the likelihood of the survival and recovery of that species in the wild.

## Public Comments Solicited

The Service intends that any final action resulting from this proposal will be as accurate and as effective as possible. Therefore, comments or suggestions from the public, other concerned governmental agencies, the scientific community, industry, or any other interested party concerning this proposed rule are hereby solicited. Comments are particularly sought concerning:

(1) Biological, commercial trade, or relevant data concerning any threat (or lack thereof) to the flatwoods salamander;

(2) The location of any additional populations of this species and the reasons why any habitat should or should not be determined to be critical habitat as provided by section 4 of the Act;

(3) Additional information concerning the range, distribution, and population size of this species; and

(4) Current or planned activities in the subject area and their possible impact on this species.

Final promulgation of the regulation on this species will take into consideration the comments and any additional information received by the Service, and such communications may lead to a final regulation that differs from this proposal.

The Act provides for one or more public hearings on the proposal, if requested. Requests must be received within 45 days of the date of publication of the proposal in the **Federal Register**. Such requests must be made in writing and addressed to the Field Supervisor (see **ADDRESSES** section).

## National Environmental Policy Act

The Fish and Wildlife Service has determined that an Environmental Assessment, as defined under the authority of the National Environmental Policy Act of 1969, need not be prepared in connection with regulations adopted pursuant to section 4(a) of the Endangered Species Act of 1973, as amended. A notice outlining the Service's reasons for this determination was published in the **Federal Register** on October 25, 1983 (48 FR 49244).

## Required Determinations

The Service has examined this regulation under the Paperwork Reduction Act of 1995 and found it to contain no information collection requirements.

## References Cited

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

Author: The primary author of this proposed rule is Linda V. LaClaire, Jackson Field Office (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, the Service hereby proposes to amend part 17, subchapter B of chapter I, 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 section 17.11(h) by adding the following, in alphabetical order under AMPHIBIANS, to the List of Endangered and Threatened Wildlife 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 | | | | | | |
| * | * | * | * | * | * | | * |
| AMPHIBIANS | | | | | | | |
| * | * | * | * | * | * | | * |
| Salamander flatwoods. | *Ambystoma cingulatum.* | U.S.A. (AL, FL, GA, SC). | Entire | T | NA | NA | |
| * | * | * | * | * | * | | * |

Dated: November 24, 1997.

**Jamie Rappaport Clark,**

*Director, Fish and Wildlife Service.*

[FR Doc. 97–32739 Filed 12–15–97; 8:45 am]

BILLING CODE 4310–55–P

# Notices

Federal Register
Vol. 62, No. 241
Tuesday, December 16, 1997

This section of the FEDERAL REGISTER contains documents other than rules or proposed rules that are applicable to the public. Notices of hearings and investigations, committee meetings, agency decisions and rulings, delegations of authority, filing of petitions and applications and agency statements of organization and functions are examples of documents appearing in this section.

## DEPARTMENT OF AGRICULTURE

### Office of the Secretary

### Committee on Scientists; Appointment of Committee Members

**AGENCY:** Forest Service, USDA.

**ACTION:** Notice.

**SUMMARY:** The Secretary of Agriculture has appointed 13 persons to serve on the Committee of Scientists, which is chartered to provide scientific and technical advice to the Secretary of Agriculture and the Chief of the Forest Service on improvements to the Forest Service land management planning process.

**FOR FURTHER INFORMATION CONTACT:** Jonathan Stephens, Ecosystem Management Coordination Staff, Forest Service, telephone: (202) 205–0948.

**SUPPLEMENTARY INFORMATION:** Notice of establishment of the Committee of Scientists, along with a request for nominations, was published August 15, 1997 (62 FR 43691). The following individuals have been appointed to serve on the Committee:

1. Committee Chair: Dr. Norman Johnson, Professor, Department of Forest Resources, Oregon State University, Corvallis, OR.
2. Dr. James Agee, Professor, Forest Ecology, University of Washington, Seattle, WA.
3. Dr. Virginia Dale, Senior Scientist, Environmental Sciences Division, Oak Ridge National Laboratory, Oak Ridge, TN.
4. Dr. Roger Sedjo, Senior Fellow, Resources for the Future, Washington, D.C.
5. Dr. Bob Beschta, Professor, Forest Hydrology, Oregon State University, Corvallis, OR.
6. Dr. Larry Nielsen, Professor and Director, School of Forest Resources, The Pennsylvania State University, University Park, PA.
7. Dr. Barry Noon, Associate Professor, Department of Fish and Wildlife, Colorado State University, Fort Collins, CO.
8. Dr. Ron Trosper, Professor and Director, Native American Forestry Program, Northern Arizona University, Flagstaff, AZ.
9. Dr. Julia Wondolleck, Assistant Professor, School of Natural Resources and Environment, University of Michigan, Ann Arbor, MI.
10. Dr. Linda Hardesty, Associate Professor, Forest and Range Management, Washington State University, Pullman, WA.
11. Charles Wilkinson, Professor of Law, University of Colorado, Boulder, CO.
12. Dr. James Long, Professor, Department of Forest Resources, Utah State University, Logan, UT.
13. Dr. Margaret Shannon, Associate Professor, Department of Public Administration and Center for Environmental Policy and Administration, Syracuse, New York.

The first meeting of the Committee of Scientists is scheduled for December 19, 1997, at the Holiday Inn O'Hare International, 5440 North River Road, Rosemont, Illinois (62 FR 64195, December 4, 1997).

Dated: December 12, 1997.

**Brian Eliot Burke,**

*Deputy Under Secretary, Natural Resources and Environment.*

[FR Doc. 97–32949 Filed 12–15–97; 8:45 am]

BILLING CODE 3410–11–M

## DEPARTMENT OF COMMERCE

### Submission for OMB Review; Comment Request

The Department of Commerce (DOC) has submitted to the Office of Management and Budget (OMB) for clearance the following proposal for collection of information under provisions of the Paperwork Reduction Act (44 U.S.C. Chapter 35). This collection has been submitted under the emergency Paperwork Reduction Act procedures.

*Agency:* National Oceanic and Atmospheric Administration (NOAA).

*Title:* Atlantic Bluefin Tuna Mandatory Catch Reporting.

*Agency Form Number:* None.

*OMB Approval Number:* None.

*Type of Request:* New collection—Emergency Review.

*Burden:* 117 hours.

*Number of Respondents:* 700.

*Avg. Hours Per Response:* 10 minutes.

*Needs and Uses:* The National Marine and Fisheries Service in cooperation with the North Carolina Division of Marine Fisheries will implement a pilot mandatory reporting program to conduct a census of the Recreational Winter Bluefin Tuna Harvest in North Carolina. Information on catch levels will be reported to the International Commission for the Conservation of Atlantic Tunas and will be used for stock assessment and in developing international catch sharing agreements. Anglers that currently report through an automated phone system will be exempted from this requirement during this pilot program.

*Affected Public:* Individuals.

*Frequency:* On occasion.

*Respondent's Obligation:* Mandatory.

*OMB Desk Officer:* David Rostker, (202) 395–3897.

Copies of the above information collection proposal can be obtained by calling or writing Linda Engelmeier, DOC Forms Clearance Officer, (202) 482–3272, Department of Commerce, Room 5327, 14th and Constitution Avenue, N.W., Washington, D.C. 20230.

Written comments and recommendations for the proposed information collection should be sent to David Rostker, OMB Desk Officer, Room 10202, New Executive Officer building, 725 17th Street, N.W., Washington, D.C. 20503. A clearance has been requested by December 19, 1997.

Dated: December 10, 1997.

**Linda Engelmeier,**

*Departmental Forms Clearance Officer, Office of Management and Organization.*

[FR Doc. 97–32783 Filed 12–15–97; 8:45 am]

BILLING CODE: 3510–22–P

## DEPARTMENT OF COMMERCE

### Bureau of the Census

### Current Population Survey (CPS) Fertility and Birth Expectation Supplement; Proposed Collection; Comment Request

**SUMMARY:** The Department of Commerce, as part of its continuing effort to reduce paperwork and respondent burden, invites the general

public and other Federal agencies to take this opportunity to comment on proposed and/or continuing information collections, as required by the Paperwork Reduction Act of 1995, Pub. L. 104–13 (44 U.S.C. 3506(c)(2)(A)).

**DATES:** Submit written comments on or before February 17, 1998.

**ADDRESSES:** Direct all written comments to: Linda Engelmeier, Departmental Forms Clearance Officer, Department of Commerce, Room 5327, 14th and Constitution Avenue, NW, Washington, DC 20230.

**FOR FURTHER INFORMATION CONTACT:** Requests for additional information or copies of the information collection instrument(s) and instructions should be directed to Tim Marshall, Bureau of the Census, FOB 3, Room 3340, Washington, DC 20233–8400, (301) 457–3806.

**SUPPLEMENTARY INFORMATION:**

## I. Abstract

The Census Bureau is requesting clearance for the collection of data concerning the Fertility and Birth Expectations Supplement to be conducted in conjunction with the June 1998 CPS. The Census Bureau sponsors the supplement questions, which were previously collected in June 1995, and have been asked periodically since 1971.

This survey provides information used mainly by government and private analysts to project future population growth, to analyze child spacing, and to aid policy makers in their decisions affected by changes in family size and composition. Past studies have discovered noticeable changes in the patterns of fertility rates, family structures, premarital births, and the timing of the first birth. Potential needs for government assistance such as aid to families with dependent children, child care, and maternal health care for single parent households can be estimated using CPS characteristics matched with fertility data. The birth expectations data also assist researchers and analysts who explore issues such as postponement of childbirth because of education or employment responsibilities.

## II. Method of Collection

The fertility and birth expectations information will be collected by both personal visit and telephone interviews in conjunction with the regular June CPS interviewing. All interviews are conducted using computer-assisted interviewing.

## III. Data

*OMB Number:* 0607–0610.

*Form Number:* There are no forms. We conduct all interviewing on computers.

*Type of Review:* Regular.

*Affected Public:* Individuals or Households.

*Estimated Number of Respondents:* 30,000.

*Estimated Time Per Response:* 1 minute.

*Estimated Total Annual Burden Hours:* 500.

*Estimated Total Annual Cost:* There are no costs to the respondents other than their time to answer the CPS questions.

*Respondents' Obligation:* Voluntary.

**Legal Authority:** Title 13, U.S.C., Section 182; and Title 29, U.S.C., Sections 1–9.

## IV. Request for Comments

Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden (including hours and cost) of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology.

Comments submitted in response to this notice will be summarized and/or included in the request for OMB approval of this information collection; they also will become a matter of public record.

Dated: December 11, 1997.

**Linda Engelmeier,**

*Department Forms Clearance Officer, Office of Management and Organization.*

[FR Doc. 97–32784 Filed 12–15–97; 8:45 am]

BILLING CODE 3510–07–P

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## DEPARTMENT OF COMMERCE

### International Trade Administration

**[A–588–823]**

### Professional Electric Cutting Tools From Japan; Extension of Time Limits for Antidumping Duty Administrative Review

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

**ACTION:** Extension of time limits for antidumping duty administrative review of professional electric cutting tools from Japan.

**SUMMARY:** The Department of Commerce (''the Department'') is extending the time limits for the final results of the antidumping duty administrative review of the antidumping order on professional electric cutting tools from Japan. This review covers one manufacturer and exporter of the subject merchandise: Makita Corporation. The period of review is July 1, 1995 through June 30, 1996.

**EFFECTIVE DATE:** December 16, 1997.

**FOR FURTHER INFORMATION CONTACT:** Stephen Jacques, AD/CVD Enforcement Group III—Office 9, Import Administration, International Trade Administration, U.S. Department of Commerce, 14th Street and Constitution Avenue, N.W., Washington D.C. 20230, telephone (202) 482–1391.

**SUPPLEMENTARY INFORMATION:** The Department initiated this administrative review on August 15, 1996 (61 FR 42416). Because it is not practicable to complete this review within the time limits mandated by section 751(a)(3)(A) of the Tariff Act of 1930 (''the Act''), as amended by the Uruguay Round Agreements Act of 1994, the Department is extending the time limits for the preliminary results of the aforementioned review to January 7, 1998. *See* memorandum from Joseph A. Spetrini to Robert S. LaRussa, which is on file in Room B–099 at the Department's headquarters.

This extension of time limits is in accordance with section 751(a)(3)(A) of the Act.

Dated: December 8, 1997.

**Joseph A. Spetrini,**

*Deputy Assistant Secretary, AD/CVD Enforcement Group III.*

[FR Doc. 97–32799 Filed 12–15–97; 8:45 am]

BILLING CODE 3510–DS–P

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## DEPARTMENT OF COMMERCE

### International Trade Administration

### Notice

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

**ACTION:** Notice.

Secretarial Delegation to the Fifth Session of the West-East Conference of Ministers of Economy, Industry, and Trade, Prague, Czech Republic, January 15–16, 1998.

**Conference Description**

Secretary Daley will visit Prague, Czech Rep. to lead a combined U.S. Government and business delegation to the Fifth Session of the West-East Conference of Ministers of Economy, Industry and Trade. The U.S. Department of Commerce is recruiting 4–7 U.S. firms active in Central and Eastern Europe, Russia and the Newly Independent States (NIS) for the business delegation to the Conference. The Secretary and his combined delegation will represent the United States at this forum which brings together government ministers and business leaders from the industrialized Western and reforming Eastern countries of Central and Eastern Europe, Russia, and the NIS in a joint effort to promote improved conditions for private sector development in the Eastern countries and expansion of East-West investment and trade.

The Conference creates a unique government-business dialogue which centers on a private sector led Business Forum. The Forum produces a set of concrete business recommendations for consideration and adoption by the government ministers. The Conference also extends in a practical way U.S. commercial and assistance programs in the region. The theme of this year's session is ''Partners for Prosperity.'' In Prague the Secretary also will conduct bilateral meetings with many of the participating ministers to advance U.S. commercial interests in the region.

The Muenster Process is intended to improve the governmental rules, laws, and policies affecting exports, imports, and investment between the Western industrial countries and the Eastern reforming countries and focuses on the practical, micro-economic factors affecting trade and investment. It first met in Muenster, Germany, May 7–9, 1992. Subsequent Muenster Conferences were held in Tokyo, Japan; Warsaw, Poland; and Baltimore, Maryland.

Muenster IV in Baltimore (March 3–5, 1996) was attended by 15 Ministers and over 80 private sector representatives from 18 countries. It placed heightened emphasis on business participation and stressed private sector views on the practical issues affecting business in Central and Eastern Europe, Russia, and the NIS. Those private sector views were reflected in the recommendations of the Conference's Baltimore Business Report, which was endorsed by the Muenster ministers.

Current member countries in the Muenster Process are France, Italy, Germany, Canada, Japan, United Kingdom, United States, Poland, Hungary, Czech Republic, Slovakia, Romania, Bulgaria, Slovenia, Estonia, Latvia, Lithuania, Russia, Belarus, Ukraine, and Kazakstan. Croatia and Moldova will be included in the Muenster Process at the Fifth Session in Prague. Representatives of the European Union (EU), European Bank for Reconstruction and Development (EBRD) and the Organization for Economic Cooperation and Development (OECD) also participate.

**Conference Goals**

1. To encourage and support the Business Forum to produce a comprehensive, substantive report that reflects business views on the most important economic and commercial issues in trade and investment development between West and East and that will serve as a guidepost for government actions in between Muenster sessions;
2. To utilize Business Forum results to obtain commitments from the reforming country governments to create competitive trade and investment climates, including greater transparency in procurement and government decision-making, accelerated privatization to encourage investment activity, measures to prohibit with bribery and corruption in international business transactions, harmonization of standards and testing, and increased protection of intellectual property rights;
3. To strengthen the Muenster Process as the preeminent business-government forum for Western and Eastern business leaders and government officials to meet face-to-face and talk candidly about the practical actions to accelerate substantially trade and investment activity in the region;
4. To extend in a practical way U.S. support for market democratic development of the reforming countries and their integration into the world economy.
5. To use the Secretary's bilateral meetings with other Muenster ministers, as well as informal contacts, to advance specific U.S. policy/business objectives and to advocate for U.S. firms on specific projects; and
6. To advance U.S.-Czech relations through Secretarial meetings with leading Czech officials and business representatives.

**Conference Itinerary/Scenario**

The Fifth Session will be held over a two-day period (Jan 15–16, 1997). The first day will be devoted to the Business Forum comprised of the business delegations from each Muenster member country (approximately 4–7 per country). The Business Forum will meet in three sub-groups: manufacturing, infrastructure, and services. The report of the Business Forum will reflect the consensus of the business delegations on the most important economic and commercial issues that need to be brought before the ministers.

On the morning of the second day, the business representatives of the Business Forum meet with the Muenster ministers in a joint session to present and discuss their report and its recommendations. In the afternoon, the Muenster ministers meet in a government-only session to discuss the Business Forum report, to set future directions for the Muenster Process, and to review the Conference's concluding document—the Summary of Conclusions. There will also be Conference networking events which will afford the Secretary and his delegation the opportunity to meet informally with other ministers and private sector representatives.

**Criteria for Participant Selection**

Company participation will be determined on the basis of:

1. Past and present business activity in Central and Eastern Europe, Russia, and the Newly Independent States;
2. Relevance of a company's business, through either trade or investment, to one or more of the conference's three broad sectoral working groups: infrastructure, manufacturing, and services;
3. Participation by a senior corporate representative able to further the commercial policy of the mission as described herein and to develop recommendations to advise the Fifth West-East Conference of Ministers of Economy, Industry and Trade on steps that should to be taken to accelerate the growth of trade and investment between the Western economies and the Reforming economies. Participants should be senior level representatives of U.S. companies who have the ability to relate company experiences in the reforming markets of Central and Eastern Europe, Russia, and the Newly Independent States and develop action recommendations based on these experiences;
4. Diversity of company size, type, location, demographics, and traditional under-representation in business; and
5. Certification that the company meets Departmental guidelines for participation.

An applicant's partisan political activities (including political contributions) are irrelevant to the selection process. The recruitment and

selection of private sector participants in the delegation will be conducted according to the Statement of Policy Governing Department of Commerce Overseas Trade Missions announced by Secretary Daley on March 3, 1997 and reflected herein.

### Time Frame for Application

Applications may be submitted after December 15th to Cheryl Bruner, Director of the Office of Business Liaison or Eric Schwerrin, Room 5062, U.S. Department of Commerce, Washington, DC 20230. Phone (202) 482–1360, Fax (202) 482–4054. All applications must be received by December 29, 1997. Applications received after December 29th will be considered on a space available basis.

Dated: December 11, 1997.

**Susanne L. Lotarski,**

*Director, Office of Eastern Europe, Russia and the Newly Independent States.*

[FR Doc. 97–32869 Filed 12–15–97; 8:45 am]

BILLING CODE 3510–DA–P

## DEPARTMENT OF COMMERCE

### National Institute of Standards and Technology

### Announcement of Meeting of National Conference on Weights and Measures

**AGENCY:** National Institute of Standards and Technology, Commerce.

**ACTION:** Notice of meeting.

**SUMMARY:** Notice is hereby given that the Interim Meeting of the National Conference on Weights and Measures will be held January 11 through 15, 1998, at the St. Anthony Hotel, San Antonio, TX. The meeting is open to the public. The National Conference on Weights and Measures is an organization of weights and measures enforcement officials of the States, counties, and cities of the United States, and private sector representatives. The interim meeting of the conference, as well as the annual meeting to be held next July (a notice will be published in the **Federal Register** prior to such meeting), brings together enforcement officials, other government officials, and representatives of business, industry, trade associations, and consumer organizations to discuss subjects that relate to the field of weights and measures technology and administration.

Pursuant to (15 U.S.C. 272B), the National Institute of Standards and Technology acts as a sponsor of the National Conference on Weights and Measures in order to promote uniformity among the States in the complex of laws, regulations, methods, and testing equipment that comprises regulatory control by the States of commercial weighing and measuring.

**DATES:** The meeting will be held January 11–15, 1998.

**LOCATION OF MEETING:** St Anthony Hotel, San Antonio, TX.

**FOR FURTHER INFORMATION CONTACT:** Dr. Gilbert Ugiansky, Executive Secretary, National Conference on Weights and Measures, P.O. Box 4025, Gaithersburg, Maryland 20885. Telephone: (301) 975–4004, or E-mail: owm@nist.gov.

Dated: December 5, 1997.

**Elaine Bunten-Mines,**

*Director, Program Office.*

[FR Doc. 97–32699 Filed 12–15–97; 8:45 am]

BILLING CODE 3510–13–M

## COMMITTEE FOR THE IMPLEMENTATION OF TEXTILE AGREEMENTS

### Adjustment of Import Limits for Certain Cotton and Man-Made Fiber Textile Products Produced or Manufactured in India

December 10, 1997.

**AGENCY:** Committee for the Implementation of Textile Agreements (CITA).

**ACTION:** Issuing a directive to the Commissioner of Customs adjusting limits.

**EFFECTIVE DATE:** December 12, 1997.

**FOR FURTHER INFORMATION CONTACT:** Janet Heinzen, International Trade Specialist, Office of Textiles and Apparel, U.S. Department of Commerce, (202) 482–4212. For information on the quota status of these limits, refer to the Quota Status Reports posted on the bulletin boards of each Customs port or call (202) 927–5850. For information on embargoes and quota re-openings, call (202) 482–3715.

**SUPPLEMENTARY INFORMATION:**

**Authority:** Section 204 of the Agricultural Act of 1956, as amended (7 U.S.C. 1854); Executive Order 11651 of March 3, 1972, as amended.

The current limits for certain categories are being adjusted, variously, for shift and carryforward.

A description of the textile and apparel categories in terms of HTS numbers is available in the CORRELATION: Textile and Apparel Categories with the Harmonized Tariff Schedule of the United States (see **Federal Register** notice 61 FR 66263, published on December 17, 1996). Also see 61 FR 68143, published on December 27, 1996.

**Troy H. Cribb,**

*Chairman, Committee for the Implementation of Textile Agreements.*

**Committee for the Implementation of Textile Agreements**

December 10, 1997.

Commissioner of Customs,

*Department of the Treasury, Washington, DC 20229.*

Dear Commissioner: This directive amends, but does not cancel, the directive issued to you on December 20, 1996, by the Chairman, Committee for the Implementation of Textile Agreements. That directive concerns imports of certain cotton, man-made fiber, silk blend and other vegetable fiber textiles and textile products, produced or manufactured in India and exported during the twelve-month period which began on January 1, 1997 and extends through December 31, 1997.

Effective on December 12, 1997, you are directed to adjust the limits for the following categories, as provided for under the Uruguay Round Agreement on Textiles and Clothing:

| Category | Adjusted twelve-month level [1] |
|---|---|
| 334/634 | 153,057 dozen. |
| 342/642 | 1,189,071 dozen. |
| 369–S [2] | 549,831 kilograms. |

[1] The limits have not been adjusted to account for any imports exported after December 31, 1996.

[2] Category 369–S: only HTS number 6307.10.2005.

The Committee for the Implementation of Textile Agreements has determined that these actions fall within the foreign affairs exception to the rulemaking provisions of 5 U.S.C. 553(a)(1).

Sincerely,

Troy H. Cribb,

*Chairman, Committee for the Implementation of Textile Agreements.*

[FR Doc. 97–32894 Filed 12–12–97; 2:35 pm]

BILLING CODE 3510–DR–F

## DEPARTMENT OF EDUCATION

**[CFDA No.: 84.162A]**

### Emergency Immigrant Education Program; Notice Inviting Applications for New Awards for Fiscal Year (FY) 1998

*Purpose of Program:* This program provides grants to State educational agencies (SEAs) to assist local educational agencies (LEAs) that experience unexpectedly large increases in their student population due to immigration. These grants are to be used to provide high-quality instruction to immigrant children and youth and to help those children and youth make the

transition into American society and meet the same challenging State performance standards expected of all children and youth.

*Eligible Applicants:* State educational agencies.

*Deadline for Transmittal of Applications:* March 16, 1998.

*Deadline for Intergovernmental Review:* May 15, 1998.

*Applications Available:* January 5, 1998.

*Available Funds:* $150 million.

**Note:** The Department is not bound by any estimates in this notice.

*Project Period:* Up to 17 months.

*Applicable Regulations:* (a) The Education Department General Administrative Regulations (EDGAR) in 34 CFR parts 76, 77, 79, 80, 81, 82, and 85; and (b) 34 CFR part 299, General Provisions, Elementary and Secondary Education Act, published on May 22, 1997 in the **Federal Register** (62 FR 28247).

*Programmatic Information:* An SEA is eligible for a grant if it meets the eligibility requirements specified in sections 7304 and 7305 of the Elementary and Secondary Education Act of 1965 (the Act), as amended by the Improving America's School's Act of 1994 (Pub. L. 103–382, enacted October 20, 1994). (20 U.S.C. 7544 and 7545). In order to receive an award under this program, an SEA must provide a count, taken during February 1998, of the number of immigrant children and youth enrolled in public and nonpublic schools in eligible LEAs in accordance with the requirements specified in section 7304 of the Act. An eligible LEA is one in which the number of immigrant children and youth enrolled in the public and nonpublic elementary and secondary schools within the district is at least either 500 or 3 percent of the total number of students enrolled in those public and nonpublic schools. (20 U.S.C. 7544(b)(2)). Under section 7501(7) of the Act, the term ''immigrant children and youth'' means individuals who are aged 3 through 21, were not born in any State, and have not been attending one or more schools in any one or more States for more than 3 full academic years. (20 U.S.C. 7601(7)).

**FOR APPLICATIONS OR INFORMATION CONTACT:** Ms. Harpreet Sandhu, U.S. Department of Education, 600 Independence Avenue, S.W., Room 5086, Switzer Building, Washington, D.C. 20202–6510. Telephone: (202) 205–9808. Individuals who use a telecommunications device for the deaf (TDD) may call the Federal Information Relay Service (FIRS) at 1–800–877–8339 between 8 a.m. and 8 p.m., Eastern time, Monday through Friday.

Individuals with disabilities may obtain this document in an alternate format (e.g., Braille, large print, audiotape, or computer diskette) on request to the contact person listed in the preceding paragraph.

Individuals with disabilities may obtain a copy of the application package in an alternate format, also, by contacting that person. However, the Department is not able to reproduce in an alternate format the standard forms included in the application package.

*Electronic Access to This Document:* Anyone may view this document, as well as all other Department of Education documents published in the **Federal Register**, in text or portable document format (pdf) on the World Wide Web at either of the following sites:

http://ocfo.ed.gov/fedreg.htm
http://www.ed.gov/news.html

To use the pdf you must have the Adobe Acrobat Reader Program with Search, which is available free at either of the previous sites. If you have questions about using the pdf, call the U.S. Government Printing Office toll free at 1–888–293–6498.

Anyone may also view these documents in text copy only on an electronic bulletin board of the Department. Telephone: (202) 219–1511 or, toll free, 1–800–222–4922. The documents are located under Option G—Files/Announcements, Bulletins and Press Releases.

**Note:** The official version of a document is the document published in the **Federal Register**.

**Program Authority:** 20 U.S.C. 7541–7549.

Dated: December 11, 1997.

**Delia Pompa,**

*Director, Office of Bilingual Education and Minority Language Affairs.*

[FR Doc. 97–32801 Filed 12–15–97; 8:45 am]

BILLING CODE 4000–01–P

## DEPARTMENT OF EDUCATION

### National Assessment Governing Board; Meeting

**AGENCY:** National Assessment Governing Board; Education.

**ACTION:** Notice of teleconference meeting.

**SUMMARY:** This notice sets forth the schedule and proposed agenda of a forthcoming teleconference meeting of the Joint Subject Area Committees 1 and 2 of the National Assessment Governing Board. This notice also describes the functions of the Board. Notice of this meeting is required under Section 10(a)(2) of the Federal Advisory Committee Act.

**DATES:** December 18, 1997.

**TIME:** 1:00 p.m.

**LOCATION:** National Assessment Governing Board, Suite 825, 800 North Capitol Street, NW., Washington, D.C. 20002–4233, Telephone: (202) 357–6938.

**FOR FURTHER INFORMATION CONTACT:** Mary Ann Wilmer, Operations Officer, National Assessment Governing Board, Suite 825, 800 North Capitol Street, N.W., Washington, D.C. 20002–4233, Telephone: (202) 357–6938.

**SUPPLEMENTARY INFORMATION:** The National Assessment Governing Board is established under section 412 of the National Education Statistics Act of 1994 (Title IV of the Improving America's Schools Act of 1994), (Pub. L. 103–382).

The Board is established to formulate policy guidelines for the National Assessment of Educational Progress. The Board is responsible for selecting subject areas to be assessed, developing assessment objectives, identifying appropriate achievement goals for each grade and subject tested, and establishing standards and procedures for interstate and national comparisons. Under Pub. L. 105–78, the National Assessment Governing Board is granted exclusive authority over developing Voluntary National Tests pursuant to contract number RJ97153001 and is required to review within 90 days (i.e., by February 11, 1998) and modify the contract to the extent the Board determines necessary, if the contract cannot be modified to the extent the Board determines necessary, the contract shall be terminated, and a new contract negotiated.

On December 18 between the hours of 1:00 p.m. the Joint Subject Area Committees #1 and #2 of the National Assessment Governing Board will hold a teleconference meeting to provide an update on progress for review of Voluntary National Tests specifications in reading and math, and to finalize plans for technical analysis and peer reviewers of this information. Because this is a teleconference meeting, facilities will be provided so the public will have access to the Committee's deliberations.

Records are kept of all Board proceedings and are available for public inspection at the U.S. Department of Education, National Assessment Governing Board, Suite 825, 800 North Capital Street, N.W., Washington, D.C., from 8:30 a.m. to 5:00 p.m.

Dated: December 11, 1997.

**Roy Truby,**

*Executive Director, National Assessment Governing Board.*

[FR Doc. 97–32726 Filed 12–15–97; 8:45 am]

BILLING CODE 4000–01–M

## DEPARTMENT OF ENERGY

### Federal Energy Regulatory Commission

**[Docket No. ER98–171–000]**

### Energy 2000 Incorporated, Notice of Issuance of Order

December 11, 1997.

Energy 2000 Incorporated (Energy 2000) submitted for filing a rate schedule under which Energy 2000 will engage in wholesale electric power and energy transactions as a marketer. Energy 2000 also request waiver of various Commission regulations. In particular, Energy 2000 requested that the Commission grant blanket approval under 18 CFR Part 34 of all future issuances of securities and assumptions of liability by Energy 2000.

On November 25, 1997, pursuant to delegated authority, the Director, Division of Rate Applications, Office of Electric Power Regulation, granted requests for blanket approval under Part 34, subject to the following:

Within thirty days of the date of the order, any person desiring to be heard or to protest the blanket approval of issuances of securities or assumptions of liability by Energy 2000 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).

Absent a request for hearing within this period, Energy 2000 is authorized to issue securities and assume obligations or liabilities as a guarantor, endorser, surety, or otherwise in respect of any security of another person; provided that such issuance or assumption is for some lawful object within the corporate purposes of the applicant, and compatible with the public interest, and is reasonably necessary or appropriate for such purposes.

The Commission reserves the right to require a further showing that neither public nor private interests will be adversely affected by continued approval of Energy 2000's issuances of securities or assumptions of liability.

Notice is hereby given that the deadline for filing motions to intervene or protests, as set forth above, is December 29, 1997. Copies of the full text of the order are available from the Commission's Public Reference Branch, 888 First Street, NE., Washington, DC 20426.

**Lois D. Cashell,**

*Secretary.*

[FR Doc. 97–32764 Filed 12–15–97; 8:45 am]

BILLING CODE 6717–01–M

## DEPARTMENT OF ENERGY

### Federal Energy Regulatory Commission

**[Docket No. ER98–13–000]**

### Enron Energy Services Power, Inc.; Notice of Issuance of Order

December 11, 1997.

Enron Energy Services Power, Inc. (Enron Energy), is a power marketing affiliate of Enron Corporation and Portland General Electric Company. It also is an affiliate of Enron Power Marketing, Inc., another power-marketer with market-based rate authorization. Enron Energy filed an application for authorization to sell electric energy and capacity at market-based rates, and for certain waivers and authorizations. In particular, Enron Energy requested that the Commission grant blanket approval under 18 CFR Part 34 of all future issuances of securities and assumptions of liabilities by Enron Energy. On November 26, 1997, the Commission issued an Order Conditionally Accepting For Filing Proposed Market-Based Rates (Order), in the above-docketed proceeding.

The Commission's November 26, 1997 Order granted the request for blanket approval under Part 34, subject to the conditions found in Ordering Paragraphs (D), (E), and (G):

(D) 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 Enron Energy should file a motion to intervene or protest with the Federal Energy Regulatory Commission, 888 First Street, N.E., Washington, D.C. 20426, in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure, 18 CFR 385.211 and 385.214.

(E) Absent a request to be heard within the period set forth in Ordering Paragraph (D) above, Enron Energy is hereby authorized, pursuant to section 204 of the FPA, 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 Enron Energy, compatible with the public interest, and reasonably necessary or appropriate for such purposes.

(G) 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 Enron Energy'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 December 29, 1997.

Copies of the full text of the Order are available from the Commission's Public Reference Branch, 888 First Street, N.E., Washington, D.C. 20426.

**Lois D. Cashell,**

*Secretary.*

[FR Doc. 97–32765 Filed 12–15–97; 8:45 am]

BILLING CODE 6717–01–M

## DEPARTMENT OF ENERGY

### Federal Energy Regulatory Commission

**[Docket No. ER97–4787–000]**

### High Island Marketing, Inc.; Notice of Issuance of Order

December 11, 1997.

High Island Marketing, Inc. (High Island) submitted for filing a rate schedule under which High Island will engage in wholesale electric power and energy transactions as a marketer. High Island also requested waiver of various Commission regulations. In particular, High Island requested that the Commission grant blanket approval under 18 CFR Part 34 of all future issuances of securities and assumptions of liability by High Island.

On November 25, 1997, pursuant to delegated authority, the Director, Division of Rate Applications, Office of Electric Power Regulation, granted requests for blanket approval under Part 34, subject to the following:

Within thirty days of the date of the order, any person desiring to be heard or to protest the blanket approval of issuances of securities or assumptions of liability by High Island should file a motion to intervene or protest with the Federal Energy Regulatory Commission, 888 First Street, N.E., Washington, D.C. 20426, in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211 and 385.214).

Absent a request for hearing within this period, High Island is authorized to

issue securities and assume obligations or liabilities as a guarantor, indorser, surety, or otherwise in respect of any security of another person; provided that such issuance or assumption is for some lawful object within the corporate purposes of the applicant, and compatible with the public interest, and is reasonably necessary or appropriate for such purposes.

The Commission reserves the right to require a further showing that neither public nor private interests will be adversely affected by continued approval of High Island's issuances of securities or assumptions of liability.

Notice is hereby given that the deadline for filing motions to intervene or protests, as set forth above, is December 29, 1997. Copies of the full text of the order are available from the Commission's Public Reference Branch, 888 First Street, N.E., Washington, D.C. 20426.

**Lois D. Cashell,**

*Secretary.*

[FR Doc. 97–32766 Filed 12–15–97; 8:45 am]

BILLING CODE 6717–01–M

## DEPARTMENT OF ENERGY

### Federal Energy Regulatory Commission

**[Docket No. MT98–5–000]**

### Midcoast Interstate Transmission, Inc.; Notice of Proposed Changes in FERC Gas Tariff

December 10, 1997.

Take notice that on December 5, 1997, Midcoast Interstate Transmission, Inc. (MIT) tendered for filing in its FERC Gas Tariff, Second Revised Volume No. 1, the following tariff sheets to become effective January 1, 1998:

Fourth Revised Sheet No. 148
Third Revised Sheet No. 149
Third Revised Sheet No. 150

MIT states that the purpose of the filing of the Revised Tariff Sheets is to update its tariff to reflect certain recent changes related to the offices and personnel of its marketing affiliate.

Any person desiring to be heard or to protest said filing should file a motion to intervene or protest with the Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426, in accordance with Sections 385.214 and 385.211 of the Commission's Rules and Regulations. All such motions or protests should be filed in accordance with Section 154.211 of the Commission's Rules and Regulations. All such motions or protests should be filed in accordance with Section 154.210 of the Commission's Regulations. Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Any person wishing to become a party must file a motion to intervene. Copies of this filing are on file with the Commission and are available for public inspection in the Public Reference Room.

**Lois D. Cashell,**

*Secretary.*

[FR Doc. 97–32712 Filed 12–15–97; 8:45 am]

BILLING CODE 6717–01–M

## DEPARTMENT OF ENERGY

### Federal Energy Regulatory Commission

**[Docket No. CP96–27–002]**

### Natural Gas Pipeline Company of America; Notice of Application to Amend Certificate

December 10, 1997.

Take notice that on November 12, 1997, as supplemented on December 5, 1997, Natural Gas Pipeline Company of America (Natural), located at 701 East 22nd Street, Lombard, Illinois 60148, filed in Docket No. CP96–27–002 an Application to Amend Certificate (Amendment) pursuant to Section 7 of the Natural Gas Act (NGA).[1] The certificate authority in this docket was issued pursuant to the Preliminary Determination issued on August 1, 1996 (76 FERC 61,142) and the Order Issuing Certificate issued on August 1, 1997 (80 FERC 61,147). The details of Natural's proposal are more fully set forth in its Amendment which is on file with the Commission and open for public inspection.

The above referenced Commission Orders authorized the expansion of Natural's Amarillo Mainline by 345 MMcf/d to help serve 525 MMcf/d of new load expected to come on-line at Harper, Iowa, as of November 1, 1998. The Commission's Orders recognized that the difference between the expected new load and the amount of new capacity to be constructed would be provided by capacity to be turned back by MidCon Gas Services Corporation (MidCon Gas). Now, Natural has gotten an additional 120 MMcf/d of turned back capacity and expects to get 110 MMcf/d more before the 520 MMcf/d of new load comes on-line.

The Amendment notes, first, that the new load has been reduced to 520 MMcf/d because one of the shippers has been unable to obtain upstream capacity. However, the primary purpose of the Amendment is to reduce the amount of new capacity to be built to help serve the 520 MMcf/d of new load. Natural requests that two specific expansion levels be authorized, in lieu of the 345 MMcf/d level. They are 220 MMcf/d (estimated to cost $55.1 million) and 110 MMcf/d (estimated to cost $23.7 million).

The 9,000 horsepower of additional compression at Station 110 in Henry County, Illinois and the Mississippi River crossing, already approved in the previous orders, will still be used. The Amendment will reduce the number of miles of new 36-inch loop line that will be constructed. As originally certificated, the project required 85.7 miles of new pipeline looping in various segments. The 220 case will reduce that to 34.8 miles. The 110 case will reduce it to 4.1 miles. In both cases, the new loop line will be constructed in right-of-way that was approved in the previous orders. The only changes will be the locations of the necessary crossover points, where the new loop line and, in the 110 case, the Mississippi River crossing will be interconnected with existing facilities of the Amarillo Mainline.

Natural states that it will actually construct the facilities for only one of the two new expansion levels, depending on the total amount of existing capacity that is actually available to help serve the new load. The Amendment states that no significant environmental issues are presented, because the lower expansion levels will result from a shortening of the loop line mileage previously authorized in this docket. A continuation of rolled-in rate treatment is said to be warranted, because each of the two new expansion levels will have only a minimal impact on Natural's existing rates.

Any person desiring to be heard or making any protest with reference to said Amendment should on or before December 31, 1997, file with the Federal Energy Regulatory Commission, 888 First Street, NE, Washington, D.C. 20426, a motion to intervene or a protest in accordance with the requirements of the Commission's Rules of Practice and Procedure (18 CFR 385.214 or 385.211) and the Regulations under the Natural Gas Act (18 CFR 157.10). All protests filed with the commission will be considered by it in determining the appropriate action to be taken but will not serve to make the protestants parties to the proceeding. The Commission's rules require that protestors provide

[1] Natural's Amendment was incomplete until the supplement was filed on December 5, 1997.

copies of their protests to the party or person to whom the protests are directed. Any person wishing to become a party to a proceeding or to participate as a party in any hearing therein must file a motion to intervene in accordance with the Commission's Rules. Persons who previously filed motions to intervene on Docket No. CP96–27–000 and 001 need not file again.

A person obtaining intervenor status will be placed on the service list maintained by the Secretary of the Commission and will receive copies of all documents issued by the Commission, filed by the applicant, or filed by all other intervenors. An intervenor can file for rehearing of any Commission order and can petition for court review of any such order. However, an intervenor must serve copies of comments or any other filing it makes with the Commission to every other intervenor in the proceeding, as well as filing an original and 14 copies with the Commission.

A person does not have to intervene, however, in order to have comments considered. A person, instead, may submit two copies of such comments to the Secretary of the Commission. Commenters will be placed on the Commission's environmental mailing list, will receive copies of environmental documents, and will be able to participate in meetings associated with the Commission's environmental review process. Commenters will not be required to serve copies of filed documents on all other parties. However, commenters will not receive copies of all documents filed by other parties or issued by the Commission, and will not have the right to seek rehearing or appeal the Commission's final order to a Federal court.

The Commission will consider all comments and concerns equally, whether filed by commenters or those requesting intervenor status.

Take further notice that, pursuant to the authority contained in and subject to the jurisdiction conferred upon the Federal Energy Regulatory Commission by Sections 7 and 15 of the NGA and the Commission's Rules of Practice and Procedure, a hearing will be held without further notice before the Commission or its designee on these applications if no motion to intervene is filed within the time required herein, if the Commission on its own review of the matter finds that a grant of the certificate is required by the public convenience and necessity. If a motion for leave to intervene is timely filed, or if the Commission on its own motion believes that a formal hearing is required, further notice of such hearing will be duly given.

Under the procedure herein provided for, unless otherwise advised, it will be unnecessary for Natural to appear or be represented at the hearing.

**Lois D. Cashell,**

*Secretary.*

[FR Doc. 97–32711 Filed 12–15–97; 8:45 am]

BILLING CODE 6717–01–M

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## DEPARTMENT OF ENERGY

### Federal Energy Regulatory Commission

**[Docket No. RP98–85–000]**

### NorAm Gas Transmission Company; Notice of Proposed Changes in FERC Gas Tariff

December 10, 1997.

Take notice that on December 5, 1997, NorAm Gas Transmission Company (NGT) tendered for filing as part of its FERC Gas Tariff, Fourth Revised Volume No. 1, the following revised tariff sheets, to be effective April 1, 1998:

Third Revised Sheet No. 190
First Revised Sheet No. 192A
Third Revised Sheet No. 196
First Revised Sheet No. 201A
First Revised Sheet No. 204A
Third Revised Sheet No. 276
Second Revised Sheet No. 278
First Revised Sheet No. 279A
First Revised Sheet No. 279B
First Revised Sheet No. 279C
Third Revised Sheet No. 280
Third Revised Sheet No. 286
Second Revised Sheet No. 290
Second Revised Sheet No. 305
First Revised Sheet No. 305A
Third Revised Sheet No. 307
First Revised Sheet No. 307A

NGT states that the filing revises the tariff to eliminate paper nominations and paper capacity release transactions, and provides that such activities will be accomplished electronically except during times of emergency.

Any person desiring to be heard or to protest this filing should file a motion to intervene or protest with the Federal Energy Regulatory Commission, 888 First Street, N.E., Washington, D.C. 20426, in accordance with Sections 385.214 and 385.211 of the Commission's Rules of Practice and Procedure. All such motions or protests should be filed as provided in Section 154.210 of the Commission's Regulations. Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Any person wishing to become a party must file a motion to intervene. Copies of this filing are on file with the Commission and are available for public inspection in the Public Reference Room.

**Lois D. Cashell,**

*Secretary.*

[FR Doc. 97–32710 Filed 12–15–97; 8:45 am]

BILLING CODE 6717–01–M

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## DEPARTMENT OF ENERGY

### Federal Energy Regulatory Commission

**[Docket No. ER97–4352–000]**

### SEMCO Energy Services, Inc.; Notice of Issuance of Order

December 11, 1997.

SEMCO Energy Services, Inc. (SEMCO) submitted for filing a rate schedule under which SEMCO will engage in wholesale electric power and energy transactions as a marketer. SEMCO also requested waiver of various Commission regulations. In particular, SEMCO requested that the Commission grant blanket approval under 18 CFR Part 34 of all future issuances of securities and assumptions of liability of SEMCO.

On November 28, 1997, pursuant to delegated authority, the Director, Division of Rate Applications, Office of Electric Power Regulation, granted requests for blanket approval under Part 34, subject to the following:

Within thirty days of the date of the order, any person desiring to be heard or to protest the blanket approval of issuances of securities or assumptions of liability by SEMCO should file a motion to intervene or protest with the Federal Energy Regulatory Commission, 888 First Street, N.E., Washington, D.C. 20426, in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedures (18 CFR 385.211 and 385.214).

Absent a request for hearing within this period, SEMCO is authorized to issue securities and assume obligations or liabilities as a guarantor, indorser, surety, or otherwise in respect of any security of another person; provided that such issuance of assumption is for some lawful object within the corporate purposes of the applicant, and compatible with the public interest, and is reasonably necessary or appropriate for such purposes.

The Commission reserves the right to require a further showing that neither public nor private interests will be adversely affected by continued approval of SEMCO's issuances of securities or assumptions of liability.

Notice is hereby given that the deadline for filing motions to intervene or protests, as set forth above, is December 29, 1997. Copies of the full text of the order are available from the Commission's Public Reference Branch, 888 First Street, NE., Washington, DC 20426.

**Lois D. Cashell,**

*Secretary.*

[FR Doc. 97–32767 Filed 12–15–97; 8:45 am]

BILLING CODE 6717–01–M

## DEPARTMENT OF ENERGY

### Federal Energy Regulatory Commission

**[Docket No. RP98–84–000]**

### Tennessee Gas Pipeline Company; Notice of Filing

December 10, 1997.

Take notice that on December 5, 1997, Tennessee Gas Pipeline Company (Tennessee), pursuant to Section 4 of the Natural Gas Act and Part 154 of the Regulations of the Federal Energy Regulatory Commission (Commission) filed original and revised tariff sheets setting forth Tennessee's policy regarding the construction and financing of new facilities on its system for the receipt, delivery or measurement of natural gas supplies (Receipt and Delivery Facilities).

Tennessee states that its existing lateral line policy is set forth in Article XVII of the General Terms & Conditions of Tennessee's FERC Tariff, Volume No. 1 to satisfy the requirements of Section 154.109(b) of the Commission's Regulations which requires that the General Terms & Conditions of a pipeline's tariff set forth the pipeline's policy regarding the construction and financing of delivery laterals, including when the pipeline will pay for or contribute to the construction cost. Tennessee's existing policy provides that Tennessee will not build or contribute to the cost of building any service lateral. However, Tennessee has the right to seek a waiver of that policy during any proceeding before the Commission instituted under Section 7 of the Natural Gas Act.

Tennessee states that this policy is too inflexible in the competitive marketplace which exists today. Thus, Tennessee is proposing to eliminate the current provisions of Article XVII.

Tennessee states that the proposed tariff sheets establish and define two categories of Receipt and Delivery Facilities—Tap Facilities and Connecting Facilities. The proposed tariff sheets also establish two categories of cost reimbursement—prior to the construction of the facilities and over time with interest. Additionally, the proposed tariff sheets eliminate the current provisions of Article XVII and permit Tennessee to contribute to the cost of constructing service laterals as Connecting Facilities without obtaining a waiver from the Commission. Tennessee states that these proposed changes to its tariff will enable Tennessee to compete on a level playing field with other pipelines.

Although Tennessee states that it is not obligated to construct Tap Facilities or Tap and Connecting Facilities for any requesting party, the proposed tariff sheets provide that, subject to certain conditions specified in the tariff sheets, Tennessee will construct Tap Facilities or Tap and Connecting Facilities for any requesting party who agrees to pay for the cost of constructing such facilities. With respect to the financing of Tap Facilities constructed by Tennessee, the proposed tariff sheets provide that the requesting party will generally pay Tennessee for the cost of such facilities prior to the construction of the Connecting Facilities but always prior to the commencement of service at the Tap Facilities. With respect to the financing of Connecting Facilities, the proposed tariff sheets provide that the requesting party shall pay Tennessee for the cost of such facilities either prior to the construction of the Tap Facilities but always prior to the commencement of service at the Connecting Facilities, over time with interest or through some combination thereof.

Further, the tendered tariff sheets enable Tennessee to pay all or a portion of the costs of constructing Connecting Facilities which are economically or operationally beneficial to Tennessee. The proposed tariff sheets set forth the criteria that Tennessee will evaluate in determining whether the construction of Connecting Facilities is economically or operationally beneficial to Tennessee.

The proposed tariff provisions also permit Tennessee to condition its construction of Connecting Facilities on the reimbursement by the requesting party of related costs such as operating and maintenance expenses, administrative and general expenses, gross-up for state and federal income taxes, taxes other than income taxes, depreciation costs and the time value of money. These provisions recognize that, in certain circumstances, it may be appropriate to recover costs of this nature from the requesting party rather than the system as a whole. Tennessee's decision not to seek recovery of these costs from a requesting party would not preclude Tennessee from seeking to recover such costs in its general system rates in a Section 4 rate filing.

Any person desiring to be heard or to protest said filing should file a motion to intervene or protest with the Federal Energy Regulatory Commission, 888 First Street, N.E., Washington, D.C. 20426, in accordance with Section 385.211 and 385.214 of the Commission's Rules and Regulations. All such motions or protests should be filed in accordance with Section 154.210 of the Commission's Regulations. Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Any person wishing to become a party must file a motion to intervene. Copies of this filing are on file with the Commission and are available for public inspection in the Public Reference Room.

**Lois D. Cashell,**

*Secretary.*

[FR Doc. 97–32715 Filed 12–15–97; 8:45 am]

BILLING CODE 6717–01–M

## DEPARTMENT OF ENERGY

### Federal Energy Regulatory Commission

**[Docket No. EG98–13–000, et al.]**

### Ogden Energy China, (Beta) Ltd., et al. Electric Rate and Corporate Regulation Filings

December 9, 1997.

Take notice that the following filings have been made with the Commission:

**1. Ogden Energy China (Beta) Ltd.**

[Docket No. EG98–13–000]

On December 1, 1997, Ogden Energy China (Beta) Ltd., (OECB) filed with the Federal Energy Regulatory Commission (Commission) an application for determination of exempt wholesale generator status pursuant to Part 365 of the Commission's Regulations.

OECB will own a sixty percent equity interest in a 24 MW eligible facility located in Zibo, Shandong Province, Peoples Republic of China. OECB states that it will be engaged directly and exclusively in the business of owning and/or operating all or part of one of more eligible facilities (as defined in Section 32(a)(1) of the Public Utility Holding Company Act) and selling electricity at wholesale to the Huantian Power Bureau and at retail to consumers none of which will be located within the United States.

*Comment date:* December 29, 1997, 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. Boston Edison Company**

[Docket No. ER86–645–010]

Take notice that on November 13, 1997, Boston Edison Company filed a refund report in compliance with the Commission's Order on Remand Directing Refunds in this proceeding on September 29, 1997. Refunds were made to thirteen municipal customers of Boston Edison Company's Pilgrim Nuclear Plant.

*Comment date:* December 23, 1997, in accordance with Standard Paragraph E at the end of this notice.

**3. Niagara Mohawk Power Corporation**

[Docket No. ER97–2006–001]

Take notice that on November 24, 1997, Niagara Mohawk Power Corporation tendered for filing its refund report in the above-referenced docket.

*Comment date:* December 23, 1997, in accordance with Standard Paragraph E at the end of this notice.

**4. Virginia Electric and Power Company**

[Docket No. ER97–3659–001]

Take notice that on November 14, 1997, Virginia Electric and Power Company tendered for filing its refund report in the above-referenced docket.

*Comment date:* December 23, 1997, in accordance with Standard Paragraph E at the end of this notice.

**5. Florida Power Corporation**

[Docket No. ER97–4461–001]

Take notice that on November 21, 1997, Florida Power Corporation (Florida Power) tendered for filing an amended Form of Service Agreement for Network Integration Transmission Service providing for network transmission service to itself in connection with requirements service to its wholesale power customers pursuant to Part III of Florida Power's Open Access Tariff.

*Comment date:* December 23, 1997, in accordance with Standard Paragraph E at the end of this notice.

**6. Northeast Utilities Service Company**

[Docket No. ER98–533–000]

Take notice that on November 14, 1997, Northeast Utilities Service Company tendered for filing an amendment in the above-referenced docket.

*Comment date:* December 23, 1997, in accordance with Standard Paragraph E at the end of this notice.

**7. PJM Interconnection, L.L.C.**

[Docket No. ER98–536–000]

Take notice that on November 20, 1997, PJM Interconnection, L.L.C., tendered for filing an amendment in the above-referenced docket.

*Comment date:* December 23, 1997, in accordance with Standard Paragraph E at the end of this notice.

**8. Pacific Northwest Generating Cooperative**

[Docket No. ER98–706–000]

Take notice that on November 17, 1997, Pacific Northwest Generating Cooperative (PNGC), tendered for filing a Notice of Cancellation of the cost-based rate schedules established in the above-referenced docket. Instead of using these rate schedules, PNGC and its members desire that PNGC provide wholesale service to the members under the market-based rate schedule approved in Docket No. ER97–505 and OA97–32. PNGC requests an effective date of November 17, 1997, for the Notice of Cancellation.

Copies of the filing were served upon purchasers affected by the proposed cancellation.

*Comment date:* December 23, 1997, in accordance with Standard Paragraph E at the end of this notice.

**9. Central Power and Light Company; West Texas Utilities Company; Public Service Company of Oklahoma; Southwestern Electric Power Company**

[Docket No. ER98–707–000]

Take notice that on November 18, 1997, Central Power and Light Company (CPL), West Texas Utilities Company (WTU), Public Service Company of Oklahoma (PSO) and Southwestern Electric Power Company (SWEPCO) (collectively, the CSW Operating Companies) submitted for filing notices of cancellation of certain firm point-to-point transmission service agreements.

The CSW Operating Companies state that the filing has been served on the affected customers and on the Public Utility Commission of Texas.

*Comment date:* December 23, 1997, in accordance with Standard Paragraph E at the end of this notice.

**10. Interstate Power Company**

[Docket No. ER98–708–000]

Take notice that on November 18, 1997, Interstate Power Company (IPW), tendered for filing a Transmission Service Agreement between IPW and Continental Energy Services, LLC (Continental). Under the Transmission Service Agreement, IPW will provide non-firm point-to-point transmission service to Continental.

*Comment date:* December 23, 1997, in accordance with Standard Paragraph E at the end of this notice.

**11. Central Illinois Public Service Company**

[Docket No. ER98–709–000]

Take notice that on November 18, 1997, Central Illinois Public Service Company (CIPS), submitted a Service Agreement, dated November 3, 1997, establishing USGen Power Services, L.P. as a customer under the terms of CIPS' Coordination Sales Tariff CST–1 (CST–1 Tariff).

CIPS requests an effective date of November 3, 1997, for the service agreement and the revised Index of Customers. Accordingly, CIPS requests waiver of the Commission's notice requirements. Copies of this filing were served upon USGen Power Services, L.P., and the Illinois Commerce Commission.

*Comment date:* December 23, 1997, in accordance with Standard Paragraph E at the end of this notice.

**12. Entergy Services, Inc.**

[Docket No. ER98–710–000]

Take notice that on November 18, 1997, Entergy Services, Inc. (Entergy Services), on behalf of Entergy Arkansas, Inc., Entergy Gulf States, Inc., Entergy Louisiana, Inc., Entergy Mississippi, Inc., and Entergy New Orleans, Inc. (collectively, the Entergy Operating Companies), tendered for filing a Non-Firm Point-To-Point Transmission Service Agreement between Entergy Services, as agent for the Entergy Operating Companies, and Continental Energy Services, L.L.C.

*Comment date:* December 23, 1997, in accordance with Standard Paragraph E at the end of this notice.

**13. Ohio Edison Company; Pennsylvania Power Company**

[Docket No. ER98–711–000]

Take notice that on November 18, 1997, Ohio Edison Company, tendered for filing on behalf of itself and Pennsylvania Power Company, Service Agreements for Network Integration Service under the Pennsylvania Retail Pilot with Allegheny Energy Solutions, Inc., New Energy Ventures, L.L.C., DTE-CoEnergy, L.L.C., and Strategic Energy Partners, Ltd., pursuant to Ohio Edison's Open Access Tariff. These Service Agreements will enable the parties to obtain Network Integration Service under the Pennsylvania Retail Pilot in accordance with the terms of the Tariff.

*Comment date:* December 23, 1997, in accordance with Standard Paragraph E at the end of this notice.

**14. Ohio Edison Company and Pennsylvania Power Company**

[Docket No. ER98–712–000]

Take notice that on November 18, 1997, Ohio Edison Company, tendered for filing on behalf of itself and Pennsylvania Power Company, Service Agreements with WPS Energy Services, Inc., DTE-CoEnergy, L.L.C., New Energy Ventures, L.L.C., and Allegheny Energy Solutions, Inc., under Ohio Edison's Power Sales Tariff. This filing is made pursuant to § 205 of the Federal Power Act.

*Comment date:* December 23, 1997, in accordance with Standard Paragraph E at the end of this notice.

**15. Metropolitan Edison Company; Pennsylvania Electric Company**

[Docket No. ER98–713–000]

Take notice that on November 18, 1997, Metropolitan Edison Company and Pennsylvania Electric Company (d/b/a GPU Energy) filed executed Retail Transmission Service Agency Agreements between GPU Energy and (1) UGI Power Supply, Inc., dated November 10, 1997; and (2) American Energy Solutions, Inc., dated November 11, 1997.

GPU Energy requests a waiver of the Commission's notice requirements for good cause shown and an effective date of November 1, 1997, for the Retail Transmission Service Agency Agreements.

GPU Energy will be serving a copy of the filing on the Pennsylvania Public Utility Commission.

*Comment date:* December 23, 1997, in accordance with Standard Paragraph E at the end of this notice.

**16. Ohio Power Company**

[Docket No. ER98–714–000]

Take notice that on November 18, 1997, Ohio Power Company (OPC), tendered for filing with the Commission a Facilities, Operations, Maintenance and Repair Agreement dated October 6, 1997, between OPC, Buckeye Power, Inc. (Buckeye), and Licking Rural Electrification, Inc., (LRE). LRE is an Ohio electricity cooperative and a member of Buckeye Power, Inc.

LRE has requested OPC provide a new delivery point pursuant to provisions of the Power Delivery Agreement between OPC, Buckeye, The Cincinnati Gas & Electric Company, The Dayton Power and Light Company, Monongahela Power Company, Columbus Southern Power Company and Toledo Edison Company, dated January 1, 1968. OPC requests an effective date of May 1, 1998, for the tendered agreements.

OPC states that copies of its filing were served upon Licking Rural Electrification, Inc, Buckeye Power, Inc. and the Public Utilities Commission of Ohio.

*Comment date:* December 23, 1997, in accordance with Standard Paragraph E at the end of this notice.

**17. UtiliCorp United Inc.**

[Docket No. ER98–715–000]

Take notice that on November 18, 1997, UtiliCorp United Inc. (UtiliCorp), filed service agreements with Continental Energy Services for service under its Non-Firm Point-to-Point open access service tariff for its operating divisions, Missouri Public Service, WestPlains Energy-Kansas and WestPlains Energy-Colorado.

*Comment date:* December 23, 1997, in accordance with Standard Paragraph E at the end of this notice.

**18. UtiliCorp United Inc.**

[Docket No. ER98–716–000]

Take notice that on November 18, 1997, UtiliCorp United Inc. (UtiliCorp), filed service agreements with Continental Energy Services for service under its Short-Term Firm Point-to-Point open access service tariff for its operating divisions, Missouri Public Service, WestPlains Energy-Kansas and WestPlains Energy-Colorado.

*Comment date:* December 23, 1997, in accordance with Standard Paragraph E at the end of this notice.

**19. Entergy Services, Inc.**

[Docket No. ER98–717–000]

Take notice that on November 18, 1997, Entergy Services, Inc. (Entergy Services), on behalf of Entergy Arkansas, Inc., Entergy Gulf States, Inc., Entergy Louisiana, Inc., Entergy Mississippi, Inc., and Entergy New Orleans, Inc. (collectively, the Entergy Operating Companies), tendered for filing a Short-Term Market Rate Sales Agreement between Entergy Services, as agent for the Entergy Operating Companies, and Virginia Electric and Power Company for the sale of power under Entergy Services' Rate Schedule SP.

*Comment date:* December 23, 1997, in accordance with Standard Paragraph E at the end of this notice.

**20. Entergy Services, Inc.**

[Docket No. ER98–718–000]

Take notice that on November 18, 1997, Entergy Services, Inc. (Entergy Services), on behalf of Entergy Arkansas, Inc., Entergy Gulf States, Inc., Entergy Louisiana, Inc., Entergy Mississippi, Inc., and Entergy New Orleans, Inc. (collectively, the Entergy Operating Companies), tendered for filing a Short-Term Firm Point-To-Point Transmission Service Agreement between Entergy Services, as agent for the Entergy Operating Companies, and Williams Energy Services Company.

*Comment date:* December 23, 1997, in accordance with Standard Paragraph E at the end of this notice.

**21. Entergy Services, Inc.**

[Docket No. ER98–719–000]

Take notice that on November 18, 1997, Entergy Services, Inc. (Entergy Services), on behalf of Entergy Arkansas, Inc., Entergy Gulf States, Inc., Entergy Louisiana, Inc., Entergy Mississippi, Inc., and Entergy New Orleans, Inc. (collectively, the Entergy Operating Companies), tendered for filing a Short-Term Firm Point-To-Point Transmission Service Agreement between Entergy Services, as agent for the Entergy Operating Companies, and Continental Energy Services, L.L.C.

*Comment date:* December 23, 1997, in accordance with Standard Paragraph E at the end of this notice.

**22. Florida Power Corporation**

[Docket No. ER98–720–000]

Take notice that on November 18, 1997, Florida Power Corporation (FPC), tendered for filing two service agreements between FPC and Morgan Stanley Capital Group, Inc., and FPC and Carolina Power & Light Co., for service under FPC's Market-Based Wholesale Power Sales Tariff (MR–1), FERC Electric Tariff, Original Volume Number 8. This Tariff was accepted for filing by the Commission on June 26, 1997, in Docket No. ER97–2846–000. The service agreement with Carolina Power & Light Co., is proposed to be effective November 10, 1997, and the service agreement with Morgan Stanley Capital Group, Inc., is proposed to be effective November 13, 1997.

*Comment date:* December 23, 1997, in accordance with Standard Paragraph E at the end of this notice.

**23. Kansas City Power & Light Company**

[Docket No. ER98–721–000]

Take notice that on November 19, 1997, Kansas City Power & Light Company (KCPL), tendered for filing a Service Agreement dated November 17, 1997, between KCPL and Morgan Stanley Capital Group Inc. KCPL proposes an effective date of November 17, 1997, and requests waiver of the Commission's notice requirement. This Agreement provides for Non-Firm Power Sales Service.

In its filing, KCPL states that the rates included in the above-mentioned Service Agreement are pursuant to KCPL's compliance filing in Docket No. ER94–1045.

*Comment date:* December 23, 1997, in accordance with Standard Paragraph E at the end of this notice.

**24. Ohio Edison Company and Pennsylvania Power Company**

[Docket No. ER98–722–000]

Take notice that on November 19, 1997, Ohio Edison Company, tendered for filing on behalf of itself and Pennsylvania Power Company, a Service Agreement with DTE Energy Trading, Inc., under Ohio Edison's Power Sales Tariff. This filing is made pursuant to Section 205 of the Federal Power Act.

*Comment date*: December 23, 1997, in accordance with Standard Paragraph E at the end of this notice.

**25. New England Power Company**

Docket No. ER98–723–000

Take notice that on November 19, 1997, New England Power Company filed a Service Agreement and Certificate of Concurrence with Constellation Power Source, Inc., under NEP's FERC Electric Tariff, Original Volume No. 5.

*Comment date:* December 23, 1997, in accordance with Standard Paragraph E at the end of this notice.

**26. Wisconsin Public Service Corporation**

[Docket No. ER98–724–000]

Take notice that on November 19, 1997, Wisconsin Public Service Corporation (WPSC), tendered for filing an executed Transmission Service Agreement between WPSC and Western Area Power Administration, provides for transmission service under the Open Access Transmission Service Tariff, FERC Original Volume No. 11, and Revised Attachments E and I, indices of customers with agreements under WPSC's Open Access Transmission Tariff, FERC Volume No. 11.

*Comment date:* December 23, 1997, in accordance with Standard Paragraph E at the end of this notice.

**27. Maine Public Service Company**

[Docket No. ER98–726–000]

Take notice that on November 19, 1997, Maine Public Service Company (Maine Public), filed an executed Service Agreement for non-firm point-to-point transmission service under Maine Public's open access transmission tariff with Cinergy Services, Inc., as agent on behalf of The Cincinnati Gas & Electric Company and PSI Energy, Inc.

*Comment date:* December 23, 1997, in accordance with Standard Paragraph E at the end of this notice.

**28. CNG Power Services Corporation**

[Docket No. ER98–727–000]

Take notice that on November 19, 1997, CNG Power Services Corporation (CNGPS), tendered for filing and amended and restated Rate Schedule FERC No. 1 (Amended Rate Schedule). The Amended Rate Schedule would permit sales by CNGPS to affiliates that are FERC-authorized power marketers. CNGPS requests waiver of the Commission's regulations to permit the Amended Rate Schedule to become effective on November 20, 1997.

*Comment date:* December 23, 1997, in accordance with Standard Paragraph E at the end of this notice.

**29. Florida Power Corporation**

[Docket No. ER98–728–000]

Take notice that on November 19, 1997, Florida Power Corporation (FPC), tendered for filing a contract for the provision of interchange service between itself and Morgan Stanley Capital Group, Inc. The contract provides for service under Schedule J, Negotiated Interchange Service, Schedule OS, Opportunity Sales, and Schedule S, Morgan Stanley Capital Group, Inc. FERC Electric Schedule No. 1. FPC requests Commission waiver of the 60-day notice requirement in order to allow the contract to become effective as a rate schedule on November 20, 1997.

*Comment date:* December 23, 1997, in accordance with Standard Paragraph E at the end of this notice.

**30. Pacific Gas and Electric Company**

[Docket No. ER98–729–000]

Take notice that on November 20, 1997, Pacific Gas and Electric Company (PG&E), tendered for filing two Service Agreements between PG&E and: 1) Electric Clearinghouse, Inc. (ECI); 2) Wheelabrator Martell, Inc. (Wheelabrator); each entitled, ''Service Agreement for Non-Firm Point-to-Point Transmission Service'' (Service Agreements); and 3) Notices of Termination for these Service Agreements.

PG&E proposes that the Service Agreements become effective on October 22, 1997 for ECI, and November 3, 1997, for Wheelabrator. PG&E is requesting any necessary waivers. The effective date of the termination is either the requested date shown below or such other date the Commission deems appropriate for termination.

| Service agreement date | Requested effective date for termination |
|---|---|
| ECI-Service Agreement No. _____ under FERC Electric Tariff, Original Volume No. _____ ..... | December 31, 1997. |
| Wheelabrator-Service Agreement No. _____ under FERC Electric Tariff, Original Volume No. _____ ..... | December 31, 1997. |

Copies of this filing have been served upon the California Public Utilities Commission, ECI and Wheelabrator.

*Comment date:* December 23, 1997, in accordance with Standard Paragraph E at the end of this notice.

**31. Louisville Gas and Electric Company**

[Docket No. ER98–730–000]

Take notice that on November 20, 1997, Louisville Gas and Electric Company, tendered for filing copies of service agreements between Louisville Gas and Electric Company and Market Responsive Energy under Rate GSS.

*Comment date:* December 23, 1997, in accordance with Standard Paragraph E at the end of this notice.

**32. Louisville Gas and Electric Company**

[Docket No. ER98–731–000]

Take notice that on November 20, 1997, Louisville Gas and Electric Company, tendered for filing copies of service agreements between Louisville Gas and Electric Company and Electric Clearinghouse, Inc., under Rate GSS.

*Comment date:* December 23, 1997, in accordance with Standard Paragraph E at the end of this notice.

**33. Florida Power & Light Company**

[Docket No. ER98–732–000]

Take notice that on November 20, 1997, Florida Power & Light Company (FPL), tendered for filing a Sanford Plant Interconnection Agreement between FPL and Florida Power Corporation. FPL proposes to make the

Interconnection Agreement effective December 1, 1997.

*Comment date:* December 23, 1997, in accordance with Standard Paragraph E at the end of this notice.

**34. Niagara Mohawk Power Corporation**

[Docket No. ER98–733–000]

Take notice that on November 20, 1997, Niagara Mohawk Power Corporation (NMPC), tendered for filing a Notice of Cancellation of FERC Rate Schedule No. 228 and any supplements thereto, with Heartland Energy Services, Inc.

NMPC requests that this cancellation become effective December 14, 1997.

*Comment date:* December 23, 1997, in accordance with Standard Paragraph E at the end of this notice.

**35. Northern States Power Company (Minnesota Company); Northern States Power Company (Wisconsin Company)**

[Docket No. ER98–734–000]

Take notice that on November 20, 1997, Northern States Power Company (Minnesota) and Northern States Power Company (Wisconsin) (collectively known as NSP), tendered for filing an Electric Service Agreement between NSP and Willmar Municipal Utilities Commission (Customer). This Electric Service Agreement is an enabling agreement under which NSP may provide to Customer the electric services identified in NSP Operating Companies Electric Services Tariff, effective July 1, 1997.

*Comment date:* December 23, 1997, in accordance with Standard Paragraph E at the end of this notice.

**36. PacifiCorp**

[Docket No. ER98–735–000]

Take notice that on November 20, 1997, PacifiCorp, tendered for filing in accordance with 18 CFR part 35 of the Commission's Rules and Regulations, a Service Agreements with Public Utility District No. 1 of Clark County (Clark) under PacifiCorp's FERC Electric Tariff, Original Volume No. 12.

Copies of this filing were supplied to Clark, the Public Utility Commission of Oregon and the Washington Utilities and Transportation Commission.

A copy of this filing may be obtained from PacifiCorp's Regulatory Administration Department's Bulletin Board System through a personal computer by calling (503) 464–6122 (9600 baud, 8 bits, no parity, 1 stop bit).

*Comment date:* December 23, 1997, in accordance with Standard Paragraph E at the end of this notice.

**37. The Dayton Power and Light Company**

[Docket No. ER98–736–000]

Take notice that on November 20, 1997, The Dayton Power and Light Company (Dayton) submitted service agreements establishing ENERZ Corp., Public Service Electric and Gas Company as a customer under the terms of Dayton's Market-Based Sales Tariff.

Dayton requests an effective date of one day subsequent to this filing for the service agreements. Accordingly, Dayton requests waiver of the Commission's notice requirements. Copies of the filing were served upon ENERZ Corp., Public Service Electric and Gas Company and the Public Utilities Commission of Ohio.

*Comment date:* December 23, 1997, in accordance with Standard Paragraph E at the end of this notice.

**38. The Dayton Power and Light Company**

[Docket No. ER98–737–000]

Take notice that on November 20, 1997, The Dayton Power and Light Company (Dayton) submitted service agreements establishing ConAgra Energy Services, Inc. as a customer under the terms of Dayton's Open Access Transmission Tariff.

Dayton requests an effective date of one day subsequent to this filing for the service agreements. Accordingly, Dayton requests waiver of the Commission's notice requirements. Copies of the filing were served upon establishing ConAgra Energy Services, Inc., and the Public Utilities Commission of Ohio.

*Comment date:* December 23, 1997, in accordance with Standard Paragraph E at the end of this notice.

**39. The Dayton Power and Light Company**

[Docket No. ER98–738–000]

Take notice that on November 20, 1997, The Dayton Power and Light Company (Dayton) submitted service agreements establishing Williams Energy Service Company as a customer under the terms of Dayton's Open Access Transmission Tariff.

Dayton requests an effective date of one day subsequent to this filing for the service agreements. Accordingly, Dayton requests waiver of the Commission's notice requirements. Copies of the filing were served upon establishing Williams Energy Service Company and the Public Utilities Commission of Ohio.

*Comment date:* December 23, 1997, in accordance with Standard Paragraph E at the end of this notice.

**40. Illinois Power Company**

[Docket No. ER98–739–000]

Take notice that on November 20, 1997, Illinois Power Company (Illinois Power), 500 South 27th Street, Decatur, Illinois 62526, tendered for filing a Power Sales Tariff, Service Agreement under which DTE Energy Trading, Inc., will take service under Illinois Power Company's Power Sales Tariff. The agreements are based on the Form of Service Agreement in Illinois Power's tariff.

Illinois Power has requested an effective date of November 5, 1997.

*Comment date:* December 23, 1997, in accordance with Standard Paragraph E at the end of this notice.

**41. Illinois Power Company**

[Docket No. ER98–740–000]

Take notice that on November 20, 1997, Illinois Power Company (''Illinois Power''), 500 South 27th Street, Decatur, Illinois 62526, tendered for filing a Power Sales Tariff, Service Agreement under which Columbia Power Marketing Corporation will take service under Illinois Power Company's Power Sales Tariff. The agreements are based on the Form of Service Agreement in Illinois Power's tariff.

Illinois Power has requested an effective date of October 28, 1997.

*Comment date*: December 23, 1997, in accordance with Standard Paragraph E at the end of this notice.

**42. Deseret Generation & Transmission Co-operative**

[Docket No. ER98–757–000]

Take notice that Deseret Generation & Transmission Co-operative on November 21, 1997, tendered for filing an executed umbrella non-firm point-to-point service agreement with Utah Municipal Power Authority under its open access transmission tariff. Deseret requests a waiver of the Commission's notice requirements for an effective date of November 21, 1997. Deseret's open access transmission tariff is currently on file with the Commission in Docket No. OA97–487–000. Utah Municipal Power Authority has been provided a copy of this filing.

*Comment date:* December 23, 1997, in accordance with Standard Paragraph E at the end of this notice.

**43. Energy 2000, Inc.**

[Docket No. ER98–887–000]

Take notice that on November 28, 1997, Energy 2000, Inc. tendered for filing a Notice of Cancellation of the application filed on October 15, 1997 in Docket No. ER98–171–000.

*Comment date:* December 22, 1997, in accordance with Standard Paragraph E at the end of this notice.

**44. Pacific Gas and Electric Company, San Diego Gas and Electric Co.; Southern California Edison Company**

[Docket No. ER98–899–000]

Take notice that on December 2, 1997, the California Independent System Operator (ISO) tendered for filing three executed Utility Distribution Company Operating Agreements (Agreement or UDC agreements) with Pacific Gas & Electric Company, San Diego Gas and Electric Company, and Southern California Edison Company (UDCs). ISO requests that this filing be made effective no later than January 1, 1998, to enable the California Independent System Operator to coordinate facilities, procedures, and practices with the utility distribution companies that will be connected to the ISO and which plan to participate in the market for energy and ancillary services through the ISO.

These Agreements govern the facilities at the interface between the ISO and the UDCs and establish maintenance coordination standards, load shedding, emergency electrical planning, and information sharing and gathering procedures between the ISO and the UDCs. The Agreement also includes Schedules outlining for each utility the facilities that comprise the interface as well as the specific responsibilities that will be delegated by the ISO to each UDC.

Copies of this filing have been served upon all parties in these proceedings. However, because the Schedules for each agreement are so voluminous, copies of the Schedules are being filed only with the Commission. Parties wishing to see the Schedules may do so at the ISO Office, 151 Blue Ravine Road, Folsom, CA or at the office of Cameron McKenna LLP, 2000 Pennsylvania Avenue, Washington, DC, or may request copies of the Schedules.

*Comment date:* January 5, 1998, in accordance with Standard Paragraph E at the end of this notice.

**45. Nevada Power Company**

[Docket No. OA96–188–004]

Take notice that on November 12, 1997, Nevada Power Company (Nevada Power) tendered for filing, in Docket OA96–188–000, revised tariff sheets which specify the on-peak and off-peak hours of non-firm point-to-point transmission service compliance with the Commission's order dated October 17, 1997. Nevada Power requests a waiver of the 60 day notice requirement and requests that the revised tariff sheets be effective as of the date of the filing.

*Comment date:* December 23, 1997, in accordance with Standard Paragraph E at the end of this notice.

**46. Commonwealth Edison Company; Commonwealth Edison Company of Indiana, Inc.**

[Docket No. OA97–459–000]

Take notice that on November 21, 1997, Commonwealth Edison Company and Commonwealth Edison Company of Indiana, Inc. (collectively ComEd), tendered for filing with the Commission proposed revisions to ComEd's written procedures implementing the Standards of Conduct set forth at 18 CFR 37.4.

A copy of this filing has been served on the persons on the official service list in this docket.

*Comment date:* December 23, 1997, in accordance with Standard Paragraph E at the end of this notice.

**47. Public Service Company of Colorado**

[Docket No. TX98–2–000]

On November 21, 1997, Public Service Company of Colorado (PS Colorado), 1225 17th Street, Denver, Colorado 80202, filed with the Federal Energy Regulatory Commission an application requesting that the Commission order the Missouri Basin Power Project, including its Project Manager, Basin Electric Power Cooperative, Tri-State Generation & Transmission Association, Western Area Power Administration—Rocky Mountain Region, and the Rocky Mountain Generation Cooperative to provide transmission services pursuant to Section 211 of the Federal Power Act.

PS Colorado requests 140 MW of firm point-to-point transmission capacity in 1999, 360 MW in 2000, 330 MW in 2001, and 305 MW in 2002, increased to account for transmission losses. PS Colorado requests service from points in Wyoming, Nebraska, New Mexico, Utah and western Colorado to points in eastern Colorado.

*Comment date:* January 2, 1998, in accordance with Standard Paragraph E at the end of this notice.

**Standard Paragraph**

E. Any person desiring to be heard or to protest said filing should file a motion to intervene or protest with the Federal Energy Regulatory Commission, 888 First Street, N.E., Washington, D.C. 20426, in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211 and 18 CFR 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 this filing are on file with the Commission and are available for public inspection.

**Lois D. Cashell,**

*Secretary.*

[FR Doc. 97–32769 Filed 12–15–97; 8:45 am]

BILLING CODE 6717–01–P

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## DEPARTMENT OF ENERGY

## Federal Energy Regulatory Commission

## Notice of Non-Project Use of Project Lands and Waters

December 10, 1997.

Take notice that the following hydroelectric application has been filed with the Commission and is available for public inspection:

a. *Type of Application:* Non-Project Use of Project Lands and Waters.

b. *Project Name:* Catawba-Wateree Project.

c. *Project No.:* FERC Project No. 2232–353.

d. *Date Filed:* October 17, 1997.

e. *Applicant:* Duke Energy Corporation.

f. *Location:* Catawba County, North Carolina, Greenwood Subdivision, Lake Norman in Mountain Creek Township.

g. *Filed pursuant to:* Federal Power Act, 16 U.S.C. 791(a)–825(r).

h. *Applicant Contact:* Mr. E.M. Oakley, Duke Energy Corporation, P.O. Box 1006 (EC12Y), Charlotte, NC 28201–1006, (704) 382–5778.

i. *FERC Contact:* Brian Romanek, (202) 219–3076.

j. *Comment Date:* January 21, 1998.

k. *Description of the filing:* Duke Energy Corporation (Duke) proposes to grant an easement of 0.79 acre of project land to Mr. W.C. Edwards for a private residential marina to serve a proposed residential development to be known as Greenwood subdivision. The marina would consist of one access ramp and 24 floating boat slips. All slips would be constructed of treated wood with encapsulated styrofoam used for floatation. The wood decking would be supported by stationary wood pilings.

Also, as a part of this proposal, Duke requests reclassification of shoreline needed to build the above-mentioned marina. The subject shoreline is presently classified in the Commission approved Shoreline Management Plan as ''Project Operations.'' The shoreline

and adjoining property are no longer used by Duke as a lake maintenance facility. Duke requests that we reclassify the shoreline to ''Future Commercial/Residential''.

l. This notice also consists of the following standard paragraphs: B, C1, D2.

B. Comments, Protests, or Motions to Intervene—Anyone may submit comments, a protest, or a motion to intervene in accordance with the requirements of Rules of Practice and Procedure, 18 CFR 385.210, .211, .214. In determining the appropriate action to take, the Commission will consider all protests or other comments filed, but only those who file a motion to intervene in accordance with the Commission's Rules may become a party to the proceeding. Any comments, protests, or motions to intervene must be received on or before the specified comment date for the particular application.

C1. Filing and Service of Responsive Documents—Any filings must bear in all capital letters the title ''COMMENTS'', ''RECOMMENDATIONS FOR TERMS AND CONDITIONS'', ''PROTEST'', or ''MOTION TO INTERVENE'', as applicable, and the Project Number of the particular application to which the filing refers. Any of the above-named documents must be filed by providing the original and the number of copies provided by the Commission's regulations to: The Secretary, Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426. A copy of any motion to intervene must also be served upon each representative of the Applicant specified in the particular application.

D2. Agency Comments—Federal, state, and local agencies are invited to file comments on the described application. A copy of the application may be obtained by agencies directly from the Applicant. If an agency does not file comments within the time specified for filing comments, it will be presumed to have no comments. One copy of an agency's comments must also be sent to the Applicant's representatives.

**Lois D. Cashell,**

*Secretary.*

[FR Doc. 97–32714 Filed 12–15–97; 8:45 am]

BILLING CODE 6717–01–M

## DEPARTMENT OF ENERGY

### Federal Energy Regulatory Commission

**[Project No. 2188–030]**

### Montana Power Company; Notice of Intent To Hold Technical Modeling Workshop at Oak Ridge National Laboratory in Oak Ridge, Tennessee to Discuss the Modeling of Thermal Impacts Associated With the Madison Development Part of the Missouri-Madison Hydroelectric Project Proposed for Relicensing

December 10, 1997.

On January 22 and 23, 1998, a technical modeling workshop at Oak Ridge National Laboratory (ORNL) in Oak Ridge, Tennessee will be conducted to discuss the modeling of thermal impacts associated with the Madison Development. The model was used to evaluate alternatives considered in Draft Environmental Impact Statement (DEIS) considering issuance of a new license for the Missouri Madison Project. The Notice of Availability of the DEIS appeared in the **Federal Register** on October 3, 1997 (62 FR 51855).

The workshop is scheduled as follows:

8:30 am–4:30 pm, January 22, Bldg. 1503, ORNL

8:30 am–12:00 pm, January 23, Bldg. 1503, ORNL

Workshop attendees should contact: Mark Bevelhimer ((423) 576–0266 or mbs@ornl.gov) to confirm attendance and obtain lodging options and local directions to the workshop.

Anyone wishing to submit questions or comments regarding the model of thermal impacts to discuss at the workshop should address them to: Lois D. Cashell, Secretary, Federal Energy Regulatory Commission, 888 First Street, NE, Washington, DC 20426.

Written correspondence should clearly show the following caption on the first page: Missouri-Madison Hydroelectric Project No. 2188–030.

For further information, please contact Mr. R. Feller at (202) 219–2796.

**Lois D. Cashell,**

*Secretary.*

[FR Doc. 97–32713 Filed 12–15–97; 8:45 am]

BILLING CODE 6712–01–M

## ENVIRONMENTAL PROTECTION AGENCY

**[FRL–5935–5]**

### Office of Research and Development; Met One Instruments, Inc.: Application for Equivalent Method; Determination

**AGENCY:** Environmental Protection Agency.

**ACTION:** Notice of receipt of application.

**SUMMARY:** The Environmental Protection Agency (EPA) is announcing that Met One Instruments, Inc. has submitted an application for equivalent method determinations on their PM10 Beta Attenuation Ambient Particle Monitors, Models BAM 1020 and GBAM 1020.

**FOR FURTHER INFORMATION CONTACT:** Frank F. McElroy, Human Exposure and Atmospheric Sciences Division (MD–46), National Exposure Research Laboratory, U.S. Environmental Protection Agency, Research Triangle Park, North Carolina 27711, (919) 541–2622.

**SUPPLEMENTARY INFORMATION:** Notification is given that an application has been received to determine if a new PM10 monitoring method should be designated by the Administrator of the EPA as an equivalent method under 40 CFR part 53. The application was received on September 12, 1997 from Met One Instruments, Inc., 1600 Washington Blvd., Grants Pass, Oregon 97526 proposing that their PM10 Beta Attenuation Ambient Particle Monitors, Models BAM 1020, BAM 1020–1, GBAM 1020, and GBAM 1020–1 be designated as an equivalent method. If, after appropriate technical study, the Administrator determines that this method should be so designated, a document thereof will be published in a subsequent issue of the **Federal Register**.

**Henry L. Longest II,**

*Acting Assistant Administrator for Research and Development.*

[FR Doc. 97–32787 Filed 12–15–97; 8:45 am]

BILLING CODE 6560–50–P

## EQUAL EMPLOYMENT OPPORTUNITY COMMISSION

### Privacy Act of 1974; Publication of Proposed New Routine Uses

**AGENCY:** Equal Employment Opportunity Commission (EEOC).

**ACTION:** Amendment of system of records to include new routine uses.

**SUMMARY:** In accordance with the Privacy Act, 5 U.S.C. 552a(e)(11), the

Equal Employment Opportunity Commission is issuing notice of our intent to amend the system of records entitled EEOC–7 Employee Pay and Leave Records to include new routine uses.

**DATES:** The changes will become effective on January 15, 1998 unless comments dictate otherwise.

**ADDRESSES:** Written comments may be sent to the Office of the Executive Secretariat, Equal Employment Opportunity Commission, room 10402, 1801 L Street, N.W., Washington, D.C. 20507. Copies of this notice are available in the following alternate formats: Large print, braille, electronic file on computer disk, and audio-tape. Copies may be obtained from the Publications Center by calling 1–800–699–3362.

**FOR FURTHER INFORMATION CONTACT:** Nicholas M. Inzeo, Deputy Legal Counsel, Thomas J. Schlageter, Assistant Legal Counsel or Kathleen Oram, Senior Attorney (202) 663–4669 (voice) or (202) 663–7026 (TDD).

**SUPPLEMENTARY INFORMATION:**

## I. Discussion of Proposed Routine Use

Pursuant to the Personal Responsibility and Work Opportunity Reconciliation Act of 1996, Pub. L. 104–193, EEOC will disclose data from its system of records, EEOC–7, Employee Pay and Leave Records, to the Office of Child Support Enforcement, Administration for Children and Families, Department of Health and Human Services, for use in its Federal Parent Locator System (FPLS) and Federal Tax Offset system. Information on this system was last published at 61 FR 38754, July 25, 1996.

FPLS is a computerized network through which states may request location information from federal and state agencies to find non-custodial parents and/or their employers for purposes of establishing paternity and securing support. Effective October 1, 1997, the FPLS was enlarged to include the National Directory of New Hires, a database containing information on employees commencing employment, quarterly wage data on private and public sector employees, and information on unemployment compensation benefits. Effective on October 1, 1998, FPLS will be expanded to include a Federal Case Registry. The Federal Case Registry will contain abstracts on all participants involved in child support enforcement cases. When the Federal Case Registry is instituted, its files will be matched on an ongoing basis against the files in the National Directory of New Hires to determine if an employee is a participant in a child support case anywhere in the country. If the FPLS identifies a person as being a participant in a state child support case, that state will be notified of the participant's current employer. State requests to the FPLS for location information will also continue to be processed after October 1, 1998.

The data to be disclosed by EEOC to the Office of Child Support Enforcement for use in the FPLS include employees' names, addresses, social security numbers and wages paid quarterly. In addition, names and social security numbers submitted by EEOC for use in the FPLS will be disclosed by the Office of Child Support Enforcement to the Social Security Administration for verification to ensure that the social security number provided is correct.

The data disclosed by EEOC to the Office of Child Support Enforcement will also be disclosed by that office to the Secretary of the Treasury for use in verifying claims for the advance payment of earned income tax credit or to verify a claim of employment on a tax return.

## II. Compatibility of Proposed Routine Uses

We are proposing these routine uses in accordance with the Privacy Act (5 U.S.C. 552a(b)(3)). The Privacy Act permits the disclosure of information about individuals without their consent for a routine use where the information will be used for a purpose which is compatible with the purpose for which the information was originally collected. The Office of Management and Budget has indicated that a ''compatible'' use is a use that is necessary and proper. *See* OMB Guidelines, 51 FR 18982, 18985 (1986). Since the proposed uses of the data are required by the Personal Responsibility and Work Opportunity Reconciliation Act of 1996, Pub. L. No. 104–193, they are clearly necessary and proper uses, and therefore, ''compatible'' uses that meet Privacy Act requirements.

## III. Effect of the Proposed Changes on Individuals

We will disclose information under the proposed routine uses only as required by the Personal Responsibility and Work Opportunity Reconciliation Act of 1996 and as permitted by the Privacy Act.

Accordingly, EEOC–7, Employee Pay and Leave Records, most recently published at 46 FR 11056, 11061 (March 9, 1994), is amended as set forth below.

* * * * *

Routine uses of records maintained in the system, including categories of users and the purposes of such uses:

* * * * *

c. To disclose information to the Office of Child Support Enforcement, Administration for Children and Families, Department of Health and Human Services Federal Parent Locator System (FPLS) and Federal Tax Offset System for use in locating individuals and identifying their income sources to establish paternity, establish and modify orders of support and for enforcement action.

d. To disclose information to the Office of Child Support Enforcement for release to the Social Security Administration for verifying social security numbers in connection with the operation of the FPLS by the Office of Child Support Enforcement.

e. To disclose information to the Office of Child Support Enforcement for release to the Department of Treasury for purposes of administering the Earned Income Tax Credit Program (Section 32, Internal Revenue Code of 1986) and verifying a claim with respect to employment in a tax return.

Dated: November 19, 1997.

For the Commission.

**Gilbert F. Casellas,**

*Chairman.*

[FR Doc. 97–32717 Filed 12–15–97; 8:45 am]

BILLING CODE 6570–06–P

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## FEDERAL COMMUNICATIONS COMMISSION

### Open Commission Meeting Thursday, December 18, 1997

The Federal Communications Commission will hold an Open Meeting on the subjects listed below on Thursday, December 18, 1997, which is scheduled to commence at 9:30 a.m. in Room 856, at 1919 M Street, NW., Washington, DC.

*Item No., Bureau, Subject*

1—Wireless Telecommunications—Title: Amendment of Part 1 of the Commission's Rules -- Competitive Bidding Proceeding (WT Docket No. 97–82); Allocation of Spectrum Below 5 GHz Transferred from Federal Government Use -- 4660–4685 MHz (ET Docket No. 94–32). Summary: The Commission will consider action concerning substantive amendment and modifications to the Commission's general competitive bidding rules for all auctionable services that are intended to simplify the Commission's regulations,

eliminate unnecessary rules wherever possible and increase the efficiency of the competitive bidding process.

2—Mass Media—Title: Fees for Ancillary or Supplementary Use of Digital Television Spectrum. Summary: The Commission will consider action concerning implementing the transition to digital television (DTV) for existing television broadcasters in accordance with the provisions of the Telecommunications Act of 1996 regarding fees for ancillary or supplementary use of DTV spectrum.

3—Cable Services—Title: Implementation of the Cable Television Consumer Protection and Competition Act of 1992 -- Petition for Rulemaking of Ameritech New Media, Inc., Regarding Development of Competition and Diversity in Video Programming Distribution and Carriage (RM–9097). Summary: The Commission will consider a petition for rulemaking concerning enforcement and other matters relating to the Commission's program access rules.

After consideration of these items, the Commission will hold an en banc presentation on the status of competition in the marketplace for multichannel video services.

Additional information concerning this meeting may be obtained from Maureen Peratino or David Fiske, Office of Public Affairs, telephone number (202) 418–0500.

Copies of materials adopted at this meeting can be purchased from the FCC's duplicating contractor, International Transcription Services, Inc. (ITS, Inc.) at (202) 857–3800 or fax (202) 857–3805 and 857–3184. These copies are available in paper format and alternative media, including large print/type; digital disk; and audio tape. ITS may be reached by e-mail: its—inc@ix.netcom.com. Their Internet address is http://www.itsi.com.

This meeting can be viewed over George Mason University's Capitol Connection. For information on this service call (703) 993-3100. The audio portion of the meeting will be broadcast live on the Internet via the FCC's Internet audio broadcast page at <http://www.fcc.gov/realaudio/>. The meeting can also be heard via telephone, for a fee, from National Narrowcast Network, telephone (202) 966–2211 or fax (202) 966–1770; and from Conference Call USA (available only outside the Washington, DC. metropolitan area), telephone 1–800–962–0044. Audio and video tapes of this meeting can be purchased from Infocus, 341 Victory Drive, Herndon, VA 20170, telephone (703) 834–0100; fax number (703) 834–0111.

Dated December 11, 1997.

Federal Communications Commission.

**Magalie Roman Salas,**

*Secretary.*

[FR Doc. 97–32888 Filed 12-12-97; 11:19 am]

BILLING CODE 6712–01–F

## FEDERAL EMERGENCY MANAGEMENT AGENCY

**[FEMA–1191–DR]**

### Iowa; Amendment to Notice of a Major Disaster Declaration

**AGENCY:** Federal Emergency Management Agency (FEMA).

**ACTION:** Notice.

**SUMMARY:** This notice amends the notice of a major disaster for the State of Iowa, (FEMA–1191–DR), dated November 20, 1997, and related determinations.

**EFFECTIVE DATE:** December 3, 1997

**FOR FURTHER INFORMATION CONTACT:** Madge Dale, Response and Recovery Directorate, Federal Emergency Management Agency, Washington, DC 20472, (202) 646–3260.

**SUPPLEMENTARY INFORMATION:** The notice of a major disaster for the State of Iowa, is hereby amended to include the following areas among those areas determined to have been adversely affected by the catastrophe declared a major disaster by the President in his declaration of November 20, 1997:

The counties of Cass and Poweshiek for Public Assistance.

(Catalog of Federal Domestic Assistance No. 83.516, Disaster Assistance.)

**Lacy E. Suiter,**

*Executive Associate Director, Response and Recovery Directorate.*

[FR Doc. 97–32782 Filed 12–15–97; 8:45 am]

BILLING CODE 6718–02–P

## FEDERAL EMERGENCY MANAGEMENT AGENCY

**[FEMA–1190–DR]**

### Nebraska; Amendment to Notice of a Major Disaster Declaration

**AGENCY:** Federal Emergency Management Agency (FEMA).

**ACTION:** Notice.

**SUMMARY:** This notice amends the notice of a major disaster for the State of Nebraska, (FEMA–1190–DR), dated November 1 1997, and related determinations.

**EFFECTIVE DATE:** December 4, 1997.

**FOR FURTHER INFORMATION CONTACT:** Madge Dale, Response and Recovery Directorate, Federal Emergency Management Agency, Washington, DC 20472, (202) 646–3260.

**SUPPLEMENTARY INFORMATION:** The notice of a major disaster for the State of Nebraska, is hereby amended to include the following areas among those areas determined to have been adversely affected by the catastrophe declared a major disaster by the President in his declaration of November 1, 1997:

Dodge County for Category F under the Public Assistance program (already designated for Categories A and B under the Public Assistance program).

(Catalog of Federal Domestic Assistance No. 83.516, Disaster Assistance)

**Lacy E. Suiter,**

*Executive Associate Director, Response and Recovery Directorate.*

[FR Doc. 97–32781 Filed 12–15–97; 8:45 am]

BILLING CODE 6718–02–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. 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 9, 1998.

**A. Federal Reserve Bank of Atlanta** (Lois Berthaume, Vice President) 104 Marietta Street, N.W., Atlanta, Georgia 30303-2713:

*1. Regions Financial Corporation*, Birmingham, Alabama; to merge with First United Bancorporation, Anderson, South Carolina, and thereby indirectly acquire Anderson National Bank, Anderson, South Carolina, and Spartanburg National Bank, Spartanburg, South Carolina.

In connection with this application, Applicant also has applied to acquire Quick Credit Corporation, Anderson, South Carolina, and thereby engage in consumer finance activities and credit insurance activities, pursuant to §§ 225.28(b)(1) and (b)(11)(ii) of the Board's Regulation Y.

*2. Regions Financial Corporation*, Birmingham, Alabama; to merge with St. Mary Holding Corporation, Franklin, Louisiana, and thereby indirectly acquire The St. Mary Bank and Trust Company, Franklin, Louisiana.

Board of Governors of the Federal Reserve System, December 11, 1997.

**Jennifer J. Johnson,**

*Deputy Secretary of the Board.*

[FR Doc. 97–32803 Filed 12–15–97; 8:45 am]

BILLING CODE 6210–01–F

## FEDERAL RESERVE SYSTEM

### Formations of, Acquisitions by, and Mergers of Bank Holding Companies; Correction

This notice corrects a notice (FR Doc. 97-32055) published on pages 64589 and 64590 of the issue for Monday, December 8, 1997.

Under the Federal Reserve Bank of New York heading, the entry for First Empire State Corporation and Olympia Financial Corp., both of Buffalo, New York; is revised to read as follows:

**A. Federal Reserve Bank of New York** (Betsy Buttrill White, Senior Vice President) 33 Liberty Street, New York, New York 10045-0001:

*1. First Empire State Corporation, and Olympia Financial Corp.*, both of Buffalo, New York; to acquire 100 percent of the voting shares of OnBancorp, Inc., Syracuse, New York, and thereby indirectly acquire OnBank & Trust Co., Syracuse, New York. Olympia Financial Corp., also has applied to become a bank holding company and to acquire Manufactures and Traders Trust Company, Buffalo, New York.

In connection with these applications, Applicants also have applied to acquire Franklyn First Savings Bank, Wilkes-Barre, Pennsylvania, and thereby engage in operating a savings association, pursuant to § 225.28(b)(4)(ii) of the Board's Regulation Y.

Comments on this application must be received by January 2, 1998.

Board of Governors of the Federal Reserve System, December 11, 1997.

**Jennifer J. Johnson,**

*Deputy Secretary of the Board.*

[FR Doc. 97–32804 Filed 12–15–97; 8:45 am]

BILLING CODE 6210–01–F

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Office of the Secretary

### Agency Information Collection Activities: Submission for OMB Review; Comment Request

The Department of Health and Human Services, Office of the Secretary publishes a list of information collections it has submitted to the Office of Management and Budget (OMB) for clearance in compliance with the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35) and 5 CFR 1320.5. The following are those information collections recently submitted to OMB.

Annual Report for OPA Title X Family Planning Program Grantees—0915–0193—Extension—The Office of Family Planning (OPA) collects annual data from Title X Grantees to ensure compliance with legislative mandates, report to Congress, and identify areas where grantees may require assistance. *Respondents:* Title X Family Planning Program Grantees; *Annual Number of Respondents:* 90; *Burden per Response:* 16 hours; *Total Annual Burden:* 1,440 hours. OMB Desk Officer: Allison Eydt.

Copies of the information collection packages listed above can be obtained by calling the OS Reports Clearance Officer on (202) 690–6207. Written comments and recommendations for the proposed information collection should be sent directly to the OMB desk officer designated above at the following address: Human Resources and Housing Branch, Office of Management and Budget, New Executive Office Building, Room 10235, 725 17th Street N.W., Washington, D.C. 20503.

Comments may also be sent to Cynthia Agens Bauer, OS Reports Clearance Officer, Room 503H, Humphrey Building, 200 Independence Avenue S.W., Washington, DC, 20201. Written comments should be received on or before January 15, 1998.

Dated: December 9, 1997.

**Dennis P. Williams,**

*Deputy Assistant Secretary, Budget.*

[FR Doc. 97–32746 Filed 12–15–97; 8:45 am]

BILLING CODE 4150–04–M

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

**[Docket No. 97N–0489]**

### Agency Information Collection Activities: Proposed Collection; Comment Request

**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 reinstatement of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on requirements for parties filing a petition for administrative reconsideration of an action.

**DATES:** Submit written comments on the collection of information by February 17, 1998.

**ADDRESSES:** Submit written comments on the collection of information to the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857. All comments should be identified with the docket number found in brackets in the heading of this document.

**FOR FURTHER INFORMATION CONTACT:** JonnaLynn P. Capezzuto, Office of Information Resources Management (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–4659.

**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 reinstatement 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 listed below.

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.

**Petition For Administrative Reconsideration of Action—21 CFR Part 10.33—(OMB Control Number 0910–0192)—Reinstatement**

Section 10.33 (21 CFR 10.33), issued under section 701(a) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 371(a)), sets forth the format and procedures by which an interested person may petition the Commissioner of Food and Drugs (the Commissioner) for reconsideration of an agency's action. A petition for reconsideration must contain a full statement in a well-organized format of the factual and legal grounds upon which the petition relies. The grounds must demonstrate that relevant information and views contained in the administrative record were not previously or not adequately considered by the Commissioner. Each petition must be submitted no later than 30 days after the decision involved. The Commissioner may, for good cause, permit a petition to be filed after 30 days. An interested person who wishes to rely on information or views not included in the administrative record shall submit them with a new petition to modify the decision. FDA uses the information provided to determine whether to grant the petition for reconsideration. Respondents to this collection of information are individuals of households, state or local governments, not-for-profit institutions, and businesses or other for-profit institutions.

FDA estimates the burden of this collection of information as follows:

ESTIMATED ANNUAL REPORTING BURDEN[1]

| 21 CFR Section | No. of Respondents | Annual Frequency per Response | Total Annual Responses | Hours per Response | Total Hours |
|---|---|---|---|---|---|
| 10.33(b) | 7 | 1 | 7 | 100 | 700 |

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

The burden estimate for this collection of information is based on agency records and experience over the past 3 years. Agency personnel handling the petitions for administrative reconsideration of an action estimate approximately seven requests being received by the agency annually, each requiring an average of 100 hours preparation time.

Dated: December 10, 1997.

**William K. Hubbard,**

*Associate Commissioner for Policy Coordination.*

[FR Doc. 97–32805 Filed 12–15–97; 8:45 am]

BILLING CODE 4160–01–F

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

**[Docket No. 97N–0182]**

### Agency Information Collection Activities; Announcement of OMB Approval

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing that a collection of information entitled ''Transmittal of Labels and Circulars, Form FDA 2567'' has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (the PRA).

**FOR FURTHER INFORMATION CONTACT:** JonnaLynn P. Capezzuto, Office of Information Resources Management (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–4659.

**SUPPLEMENTARY INFORMATION:** In the **Federal Register** of September 19, 1997 (62 FR 49244), the agency announced that the proposed information collection had been submitted to OMB for review and clearance under section 3507 of the PRA (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 0910–0039. The approval expires on November 30, 2000.

Dated: December 10, 1997.

**William K. Hubbard,**

*Associate Commissioner for Policy Coordination.*

[FR Doc. 97–32808 Filed 12–15–97; 8:45 am]

BILLING CODE 4160–01–F

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Health Care Financing Administration

### Statement of Organization, Functions, and Delegations of Authority

Part F, of the Statement of Organization, Functions and Delegations of Authority of the Department of Health and Human Services, Health Care Financing Administration (HCFA), (49 Federal Register 34247, dated September 6, 1984) is amended to include the following delegation of authority from the Secretary to the Administrator for Title XXI of the Social Security Act.

The specific amendments to Part F are described below:

I. Section F.30., Delegations of Authority is amended by adding the following paragraph: SS. The authority vested in the Secretary under Title XXI of the Security Act (42 U.S.C. 1397aa *et seq.*).

Limitation: No State plan or amendment shall be finally disapproved without consultation and discussion by the Administrator with the Secretary.

II. Section F.30., Delegations of Authority, paragraph RR is revised to include title XXI, the revised paragraph reads as follows:

RR. The authority vested in the Secretary or that may become vested in the Secretary, and not otherwise delegated, limited, or reserved, to conduct studies and demonstration projects, as directed by Congress, that relate to the programs established by Title XI of the Social Security Act (Act), insofar as they relate to the mission of the Health Care Financing Administration (HCFA), and Titles XVIII, XIX, and XXI. This delegation encompasses the authority to approve related program activities required by the studies and demonstration projects if such authority is or becomes vested in the Secretary and is not otherwise delegated, limited, or reserved. These activities include, but are not limited to, direct performance, entering into contracts or cooperative agreements, making grants, approving payments for contracts, cooperative agreements, and grants and approving authorized waivers of compliance with certain requirements of titles XI, XVIII, and XIX and XXI of the Act when such actions are for the purpose of conducting studies and demonstration projects.

This delegation shall be exercised under the Department's existing delegation of authority and policy on regulations. In addition, I hereby ratify and affirm any actions taken by the Administrator or other HCFA officials which, in effect, involved the exercise of this authority prior to the effective date of this delegation. This delegation is effective immediately.

Dated: December 2, 1997.

**Donna E. Shalala,**

*Secretary.*

[FR Doc. 97–32747 Filed 12–15–97; 8:45 am]

BILLING CODE 4120–03–M

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

### National Cancer Institute; 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 National Cancer Institute Special Emphasis Panel (SEP) meeting:

*Name of SEP:* Cancer Education Program, Telephone Conference Call.

*Date:* December 18, 1997.

*Time:* 3:30 p.m. to Adjournment.

*Place:* National Cancer Institute, Executive Plaza North, Room 611A, 6130 Executive Boulevard, Bethesda, MD 20892.

*Contact Person:* Mary Bell, Ph.D., Scientific Review Administrator, National Cancer Institute, NIH, Executive Plaza North, Room 611A, 6130 Executive Boulevard, Bethesda, MD 20892, Telephone: 301/496–7978.

*Purpose/Agenda:* To review, discuss and evaluate grant applications.

This notice is being published less than 15 days prior to the meeting due to the urgent need to meet timing limitations imposed by the review and funding cycle.

The meeting will be closed in accordance with the provisions set forth in secs. 552b(c)(4) and 552b(c)(6), Title 5 U.S.C. Grant applications and the discussions could reveal confidential trade secrets or commercial property such as patentable material and personal information concerning individuals associated with the proposals, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

(Catalog of Federal Domestic Assistance Program Numbers: 93.393, Cancer Cause and Prevention Research; 93.394, Cancer Detection and Diagnosis Research; 93.395, Cancer Treatment Research; 93.396, Cancer Biology Research; 93.397, Cancer Centers Support; 93.398, Cancer Research Manpower, 93.399, Cancer Control.)

Dated: December 10, 1997.

**LaVerne Y. Stringfield,**

*Committee Management Officer, NIH.*

[FR Doc. 97–32745 Filed 12–15–97; 8:45 am]

BILLING CODE 4140–01–M

## DEPARTMENT OF HEALTH AND HUMAN RESOURCES

### National Institutes of Health

### Electric and Magnetic Fields Research and Public Information; Dissemination (EMFRAPID) Program; Environmental Toxicology Program, Office of Special Programs; National Institute of Environmental Health Sciences, National Institutes of Health

**NOTICE:** Second EMF Science Review Symposium—EMFRAPID Program.

### Background

The National Institute of Environmental Health Sciences (NIEHS) and the Department of Energy (DOE) are coordinating the implementation of the Electric and Magnetic Fields (EMF) Research and Public Information Dissemination (RAPID) Program. EMFRAPID was established by the 1992 Energy Policy Act (Section 2118 for Public Law 102–486) which was signed in October 1992. This five-year effort is designed to determine the potential effect from exposure to 60 Hz electric and magnetic fields on biological systems, especially those produced by the generation, transmission and use of electric energy. DOE is responsible for characterizing field exposures and for mitigating exposures which may be hazardous. The NIEHS is responsible for the development and implementation of a research program on the possible human health effects of electric and magnetic fields (EMF). The RAPID Program requires the NIEHS to report on the extent to which exposure to electric and magnetic fields adversely affects human health.

The NIEHS has three groups that assist in managing and directing the science portion of RAPID and who will provide guidance on reporting on the health effects of electric and magnetic fields. The first, known as the Interagency Agency Committee on Electric and Magnetic Fields (IAC) is composed of representatives from 10 federal agencies with responsibilities related to electric and magnetic fields (DOE, NIEHS, the Environmental Protection Agency (EPA), the Department of Defense (DOD), the Occupational Safety and Health Administration (OSHA), the National Institute of Standards and Technology (NIST), the Department of Transportation (DOT), the Rural Electrification Administration (REA), the Department of the Interior (DOI), and the Federal Energy Regulatory Commission (FERC)). The IAC, established by the President of the United States, must also prepare a final report for Congress.

The second is the National Electric and Magnetic Field Advisory Committee (NEMFAC). NEMFAC consists of representatives from public interest groups, organized labor, state governments, academia, and industry. This groups advises DOE and NIEHS on the design and implementation of the program. NEMFAC also provides recommendations to the IAC.

Finally, the NIEHSA has an internal EMF Steering Committee (SC) consisting of senior scientists with broad programmatic responsibilities and a broad scientific perspective. The SC manages all aspects of the EMFRAPID Research Program at the NIEHS.

### NIEHS Report on Human Health Effects of EMF

The report development process combines a critical evaluation of the scientific literature with an assessment of the strength of the evidence for human health effects resulting from EMF exposures. To accomplish the initial part of this process, the NIEHS is convening a series of open, public symposia on science related to EMF exposures and their biological effects for these study areas: theoretical/*in vitro* research findings, epidemiological results, and *in vivo*/clinical laboratory findings. The symposia (March 1997, January 1998, and April 1998) provide

a forum for the discussion and evaluation of the research findings in the selected area. At each symposia the participants consider the quality and reproducibility of the research findings for evaluating the degree to which scientific evidence can support a causal linkage between EMF and biological/health effects. Written reports summarizing the deliberations of breakout group discussion sessions are publicly available for the first symposium (send name and address to f:919–541–0144 or from EMFRAPID Progrm/LCBRA, NIEHS, PO Box 12233, MD EC–16, Research Triangle Park, NC 27709). The participants for each symposium include scientists studying EMF effects in the science area being reviewed, experts on measuring and producing EMF exposures, risk assessment experts, and recognized scientists in the area being evaluated who may have little EMF experience but can contribute to a broader understanding of the research findings.

Following the symposia a working group meeting is planned for June 1998. The working group will use information from the symposia's discussions as well as perform on overall critical evaluation of the literature and produce a report. This document will draw conclusions on the strength and robustness of the data and its implications for human health effects and disease etiology.

Per the request from Congress, the NIEHS will use the final report of the working group, information obtained from the science review symposia and other relevant information to prepare a report to Congress on the potential for human health effects from exposure to EMF that result from the production and distribution of electricity. This report will be made publicly available at the time it is sent to Congress. Detailed information about the EMFRAPID Program is available at the time it is sent to Congress. Detailed information about the EMFRAPID Program is available on the world wide web at www.niehs.nih.gov/emfrapid/home.htm.

### Science Review Symposium on Epidemiology: Open to the Public

In its series of science review symposia, the second EMF Science Review Symposium is scheduled for January 12–14, 1998 at the Camberley Gunter Hotel, San Antonio, Texas. This meeting includes plenary overview talks on exposure assessment, methodological issues and problems in epidemiological studies as well as substantive talks on disease endpoints. Breakout group sessions are planned for in-depth discussions of the research findings from epidemiological studies as well as methodological and exposure assessment issues. This meeting is open to the public and the registration fee is $85; for registration information contact t:919–541–7534 or f:919–541–0144.

### Science Review Symposium on Clinical and In vivo Research Studies

Planning is underway for the third EMF Science Review Symposium, April 6–9, 1998 at the Hyatt Regency at Civic Plaza, Phoenix, Arizona. To receive additional information about this meeting, send your name and address to f:919–541–0144 or EMFRAPID Program/LCBRA, NIEHS, PO Box 12233, MD EC–16, Research Triange Park, NC 27709.

Dated: December 2, 1997.

**Samuel H. Wilson,**

*Deputy Director, National Institute of Environmental Health Sciences.*

[FR Doc. 97–32742 Filed 12–15–97; 8:45 am]

BILLING CODE 4140–01–M

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

## National Institutes of Health

## National Institute of Allergy and Infectious Diseases; Notice of Meeting: AIDS Research Advisory Committee, NIAID

Pursuant to Public Law 92–463, notice is hereby given of the meeting of the AIDS Research Advisory Committee, National Institute of Allergy and Infectious Diseases, on January 28, 1998 in Conference Room 1A1 in the Solar Building located at 6003 Executive Blvd, Rockville, Maryland.

The entire meeting will be open to the public from 8:30 a.m. until adjournment. The AIDS Research Advisory Committee (ARAC) advises and makes recommendations to the Director, National Institute of Allergy and Infectious Diseases, on all aspects of research on HIV and AIDS related to the mission of the Division of AIDS (DAIDS).

The Committee will provide advice on scientific priorities, policy, and program balance at the Division level. The Committee will review the progress and productivity of ongoing efforts, and identify critical gaps/obstacles to progress. Attendance by the public will be limited to space available.

Ms. Rona L. Siskind, Executive Secretary , AIDS Research Advisory Committee, DAIDS, NIAID, NIH, Solar Building, Room 2A21, telephone 301–435–3732, will provide a summary of the meeting and a roster of committee members upon request. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should contact Ms. Siskind in advance of the meeting.

(Catalog of Federal Domestic Assistance Program Nos. 93.855, Immunology, Allergic and Immunologic Diseases Research; 93.856, Microbiology and Infectious Diseases Research, National Institutes of Health).

Dated: December 10, 1997.

**LaVerne Y. Stringfield,**

*Committee Management Officer, NIH.*

[FR Doc. 97–32743 Filed 12–15–97; 8:45 am]

BILLING CODE 4140–01–M

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

## National Institutes of Health

## National Institute of Allergy and Infectious Diseases; 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 National Institute of Allergy and Infectious Diseases Special Emphasis Panel (SEP) meeting:

*Name of SEP:* Amended Unsolicited R01 (Telephone Conference Call).

*Date:* January 6, 1998.

*Time:* 1:00 p.m. to Adjournment.

*Place:* Teleconference, 6003 Executive Blvd., Solar Building, Room 4C01, Bethesda, MD 20892, (301) 496–2500.

*Contact Person:* Dr. Dianne E. Tingley, Scientific Review Adm., 6003 Executive Boulevard, Solar Bldg., Room 4C07, Bethesda, MD 20892, (301) 496–2550.

*Purpose/Agenda:* To evaluate a grant application.

The meeting will be closed in accordance with the provision set forth in secs. 552b(c)(4) and 552b(c)(6), Title 5, U.S.C. Application and/or proposals and the discussions could reveal confidential trade secrets or commercial property such as patentable material and personal information concerning individuals associated with the applications and/or proposals, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

(Catalog of Federal Domestic Assistance Programs Nos. 93.855, Immunology, Allergic and Immunologic Diseases Research; 93.856, Microbiology and Infectious Diseases Research, National Institutes of Health.)

Dated: December 10, 1997.

**LaVerne Y. Stringfield,**

*Committee Management Officer, NIH.*

[FR Doc. 97–32744 Filed 12–15–97; 8:45 am]

BILLING CODE 4140–01–M

## DEPARTMENT OF THE INTERIOR

### Fish and Wildlife Service

### Availability of an Environmental Assessment and Finding of No Significant Impact, and Receipt of an Application for an Incidental Take Permit for a Proposed Residential Development Called Heron's Cove, Charlotte County, Florida

**AGENCY:** Fish and Wildlife Service, Interior.

**ACTION:** Notice.

Heron's Cove, L.C. (Applicant), seeks an incidental take permit (ITP) from the Fish and Wildlife Service (Service), pursuant to Section 10(a)(1)(B) of the Endangered Species Act of 1973 (16 U.S.C. 1531 *et seq.*), as amended (Act). The ITP would authorize for a period of 15 years the incidental take of a threatened species, the Florida scrub-jay, *Aphelocoma coerulescens.* The proposed residential development is called Heron's Cove and will consist of 16 homes located on about 173 acres in section 7, Township 40 south, Range 23 East, Charlotte County, Florida (Project). Approximately 40 acres of the Project site are considered habitat for the Florida scrub-jay. A more detailed description of the mitigation and minimization measures to address the effects of the Project to the protected species are outlined in the Applicant's Habitat Conservation Plan (HCP), the Service's Environmental Assessment (EA), and in the **SUPPLEMENTARY INFORMATION** section below.

The Service also announces the availability of an EA and HCP for the incidental take application. Copies of the EA and/or HCP may be obtained by making a request to the Regional Office (see **ADDRESSES**). Requests must be in writing to be processed. This notice also advises the public that the Service has made a preliminary determination that issuing the ITP is not a major Federal action significantly affecting the quality of the human environment within the meaning of Section 102(2)(C) of the National Environmental Policy Act of 1969, as amended (NEPA). The Finding of No Significant Impact (FONSI) is based on information contained in the EA and HCP. The final determination will be made no sooner than 30 days from the date of this notice. This notice is provided pursuant to Section 10 of the Act and NEPA regulations (40 CFR 1506.6). The Service specifically requests comment on the appropriateness of the ''No Surprises'' assurances should the Service determine that an ITP will be granted and based upon the submitted HCP. Although not explicitly stated in the HCP, the Service has, since August 1994, announced its intention to honor a ''No Surprises'' Policy for applicants seeking ITPs. Copies of the Service's ''No Surprises'' Policy may be obtained by making a written request to the Regional Office (see **ADDRESSES**). The Service is soliciting public comments and review of the applicability of the ''No Surprises'' Policy to this application and HCP.

**DATES:** Written comments on the ITP application, EA, and HCP should be sent to the Service's Regional Office (see **ADDRESSES**) and should be received on or before January 15, 1998.

**ADDRESSES:** Persons wishing to review the application, HCP, and EA may obtain a copy by writing the Service's Southeast Regional Office, Atlanta, Georgia. Documents will also be available for public inspection by appointment during normal business hours at the Regional Office, 1875 Century Boulevard, Suite 200, Atlanta, Georgia 30345 (Attn: Endangered Species Permits), or U.S. Fish and Wildlife Service, 1360 U.S. Highway 1, Suite 5, Vero Beach, Florida 32961–2676. Written data or comments concerning the application, EA, or HCP should be submitted to the Regional Office. Requests for the documentation must be in writing to be processed. Comments must be submitted in writing to be adequately considered in the Service's decision-making process. Please reference permit number PRT–837313 in such comments, or in requests of the documents discussed herein.

**FOR FURTHER INFORMATION CONTACT:** Mr. Rick G. Gooch, Regional Permit Coordinator, (see **ADDRESSES** above), telephone: 404/679–7110; or Mr. Mike Jennings, Fish and Wildlife Biologist, South Florida Ecosystem Office, Vero Beach, Florida (see **ADDRESSES** above), telephone: 561/562–3909.

**SUPPLEMENTARY INFORMATION:** The Florida scrub-jay (FSJ) is geographically isolated from other subspecies of scrub jays found in Mexico and the Western United States. The FSJ is found exclusively in peninsular Florida and is restricted to scrub habitat. The total estimated population is between 7,000 and 11,000 individuals. Due to habitat loss and degradation throughout the State of Florida, it has been estimated that FSJ numbers have been reduced by at least half in the last 100 years. In Charlotte County alone, it is estimated that as of 1992, only 1,793 acres of scrub habitat remained. Many of the remaining FSJ now occupy small, isolated patches of habitat and are vulnerable to extirpation because of habitat fragmentation, fire suppression, increased predation, natural stochastic events, and other anthropogenic impacts. Most of the scrub habitat on the Project site is also overgrown or was previously altered due to land clearing. The Service, through consultation with other experts, believes that FSJ will decline, over time, in these type of situations without active management of remaining habitat patches.

Based on existing soils data, much of the FSJ habitat that was once widespread along coastal and riverine portions of Lee, Charlotte, and Sarasota Counties has been lost or degraded, including xeric habitat within the Project area and adjoining lands. Even with the large loss of habitat, FSJ using the Project are still considered to be part of a larger complex of demographically connected FSJ that occupy xeric uplands of southwest Florida. This complex of FSJ families is considered one of five remaining areas where relatively large numbers of birds remain demographically linked. The continued survival of FSJ in southwest Florida may be dependent on the maintenance of suitable habitat and the restoration of unsuitable habitat in northern Charlotte County, including the Project site and adjoining lands.

FSJ use of the Project site and adjacent lands has been assessed on two occasions. In 1994, banding studies revealed that five scrub-jay families containing at least 20 individuals used parts of the Project site. However, no single territory was exclusively encompassed within the Project site nor were any nests documented within the Project site. Nesting surveys conducted in 1997 located five nests on vacant lots in the subdivision adjacent to the Project site. The principal value of the Project site to FSJ is for foraging and cover.

Construction of the Project's infrastructure and subsequent construction of the individual homesites will likely result in death of, or injury to, FSJ incidental to the carrying out of these otherwise lawful activities. Habitat alteration associated with the proposed residential development will reduce the availability of feeding and sheltering habitat.

The Applicant's HCP and the Service's EA describe the following minimization and mitigation strategy to be employed by the Applicant to offset the impacts of the Project to the FSJ:

- Micro sighting of access roads, driveways, home foundations to avoid or minimize impacts to xeric vegetation.

• To compensate for the destruction of 18 acres of FSJ habitat by preserving, restoring, and managing about 37 acres of xeric uplands. Seventeen acres of the proposed mitigation will be implemented within the boundaries of the Project.

• The Applicant will conserve an additional 20 acres of FSJ habitat, via a perpetual management agreement, within Serene Estates (section 20, Township 40 East, Range 24 South, Charlotte County), a 200 acre parcel of land controlled by the Applicant.

• Within the larger 200 acre parcel owned by the Applicant, the Applicant has also agreed to preserve and manage an additional 80 acres of xeric uplands. Although not intended for the mitigation needs of the Project, the Applicant has requested that the 80 acres of habitat be available for use as a future private mitigation bank.

• Funding and perpetual management of the on-site conserved area encompassing 17 acres and the 20 acre off-site mitigation area will be provided via terms and conditions of the ITP and an Implementation Agreement (IA), respectively. The IA will be executed between the Service and the Applicant, and will outline specific funding and management commitments for the on-site and off-site mitigation areas for a 99 year period. A copy of the final IA will be provided to interested parties upon request.

• Clearing of vegetation and/or construction would not be allowed within 150 feet of any active FSJ nest during the nesting season, approximately March 1 to June 30 to comply with State law.

The EA considers the environmental consequences of four alternatives. Two alternatives involve a project design of a lesser construction footprint (e.g., lesser number of homesites and associated infrastructure). The no action alternative may result in loss of habitat for FSJ and exposure of the Applicant under Section 9 of the Act. The proposed action alternative is issuance of the ITP according to the HCP as submitted and described above. Under the proposed alternative, the effect of the minimization and mitigation strategy will be that the majority of the FSJ habitat on site will be conserved for FSJ use, even after the Project is completed. Further, the restoration/conservation of the 20 acres of off site FSJ habitat, along with the Applicant's commitment to manage an additional 80 acres of FSJ habitat, will result in a protected and managed area capable of supporting about five families of FSJ under optimal habitat. Though the proposed mitigation bank will be used to off-set future impacts to FSJ in portions of southwest Florida, the Service believes that the protection of an 80 acre block of xeric habitat along with the 20 acres needed for mitigating Project impacts will enhance FSJ survival in this part of the state.

Suitable or restorable FSJ habitat also exists on property surrounding the Serene Estates mitigation site. Future land acquisition by the County, State, or for other mitigation needs may result in additional protected lands adjoining the off-site mitigation area. Increases in the size of protected and managed FSJ habitat in this area will increase the probability of FSJ persistence in northern Charlotte County.

As stated above, the Service has made a preliminary determination that the issuance of the ITP is not a major Federal action significantly effecting the quality of the human environment within the meaning of Section 102(2)(C) of NEPA. This preliminary information may be revised due to public comment received in response to this notice and is based on information contained in the EA and HCP. An appropriate excerpt from the FONSI reflecting the Service's finding on the application is provided below:

Based on the analysis conducted by the Service, it has been determined that:

• Issuance of the ITP will not appreciably reduce the likelihood of survival and recovery of the affected species in the wild.

• The HCP contains provisions which sufficiently minimize and/or mitigate the impacts of issuing the ITP.

• Issuance of the ITP would not have significant effects on the human environment in the project area.

• The proposed take is incidental to an otherwise lawful activity.

• Adequate funding will be provided to implement the measures proposed in the submitted HCP and authorizing ITP.

The Service will also evaluate whether the issuance of a Section 10(a)(1)(B) ITP complies with Section 7 of the Act by conducting an intra-Service Section 7 consultation. The results of the biological opinion, in combination with the above findings, will be used in the final analysis to determine whether or not to issue the ITP.

Dated: December 4, 1997.

**H. Dale Hall,**

*Deputy Regional Director.*

[FR Doc. 97–32719 Filed 12–15–97; 8:45 am]

BILLING CODE 4310–55–P

## DEPARTMENT OF THE INTERIOR

### Bureau of Indian Affairs

### Draft Department of the Interior and Department of Health and Human Services Internal Agency Procedures Manual for Contracting Under Title I of the Indian Self-Determination and Education Assistance Act

**AGENCY:** Bureau of Indian Affairs and Indian Health Service, Interior.

**ACTION:** Notice.

**SUMMARY:** The congress has declared that each provision of the Indian Self-Determination and Education Assistance Act (Act) and each provision of contracts entered into thereunder shall be liberally construed for the benefit of the Indian tribes or tribal organizations (T/TO). To carry out this policy, the Department of the Interior and Department of Health and Human Services Internal Agency Procedures Manual for Contracting Under Title I of the Indian Self-Determination and Education Assistance Act (Manual) was drafted to facilitate and enhance contracting with T/TOs under Title I of the Act, as amended, 25 U.S.C. 450 *et seq.*, and the regulations promulgated thereunder, 25 CFR part 900 (published in the **Federal Register** on June 24, 1996, and effective on August 23, 1996). The public is invited to review and comment on the draft Manual.

**DATES:** All written comments on the Manual should be submitted by January 15, 1998.

**ADDRESSES:** Written comments must be addressed to: Merry L. Elrod, Office of Tribal Programs, Indian Health Service, 5600 Fishers Lane, Room 6A–05, Rockville, Maryland 20857.

**FOR FURTHER INFORMATION CONTACT:** For additional information and/or to receive copies of the manual and letter dated October 30, 1997, to tribal leaders and other interested parties inviting comments on the draft Manual, the public may contact either: James Thomas, Division of Self-Determination Services, Bureau of Indian Affairs, 1949 C Street, NW. , MS 4603–MIB, Washington, D.C., 20240, telephone 202/208–5727, or Merry Elrod, Office of Tribal Programs, Indian Health Service, 5600 Fishers Lane, Parklawn Building, Room 6A–05, Rockville, MD, 20857, telephone 301/443–1044.

Dated: December 9, 1997.

**Hilda A. Manuel,**

*Deputy Commissioner of Indian Affairs.*

[FR Doc. 97–32696 Filed 12–15–97; 8:45 am]

BILLING CODE 4310–02–P

## DEPARTMENT OF THE INTERIOR

### Bureau of Land Management

**[NV–930–1430–00; N–59678]**

### Notice of Realty Action: Change of Use for Recreation and Public Purposes Lease/Conveyance N–41279

**AGENCY:** Bureau of Land Management, Interior.

**ACTION:** Recreation and Public Purpose change of use.

**SUMMARY:** The following described public land in Las Vegas, Clark County, Nevada has been leased for public purposes under the provisions of the Recreation and Public Purposes Act, as amended (43 U.S.C. 869 *et seq.*). Nevada Children's Center proposes to use the land for a children's after school day treatment program facility.

**Mount Diablo Meridian, Nevada**

T. 21 S., R. 60 E.,
Sec. 16: NE¼NE¼SW¼
Containing 10.00 acres, more or less.

The land is not required for any federal purpose. The lease/conveyance is consistent with current Bureau planning for this area and would be in the public interest. The lease/patent, when issued, will be subject to the provisions of the Recreation and Public Purposes Act and applicable regulations of the Secretary of the Interior, and will contain the following reservations to the United States:

1. A right-of-way thereon for ditches or canals constructed by the authority of the United States, Act of August 30, 1890 (43 U.S.C. 945).

2. All minerals shall be reserved to the United States, together with the right to prospect for, mine and remove such deposits from the same under applicable law and such regulations as the Secretary of the Interior may prescribe.

and will be subject to:

1. An easement for the North 40 feet, the West 30 feet and the East 40 feet in favor of Clark County for roads, public utilities and flood control purposes.

Detailed information concerning this action is available for review at the office of the Bureau of Land Management, Las Vegas District, 4765 W. Vegas Drive, Las Vegas, Nevada. Contact Cheryl Ruffridge by calling (702) 647–5064. For a period of 45 days from the date of publication of this notice in the **Federal Register**, interested parties may submit comments regarding the lease/conveyance of the lands to the District Manager, Las Vegas District, 4765 W. Vegas Drive, Las Vegas, Nevada 89108.

**Application Comments**

Interested parties may submit comments regarding the specific use proposed in the application and plan of development, whether the BLM followed proper administrative procedures in reaching the decision, or any other factor not directly related to the suitability of the land for a children's after school day treatment program facility. Any adverse comments will be reviewed by the State Director. In the absence of any adverse comments, the change of use for the land described in this Notice will become effective 60 days from the date of publication in the **Federal Register**.

Dated: December 1, 1997.

**Mark R. Chatterton,**

*Assistant District Manager, Non-Renewable Resources, Las Vegas, NV.*

[FR Doc. 97–32716 Filed 12–15–97; 8:45 am]

BILLING CODE 4310–HC–P

## DEPARTMENT OF THE INTERIOR

### Minerals Management Service

### Agency Information Collection Activities: Proposed Collection; Comment Request

**AGENCY:** Minerals Management Service, DOI.

**ACTION:** Notice of information collection solicitation.

**SUMMARY:** Under the Paperwork Reduction Act of 1995, the Minerals Management Service (MMS) is soliciting comments on an information collection, Stripper Royalty Rate Reduction Notification (OMB Control Number 1010–0090, Form MMS–4377), which expires on May 31, 1998.

**FORM:** MMS–4377, Stripper Royalty Rate Reduction Notification

**DATES:** Written comments should be received on or before February 17, 1998.

**ADDRESSES:** Comments sent via the U.S. Postal Service should be sent to Minerals Management Service, Royalty Management Program, Rules and Publications Staff, P.O. Box 25165, MS 3021, Denver, Colorado 80225–0165; courier address is Building 85, Room A613, Denver Federal Center, Denver, Colorado 80225; e-mail address is David____Guzy@mms.gov.

**FOR FURTHER INFORMATION CONTACT:** Dennis C. Jones, Rules and Publications Staff, phone (303) 231–3046, FAX (303) 231–3385, e-mail Dennis____C____Jones@mms.gov.

**SUPPLEMENTARY INFORMATION:** To encourage continued production, provide an incentive for enhanced oil recovery projects, discourage abandonment of properties producing less than 15 barrels of oil per well-day, and reduce the operator's expenses, the Bureau of Land Management (BLM) will grant royalty rate reductions to operators of low-producing, stripper oil properties. BLM amended 43 CFR 3103.4–1 to establish the conditions under which an operator or owner of a stripper oil property can obtain a reduction in the royalty rate for a property producing less than 15 barrels of oil per well-day. The amended regulations provided instructions for calculation of royalty rates based on the property's annual production rate.

Operators of stripper oil properties use a formula developed by BLM [royalty rate (%) = 0.5 + (0.8 x average daily production)] and included under 43 CFR 3103.4–1(d)(3)(ii) to determine the reduced royalty rate. Operators are then required to notify MMS of the reduced royalty rate. The reduced rate will become effective for all oil production from qualifying properties the first day of the month after MMS receives notification of the rate change. Failure to inform MMS of the new royalty rate would result in the generation of exceptions by MMS computer systems processing financial and production data. The operator would then be held liable for royalty at the old rate and be subject to interest charges as well.

MMS has developed Form MMS–4377, Stripper Royalty Rate Reduction Notification, to be used to notify MMS of the reduced royalty rate. The form requires identification of the operator, name of the contact person, lease and agreement numbers, calculated royalty rate, current royalty rate and period covered. Since implementation of the final rule on September 10, 1992, MMS has received over 7,000 of these notifications. MMS uses the information provided on the form to update the database with accepted reduced royalty rates.

There are approximately 4,500 stripper leases or agreements on Federal lands and a total of 900 operators. Royalty rate calculations were made for the initial qualifying period, August 1, 1990, through July 31, 1991, and are now submitted for each 12-month period. We estimate that an operator may require 30 minutes per property to research production for one 12-month period, determine average annual well production, and calculate and report a new royalty rate or an annual burden of 2,250 hours (1/2 hour x 4,500 properties). We estimate that an operator may require 15 minutes annually to perform the necessary

recordkeeping responsibilities associated with this information collection or an annual burden of 225 hours (1/4 hour x 900 operators).

Dated: December 10, 1997.

**R. Dale Fazio,**

*Acting Associate Director for Royalty Management.*

[FR Doc. 97–32718 Filed 12–15–97; 8:45 am]

BILLING CODE 4310–MR–P

## DEPARTMENT OF THE INTERIOR

## National Park Service

## Visitor Services Plan/Environmental Impact Statement, Crater Lake National Park, Oregon

**AGENCY:** National Park Service, Interior.

**ACTION:** Notice of availability of Draft Environmental Impact Statement.

**SUMMARY:** Pursuant to Section 102(2)(C) of the National Environmental Policy Act of 1969 (P.L. 91–190 as amended), the National Park Service (NPS), Department of the Interior, has prepared a draft environmental impact statement (DEIS) assessing the potential impacts of the proposed Visitor Services Plan for Crater Lake National Park, Oregon. Once approved, the plan will guide the management and use of the developed areas of the park.

The alternatives presented in the DEIS define appropriate levels and kinds of visitor services and set the basis for a new concession contract. Alternative A (the proposed action) is a mix of proposals that are intended to protect park resources and enhance the visitor experience. Educational and interpretive opportunities would be enhanced to promote better visitor understanding, appreciation, and preservation of Crater Lake. NPS interpretive services would be emphasized, commercial services would be modified to better serve visitors, and some historic structures would be used more as they were initially intended. Alternative B (no action) would continue the existing conditions at the park and would allow for the completion of any facilities currently under construction. Alternative C would offer a more self-directed visitor experience that would be less facility-dependent and less structured than at present. Alternative D would enhance interpretation and provide a wider variety of commercial and NPS visitor services. Alternative E is primarily based on the planning direction presented in the Record of Decision for the 1995 Development Concept Plan/Environmental Impact Statement, and would concentrate visitor facilities at Rim Village.

The environmental consequences of the proposed action and the alternatives are fully documented, and mitigation provided as appropriate to minimize impacts.

**SUPPLEMENTARY INFORMATION:** Copies of the DEIS will be available for public inspection at the park. Requests for copies of the DEIS should be directed to the Superintendent, Crater Lake National Park, P.O. Box 7, Crater Lake, Oregon 97064 or by telephone at (541) 594–2211. Written comments on the draft plan should also be directed to the Superintendent at the above address and must be received by January 26, 1998. All review comments received will become part of the public record and copies of comments, including names, addresses and telephone numbers provided by respondents, may be released for public inspection.

Dated: December 3, 1997.

**Cynthia R. Young,**

*Chief, Resource Planning, Denver Service Center, National Park Service.*

[FR Doc. 97–32798 Filed 12–15–97; 8:45 am]

BILLING CODE 4310–70–P

## DEPARTMENT OF THE INTERIOR

## National Park Service

## Wild and Scenic River Study and Environmental Impact Statement for the Lower Sheenjek River in Alaska

**AGENCIES:** National Park Service, Interior.

**ACTION:** Notice of intent to prepare a Wild and Scenic River Study and revised draft legislative environmental impact statement for the lower Sheenjek River in Alaska.

**SUMMARY:** The National Park Service (NPS) is preparing an update to the 1984 draft Wild and Scenic River Study and Legislative Environmental Impact Statement (LEIS) for the Lower Sheenjek River in Alaska as required by Section 5(a) of the Wild and Scenic Rivers Act. The purpose of the study and LEIS is to study the Lower Sheenjek River for potential addition to the National Wild and Scenic River System. The U.S. Fish and Wildlife Service (USFWS) is a cooperating agency on this EIS.

The Sheenjek River is a 277 mile-long free flowing, unpolluted tributary of the Porcupine River. The study area is the lower part of the river within the Yukon Flats National Wildlife Refuge, and is 99 miles in length. A 1984 draft study recommended the study area as eligible and suitable as a wild river for inclusion in the National Wild and Scenic Rivers System. The upper river outside the study area (within the Arctic National Wildlife Refuge) was designated in 1980 by The Alaska National Interest Lands Conservation Act as part of the National Wild and Scenic Rivers System.

The Revised Draft Legislative EIS will consider a proposed action and a no-action alternative. The proposed action would recommend for designation the 99-mile segment of the Sheenjek River as a National Wild River. Designation would ensure long-term protection of the entire river's outstanding values through mandatory development of a river management plan for the lower river. Under the no-action alternative the lower Sheenjek River would not be recommended for designation. No additional protection would be provided to the lower river.

The Revised Draft Legislative EIS will be prepared in accordance with the requirements of the National Environmental Policy Act of 1969, as amended (42 U.S.C. 4331 *et seq.*) and its implementing regulations at 40 CFR part 1500. The NPS will prepare the EIS in conjunction with preparation of the Wild and Scenic River Study. In May/June of 1997 the NPS and USFWS held meetings in Fairbanks and Fort Yukon, Alaska to discuss the lower Sheenjek River wild and scenic study with the public. The Revised Draft Study/EIS is scheduled for public review in early 1988. Public meetings will be held in Fairbanks and Fort Yukon, Alaska. The locations and times of the public meetings will be announced in the **Federal Register**, local newspapers, and radio.

**FOR FURTHER INFORMATION CONTACT:** Jack Mosby, National Park Service 2525 Gambell Street, Anchorage, Alaska 99503–2892 Phone: (907) 257–2650.

Dated: December 8, 1997.

**Paul R. Anderson,**

*Regional Director, Alaska.*

[FR Doc. 97–32797 Filed 12–15–97; 8:45 am]

BILLING CODE 4310–70–P

## DEPARTMENT OF THE INTERIOR

## National Park Service

## Agenda for the January 14, 1998 Public Meeting of the Advisory Commission for the San Francisco Maritime National Historical Park

### Public Meeting

*Fort Mason, Building F, 10:00 am–12:45 pm*

10:00 AM

Welcome—Neil Chaitin, Chairman

Opening Remarks—Neil Chaitin, Chairman; William G. Thomas, Superintendent
10:15 AM
Update—General Management Plan, Phase II Implementation, William G. Thomas
10:30 AM
Update—Haslett Warehouse, William G. Thomas, Superintendent
10:45 AM
Update—SAFR Space needs for Haslett Warehouse, Building E, Tom Mulhern, Museum Services Manager
11:00 AM
Status—Fiscal Year 98 Budget/Projects, Jeanne Haugh, Administrative Officer
11:15 AM
Status—Ship Preservation Update, Wayne Boykin, Ships Manager and Staff
11:45 AM
Update—Disaster Plan; Museum Building Preservation/Restoration Projects, Marc Hayman, Chief IRM
12:00 PM
Status—Volunteer Program, Sue Schmidt, Volunteer Coordinator
12:15 PM
Update—National Maritime Museum Association Programs/Projects, Kathy Lohan, Chief Executive Officer
12:30 PM
Public Comments and Questions
12:45 PM
Agenda items/Date for next meeting

**Jeanne C. Vaughn,**

*Superintendent.*

[FR Doc. 97–32796 Filed 12–15–97; 8:45 am]

BILLING CODE 4310–70–P

## DEPARTMENT OF LABOR

### Office of the Secretary

### Submission of OMB Emergency Review; Comment Request

December 12, 1997.

The Department of Labor has submitted the following information collection request (ICR), utilizing emergency review procedures, to the Office of Management and Budget (OMB) for review and clearance in accordance with the Paperwork Reduction Act of 1995 (Pub. L. 104–13, 44 U.S.C. Chapter 35). OMB approval has been requested by December 17, 1997. A copy of this ICR, with applicable supporting documentation, may be obtained by calling the Department of Labor Departmental Clearance Officer, Todd R. Owen ((202) 219–5096 x143).

Comments and questions about the ICR listed below should be forwarded to the Office of Information and Regulatory Affairs, Attn: OMB Desk Officer for Employment and Training, Office of Management and Budget, Room 10235, Washington, D.C. 20503 (202) 395–7316.

The Office of Management and Budget is particularly interested in comments which:

- Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;
- Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;
- Enhance the quality, utility, and clarity of the information to be collected; and
- Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submissions of responses.

*Agency:* Employment and Training Administration.

*Title:* Welfare-to-Work Competitive Grants: Solicitation for Grant Applications.

*OMB Number:* 1205–Onew.

*Frequency:* Annually.

*Affected Public:* Public and private entities.

*Number of Respondents:* 600.

*Estimated Time Per Respondent:* 20 hours.

*Total Burden Hours:* 12,000.

*Total Burden Cost (capital/startup):* $480,000.

*Total Burden Cost (operating/maintaining):* 0.

*Description:* The Balanced Budget Act of 1997, signed by the President on August 5, 1997, authorized the Department of Labor to provide Welfare-to-Work (WtW) grants to State and local communities to provide transitional employment assistance to move Temporary Assistance for Needy Families (TANF) recipients with significant employment barriers into unsubsidized jobs providing long-term employment opportunities. Under the WtW grants program, 25% of funds not allocated by the formula grants (to the States) will be provided through competitive grants to local governments, PICs, and private entities. In order to receive competitive grant funds, the statute provides that the public or private entity must submit an application in conjunction with the applicable PIC or political subdivision.

**Todd R. Owen,**

*Departmental Clearance Officer.*

[FR Doc. 97–32943 Filed 12–15–97; 8:45 am]

BILLING CODE 4510–23–M

## NATIONAL ARCHIVES AND RECORDS ADMINISTRATION

### Records Schedules; Availability and Request for Comments

**AGENCY:** National Archives and Records Administration, Office of Records Services.

**ACTION:** Notice of availability of proposed records schedules; request for comments.

**SUMMARY:** The National Archives and Records Administration (NARA) publishes notice at least once monthly of certain Federal agency requests for records disposition authority (records schedules). Records schedules identify records of sufficient value to warrant preservation in the National Archives of the United States. Schedules also authorize agencies after a specified period to dispose of records lacking administrative, legal, research, or other value. Notice is published for records schedules that propose the destruction of records not previously authorized for disposal, or reduce the retention period for records already authorized for disposal. NARA invites public comments on such schedules, as required by 44 U.S.C. 3303a(a).

**DATES:** Requests for copies must be received in writing on or before January 30, 1998. Once the appraisal of the records is completed, NARA will send a copy of the schedule. The requester will be given 30 days to submit comments.

**ADDRESSES:** Address requests for single copies of schedules identified in this notice to the Civilian Appraisal Staff (NWRC), National Archives and Records Administration, 8601 Adelphi Road, College Park, MD 20740–6001. Requesters must cite the control number assigned to each schedule when requesting a copy. The control number appears in the parentheses immediately after the name of the requesting agency.

**FOR FURTHER INFORMATION CONTACT:** Michael L. Miller, Director, Records Management Programs, National Archives and Records Administration, 8601 Adelphi Road, College Park, MD 20740–6001, telephone (301) 713–7110.

**SUPPLEMENTARY INFORMATION:** Each year U.S. Government agencies create billions of records on paper, film, magnetic tape, and other media. In order to control this accumulation, agency records managers prepare records schedules specifying when the agency no longer needs the records and what happens to the records after this period. Some schedules are comprehensive and cover all the records of an agency or one of its major subdivisions. These comprehensive schedules provide for the eventual transfer to the National Archives of historically valuable records and authorize the disposal of all other records. Most schedules, however, cover records of only one office or program or a few series of records, and many are updates of previously approved schedules. Such schedules also may include records that are designated for permanent retention.

Destruction of records requires the approval of the Archivist of the United States. This approval is granted after a thorough study of the records that takes into account their administrative use by the agency of origin, the rights of the Government and of private persons directly affected by the Government's activities, and historical or other value.

This public notice identifies the Federal agencies and their subdivisions requesting disposition authority, includes the control number assigned to each schedule, and briefly describes the records proposed for disposal. The records schedule contains additional information about the records and their disposition. Further information about the disposition process will be furnished to each requester.

### Schedules Pending

1. U.S. Office of Government Ethics (N1–522–98–1). Questionnaire files, training plans, and internal training program files maintained by the Education and Program Services Division.

2. Administrative Office of the United States Courts (N1-116–96–2). Jury Modernization System.

3. Department of Agriculture, Agricultural Research Service, (N1–310–97–2). Routine administrative files related to the input of information into an automated system used to keep track of USDA research projects.

4. Department of the Treasury, Internal Revenue Service (N1–58–97–3). Records accumulated by the Communications Division in the National Office's field offices (RCS 205).

5. Department of the Treasury, Internal Revenue Service (N1–058–97–6). Records accumulated by the Legislative Affairs Division.

6. Department of the Treasury, Internal Revenue Service (N1–058–97–10). Records accumulated by the Appeals Division in the National office and field offices.

7. Department of the Treasury, Internal Revenue Service (N1–058–98–7). Electronic records of the Audit Information Management System (AIMS).

8. Bureau of Public Debt (N1–53–96–4). Electronic records systems.

9. Federal Retirement Thrift Investment Board (N1–474–97–6). TSP forms filed by plan participants and/or annuitants.

10. United States Commission on Immigration Reform (N1–220–98–4). Comprehensive schedule.

Dated: December 9, 1997.

**Michael J. Kurtz,**

*Assistant Archivist for Record Services—Washington, DC.*

[FR Doc. 97–32776 Filed 12–15–97; 8:45 am]

BILLING CODE 7515–01–P

## NATIONAL CREDIT UNION ADMINISTRATION

### Notice of Meetings

*Time and Date:* 10:00 a.m., Thursday, December 18, 1997.

*Place:* Board Room, 7th Floor, Room 7047 1775 Duke Street, Alexandria, VA 22314–3428

*Status:* Open.

*Matters to be Considered:*

1. Request from a Credit Union to Convert to Private Insurance.
2. Request from a Federal Credit Union to Convert to Community Charter.
3. Request from a Federal Credit Union to Merge and Convert Insurance.
4. Request from a Federal Credit Union to Convert from a Federal Credit Union and Merge into a Federal Mutual Savings Bank.
5. Final Rule: amendment to Part 725.19, NCUA's Rules and Regulation, Central liquidity Facility Collateral Requirements.
6. Community Development Revolving Loan Program for Credit Unions: Notice of Applications for Participation.
7. Proposed Operating Fee Scale.
8. Proposed National Fields of Membership for Corporate Credit Unions.

*Recess:* 11:15 a.m.

*Time and Date:* 11:30 a.m., Thursday, December 18, 1997.

*Place:* Board Room, 7th Floor, Room 7047 1775 Duke Street, Alexandria, VA 22314–3428.

*Status:* Closed.

*Matters to be Considered:*

1. One (1) Administrative Action under Section 208 of the Federal Credit Union Act. Closed pursuant to exemptions (8), (9)(A)(ii) and (9)(B).
2. Four (4) Administrative Actions under Par 704 of NCUA's Rules and Regulations. Closed pursuant to exemptions (8), (9)(A)(ii) and (9)(B).
3. Adoption of Robert's Rules of Order in the Absence of NCUA Rules and Regulations. Closed pursuant to exemptions (2) and (6).
4. Approval (In Part) of September 17, 1997, Open Board Minutes. Closed pursuant to exemptions (2) and (6).
5. Two (2) Personnel Actions. Closed pursuant to exemptions (2) and (6).

**FOR FURTHER INFORMATION CONTACT:** Becky Baker, Secretary of the Board, Telephone 703–518–6304.

**Becky Baker,**

*Secretary of the Board.*

[FR Doc. 97–32852 Filed 12–11–97; 5:12 pm]

BILLING CODE 7535–01–M

## NATIONAL CREDIT UNION ADMINISTRATION

### Notice of Previously Held Emergency Meeting

*Time and Date:* 9:09 a.m., Thursday, December 11, 1997.

*Place:* Board Room, 7th Floor, Room 7047, 1775 Duke Street, Alexandria, Virginia 22314–3428.

*Status:* Closed.

*Matters Considered:*

1. Personnel Actions. Closed Pursuant to exemptions (2), (5), (6) and (9)(B).
2. Matters Relating to OPM Report. Closed pursuant to exemptions (2) and (6).

The Board voted unanimously that Agency business required that a meeting be held with less than the usual seven days advance notice, that it be closed to the public, and that earlier announcement of this was not possible.

The Board voted unanimously to close the meeting under the exemptions stated above. Deputy General Counsel James Engel certified that the meeting could be closed under those exemptions.

**FOR FURTHER INFORMATION CONTACT:** Becky Baker, Secretary of the Board, Telephone (703) 518–6304.

**Becky Baker,**

*Secretary of the Board.*

[FR Doc. 97–32853 Filed 12–11–97; 5:12 pm]

BILLING CODE 7535–01–M

## NUCLEAR REGULATORY COMMISSION

**[Docket 70–7001]**

### Notice of Amendment to Certificate of Compliance GDP–1 for the U.S. Enrichment Corporation Paducah Gaseous Diffusion Plant, Paducah, KY

The Director, Office of Nuclear Material Safety and Safeguards, has made a determination that the following amendment request is not significant in accordance with 10 CFR 76.45. In making that determination, the staff

concluded that: (1) There is no change in the types or significant increase in the amounts of any effluents that may be released offsite; (2) there is no significant increase in individual or cumulative occupational radiation exposure; (3) there is no significant construction impact; (4) there is no significant increase in the potential for, or radiological or chemical consequences from, previously analyzed accidents; (5) the proposed changes do not result in the possibility of a new or different kind of accident; (6) there is no significant reduction in any margin of safety; and (7) the proposed changes will not result in an overall decrease in the effectiveness of the plant's safety, safeguards or security programs. The basis for this determination for the amendment request is shown below.

The NRC staff has reviewed the certificate amendment application and concluded that it provides reasonable assurance of adequate safety, safeguards, and security, and compliance with NRC requirements. Therefore, the Director, Office of Nuclear Material Safety and Safeguards, is prepared to issue an amendment to the Certificate of Compliance for the Paducah Gaseous Diffusion Plant. The staff has prepared a Compliance Evaluation Report which provides details of the staff's evaluation.

The NRC staff has determined that this amendment satisfies the criteria for a categorical exclusion in accordance with 10 CFR 51.22. Therefore, pursuant to 10 CFR 51.22(b), no environmental impact statement or environmental assessment need be prepared for this amendment.

USEC or any person whose interest may be affected may file a petition, not exceeding 30 pages, requesting review of the Director's Decision. The petition must be filed with the Commission not later than 15 days after publication of this **Federal Register** Notice. A petition for review of the Director's Decision shall set forth with particularity the interest of the petitioner and how that interest may be affected by the results of the decision. The petition should specifically explain the reasons why review of the Decision should be permitted with particular reference to the following factors: (1) The interest of the petitioner; (2) how that interest may be affected by the Decision, including the reasons why the petitioner should be permitted a review of the Decision; and (3) the petitioner's areas of concern about the activity that is the subject matter of the Decision. Any person described in this paragraph (USEC or any person who filed a petition) may file a response to any petition for review, not to exceed 30 pages, within 10 days after filing of the petition. If no petition is received within the designated 15-day period, the Director will issue the final amendment to the Certificate of Compliance without further delay. If a petition for review is received, the decision on the amendment application will become final in 60 days, unless the Commission grants the petition for review or otherwise acts within 60 days after publication of this **Federal Register** Notice.

A petition for review must be filed with the Secretary, 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, the Gelman Building, 2120 L Street, NW, Washington, DC, by the above date.

For further details with respect to the action see (1) the application for amendment and (2) the Commission's Compliance Evaluation Report. These items are available for public inspection at the Commission's Public Document Room, the Gelman Building, 2120 L Street, NW, Washington, DC, and at the Local Public Document Room.

*Date of amendment request:* August 29, 1997.

*Brief description of amendment:* The amendment proposes to revise the Technical Safety Requirements (TSRs) for the uranium hexafluoride release detection systems located in Zones 1 and 4 of Building C–360. The revision is to include operability and surveillance requirements for additional valves that are required to close upon C–360 Zone 1 or 4 uranium hexafluoride detection.

**Basis for Finding of No Significance**

1. The proposed amendment will not result in a change in the types or significant increase in the amounts of any effluents that may be released offsite.

The proposed changes establish limiting conditions for operation and associated surveillance requirements to demonstrate the operability of containment isolation valves. The change has no effect on the generation or disposition of effluents. Therefore, the proposed TSR modifications will not result in a change to the types or amount of effluents that may be released offsite.

2. The proposed amendment will not result in a significant increase in individual or cumulative occupational radiation exposure.

The proposed changes will not significantly increase any exposure to radiation. Therefore, the changes will not result in a significant increase in individual or cumulative radiation exposure.

3. The proposed amendment will not result in a significant construction impact.

The proposed changes will not result in any construction, only procedure modification, therefore, there will be no construction impacts.

4. The proposed amendment will not result in a significant increase in the potential for, or radiological or chemical consequences from, previously analyzed accidents.

Accidents of concern involve the release of uranium hexafluoride in the C–360 laboratory area (Zone 1) and the basement transfer room (Zone 4). The proposed TSR changes ensure that the TSRs adequately address the current plant configuration by establishing limiting conditions for operation and associated surveillance requirements to demonstrate the operability of containment isolation valves. These changes will enhance the overall plant safety. The changes will not increase the probability of occurrence or consequence of any postulated accident currently identified in the safety analysis report.

5. The proposed amendment will not result in the possibility of a new or different kind of accident.

The proposed TSR modifications are necessary to reflect the fact that multiple valves on the autoclave transfer and sampling piping will isolate upon detection of uranium hexafluoride. The current TSR does not reflect recent modifications requiring closure of at least two isolation valves on each transfer/sampling pathway. The proposed changes will not create the possibility of a different type of equipment malfunction or a different type of accident.

6. The proposed amendment will not result in a significant reduction in any margin of safety.

The proposed changes to the TSRs ensure that the TSRs adequately address the current plant configuration by establishing limiting conditions for operation and associated surveillance requirements to demonstrate the operability of containment isolation valves that are required to close upon detection of uranium hexafluoride. These changes do not decrease the margins of safety.

7. The proposed amendment will not result in an overall decrease in the effectiveness of the plant's safety, safeguards or security programs.

Implementation of the proposed changes do not change the safety,

safeguards, or security programs. Therefore, the effectiveness of the safety, safeguards, and security programs is not decreased.

*Effective date:* The amendment to Certificate of Compliance GDP–1 becomes effective 30 days after being signed by the Director, Office of Nuclear Material Safety and Safeguards.

*Certificate of Compliance No. GDP–1:* Amendment will revise TSR 2.1.4.1 and 2.1.4.2a to establish operability and surveillance requirements for additional valves required to close upon C–360 Zone 1 or 4 uranium hexafluoride detection.

*Local Public Document Room location:* Paducah Public Library, 555 Washington Street, Paducah, Kentucky 42003.

Dated at Rockville, Maryland, this 8th day of December 1997.

For the Nuclear Regulatory Commission.

**Carl J. Paperiello,**

*Director, Office of Nuclear Material Safety and Safeguards.*

[FR Doc. 97–32760 Filed 12–15–97; 8:45 am]

BILLING CODE 7590–01–P

## NUCLEAR REGULATORY COMMISSION

**[Docket 70–7001]**

## Notice of Amendment and Denial of Amendment Application to Certificate of Compliance GDP–1 for the U.S. Enrichment Corporation, Paducah Gaseous Diffusion Plant, Paducah, Kentucky

The Director, Office of Nuclear Material Safety and Safeguards, made a determination that the following amendment request is significant in accordance with 10 CFR 76.45. Notice of Receipt of Amendment Request appeared in the **Federal Register** on July 31, 1997, allowing a 30-day public comment period on the application.

The NRC staff has reviewed the certificate amendment application and concluded that, in part, it provides reasonable assurance of adequate safety, safeguards, and security, and compliance with NRC requirements. Therefore, the Director, Office of Nuclear Material Safety and Safeguards, is prepared to issue an amendment to the Certificate of Compliance for the Paducah Gaseous Diffusion Plant, approving portions of the amendment application. Other portions of the amendment application, as explained herein, are proposed to be denied. The staff has prepared a Compliance Evaluation Report which provides details of the staff's evaluation.

The NRC staff has determined that this amendment satisfies the criteria for a categorical exclusion in accordance with 10 CFR 51.22. Therefore, pursuant to 10 CFR 51.22(b), no environmental impact statement or environmental assessment need be prepared for this amendment.

USEC, or any person whose interest may be affected and who submitted written comments in response to the **Federal Register** Notice on the amendment application under § 76.37, may file a petition, not exceeding 30 pages, requesting review of the Director's Decision. The petition must be filed with the Commission not later than 15 days after publication of this **Federal Register** Notice. A petition for review of the Director's Decision shall set forth with particularity the interest of the petitioner and how that interest may be affected by the results of the decision. The petition should specifically explain the reasons why review of the Decision should be permitted with particular reference to the following factors: (1) the interest of the petitioner; (2) how that interest may be affected by the Decision, including the reasons why the petitioner should be permitted a review of the Decision; and (3) the petitioner's areas of concern about the activity that is the subject matter of the Decision. Any person described in this paragraph (USEC or any person who filed a petition) may file a response to any petition for review, not to exceed 30 pages, within 10 days after filing of the petition. If no petition is received within the designated 15-day period, the Director will issue the final amendment to the Certificate of Compliance without further delay. If a petition for review is received, the decision on the amendment application will become final in 60 days, unless the Commission grants the petition for review or otherwise acts within 60 days after publication of this **Federal Register** Notice.

A petition for review must be filed with the Secretary, 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, the Gelman Building, 2120 L Street, NW, Washington, DC, by the above date.

For further details with respect to the action see (1) the application for amendment and (2) the Commission's Compliance Evaluation Report. These items are available for public inspection at the Commission's Public Document Room, the Gelman Building, 2120 L Street, NW, Washington, DC, and at the Local Public Document Room.

*Date of amendment request:* April 23, 1997, revised July 31, 1997.

*Brief description of amendment:* The amendment is related to the planned modifications to upgrade the seismic capability of Buildings C–331 and C–335 at the Paducah Gaseous Diffusion plant. Specifically, the proposed amendment will move back the completion date for the seismic modifications required by Compliance Plan Issue 36, from December 31, 1997, to June 30, 1999. Additionally, the amendment approves proposed resolutions of the following three issues: (1) The increased stiffness of the buildings following completion of the modifications may change the predicted type and number of seismically-induced equipment failures inside the buildings; (2) the process of installing the new structural steel will temporarily make the building and contained equipment more susceptible to seismically-induced failures as the existing structural frames are altered and/or replaced; and (3) the process of installing the new structural steel may temporally increase the probability of equipment failures due to load handling accidents during construction. The amendment will also partially deny the USEC request. USEC will be required to begin the planned 18-month construction effort when the amendment is effective, instead of delaying until after the NRC completes review of an updated seismic risk analysis, USEC's updated safety analysis report, and USEC's final design for the planned seismic modifications. The proposed amendment will also approve two editorial changes to the Justification for Continued Operation (JCO) in Compliance Plan Issue 36; one other proposed change to the JCO will be denied.

*Effective date:* The amendment to Certificate of Compliance GDP–1 becomes effective immediately upon being signed by the Director, Office of Nuclear Material Safety and Safeguards.

*Certificate of Compliance No. GDP–1:* The amendment will revise Compliance Plan Issue 36 on the seismic modifications and will allow the planned modifications to proceed.

*Local Public Document Room location:* Paducah Public Library, 555 Washington Street, Paducah, Kentucky 42003.

Dated at Rockville, Maryland, this 8th day of December 1997.

For the Nuclear Regulatory Commission.

**Carl J. Paperiello,**

*Director, Office of Nuclear Material Safety and Safeguards.*

[FR Doc. 97–32761 Filed 12–15–97; 8:45 am]

BILLING CODE 7590–01–P

## NUCLEAR REGULATORY COMMISSION

### Advisory Committee on Reactor Safeguards

### Meeting of the ACRS Subcommittee on Plant License Renewal; Notice of Meeting

The ACRS Subcommittee on Plant License Renewal will hold a meeting on January 23, 1998, in Room T–2B3, 11545 Rockville Pike, Rockville, Maryland.

The entire meeting will be open to public attendance.

The agenda for the subject meeting shall be as follows:

*Friday, January 23, 1998—8:30 a.m. until the conclusion of business*

The Subcommittee will review the NRC staff activities regarding the license renewal implementation issues and proposed industry guidelines. The purpose of this meeting is to gather information, analyze relevant issues and facts, and formulate proposed positions and actions, as appropriate, for deliberation by the full Committee.

Oral statements may be presented by members of the public with the concurrence of the Subcommittee Chairman; written statements will be accepted and made available to the Committee. Electronic recordings will be permitted only during those portions of the meeting that are open to the public, and questions may be asked only by members of the Subcommittee, its consultants, and staff. Persons desiring to make oral statements should notify the cognizant ACRS staff engineer named below five days prior to the meeting, if possible, so that appropriate arrangements can be made.

During the initial portion of the meeting, the Subcommittee, along with any of its consultants who may be present, may exchange preliminary views regarding matters to be considered during the balance of the meeting.

The Subcommittee will then hear presentations by and hold discussions with representatives of the NRC staff, and other interested persons regarding this review.

Further information regarding topics to be discussed, whether the meeting has been canceled or rescheduled, the Chairman's ruling on requests for the opportunity to present oral statements and the time allotted therefor can be obtained by contacting the cognizant ACRS staff engineer, Dr. Medhat El-Zeftawy (telephone 301/415–6889) between 7:30 a.m. and 4:15 p.m. (EST). Persons planning to attend this meeting are urged to contact the above named individual one or two working days prior to the meeting to be advised of any potential changes to the agenda, etc., that may have occurred.

Dated: December 10, 1997.

**Gail H. Marcus,**

*Acting Deputy Executive Director.*

[FR Doc. 97–32758 Filed 12–15–97; 8:45 am]

BILLING CODE 7590–01–P

## NUCLEAR REGULATORY COMMISSION

### Advisory Committee on Reactor Safeguards, Subcommittee Meeting on Human Factors; Notice of Meeting

The ACRS Subcommittee on Human Factors will hold a meeting on January 20, 1998, Room T–2B3, 11545 Rockville Pike, Rockville, Maryland.

The entire meeting will be open to public attendance.

The agenda for the subject meeting shall be as follows:

*Tuesday, January 20, 1998—8:30 a.m. until the conclusion of business.*

The Subcommittee will review the latest version of the Human Performance and Reliability Implementation Plan, status of a technique for human error analysis (ATHEANA) pilot program, integration of human factors considerations into the inspection process, results of studies that used the Human Performance Events Database, and associated activities. The purpose of this meeting is to gather information, analyze relevant issues and facts, and formulate proposed positions and actions, as appropriate, for deliberation by the full Committee.

Oral statements may be presented by members of the public with the concurrence of the Subcommittee Chairman; written statements will be accepted and made available to the Committee. Electronic recordings will be permitted only during those portions of the meeting that are open to the public, and questions may be asked only by members of the Subcommittee, its consultants, and staff. Persons desiring to make oral statements should notify the cognizant ACRS staff engineer named below five days prior to the meeting, if possible, so that appropriate arrangements can be made.

During the initial portion of the meeting, the Subcommittee, along with any of its consultants who may be present, may exchange preliminary views regarding matters to be considered during the balance of the meeting.

The Subcommittee will then hear presentations by and hold discussions with representatives of the NRC staff, its consultants, and other interested persons regarding this review.

Further information regarding topics to be discussed, whether the meeting has been canceled or rescheduled, the Chairman's ruling on requests for the opportunity to present oral statements and the time allotted therefor can be obtained by contacting the cognizant ACRS staff engineer, Mr. Noel F. Dudley (telephone 301/415–6888) between 7:30 a.m. and 4:15 p.m. (EST). Persons planning to attend this meeting are urged to contact the above named individual one or two working days prior to the meeting to be advised of any potential changes to the agenda, etc., that may have occurred.

Dated: December 10, 1997.

**Gail H. Marcus,**

*Acting Deputy Executive Director.*

[FR Doc. 97–32759 Filed 12–15–97; 8:45 am]

BILLING CODE 7590–01–P

## NUCLEAR REGULATORY COMMISSION

### Sunshine Act Meeting

**AGENCY HOLDING THE MEETING:** Nuclear Regulatory Commission.

**DATE:** Weeks of December 15, 22, 29, and January 5, 1997.

**PLACE:** Commissioners' Conference Room, 11555 Rockville Pike, Rockville, Maryland.

**STATUS:** Public and Closed.

**MATTERS TO BE CONSIDERED:**

**Week of December 15**

*Wednesday, December 17*

2:00 p.m.

Briefing on Integration and Evaluation of Results from Recent Lessons-Learned Reviews (including 50.59 Process Improvements) (Public Meeting) (Contact: Eileen McKenna, 301–415–2189)

3:30 p.m.

Affirmation Session (Public Meeting) (if needed)

*Thursday, December 18*

10:00 a.m.

Meeting with Advisory Committee on Nuclear Waste (ACNW) (Public

Meeting) (Contact: John Larkins, 301–415–7360)

**Week of December 22—Tentative**

There are no meetings the week of December 22.

**Week of December 29—Tentative**

There are no meetings the week of December 29.

**Week of January 5—Tentative**

There are no meetings the week of January 5.

*The Schedule for Commission Meetings is Subject to Change on Short Notice. To Verify the Status of Meetings Call (Recording)—(301) 415–1292. Contact Person for More Information: Bill Hill (301) 415–1661.

The NRC Commission Meeting Schedule can be found on the Internet at:

http://www.nrc.gov/SECY/smj/schedule.htm

* * * * *

This notice is distributed by mail to several hundred subscribers; if you no longer wish to receive it, or would like to be added to it, please contact the Office of the Secretary, Attn: Operations Branch, Washington, D.C. 20555 (301–415–1661).

In addition, distribution of this meeting notice over the Internet system is available. If you are interested in receiving this Commission meeting schedule electronically, please send an electronic message to wmh@nrc.gov or dkw@nrc.gov.

* * * * *

Dated: December 12, 1997.

**William M. Hill, Jr.,**

*Secretary Tracking Officer, Office of the Secretary.*

[FR Doc. 97–32953 Filed 12–12–97; 1:53 pm]

BILLING CODE 7590–01–M

## NUCLEAR REGULATORY COMMISSION

**[NUREG–1609]**

### Standard Review Plan for Transportation Packages for Radioactive Material; Notice of Issuance and Availability

The United States Nuclear Regulatory Commission has issued a draft report NUREG–1609 entitled ''Standard Review Plan for Transportation Packages for Radioactive Material'' for review and comment.

The Standard Review Plan for Transportation Packages for Radioactive Material provides guidance for the review and approval of applications for packages used to transport radioactive material (other than irradiated nuclear fuel) under Title 10 of Code of Federal Regulations, Chapter 1, part 71 (10 CFR part 71). The document is intended for use by the U.S. Nuclear Regulatory Commission (NRC) staff. Its objectives are to (1) summarize 10 CFR Part 71 requirements for package approval, (2) describe the procedures by which the NRC staff determines that these requirements have been satisfied, and (3) document the practices developed by the staff in previous reviews of package applications.

Draft NUREG–1609 is available for inspection and copying for a fee at the NRC Public Document Room, 2120 L Street NW (Lower Level), Washington, D.C. 20555–0001. A free copy of draft NUREG–1609 may be requested by writing to the U.S. Nuclear Regulatory Commission, Printing and Graphics Branch, Washington, DC 20555–0001.

Comments on all aspects of this draft document are solicited and will be considered and may be incorporated in the Standard Review Plan, as appropriate. Appendix B to draft NUREG–1609 contains a data form that will be used to aid the NRC staff in transcribing the comments. A photocopy of the form in Appendix B or a similar form containing the same information should be used. Comments on draft NUREG–1609 should be submitted by March 31, 1998. The Standard Review Plan is scheduled for publication as an NRC NUREG document in 1998.

A separate Standard Review Plan for Transportation Packages for Spent Nuclear Fuel (NUREG–1617) is in preparation. Draft NUREG–1617 is scheduled to be published for comment in the spring of 1998.

Mail comments to: Chief, Rules and Directives Branch, Division of Administrative Services, Mail Stop T–6 D59, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001. Comments may be hand-delivered to 11545 Rockville Pike, Rockville, Maryland between 7:30 am and 4:15 pm on Federal workdays.

You may also provide comments via the NRC's interactive rulemaking website through the NRC home page (http://www.nrc.gov). This site provides the availability to upload comments as files (any format), if your web browser supports that function. For information about the interactive rulemaking website, contact Ms. Carol Gallagher, (301) 415–5905; e-mail CAG@nrc.gov.

Dated at Rockville, Maryland, this 10 day of December, 1997.

For the Nuclear Regulatory Commission.

**Cass R. Chappell,**

*Section Chief, Package Certification Section, Spent Fuel Project Office, Office of Nuclear Material Safety and Safeguards.*

[FR Doc. 97–32762 Filed 12–15–97; 8:45 am]

BILLING CODE 7590–01–P

## SECURITIES AND EXCHANGE COMMISSION

**[Investment Company Act Release No. 22935; 812–10878]**

### Emerald Funds, et al.; Notice of Application

December 10, 1997.

**AGENCY:** Securities and Exchange Commission (''SEC'').

**ACTION:** Notice of application for exemption under section 6(c) of the Investment Company Act of 1940 (the ''Act'') from section 15(a) of the Act.

**SUMMARY OF APPLICATION:** The requested order would permit the implementation, without shareholder approval, of new investment advisory and sub-advisory agreements (''New Advisory Agreements'') for a period of up to 120 days following consummation of the merger between Barnett Banks, Inc. (''Barnett Banks'') and NationsBank Corporation (''NationsBank'') or a subsidiary of NationsBank (but in no event later than May 30, 1998) (the ''Interim Period''). The order also would permit Barnett Capital Advisors, Inc. (''Adviser''), Rodney Square Management Corporation (''Rodney Square''), and Brandes Investment Partners, L.P. (''Brandes'') (Brandes and Rodney Square, the ''Sub-Advisers'') to receive all fees earned under the New Advisory Agreements following shareholder approval.

*Applicants:* Emerald Funds (the ''Trust''), the Adviser, and the Sub-Advisers.

**FILING DATE:** The application was filed on November 24, 1997 and amended on December 9, 1997. Applicants have agreed to file an amendment during the notice period, the substance of which is included in this notice.

*Hearing or Notification of Hearing:* An order granting the application will be issued unless the SEC orders a hearing. Interested persons may request a hearing by writing to the SEC's Secretary and serving applicants with a copy of the request, personally or by mail. Hearing requests should be received by the SEC by 5:30 p.m. on December 30, 1997, and should be accompanied by proof of service on applicants in the form of an affidavit or,

for lawyers, a certificate of service. Hearing requests should state the nature of the writer's interest, the reason for the request, and the issues contested. Persons who wish to be notified of a hearing may request notification by writing to the SEC's Secretary.

**ADDRESSES:** Secretary, SEC, 450 Fifth Street, N.W., Washington, D.C. 20549. Trust, 3435 Stelzer Road, Columbus, Ohio 43219; Adviser, 9000 Southside Boulevard, Building 100, Jacksonville, Florida 32256; Rodney Square, Rodney Square North, Wilmington, Delaware 19890; Brandes, 12750 High Bluff Drive, San Diego, California 92130.

**FOR FURTHER INFORMATION CONTACT:** David W. Grim, Staff Attorney, at (202) 942–0571, or Nadya B. Roytblatt, Assistant Director, at (202) 942–0564 (Office of Investment Company Regulation, Division of Investment Management).

**SUPPLEMENTARY INFORMATION:** The following is a summary of the application. The complete application may be obtained for a fee at the SEC's Public Reference Branch, 450 Fifth Street, N.W., Washington, D.C. 20549 (tel. 202–942–8090).

## Applicants' Representations

1. The Trust is a Massachusetts business trust registered under the Act as an open-end management investment company. The Trust is organized as a series investment company and currently offers fourteen investment portfolios (each, a ''Fund''). The Adviser serves as investment adviser to each Fund. The Adviser is a wholly-owned subsidiary of Barnett Banks, N.A., which is the largest banking subsidiary of Barnett Banks, a registered bank holding company, and is registered as an investment adviser under the Investment Advisers Act of 1940 (the ''Advisers Act'') Rodney Square, a wholly-owned subsidiary of Wilmington Trust Company and a registered investment adviser under the Advisers Act, acts as a sub-adviser to one Fund of the Trust, the Tax-Exempt Fund. Similarly, Brandes, a registered investment adviser under the Advisers Act, acts as sub-adviser to one Fund of the Trust, the International Equity Fund. Brandes Investment Partners, Inc. owns a controlling interest in Brandes and serves as its general partner, and Charles Brandes is the controlling shareholder of Brandes Investment Partners, Inc.

2. On August 29, 1997, Barnett Banks announced that it had reached a definitive agreement with NationsBank to merge Barnett Banks into NationsBank or a subsidiary of NationsBank (the ''Merger''). As a result of the Merger, the Adviser will become a direct or indirect wholly-owned subsidiary of NationsBank or a subsidiary of NationsBank. The consummation of the Merger is subject to certain conditions, including the receipt of certain regulatory approvals. Barnett Banks and NationsBank currently expect that the Merger will be consummated during the first quarter of 1998.

3. Applicants believe that the Merger may result in the assignment of the existing advisory agreements between the Funds and the Adviser and the existing sub-advisory agreements between the Adviser and the Sub-Advisers (the ''Existing Advisory Agreements''). Applicants request an exemption to permit (i) the implementation, during the Interim Period, prior to obtaining shareholder approval, of the New Advisory Agreements, and (ii) the Adviser to receive from each Fund (and the Sub-Advisers to receive from the Adviser) all fees earned under the New Advisory Agreement if, and to the extent, the New Advisory Agreement is approved by the shareholders of the Fund. Applicants state that the New Advisory Agreements will have the same terms and conditions as the Existing Advisory Agreements, except for the dates of commencement and termination and the inclusion of escrow arrangements.

4. A meeting of the Trust's board of trustees (the ''Board'') was held on November 13–14, 1997 at which the Merger and its implications for the Trust were discussed. A majority of the members of the Board, including a majority of the Board members who are not ''interested persons'' of the Trust, as that term is defined in section 2(a)(19) of the Act (the ''Independent Trustees''), participated in the meeting and concluded unanimously that it was in the best interests of the Trust and its shareholders to file the application as a necessary step in implementing the New Advisory Agreements during the Interim Period in a manner that would minimize the disruption in advisory services to the particular Funds involved. The Board met again on December 8, 1997 and approved the New Advisory Agreements in the manner prescribed in section 15(c) of the Act. At the December 8, 1997 meeting, the Board also voted to recommend that shareholders of the Funds approve the New Advisory Agreements during the Interim Period.

5. Fees earned under the New Advisory Agreements during the Interim Period will be maintained in an interest-bearing escrow account with a financial institution that is unaffiliated with the Adviser and Sub-Advisers. The escrow agent will release the amounts held in the escrow account (including any interest earned): (i) To the Adviser only upon approval of the New Advisory Agreement by the shareholders of the related Fund; or (ii) to the relevant Fund, in the absence of approval by such shareholders. Before amounts are released from the escrow account, the Board will be notified.

## Applicants' Legal Analysis

1. Section 15(a) of the Act provides, in pertinent part, that it is unlawful for any person to serve as an investment adviser to a registered investment company, except pursuant to a written contract that has been approved by the vote of a majority of the outstanding voting securities of the investment company. Section 15(a) further requires the written contract to provide for its automatic termination in the event of its ''assignment.'' Section 2(a)(4) of the Act defines ''assignment'' to include any direct or indirect transfer of a contract by the assignor, or of a controlling block of the assignor's outstanding voting securities by a security holder of the assignor.

2. Applicants state that, as a result of the Merger, the Adviser will become a direct or indirect wholly-owned subsidiary of NationsBank or a subsidiary of NationsBank. Applicants believe, therefore, that the Merger may result in the ''assignment'' of the Existing Advisory Agreements, thus terminating these Agreements pursuant to their terms.

3. Rule 15a–4 provides, in pertinent part, that if an investment advisory contract with a registered investment company is terminated by an assignment, the adviser may continue to serve for 120 days under a written contract that has not been approved by the company's shareholders, provided that: (i) the new contract is approved by that company's board of directors (including a majority of the non-interested directors); (ii) the compensation to be paid under the new contract does not exceed the compensation that would have been paid under the contract most recently approved by the company's shareholders; and (iii) neither the adviser nor any controlling person of the adviser ''directly or indirectly receives money or other benefit'' in connection with the assignment. Applicants state that they may not be entitled to rely on rule 15a–4 because of the benefits Barnett Banks, the indirect holding company of the Adviser, will receive from the Merger.

4. Section 6(c) of the Act provides that the SEC may exempt any person, security, or transaction from any provision of the Act, if and to the extent that such exemption is necessary or appropriate in the public interest and consistent with the protection of investors and the purposes fairly intended by the policy and provisions of the Act. Applicants believe that the requested relief meets this standard.

5. Applicants note that the timing of the Merger is influenced by a number of factors relating principally to the merging companies' commercial banking and other similar business concerns, as well as pending regulatory approvals and satisfaction of other closing conditions. Applicants state that these circumstances make it difficult, from a timing perspective, to secure prior approval of the New Advisory Agreements by the Funds' shareholders. Applicants state that, in addition, because it is likely that one or more of the Funds will be merged into corresponding funds of the Nations Funds family of funds in 1998, the granting of the requested order will allow the Funds to undertake a single proxy solicitation for obtaining shareholder approval of the plan of reorganization and the New Advisory Agreements, rather than conducting more than one proxy solicitation within a relatively short time frame, and should thus serve to reduce costs and minimize any potential shareholder confusion.

6. Applicants submit that they will take all appropriate actions to prevent any diminution in the scope of quality of services provided to the Funds during the Interim Period. Applicants state that the Existing Advisory Agreements were approved by the Board and the shareholders of the Funds. Applicants represent that the New Advisory Agreements will have the same terms and conditions as the Existing Advisory Agreements, except for the dates of commencement and termination and the inclusion of escrow arrangements. Accordingly, applicants assert that each Fund will receive, during the Interim Period, substantially identical investment advisory services, provided in the same manner, as it received prior to the Merger. Applicants state that, in the event there is any material change in the Adviser's personnel providing advisory services under the New Advisory Agreements during the Interim Period, the Adviser will apprise and consult the Board to ensure that the Board, including a majority of the Indepenednet Trustees, are satisfied that the services provided by the Adviser will not be diminished in scope or quality.

7. Applicants contend that to deprive the Adviser and Sub-Advisers of their customary fees during the Interim Period for no reason, other than the fact that the Merger may be deemed to result in an assignment of the Existing Advisory Agreements, would be an unduly harsh and unreasonable penalty to impose upon an investment adviser in the circumstances of the application. Applicants submit that, in good faith and consistent with the Act and the spirit of rule 15a-4, they seek to promote the interests of the Funds and their shareholders by undertaking the fee and other arrangements described in the application. Applicants emphasize that the fees payable to the Adviser and Sub-Advisers under the New Advisory Agreements have been approved by the Board, including a majority of the Independent Trustees, and that these fees will not be released by the escrow agent without the approval of the respective Fund's shareholders.

### Applicants' Conditions

Applicants agree as conditions to the issuance of the exemptive order requested by the application that:

1. Each New Advisory Agreement will have the same terms and conditions as the respective Existing Advisory Agreement, except for the effective and termination dates and the inclusion of escrow arrangements.

2. Fees earned by the Adviser and paid by a Fund during the Interim Period in accordance with a New Advisory Agreement will be maintained in an interest-bearing escrow account, and amounts in such account (including interest earned on such amounts) will be paid to the Adviser only upon approval of the New Advisory Agreement by the shareholders of the related Fund or, in the absence of approval by such shareholders, to the Fund.

3. The Trust will hold meetings of shareholders to vote on approval of the New Advisory Agreements on or before the 120th day following the termination of the Existing Advisory Agreements (but in no event later than May 30, 1998).

4. The Adviser will pay the costs of preparing and filing the application. The Adviser will pay the costs relating to the solicitation of approval of Fund shareholders, to the extent such costs relate to shareholder approval of the New Advisory Agreements necessitated by the Merger.

5. The Adviser will take all Appropriate actions to ensure that the scope and quality of advisory and other services provided to the Funds under the New Advisory Agreements will be at least equivalent, in the judgment of the Board, including a majority of the Independent Trustees, to the scope and quality of services provided under the Existing Advisory Agreements. In the event of any material change in personnel providing services pursuant to the New Advisory Agreements, the Adviser will apprise and consult the Board to assure that the Board and a majority of the Independent Trustees are satisfied that the services provided by the Adviser will not be diminished in scope or quality.

For the Commission, by the Division of Investment Management, pursuant to delegated authority.

**Margaret H. McFarland,**

*Deputy Secretary.*

[FR Doc. 97–32754 Filed 12–15–97; 8:45 am]

BILLING CODE 8010–01–M

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## SECURITIES AND EXCHANGE COMMISSION

**[Investment Company Act Release No. 22933; 812–10670]**

## Financial Institutions Series Trust, et al.; Notice of Application

December 10, 1997.

**AGENCY:** Securities and Exchange Commission (''SEC'').

**ACTION:** Notice of application for order under section 11(a) of the Investment Company Act of 1940 (the ''Act'').

**SUMMARY OF APPLICATION:** Applicants request an order permitting certain offers of exchange of shares (the ''Exchange Program'') between Summit Cash Reserves Fund Portfolio (''MMF''), a money market fund sponsored by Merrill Lynch, Pierce, Fenner & Smith Incorporated (''Merrill Lynch'') and certain non-money market funds in other groups of investment companies (the ''Participating Funds'') on a basis other than their respective net asset values per share.

**APPLICANTS:** Financial Institutions Series Trust; Fund Asset Management, L.P. (''FAM''); Merrill Lynch Asset Management, L.P. (''MLAM''); Merrill Lynch Funds Distributor, Inc. (''MLFD''); and Merrill Lynch.

**FILING DATES:** The application was filed on May 15, 1997. Counsel for applicants has agreed to file an amendment to the application during the notice period, the substance of which is incorporated herein.

**HEARING OR NOTIFICATION OF HEARING:** An order granting the application will be issued unless the SEC orders a hearing. Interested persons may request a hearing by writing to the SEC's

Secretary and serving applicants with a copy of the request, personally or by mail. Hearing requests should state the nature of the writer's interest, the reason for the request and the issues contested. All requests must be received by the SEC by 5:30 p.m. on January 2, 1998, and should be accompanied by proof of service on applicants, in the form of an affidavit or, for lawyers, a certicate of service. Persons who wish to be notified of the date of a hearing may request notification by writing to the SEC's Secretary.

**ADDRESSES:** Secretary, SEC, 450 Fifth Street N.W., Washington, D.C. 20549. Applicants, c/o Merrill Lynch Asset Management, L.P. Attn: Robert Harris, Esq., 800 Scudders Mill Road, Plainsboro, New Jersey 08536.

**FOR FURTHER INFORMATION CONTACT:** H.R. Hallock, Jr., Senior Counsel, at (202) 942–0568 (Division of Investment Management, Office of Disclosure and Review), or Mercer E. Bullard, Special Counsel, at (202) 942–0659 (Division of Investment Management, Office of Chief Counsel).

**SUPPLEMENTARY INFORMATION:** The following is a summary of the application. The complete application may be obtained for a fee by writing the SEC's Public Reference Branch at 450 Fifth Street, N.W., Washington, D.C., or by telephone at (202) 942–8090.

## Applicants' Representations

1. MMF, a money market fund, is a series of Financial Institutions Series Trust, an open-end management investment company registered under the Act. FAM and MLAM are wholly-owned by Merrill Lynch & Co. (''ML&Co.'') and are registered as investment advisers under the Investment Advisers Act of 1940. FAM serves as MMF's investment adviser.[1] MLFD, a broker-dealer registered under the Securities Exchange Act of 1934 (the ''1934 Act'') and a member of the National Association of Securities Dealers, Inc. (the ''NASD''), serves as MMF's distributor. Merrill Lynch, a wholly-owned subsidiary of ML&Co., is a broker-dealer registered under the 1934 Act and a member of the NASD.

2. The Participating Funds will be non-money market open-end management investment companies registered under the Act (a) that are or will be sold to customers of Merrill Lynch under agreements whereby Merrill Lynch serves as a selected dealer or agent; (b) whose investment adviser is other than FAM or MLAM; (c) whose principal underwriter is other than MLFD; and (d) that have agreed to participate in the Exchange Program. Shares of Participating Funds may be sold with a front-end sales load (''FESL''), subject to a contingent deferred sales charge (''CDSC'') or subject to alternative sales charge arrangements (*e.g.*, a level load). Each of the principal underwriters of the Participating Funds will be registered as a broker-dealer under the 1934 Act and a member of the NASD.

3. Customers of Merrill Lynch who have acquired shares of Participating Funds typically have such shares held in nominee name on the books of Merrill Lynch. Merrill Lynch provides consolidated account statements and year-end tax reports for its customers reflecting all positions held on the books of Merrill Lynch, including shares of Participating Funds. Merrill Lynch does not typically act as a selected dealer for money market funds other than those in the Merrill Lynch ''group of investment companies'' (including MMF), as that term is defined in rule 11a–3.[2] Accordingly, Merrill Lynch does not typically hold on its books shares of money market funds that currently have exchange privileges with the Participating Funds.

4. The Participating Funds generally offer exchange privileges that permit an investor to exchange shares of one Participating Fund for shares of another Participating Fund in the same group of investment companies without paying a CDSC on the redemption of the shares exchanged or a FESL on the shares purchased, depending on the sales loads charged by each Fund. Currently, a Merrill Lynch customer who is a shareholder of a Participating Fund may exchange into a money market fund with which the Participating Fund has an exchange privilege. In that event, because the customer's interest in that money market fund will not be carried on Merrill Lynch's books, Merrill Lynch is unable to provide a consolidated report of the customer's entire position. Alternatively, the customer could acquire a money market fund in the Merrill Lynch group of investment companies, the shares of which can be recorded on the books of Merrill Lynch. In that case, however, the customer would have to redeem shares of the Participating Fund and pay any applicable CDSC or, if Participating Fund shares subject to an FESL are redeemed, the customer may have to pay the FESL upon any subsequent repurchase of those shares.

5. The Exchange Program would enable Merrill Lynch customers who hold Participating Fund shares to maintain all of their holdings at Merrill Lynch, while also being able to avail themselves of the exchange privileges offered by the Participating Fund in which they have invested. These shareholders would be able to make exchanges into MMF, or exchanges back into shares of the same Participating Fund involved in the original exchange, without incurring a sales load. These shareholders also would be able to exchange their MMF shares at a reduced or no sales load into shares of certain other Participating Funds in the same group of investment companies as the Participating Fund involved in the original exchange.

6. Any exchange under the Exchange Program will be made in accordance with the exchange privileges offered by the Participating Fund group in which the Merrill Lynch customer has invested. Thus, shareholders of a Participating Fund who exchange their shares for shares of MMF may not exchange the MMF shares for shares of another fund that is not in the same group of investment companies as the Participating Fund. The Exchange Program also will not enable Participating Fund shareholders to exchange their shares directly for shares of another Participating Fund except in accordance with the exchange privileges offered by the particular Participating Fund group.

7. All shares involved in the Exchange Program will be held in Merrill Lynch's omnibus account on each Fund's books.[3] Merrill Lynch, as selected dealer for both MMF and the Participating Fund involved in the exchange, will process the sale and related purchase of shares at the price calculated in accordance with each Fund's prospectus. Merill Lynch will accept and record the payment of sales loads, administrative fees and redemption fees. In particular, upon receipt of a share exchange request, Merrill Lynch will process the share exchange on its mutual fund shareholder software system in accordance with the directions of the prospectuses for MMF and for the Participating Fund involved

[1] In the future, MMF may be a feeder fund to another money market fund in reliance on section 12(d)(1)(E) of the Act, in which case the only investment securities it would hold would be shares of the master fund. In that event, either FAM or MLAM will serve as the investment adviser of the fund in which MMF invests.

[2] Rule 11a–3 defines ''group of investment companies'' to mean two or more open-end investment companies that hold themselves out as being related and that have a common adviser or principal underwriter (or advisers and underwriters that are affiliated persons of one another within the meaning of section 2(a)(3) of the Act).

[3] Shares held in certificated form will not be eligible for the Exchange Program.

in the exchange. Merrill Lynch also will prepare and mail appropriate confirmations or statements related to the share exchange transactions.

8. The exchange arrangements for MMF and each Participating Fund will be described in general terms in MMF's prospectus, including the existence of any administrative or redemption fees charged (without necessarily identifying the specific Funds available for exchange). Each Participating Fund's prospectus will be required to disclose the amount of any administrative or redemption fees that will be imposed in connection with an exchange to or from MMF.

**Applicants' Legal Analysis**

1. Section 11(a) of the Act prohibits any offer by a registered open-end management investment company or its principal underwriter involving the exchange of the company's shares on any basis other than the relative net asset value of the securities to be exchanged, unless the terms of the offer have been approved in advance by the SEC or meet the requirements of any rules adopted to regulate exchange offers.

2. Rule 11a–3 allows an investment company or its principal underwriter to make exchange offers to its shareholders or to shareholders in another company in the same group of investment companies, and to charge a sales load, redemption fee, administrative fee or any combination thereof in connection with the exchange, subject to compliance with certain requirements. Among other requirements, paragraph (b)(6)(i) of the rule requires that the prospectus of the offering company disclose the amount of any administrative or redemption fee charged in connection with an exchange.

3. Applicants request an order under section 11(a) to permit the exchange of shares of MMF for shares of Participating Funds, and shares of Participating Funds for shares of MMF, at other than their respective net asset values at the time of exchange. Applicants state that these exchanges would include, for example, (i) exchanges of MMF shares for shares of a Participating Fund sold with an FESL or a CDSC (''CDSC Shares''), (ii) exchanges of CDSC Shares of a Participating Fund for MMF shares, and (iii) the imposition of an ''administrative'' and/or ''redemption'' fee (as defined in rule 11a–3) in connection with the exchanges.

4. Applicants state that each exchange will comply with all the requirements of rule 11a–3, except (a) the requirement that the Participating Funds and MMF be part of the same ''group of investment companies,'' as that term is defined in paragraph (a)(5) of the rule, and (b) the requirement of paragraph (b)(6)(i) that MMF's prospectus disclose the amount of any administrative or redemption fee imposed on an exchange transaction for its securities, provided that MMF's prospectus will disclose the existence of these fees.

5. Applicants submit that the Exchange Program would not create any opportunity for improper gain by the underwriters of the Participating Funds, by MLFD, or by Merrill Lynch, and would not raise the possibility of inducing exchanges for the purpose of exacting additional sales charges, the abuse against which section 11(a) was directed. Furthermore, if the exchanges were always made at relative net asset values, applicants believe that the distribution systems of the Participating Funds could be disrupted because an investor could easily avoid applicable FESLs by acquiring shares of MMF and immediately exchanging those shares for Participating Fund shares, or avoid applicable CDSCs by exchanging CDSC Shares for MMF shares and then redeeming such shares without payment of any otherwise applicable CDSC. Applicants contend that the Exchange Program would avoid these problems.

6. Applicants also contend that the Exchange Program would benefit exchanging shareholders by crediting them for FESLs already paid, or, in the case of CDSC Shares, for the time the MMF shares are held or for distribution fees paid with respect to MMF shares under rule 12b–1 under the Act, consistent with the requirements of rule 11a–3. Finally, applicants contend Merrill Lynch is logically positioned to implement the Exchange Program even though members of different ''groups of investment companies'' are involved because it is the single entity with the information needed to execute both the redemption and purchase orders involved in a share exchange.

7. Applicants believe there will be such a wide variety of potential exchange arrangements offered by different families of Participating Funds that it would be impractical for MMF's prospectus to state the amounts of administrative or redemption fees imposed on an exchange transaction. Applicants also submit that shareholders will be fully informed of the fees and charges applicable to any exchange, because each Participating Fund's prospectus will include the information required by rule 11a–3.

Finally, applicants note that MMF's prospectus will include general information about the Exchange Program and refer shareholders to their financial consultants for more detailed information.

**Applicants' Conditions**

Applicants agree that any order granting the requested relief will be subject to the following conditions:

1. Merrill Lynch will be responsible for tracking the payment of sales loads, administrative fees and redemption fees by shareholders of investment companies or portfolios covered by the application, and otherwise will conduct share exchanges in accordance with the applicants' representations.

2. Offers of exchange pursuant to the applicants' Exchange Program will be conducted in accordance with rule 11a–3 under the Act, except that:

(a) An offering company will not be limited to making an exchange offer only to the holder of a security of the offering company, or of another open-end investment company within the same group of investment companies as the offering company;

(b) MMF's prospectus will describe the existence (but not the amount) of any administrative or redemption fees imposed on an exchange pursuant to the Exchange Program.

3. Merrill Lynch will maintain and enforce internal control procedures that are designed to assure the Exchange Program's compliance with all applicable provisions of rule 11a–3 under the Act.

For the Commission, by the Division of Investment Management, under delegated authority.

**Margaret H. McFarland,**

*Deputy Secretary.*

[FR Doc. 97–32749 Filed 12–15–97; 8:45 am]

BILLING CODE 8010–01–M

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## SECURITIES AND EXCHANGE COMMISSION

**[Rel. No. IC–22937; 811–5517]**

## Heartland Technology, Inc. (Formerly Milwaukee Land Company); Notice of Application

December 10, 1997.

**AGENCY:** Securities and Exchange Commission (''SEC'').

**ACTION:** Notice of application for deregistration under section 8(f) of the Investment Company Act of 1940 (the ''Act'').

**SUMMARY OF APPLICATION:** Applicant seeks an order declaring that it has ceased to be an investment company.

*Filing Dates:* The application was filed on June 20, 1997, and amended on

December 2, 1997. Applicant has agreed to file an amendment during the notice period, the substance of which is included in this notice.

*Hearing or Notification of Hearing:* An order granting the application will be issued unless the SEC orders a hearing. Interested persons may request a hearing by writing to the SEC's Secretary and serving applicant with a copy of the request, personally or by mail. Hearing requests should be received by the SEC by 5:30 p.m. on December 30, 1997, and should be accompanied by proof of service on applicant, in the form of an affidavit or, for lawyers, a certificate of service. Hearing requests should state the nature of the writer's interest, the reason for the request, and the issues contested. Persons may request notification of a hearing by writing to the SEC's Secretary.

**ADDRESSES:** Secretary, SEC, 450 5th Street, N.W., Washington, DC 20549. Applicant, 547 West Jackson Blvd., Chicago, IL 60661.

**FOR FURTHER INFORMATION CONTACT:** Lisa McCrea, Attorney Adviser, at (202) 942–0562, or Nadya B. Roytblat, Assistant Director, at (202) 942–0564 (Division of Investment Management, Office of Investment Company Regulation).

**SUPPLEMENTARY INFORMATION:** The following is a summary of the application. The complete application may be obtained for a fee at the SEC's Public Reference Branch, 450 5th Street, N.W., Washington, DC 20549 (tel. 202–942–8090).

## Applicant's Representations

1. Milwaukee Land Company is a registered closed-end management investment company organized as a Delaware corporation. On October 31, 1997, Milwaukee Land Company amended its charter to change its name to Heartland Technology, Inc. (the ''Company''). That charter amendment was approved by shareholders on September 17, 1997.

2. From its date of incorporation in 1881 until 1989, the Company was a subsidiary of the Chicago, Milwaukee, St. Paul and Pacific Railroad (the ''Railroad''). The Company was formed for the purpose, among other things, of acquiring and managing land used in the Railroad's operations. Immediately prior to November 30, 1989, the Company was a wholly-owned subsidiary of CMC Real Estate Corporation (''CMC Real Estate''), the successor to the Railroad, which was in turn a wholly-owned subsidiary of Chicago Milwaukee Corporation (''CMC''). CMC filed a notification of registration under the Act in March, 1988, and as a result, the Company and CMC Real Estate each registered under the Act in March, 1988. CMC Real Estate was liquidated on November 30, 1989, and the Company became a wholly-owned subsidiary of CMC.

3. In 1991, the real estate assets held by the Company and certain other assets and liabilities were contributed by the Company and CMC to two newly-organized partnerships, Heartland Partners, L.P. (''Heartland'') and CMC Heartland Partners (''CMC Heartland''). Heartland is a publicly traded limited partnership in which the Company is the general partner and holds a class B limited partner interest. CMC Heartland is a general partnership in which the Company and Heartland are the general partners and the Company is the managing general partner. Through Heartland and CMC Heartland, the Company is engaged in the business of developing real estate, including the properties formerly owned by the Company. In 1993, CMC distributed the Company's common stock to CMC's shareholders, spinning off the Company as a separate publicly-held company. The Company's stock has not otherwise been offered to the public, and the Company has never filed a registration statement under the Securities Act of 1933.

4. Since its spin-off from CMC in 1993, the Company has represented to its stockholders that it has been engaged in a search for one or more acquisitions of operating businesses. The Company disclosed to its stockholders and to the investing public that such an acquisition would likely result in the Company ceasing to be an investment company and would therefore require stockholder approval. The Company disclosed in its proxy statement to shareholders that deregistration would result in shareholders no longer having the benefit of the regulatory protections afforded by the Act. The Company states that it communicated to its shareholders, in the Company's semiannual report for the period ending June 30, 1997, that it no longer holds itself out as being engaged in the business of investing, reinvesting, or trading in securities within the meaning of section 3(a)(1)(A) of the Act. Applicant states that it communicated to shareholders that the Company's assets would be better used to acquire an operating business that would be managed by the Company.

5. On April 4, 1997, the board of directors of the Company (the ''Board''), including those directors who are not ''interested persons'' of the Company under the Act, considered and approved for submission to the Company's shareholders a proposal for the Company and a new wholly-owned subsidiary of the Company called PG Newco Corp. (''PG Newco'') to purchase substantially all the assets and assume certain liabilities of PG Design Electronics, Inc. (''PG Design''). PG Design is a company engaged in the business of contract design and manufacture of printed circuit boards for computer products. Proxy materials that were sent to shareholders were filed with the SEC on April 28, 1997. On May 27, 1997, the shareholders of the Company approved the acquisition of PG Design, certain changes in the Company's investment policies necessary to permit the acquisition, and the deregistration of the Company under the Act.

6. In determining that it was in the best interests of the Company and its shareholders that the Company cease to be an investment company, the Board considered the following factors: (a) The difficulty of managing operating businesses under the Act; (b) the limits on the Company's capital structure imposed by section 18 of the Act, which constrain the Company's ability to borrow and otherwise manage its capital structure in ways the Board believes prudent for an operating company, but prohibited for a registered investment company; and (c) the prohibitions on transactions with affiliates under section 17 of the Act, which prohibit many types of incentive-based compensation the Board considers reasonable and necessary to attract and retain the best-qualified persons to manage the Company's businesses. The Company believes that ceasing to be registered under the Act would result in the potential for greater long-term capital appreciation through its investment in PG Newco and potential further expansion into other operating businesses.

7. The acquisition of PG Design was completed on May 30, 1997, and PG Newco's name has since been changed to P.G. Design Electronics, Inc. (''PG Design Electronics''). The Company intends to continue investment in and expansion of the business of PG Design Electronics, specifically, the contract design and manufacture of printed circuit boards and other components for computer products, and, if and when feasible, entry into other operating businesses. The Company intends to maintain its interest in Heartland and CMC Heartland and through those entities continue to engage in the business of real estate development. However, the Company expects that it will focus its efforts and resources in the

business of PG Design Electronics and other potential operations.

8. On September 30, 1997, the Company entered into a letter of intent to acquire all of the outstanding common stock of Solder Station One, Inc. (''Solder Station One''), a service provider to the circuit board industry. Subject to certain adjustments, the purchase price is expected to be $7,250,000. The Company expects to form a new wholly-owned subsidiary which will serve as the acquisition vehicle. The Company expects to invest $1,500,000 in cash in that subsidiary, all of which the Company expects to obtain from repayment of debt owned to the Company by PG Design Electronics. The new subsidiary then expects to borrow against the receivables and equipment of Solder Station One to raise additional cash, and to pay the shareholders of Solder Station One: (i) $5,250,000 in cash at closing, and (ii) notes to be issued by the new subsidiary in the aggregate amount of $2,000,000, bearing interest at 8% annually. The close of the Solder Station One acquisition is currently scheduled for January 2, 1998.

9. A predecessor of the Company was petitioner in a suit in the U.S. Court of Federal Claims for refund of claimed overpaid railroad retirement taxes. That claim was transferred to the Company as part of the Company's spin-off from its former parent corporation, CMC. A judgment adverse to the Company was entered in the trial court on April 26, 1996. The Company appealed to the U.S. Court of Appeals for the Federal Circuit, and is awaiting decision. The Company is not a party to any other litigation or administrative proceeding.

10. The Company states that it is not now operating and will not in the future operate its business so as to be an investment company required to be registered under the Act. The Company states that it does not now and will not in the future hold itself out as being engaged primarily in the business of investing, reinvesting or trading in securities.

**Applicant's Legal Analysis**

1. The Company asserts that it no longer holds itself out as being engaged in the business of investing, reinvesting, or trading in securities within the meaning of section 3(a)(1)(A) of the Act. For example, in the Company's semiannual report to shareholders for the period ended June 30, 1997, the Company stated: ''During the second quarter of 1997, the Company liquidated its entire non-affiliated investment portfolio. Most of the resulting cash was used on May 30, 1997 to acquire the assets, subject to certain liabilities, of PG Design. Shortly after the successful acquisition of PG Design, the Company applied for deregistration under the Act.''

2. Section 3(a)(1)(C) of the Act defines an investment company as any issuer which ''is engaged in the business of investing, reinvesting, owning, holding, or trading in securities, and owns or proposes to acquire investment securities having a value exceeding forty percent of the value of such issuer's total assets (exclusive of Government securities and cash items) on an unconsolidated basis.'' [1] The Company asserts that it no longer meets the definition of an investment company under section 3(a)(1)(C) because it does not own, and does not propose to acquire ''investment securities'' having a value exceeding 40% of the value of its total assets.

3. The Company asserts that because PG Design Electronics is a wholly-owned subsidiary of the Company, its common stock owned by the Company is not an ''investment security'' within the meaning of section 3(a)(2) of the Act. The Company states that, at September 30, 1997, its ''investment securities'' for purposes of section 3(a)(1)(C), represented 32.6% of its total assets, excluding cash and Government securities.

4. The Company's total assets at September 30, 1997, totaled $24,087,022. The Company's interests in Heartland and CMC Heartland were valued at $7,589,129 and the Company's investment in PG Design Electronics was valued at $15,085,543. The Company's accounts payable and accrued liabilities at September 30, 1997 consisted of liabilities of a predecessor corporation, accrued federal income taxes, and other liabilities.

5. The Company states that its income from the date of the close of the acquisition of PG Design has consisted primarily of income generated by PG Design Electronics, and less than 5% of the Company's income during the period June 1, 1997 through September 30, 1997 was derived from ''investment securities.'' The Company states that it anticipates receiving income from PG Design Electronics, the amount of which will be within the Company's control but limited by PG Design Electronics' net income. PG Design's 1996 revenues totaled $25,022,000, resulting in net income of $1,255,000. For the period June 1, 1997 through September 30, 1997, PG Design Electronics had net income of approximately $1,727,974. The Company anticipates similar revenues and income for PG Design Electronics for the coming year although there can be no assurance that such levels will be achieved.

6. If the planned acquisition of Solder Station One is consummated, the Company anticipates that it will receive income from that company. The amount will be within the Company's control, but limited by Solder Station One's net income. Solder Station One's revenues for the nine months ended September 30, 1997 were approximately $5,941,000 and net income before taxes was about $1,399,000. The Company anticipates similar revenues and net income for Solder Station One after consummation of the acquisition although there can be no assurance that such levels will be achieved.

7. The Company states that it receives an annual management fee of $425,000 from CMC Heartland, and that it does not anticipate receiving any significant income other than the management fee from Heartland or CMC Heartland.

8. The Company states that it currently intends to continue to develop and expand its operating business. The Company believes that the percentage of its total assets represented by its interests in Heartland and CMC Heartland will decline. Giving effect to the planned Solder Station One acquisition, the Company's investment securities would be 32.6% of the Company's total assets. The Company states that it has no intention to increase the number of investment securities it holds. The Company does not expect to invest its net income in investment securities within the meaning of section 3(a)(2) of the Act, except as discussed below. The Company expects that it may invest in short-term securities as a cash management tool when accumulation of cash is necessary or appropriate to meet the Company's requirements, including pending payment of dividends, to make additional investments in the Company's subsidiaries or to acquire other companies or businesses, or to repay borrowings. In addition, the Company expects that it may invest in longer-term debt securities to offset particular Company liabilities. The Company intends to manage its cash and its investments in such a way as to avoid again coming within the definition of investment company under the Act.

[1] Investment securities are defined in section 3(a)(2) of the Act to include all securities except (A) Government securities, (B) securities issued by employees' securities companies, and (C) securities issued by majority owned subsidiaries of the owner which are not investment companies, and are not relying on the exception from the definition of investment company in sections 3(c)(1) or 3(c)(7) of the Act.

For the SEC, by the Division of Investment Management, under delegated authority.

**Margaret H. McFarland,**

*Deputy Secretary.*

[FR Doc. 97–32775 Filed 12–15–97; 8:45 am]

**BILLING CODE 8010–01–M**

## SECURITIES AND EXCHANGE COMMISSION

**[Investment Company Act Release No. 22936; 812–10882]**

## Mentor Funds, et al.; Notice of Application

December 10, 1997.

**AGENCY:** Securities and Exchange Commission (''SEC'').

**ACTION:** Notice of application for exemption under section 6(c) of the Investment Company Act of 1940 (the ''Act'') from section 15(a) of the Act.

**SUMMARY OF APPLICATION:** Applicants seek an order to permit the implementation, without shareholder approval, of new investment advisory agreements (''New Agreements'') between Mentor Funds, Mentor Institutional Trust, Cash Resource Trust (collectively, the ''Trusts''), America's Utility Fund, Inc., and Mentor Income Fund, Inc. (collectively with the Trusts, the ''Funds''); and one or more of Mentor Investment Advisors, LLC (''Mentor Advisors''), Mentor Perpetual Advisors, LLC (''Mentor Perpetual'') (each, an ''Advisor''); Van Kampen American Capital Management, Inc. (''Van Kampen''), and Wellington, Management Company, LLP (''Wellington'') (each, a ''Sub-advisor''), for a period of up to 60 days following the date of consummation of a merger (but in no event later than March 31, 1998) (the ''Interim Period''). The order also would permit the Advisors and Sub-advisors to receive all fees earned under the New Agreements following shareholder approval.

*Applicants:* Funds, Advisors, and Sub-advisors.

**FILING DATES:** The application was filed on November 20, 1997. Applicants have agreed to file an amendment during the notice period, the substance of which is included in this notice.

*Hearing or Notification of Hearing:* An order granting the application will be issued unless the SEC orders a hearing. Interested persons may request a hearing by writing to the SEC's Secretary and serving applicants with a copy of the request, personally or by mail. Hearing requests should be received by the SEC by 5:30 p.m. on December 30, 1997, and should be accompanied by proof of service on applicants in the form of an affidavit or, for lawyers, a certificate of service. Hearing requests should state the nature of the writer's interest, the reason for the request, and the issues contested. Persons who wish to be notified of a hearing may request notification by writing to the SEC's Secretary.

**ADDRESSES:** Secretary, SEC, 450 Fifth Street, N.W., Washington, D.C. 20549. Applicants: Mentor Funds, Mentor Institutional Trust, Cash Resource Trust, America's Utility Fund, Inc., Mentor Income Fund, Inc., Mentor Advisors, and Mentor Perpetual, 901 East Byrd Street, Richmond, VA 23219; Van Kampen, One Parkview Plaza, Oakbrook Terrace, IL 60181; Wellington, 75 State Street, Boston, MA 02109.

**FOR FURTHER INFORMATION CONTACT:** John K. Forst, Attorney Advisor, at (202) 942–0569, or Christine Y. Greenlees, Branch Chief, at (202) 942–0564 (Office of Investment Company Regulation, Division of Investment Management).

**SUPPLEMENTARY INFORMATION:** The following is a summary of the application. The complete application may be obtained for a fee at the SEC's Public Reference Branch, 450 Fifth Street, N.W., Washington, D.C. 20549 (tel. 202–942–8090).

### Applicants' Representations

1. The Trusts, each a Massachusetts business trust, are registered under the Act as open-end management investment companies. America's Utility Fund, Inc., a Maryland corporation, is registered under the Act as an open-end management investment company. Mentor Income Fund, Inc., a Virginia corporation, is registered under the Act as a closed-end management investment company. The Funds currently offer twenty-three portfolios.[1]

2. The Advisors, investment advisers registered under the Investment Advisers Act of 1940 (the ''Advisers Act''), serve as investment adviser for the Funds pursuant to existing investment advisory agreements that comply with section 15 of the Act (with existing sub-advisory agreements, the ''Existing Agreements''). Mentor Perpetual serves as investment adviser to Mentor Perpetual Global Portfolio and Mentor Perpetual International Portfolio. Mentor Advisors serves as investment adviser to each of the other Funds. The Sub-advisors, investment advisers registered under the Advisers Act, serve as sub-advisers for certain of the Funds pursuant to the Existing Agreements. Van Kampen serves as Sub-advisor to the Mentor Municipal Income Portfolio. Wellington serves as Sub-advisor to the Mentor Income and Growth Portfolio.[2]

3. On August 20, 1997, Wheat First Butcher Singer, Inc. (''Wheat First''), the Advisors' parent, entered into an agreement and plan of merger with First Union Corporation (''First Union''), under which Wheat First will be merged into First Union (the ''Merger''). Upon consummation of the Merger (expected to occur on December 31, 1997), First Union will become the owner of a majority of the beneficial interest in Mentor Advisors and of one-half of the beneficial interest in Mentor Perpetual.

4. Applicants believe that the Merger will result in an assignment of the Existing Agreements. Applicants request an exemption to permit: (a) The implementation during the Interim Period, prior to obtaining shareholder approval, of the New Agreements; and (b) the Advisors and Sub-advisors to receive from each Fund, upon approval of that Fund's shareholders of the relevant New Agreement, any and all fees earned under the New Agreement during the applicable Interim Period. Applicants state that the New Agreements will have substantially the same terms and conditions as the respective Existing Agreements, except in each case for the effective date, termination date, and escrow provisions.

5. The boards of trustees of the Trusts and the boards of directors of Mentor Income Fund, Inc. and America's Utility Fund, Inc. (collectively, the ''Boards''), met on October 14, 1997, September 10, 1997, and November 19, 1997, respectively, to discuss the Merger and its implications for the Funds. At the meetings, the Boards, including a majority of the members who are not ''interested persons'' of any Fund, as

[1] Mentor Funds is comprised of eleven portfolios: Mentor Growth Portfolio, Mentor Capital Growth Portfolio, Mentor Strategy Portfolio, Mentor Income and Growth Portfolio, Mentor Perpetual Global Portfolio, Mentor Quality Income Portfolio, Mentor Municipal Income Portfolio, Mentor Short-Duration Income Portfolio, Mentor Balanced Portfolio, Mentor Institutional Money Market Portfolio, and Mentor Institutional U.S. Government Money Market Portfolio. Mentor Institutional Trust is comprised of five portfolios: Mentor U.S. Government Cash Management Portfolio, Mentor Intermediate Duration Portfolio, Mentor Fixed-Income Portfolio, Mentor Perpetual International Portfolio, and SNAP Fund. Cash Resource Trust is comprised of five funds: Cash Resource Money Market Fund, Cash Resource U.S. Government Money Market Fund, Cash Resource Tax-Exempt Money Market Fund, Cash Resource California Tax-Exempt Money Market Fund, and Cash Resource New York Tax-Exempt Money Market Fund. Each of America's Utility Fund, Inc. and Mentor Income Fund, Inc. constitutes a single portfolio.

[2] In each of the foregoing cases, whether acting as investment adviser or subadviser, each Advisor and Sub-Advisor is acting as an investment adviser within the meaning of section 2(a)(20) of the Act.

that term is defined in section 2(a)(19) of the Act (the ''Independent Board Members''), voted in accordance with section 15(c) of the Act to approve the New Agreements and to submit the New Agreements to the shareholders of each of the Funds at a meeting to be held on December 22, 1997 (the ''Meeting''). On December 8, 1997, the Boards of the Trusts met in person and approved the escrow provisions of each of the New Agreements in accordance with section 15(c) of the Act. The Boards of Mentor Income Fund, Inc. and America's Utility Fund, Inc. will meet in person prior to the commencement of the Interim Period to approve the escrow provisions of each of the New Agreements in accordance with section 15(c) of the Act.

6. Applicants state that proxy materials were mailed to the Funds' shareholders on or about November 25, 1997. Applicants submit that, while it is possible that shareholders of each of the Funds will approve the New Agreements at the Meeting, it also is possible that an insufficient number of votes will have been received by the date of the Meeting to act upon the New Agreements in respect of one or more Funds, and that it may be necessary to adjourn the Meeting to permit additional shareholders to vote their shares by proxy. Applicants believe that the requested relief is necessary to permit continuity of investment management of the Funds during the Interim Period so that services to each Fund would not be disrupted if the Meeting is adjourned as to that Fund.

7. Applicants propose to enter into an escrow arrangement with an unaffiliated financial institution. The fees payable to the Advisors and Sub-advisors during the Interim Period under the New Agreements will be paid into an interest-bearing escrow account maintained by the escrow agent. The escrow agent will release the amounts held in the escrow account (including any interest earned): (a) To the relevant Advisors or Sub-advisor only upon approval of the relevant New Agreement by the shareholders of the relevant Fund; or (b) to the relevant Fund if the Interim Period has ended and its New Agreement has not received the requisite shareholder approval. Before any such release is made, the Boards will be notified.

**Applicants' Legal Analysis**

1. Section 15(a) of the Act provides, in pertinent part, that it is unlawful for any person to serve as an investment adviser to a registered investment company, except pursuant to a written contract that has been approved by the vote of a majority of the outstanding voting securities of the investment company. Section 15(a) further requires the written contract to provide for its automatic termination in the event of its ''assignment.'' Section 2(a)(4) of the Act defines the term ''assignment'' to include any direct or indirect transfer of a contract by the assignor, or of a controlling block of the assignor's outstanding voting securities by a security holder of the assignor.

2. Applicants state that, following the Merger, First Union will own 100% of the voting securities of Wheat First. Applicants believe, therefore, that the Merger will result in an assignment of the Existing Agreements, and that the Existing Agreements will terminate by their terms upon consummation of the Merger.

3. Rule 15a–4 provides, in pertinent part, that if an investment advisory contract with a registered investment company is terminated by an assignment, the adviser may continue to serve for 120 days under a written contract that has not been approved by the company's shareholders, provided that (a) the new contract is approved by the company's board of directors (including a majority of the non-interested directors); (b) the compensation to be paid under the new contract does not exceed the compensation that would have been paid under the contract most recently approved by the company's shareholders; and (c) neither the adviser nor any controlling person of the adviser ''directly or indirectly receives money or other benefit'' in connection with the assignment. Applicants state that because the Advisors and their affiliates may be deemed to receive a benefit in connection with the Merger, applicants may not be entitled to rely on rule 15a–4.

4. Section 6(c) provides that the SEC may exempt any person, security, or transaction from any provision of the Act, if and to the extent that such exemption is necessary or appropriate in the public interest and consistent with the protection of investors and the purposes fairly intended by the policy and provisions of the Act. Applicants believe that the requested relief meets this standard.

5. Applicants note that the terms and timing of the Merger were determined by Wheat First and First Union in response to a number of factors beyond the scope of the Act and unrelated to the Funds and the Advisors. Applicants believe that allowing the Advisors and Sub-advisors to continue to provide investment advisory services to the Funds during the Interim Period is in the best interests of the Funds and their shareholders to avoid any interruption in services to the Funds and is in keeping with the spirit of the provisions of rule 15a–4 and with the purposes of section 15 of the Act.

6. Applicants submit that the scope and quality of services provided to the Funds during the Interim Period will not be diminished. During the Interim Period, the Advisors and Sub-advisors would operate under the New Agreements, which would be substantially the same as the Existing Agreements, except for their effective dates, termination dates, and escrow provisions. The Advisors have advised the Boards that they are not aware of any material changes in the personnel who will provide investment management services during the Interim Period. Accordingly, the Funds should receive, during the Interim Period, the same advisory services, provided in the same manner, at the same fee levels, and by substantially the same personnel as they received before the Merger.

7. Applicants contend that the best interests of shareholders of the Funds would be served if the Advisors and Sub-advisors receive fees for their services during the Interim Period. Applicants submit that to deprive the Advisors and Sub-advisors of their customary fees during the Interim Period for no reason, other than the fact that the Merger may be deemed to result in an assignment of the Existing Agreements, would be an unduly harsh and unreasonable penalty. Applicants note that the fees to be paid during the Interim Period will be at the same rate as the fees that currently are being paid under the Existing Agreements, which have been approved by the Board and the shareholders of each Fund.

**Applicants' Conditions**

Applicants agree as conditions to the issuance of the exemptive order requested by the application that:

1. Each New Agreement will have substantially the same terms and conditions as the respective Existing Agreement, except for the effective date, termination date, and escrow provisions.

2. Advisory fees earned by an Advisor or Sub-advisor, as the case may be, during the Interim Period will be maintained in an interest-bearing escrow account, and amounts in the account (including interest earned on such amounts) will be paid (a) to the Advisor or Sub-advisor, as the case may be, in accordance with the relevant New Agreement, after the requisite shareholder approval is obtained, or (b)

to the Fund, in the absence of such approval.

3. Each of the Funds will hold a meeting of shareholders to vote on approval of the New Agreements on December 22, 1997, or within the 60 day period following the consummation of the Merger (but in no event later than March 31, 1998).

4. First Union or Mentor Advisors will bear the costs of preparing and filing the application, and First Union will bear any costs relating to the solicitation of shareholder approval necessitated by the Merger.

5. The Advisors and Sub-advisors will take all appropriate actions to ensure that the scope and quality of advisory and other services provided to the Funds during the Interim Period will be at least equivalent, in the judgment of the Boards, including a majority of the Independent Board Members, to the scope and quality of services previously provided. In the event of any material change in personnel providing services pursuant to the New Agreements caused by the Merger, the Advisors will apprise and consult with the Boards to assure that the Boards, including a majority of the Independent Board Members, are satisfied that the services provided will not be diminished in scope or quality.

For the Commission, by the Division of Investment Management, pursuant to delegated authority.

**Margaret H. McFarland,**

*Deputy Secretary.*

[FR Doc. 97–32755 Filed 12–15–97; 8:45 am]

BILLING CODE 8010–01–M

## SECURITIES AND EXCHANGE COMMISSION

**[Release No. 35–26792]**

## Filings Under the Public Utility Holding Company Act of 1935, as Amended (''Act'')

December 10, 1997.

Notice is hereby given that the following filing(s) has/have been made with the Commission pursuant to provisions of the Act and rules promulgated thereunder. All interested persons are referred to the application(s) and/or declaration(s) for complete statements of the proposed transaction(s) summarized below. The application(s) and/or declaration(s) and any amendments thereto is/are available for public inspection through the Commission's Office of Public Reference.

Interested persons wishing to comment or request a hearing on the application(s) and/or declaration(s) should submit their views in writing by January 5, 1998, to the Secretary, Securities and Exchange Commission, Washington, D.C. 20549, and serve a copy on the relevant applicant(s) and/or declarant(s) at the address(es) specified below. Proof of service (by affidavit or, in case of an attorney at law, by certificate) should be filed with the request. Any request for hearing shall identify specifically the issues of fact or law that are disputed. A person who so requests will be notified of any hearing, if ordered, and will receive a copy of any notice or order issued in the matter. After said date, the application(s) and/or declaration(s), as filed or as amended, may be granted and/or permitted to become effective.

**Northeast Utilities, et al.**

(70–8875)

Northeast Utilities (''Northeast''), 174 Brush Hill Avenue, West Springfield, Massachusetts 01090–0010, a registered holding company, and its electric utility subsidiary companies, Western Massachusetts Electric Company, 174 Brush Hill Avenue, West Springfield, Massachusetts 01090–0010, The Connecticut Light and Power Company, 107 Selden Street, Berlin, Connecticut 06037, Holyoke Water Power Company, Canal Street, Holyoke, Massachusetts 01040, and Public Service Company of New Hampshire and North Atlantic Energy Corporation, both of 1000 Elm Street, Manchester, New Hampshire 03015, (collectively, ''Applicants'') have filed a post-effective amendment to their application-declaration filed under sections 6(a), 7, 9(a), 10 and 12(b) of the Act and rules 43, 45, and 54 under the Act.

By orders (''Orders'') dated February 11, 1997 and March 25, 1997 (HCAR Nos. 26665 and 26692), Applicants were authorized to, among other things, enter into an unsecured revolving credit facility (''Existing Facility'') with various lending institutions permitting borrowings aggregating up to $313.75 million. Among other Applicants, Northeast was authorized pursuant to the Orders to make short-term borrowings through December 31, 2000, evidenced by short-term notes issued to lending institutions through formal and informal lines of credit, including the Existing Facility. Under the Existing Facility, Northeast has a maximum borrowing limit of $150 million. Applicants state that Northeast is currently unable to borrow under the Existing Facility.

Northeast now proposes to issue and sell notes (''Notes'') through December 31, 2000 under a supplementary revolving credit facility (''Supplementary Revolver'') in the aggregate principal amount of up to $25 million. Under the Supplementary Revolver, the interest rate applicable to the Notes will be increased to an amount not to exceed the greater of (i) four percentage points over the London Interbank Offered Rate or (ii) three percentage points over the lender's base rate. In addition, the maximum annual fee payment for the issuance of the notes will be increased from 0.30% per annum to 1% per annum. Advances from the Supplementary Revolver will be used to meet Northeast's debt service requirements under its Employee Stock Option Plan and to support its other financial requirements until such time as Northeast begins to receive dividends from its subsidiaries again.

For the Commission, by the Division of Investment Management, pursuant to delegated authority.

**Margaret H. McFarland,**

*Deputy Secretary.*

[FR Doc. 97–32722 Filed 12–15–97; 8:45 am]

BILLING CODE 8010–01–M

## SECURITIES AND EXCHANGE COMMISSION

**[Rel. No. IC–22934; International Series Release No. 1108/812–10646]**

## Toronto Dominion Holdings, Inc.; Notice of Application

December 10, 1997.

**AGENCY:** Securities and Exchange Commission (''SEC'').

**ACTION:** Notice of application for exemption under section 6(c) of the Investment Company Act of 1940 (the ''Act'') from all provisions of the Act.

**SUMMARY OF APPLICATION:** Applicant Toronto Dominion Holdings (U.S.A.), Inc. (''Toronto Dominion'') requests an order that would permit it to sell certain debt securities and use the proceeds to finance the business activities of its parent company, The Toronto-Dominion Bank (''TD'') and other companies controlled by TD.

**FILING DATES:** The application was filed on May 9, 1997, and amended on November 12, 1997. Applicants have agreed to file an amendment to the application during the notice period, the substance of which is included in this notice.

**HEARING OR NOTIFICATION OF HEARING:** An order granting the application will be issued unless the SEC orders a hearing. Interested persons may request a hearing by writing to the SEC's Secretary and serving applicant with a copy of the request, personally or by

mail. Hearing requests should be received by the SEC by 5:30 p.m. on January 5, 1998 and should be accompanied by proof of service on the applicant, in the form of an affidavit or, for lawyers, a certificate of service. Hearing requests should state the nature of the writer's interest, the reason for the request, and the issues contested. Persons may request notification of a hearing by writing to the SEC's Secretary.

**ADDRESSES:** Secretary, SEC, 450 Fifth Street, N.W., Washington, D.C. 20549. Applicant, 31 West 52nd Street, New York, New York 10019.

**FOR FURTHER INFORMATION CONTACT:** Joseph B. McDonald, Jr., Senior Counsel, at (202) 942–0533, or Nadya B. Roytblat, Assistant Director, at (202) 942–0564 (Division of Investment Management, Office of Investment Company Regulation).

**SUPPLEMENTARY INFORMATION:** The following is a summary of the application. The complete application may be obtained for a fee from the SEC's Public Reference Branch, 450 Fifth St., N.W., Washington, D.C. 20549 (tel. 202–942–8090).

## Applicant's Representations

1. Toronto Dominion is a Delaware corporation incorporated in 1982. All of Toronto Dominion's outstanding voting securities are owned by TD. TD, a chartered bank governed by the Bank Act of Canada, offers a wide range of financial services to individuals, corporate and commercial enterprises, financial institutions and governments throughout Canada. In the United States, TD offers a broad range of credit and non-credit services to corporations, financial institutions and governments, as well as discount brokerage services through Waterhouse Investors Services, Inc. (''Waterhouse''). Outside North America, TD conducts treasury and wholesale corporate operations in the world's major financial centers.

2. Toronto Dominion's principal subsidiaries, all wholly-owned, are TD Securities (USA) Inc., The Toronto-Dominion Bank Trust Company, Toronto Dominion (New York), Inc., Toronto-Dominion (Texas), Inc., Toronto Dominion Investments, Inc., and Toronto Dominion Capital (U.S.A.), Inc. TD Securities (USA) Inc. is a registered broker-dealer operating under Section 20 of the Glass-Steagall Act, and is engaged in selling, trading and financing U.S. and Canadian government, corporate debt, equity and money market securities. It also acts as agent on behalf of various TD entities in the distribution and private placement of debt securities, swaps and derivatives, in arranging for loan products and in trading loans. The Toronto-Dominion Bank Trust Company is a New York trust company that provides limited corporate trust functions to its affiliates. Toronto Dominion (New York), Inc. and Toronto-Dominion (Texas), Inc. are engaged primarily in the loan servicing business and participate with unaffiliated companies in making loans. Toronto Dominion Investments, Inc. is an investment vehicle that holds debt and equity securities as well as limited partnership interests pursuant to section 4(c)(7) of the Bank Holding Company Act. Toronto Dominion Capital (U.S.A.), Inc. is organized for the sole purpose of operating as a specialized financing corporation under the Small Business Investment Act of 1958, as amended. It makes investments in small business concerns with a capacity for growth. Toronto Dominion's subsidiaries other than those described above are companies organized to hold real estate that was required in satisfaction of debt previously contracted in good faith.

3. Toronto Dominion was organized to act as a holding company and to engage in financing activities and provide funds for TD and companies controlled by TD. Toronto Dominion received a previous order under section 6(c) of the Act exempting it from all provisions of the Act on December 18, 1984.[1] However, Toronto Dominion may no longer be able to rely on the 1984 Order for its exemption from the Act because a statement made in the application for the 1984 Order (that Toronto Dominion ''and its subsidiaries do not and will not constitute more than 10% of [TD's] assets.'') is no longer true.

4. Toronto Dominion regularly issues commercial paper in the United States pursuant to the exemption contained in section 3(a)(3) of the Securities Act of 1933 (the ''1933 Act''). Subject to the grant by the SEC of the order requested in the application, Toronto Dominion intends to obtain additional funds through the offer and sale of its debt securities in the United States, Europe and other overseas markets and to lend the proceeds to or invest the proceeds in TD and other companies that, after giving effect to the exemption requested hereby, will be companies controlled by TD within the meaning of rule 3a–5(b).

5. Any issuance of debt securities by Toronto Dominion will be guaranteed unconditionally by TD as to the timely payment of principal, interest, and premium, if any (the ''Guarantee''). The Guarantee will provide each holder of debt securities issued by Toronto Dominion a direct right of action against TD to enforce TD's obligations under the Guarantee without first proceeding against Toronto Dominion. The Guarantee for a particular issuance may not be modified or amended in any manner adverse to the holders except with the consent of each holder affected.

6. Due to the nature of debt markets, Toronto Dominion may from time to time borrow amounts in excess of the amounts required by TD and companies controlled by TD at any given time. In accordance with rule 3a–5(a)(5) of the Act, at least 85% of any cash or cash equivalents raised by Toronto Dominion will be invested in or loaned to TD and subsidiaries of Toronto Dominion and TD and other companies that, after giving effect to the exemption requested in the application, will be companies controlled by TD within the meaning of rule 3a–5(b) as soon as practicable, but in no event later than six months after Toronto Dominion's receipt of such cash or cash equivalents. In the event that Toronto Dominion borrows amounts in excess of the amounts required TD and companies controlled by TD at any given time, Toronto Dominion will invest such excess in temporary investments pending investing the money in or lending the money to TD and companies controlled by TD. All investments by Toronto Dominion, including temporary investments, will be made in government securities, securities of TD or subsidiaries of Toronto Dominion or TD or other companies that, after giving effect to the exemption requested in the application, will be companies controlled by TD within the meaning of rule 3a–5(b) (or in the case of a partnership or joint ventures, the securities of the partners of participants in the joint ventures), debt securities that are exempted from the provisions of the 1933 Act by section 3(a)(3) of the 1933 Act, or equity securities of unaffiliated companies in an amount that does not exceed 4% of Toronto Dominion's assets. Applicant states that limited amounts of U.S. equities are acquired either as part of hedging activities for equity derivatives transactions or as proprietary positions. Were TD to own such securities itself, it would be subject to withholding taxes on the dividends it receives on such shares. Ownership of such securities by Toronto Dominion prevents the imposition of such taxes.

## Applicant's Legal Analysis

1. Toronto Dominion requests relief under section 6(c) of the Act for an

[1] Investment Company Act Release Nos. 14245 (Nov. 21, 1984) (notice) and 14280 (Dec. 18, 1984) (order) (''1984 Order'').

exemption from all provisions of the Act. Applicant notes that in the release adopting rule 3a–5,[2] the SEC stated that it may be appropriate to grant exemptive relief to the finance subsidiary of a section 3(c) issuer, but only on a case-by-case basis so that it can have the opportunity to evaluate all of the relevant factors. According to the adopting release, the concern was that a company may be considered a non-investment company for the purposes of the Act under section 3(c) and still be engaged primarily in investment company activities.

2. Rule 3a–5(b)(3)(i) in relevant part defines a ''company controlled by the parent company'' to be a corporation, partnership, or joint venture that is not considered an investment company under section 3(a) or that is excepted or exempted by order from the definition of investment company by section 3(b) or by the rules and regulations under section 3(a). Certain of Toronto Dominion's subsidiaries do not fit within the technical definition of ''companies controlled by the parent company'' because they derive their non-investment company status from section 3(c) of the Act.

3. Toronto Dominion states that neither itself and its subsidiaries, nor TD and its subsidiaries, engage primarily in investment company activities. In addition, if TD were itself to issue the securities that are to be issued by Toronto Dominion and use the proceeds for its own purposes or advance them to its subsidiaries or affiliates, none of TD, Toronto Dominion nor any of their respective subsidiaries or affiliates would be subject to regulation under the Act. While TD has chosen to use Toronto Dominion as a financing vehicle, by virtue of the Guarantee, the holders of the securities issued by Toronto Dominion will have direct access to TD's credit.

4. Under rule 3a–5(a)(6), a finance subsidiary may only invest in government securities, securities of its parent company or a company controlled by its parent company or debt securities exempt under section 3(a)(3) of the 1933 Act. Toronto Dominion will hold equity securities of unaffiliated companies in an amount that does not exceed 4% of its assets. Toronto Dominion will hold such securities due to non-U.S. tax constraints applicable to TD. The primary purpose of Toronto Dominion, however, will continue to be to finance the business operations of TD and companies controlled by TD. Moreover, purchasers of Toronto Dominion's debt securities will receive disclosure documents that make clear that such purchasers should ultimately look to TD for repayment pursuant to the Guarantee. Neither Toronto Dominion's structure nor its mode of operation will resemble that of an investment company.

5. Section 6(c) of the Act, in pertinent part, provides that the SEC, by order upon application, may conditionally or unconditionally exempt any person, security or transaction, or any class or classes of persons, securities or transactions, from any provision or provisions of the Act to the extent that such exemption is necessary or appropriate, in the public interest and consistent with the protection of investors and the purposes fairly intended by the policy and provisions of the Act. Toronto Dominion submits that its exemptive request meet the standards set out in section 6(c) and should therefore be granted.

**Applicant's Condition**

Toronto Dominion agrees that the order granting the requested relief will be subject to the following condition:

1. Toronto Dominion will comply with all of the provisions of rule 3a–5 under the Act, except: (1) Toronto Dominion will be permitted to invest in or make loans to, corporations, partnerships, and joint ventures that do not meet the portion of the definition of ''company controlled by the parent company'' in rule 3a–5(b)(3)(i) solely because they are excluded from the definition of investment company by section 3(c)(1), (2), (3), (4), (6) or (7), provided that any such entity that Toronto Dominion invests in or makes loans to that is excluded from the definition of investment company pursuant to section 3(c)(1) or section 3(c)(7) will be engaged solely in lending, leasing or related activities (such as entering into credit derivatives to manage the credit risk exposures of its lending and leasing activities) and will not be structured as a means of avoiding regulation under the Act, and provided, further, that any such entity excluded from the definition of investment company pursuant to section 3(c)(6) of the Act will not be engaged primarily, directly or indirectly, in one or more of the businesses described in section 3(c)(5) of the Act; and (2) Toronto Dominion will be permitted to invest in, reinvest in, own, hold or trade in equity securities of unaffiliated companies with a purchase price not in excess of 4% of Toronto Dominion's assets.

For the SEC, by the Division of Investment Management, pursuant to delegated authority.

**Margaret H. McFarland,**

*Deputy Secretary.*

[FR Doc. 97–32751 Filed 12–15–97; 8:45 am]

BILLING CODE 8010–01–M

[2] Rule 3a–5 provides an exemption from the definition of investment company for certain companies organized primarily to finance the business operations of their parent companies or companies controlled by their parent companies.

## SECURITIES AND EXCHANGE COMMISSION

**[Release No. 34–39412; File No. SR–Amex–97–42]**

## Self-Regulatory Organizations; Notice of Filing and Immediate Effectiveness of Proposed Rule Change and Amendment No. 1 Thereto by the American Stock Exchange, Inc. Providing for the Waiver of Shareholder Approval as a Prerequisite to Certain Issuances of Securities and the Removal of the Term ''Backdoor Listing'' From the Exchange's Company Guide

December 8, 1997.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act''),[1] notice is hereby given that on November 3, 1997, the American Stock Exchange, Inc. (''Amex'' or ''Exchange'') filed with the Securities and Exchange Commission (''Commission'') the proposed rule change as described in Items I, II, and III below, which Items have been prepared by the Exchange. On December 5, 1997, the Exchange filed with the Commission Amendment No. 1 to the proposed rule change.[2] The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

### I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange seeks to amend Section 710 of its *Company Guide* to provide for the waiver of shareholder approval as a prerequisite to certain issuances of securities, when obtaining such approval would seriously jeopardize the financial viability of the issuer. The Exchange also seeks to revise Sections 142, 341, 713, and 1003 of its *Company Guide* to eliminate the term ''backdoor listing.''

[1] 15 U.S.C. § 78s(b)(1).

[2] Amendment No. 1 corrected a drafting error that inadvertently omitted Section 142 of the Exchange's *Company Guide* from the proposed rule change provision that would eliminate the term ''backdoor listing.'' *See* Letter from Claudia Crowley, Special Counsel, Legal & Regulatory Policy, Exchange, to Michael L. Loftus, Attorney, Division of Market Regulation, Commission, dated December 3, 1997.

The text of the proposed rule change is available at the Office of the Secretary, the Exchange, and at the Commission.

## II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

*A. Self-Regulatory Organization's Statement of the Purpose of, and the Statutory Basis for, the Proposed Rule Change*

1. Purpose

The Exchange, along with the New York Stock Exchange (''NYSE'') and The Nasdaq Stock Market, Inc. (''Nasdaq''), maintains guidelines requiring shareholder approval for certain issuances of securities. The Exchange's guidelines are set forth in Sections 711–713 of the Exchange's *Company Guide.* These requirements typically apply to the issuance of securities in connection with management stock option plans, large acquisitions, or discounted private placements involving the issuance of 20% or more of the issuer's shares. Because the process of obtaining shareholder approval may be time-consuming, the Exchange has long observed an unwritten policy allowing the waiver of the shareholder approval requirement in circumstances where the very process of obtaining shareholder approval would seriously jeopardize the issuer's ability to survive. The Exchange notes that the rules of the NYSE and Nasdaq specifically provide for such an exception.

To conform its rules to those of the other marketplaces, the Exchange proposes to amend Section 710 of the *Company Guide* to provide that waivers of the shareholder approval required for certain issuances of securities may be granted, upon written application to the Exchange when: (i) The delay in securing shareholder approval would seriously jeopardize the financial viability of the issuer; (ii) reliance by the issuer on this exception is expressly approved by the audit committee of the issuer's board of directors or a comparable body; and (iii) the issuer mails a letter to all shareholders, at least ten days before the shares are to be issued, describing the transaction, alerting the shareholders to its omission to seek the shareholder approval that would otherwise be required, and indicating that the audit committee of the issuer's board of directors or a comparable body has expressly approved the exception.

In addition, the Exchange proposes to eliminate the term ''backdoor listing'' from Section 341 of the *Company Guide* and certain related provisions.[3] The Exchange currently uses the term to describe a merger between a listed and unlisted company, the net effect of which is so substantial that the Exchange considers it appropriate to evaluate the listing eligibility of the surviving entity under the Exchange's original listing guidelines. The Exchange will retain the substance of the affected Sections, but eliminate the term ''backdoor listing'' because the Exchange believes the phrase creates an undesirable image. The Exchange contends that Section 341 actually enhances regulation by requiring a substantially changed company to meet original listing guidelines in order to remain listed.

2. Statutory Basis

The Exchange believes that the proposed rule change is consistent with Section 6(b) of the Act,[4] in general, and furthers the objectives of Section 6(b)(5),[5] in particular, in that it is designed to promote just and equitable principles of trade, to remove impediments to and perfect the mechanism of a free and open market and a national market system, and to protect investors and the public interest.

*B. Self-Regulatory Organization's Statement on Burden on Competition*

The Exchange does not believe the proposed rule change will impose any inappropriate burden on competition.

*C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants or Others*

The Exchange did not solicit or receive written comments with respect to the proposed rule change.

[3] Conforming changes are also proposed to be made to Sections 142, 713 and 1003 of the *Company Guide.*

[4] 15 U.S.C. § 78f(b).

[5] 15 U.S.C. § 78f(b)(5).

## III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Because the foregoing proposed rule change: (i) Does not significantly affect the protection of investors or the public interest; (ii) does not impose any significant burden on competition; and (iii) does not become operative for 30 days from December 5, 1997, the date on which it was filed,[6] and the Exchange provided the Commission with written notice of its intent to file the proposed rule change at least five business days prior to the filing date, it has become effective pursuant to Section 19(b)(3)(A) of the Act[7] and Rule 19b–4(e)(6)[8] thereunder.

At any time within 60 days of the filing of the proposed rule change, the Commission may summarily abrogate such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act.

## IV. Solicitation of Comments

Interested persons are invited to submit written data, views and arguments concerning the foregoing. Persons making written submissions should file six copies thereof with the Secretary, Securities and Exchange Commission, 450 Fifth Street, NW., Washington, DC 20549. Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any persons, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. § 552, will be available for inspection and copying in the Commission's Public Reference Section, 450 Fifth Street, NW., Washington, DC 20549. Copies of such filing will also be available for inspection and copying at the principal office of the Exchange. All submissions should refer to File No. SR–Amex–97–42 and should be submitted by January 6, 1998.

For the Commission, by the Division of Market Regulation, pursuant to delegated authority.[9]

[6] The proposed rule change filing is deemed filed as of the date Amendment No. 1 was received by the Commission.

[7] 15 U.S.C. § 78s(b)(3)(A).

[8] 17 CFR 240.19b–4(e)(6).

[9] 17 CFR 200.30–3(a)(12).

**Jonathan G. Katz,**
*Secretary.*
[FR Doc. 97–32750 Filed 12–15–97; 8:45 am]
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## SECURITIES AND EXCHANGE COMMISSION

**[Release No. 34–39417; File No. SR–NASD–97–80]**

## Self-Regulatory Organizations; Notice of Filing of Proposed Rule Change by the National Association of Securities Dealers, Inc., Relating to Options Position Limits

December 9, 1997.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Exchange Act'' or ''Act''),[1] notice is hereby given that on October 30, 1997, NASD Regulation, Inc. (''NASD Regulation'') filed with the Securities and Exchange Commission (''SEC'' or ''Commission'') the proposed rule change as described in Items I, II, and III below, which Items have been prepared by the self-regulatory organization. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

### I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

NASD Regulation is proposing to amend Rule 2860 of the Conduct Rules of the National Association of Securities Dealers, Inc. (''NASD'' or ''Association''), to exempt conventional equity option transactions that are intermediated by a member pursuant to Exchange Act Rule 15a–6(a)(3) from options position limits provided that the member reports such transactions to the Association in accordance with the options position reporting requirements. Below is the text of the proposed rule change. Proposed new language is italicized.

2860. Options

(b)(3) Position Limits;

(A) Stock Options—Except in highly unusual circumstances, and with the prior written approval of the Association pursuant to the Rule 9600 Series for good cause shown in each instance, no member shall effect for any account in which such member has an interest, or for the account of any partner, officer, director or employee thereof, or for the account of any customer, an opening transaction through Nasdaq, the over-the-counter market or on any exchange in a stock option contract of any class of stock options if the member has reason to believe that as a result of such transaction the member or partner, officer, director or employee thereof, or customer would, acting alone or in concert with others, directly or indirectly, hold or control or be obligated in respect of an aggregate position in excess of:

* * * * *

*(E) Conventional equity option transactions effected by a member pursuant to Exchange Act Rule 15a–6(a)(3) shall not be subject to position limits set forth in this subparagraph, provided that such conventional equity option transactions are reported to the Association in accordance with the requirements of subparagraph (5).*

### II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the self-regulatory organization included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The self-regulatory organization has prepared summaries, set forth in Sections A, B, and C below, of the most significant aspects of such statements.

*A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change*

1. Purpose

The proposed rule change would exempt conventional equity option transactions in which members act as agent or intermediary pursuant to Exchange Act Rule 15a–6(a)(3) from options position limits provided that such conventional equity option transactions are reported to the Association pursuant to Rule 2860(b)(5). NASD Rule 2860(b)(3) establishes limits on the number of options contracts that a member, a customer, or a group of investors acting in concert can write or hold. Specifically, Rule 2860(b)(3) provides that ''no member shall effect * * * for the account of any customer, an opening transaction through Nasdaq, the over-the-counter market or on any exchange in a stock option contract of any class of stock options if the * * * customer would * * * hold or control or be obligated in respect to an aggregate position in excess of [certain prescribed limits].''[2] Members have expressed uncertainty as to whether U.S. broker/dealers that intermediate conventional equity option transactions between their affiliated foreign broker/dealers and U.S. institutional investors and major U.S. institutional investors pursuant to Rule 15a–6(a)(3), and that do not carry such options positions, are subject to the limits of the Rule. The NASD's options position limits apply to both conventional and standardized equity options. The proposed rule change, however, would affect only transactions in conventional equity options intermediated by a member pursuant to Rule 15a–6(a)(3). Position limits for all other conventional equity options transactions, as well as for standardized options, would remain unchanged.

NASD Regulation believes that Rule 2860 is ambiguous as to whether the limits specified in the Rule apply to option position transactions intermediated by a member firm under Rule 15a–6(a)(3),[3] and understands that industry practice in this respect is inconsistent. NASD Regulation is filing this proposed rule change in order to provide clarity and consistency of treatment for all member firms participating in transactions with foreign broker/dealers under Rule 15a–6(a)(3), and also to ensure that such transactions are reported under paragraph (b)(5) of the Rule.

NASD Regulation proposes amending Rule 2860(b)(3) to expressly exempt conventional equity option transactions intermediated by U.S. broker/dealers pursuant to Rule 15a–6(a)(3), provided that the member report to the Association such transactions which establish an aggregate position of 200 or more option contracts pursuant to Rule 2860(b)(5). Exchange Act Rule 15a–6(a)(3) provides that a foreign broker or dealer may, without registering under the Securities Exchange Act of 1934, induce or attempt to induce the

[1] 15 U.S.C. § 78s(b)(1).

[2] On September 5, 1997, the NASD filed a proposed rule change to Rule 2860(b) to disaggregate conventional equity options from exchange-traded equity options for position limit purposes and to amend the OTC Collar Exemption to provide that the exemption may be utilized with respect to an entire conventional equity option position, not just that portion that was established pursuant to the NASD's position limit hedge exemption rule. SR–NASD–97–67. This proposed rule change is currently pending with the Commission.

[3] In NASD Notice to Members 94–46, the NASD answered common questions concerning position limits, and included the following:

Question #5: Do the NASD options rules apply to conventional option transactions effected abroad by an NASD member or a foreign branch of an NASD member?

Answer: Yes. If the option is booked and carried with an NASD member, it is subject to the NASD position-limit rule.

purchase or sale of any security by a U.S. institutional investor or major U.S. institutional investor so long as a registered U.S. broker/dealer intermediates such transaction.[4] By intermediating transactions, the U.S. broker/dealer is responsible for: (1) Effecting the transactions, other than negotiating their terms; (2) issuing all required confirmations and statements; (3) extending or arranging any credit to the U.S. institutional investor or major U.S. institutional investor in connection with the transactions; (4) maintaining required books and records relating to the transactions; (5) complying with the net capital requirements of Exchange Act Rule 15c3–1 with respect to the transactions; and (6) receiving, delivering, and safeguarding funds and securities in connection with the transactions on behalf of the U.S. institutional investor or the major U.S. institutional investor in compliance with Exchange Act Rule 15c3–3. While the responsibilities of a U.S. broker/dealer under Rule 15a–6(a)(3) may be significant, they do not otherwise change what is essentially a foreign transaction between a U.S. institutional customer and a foreign broker/dealer. Further, as a jurisdictional matter, the NASD's options position limits do not apply to transactions that occur directly between a U.S. customer and a foreign broker/dealer.

The proposed rule change would require Rule 15a–6(a)(3) conventional equity option transactions to be reported to the NASD in accordance with the reporting requirements for large options positions generally. Rule 2860(b)(5)(ii) imposes reporting obligations on ''each account in which the member has an interest * * * and each customer account, which has established an aggregate position of 200 or more option contracts * * *.'' Under the proposed rule change, conventional equity option transactions intermediated by a member pursuant to Rule 15a–6(a)(3) that establish an aggregate position of 200 or more option contracts would be reported to the Association. Although an institutional investor entering into an option transaction with a foreign broker/dealer that is booked with a member pursuant to Rule 15a–6(a)(3) is a customer of the foreign broker/dealer, and not the member, the proposed rule change would require the member to report the identity of the person or persons having an interest in an option position and the total of number of contracts in accordance with Rule 2860(b)(5)(ii). The information reported to the Association would be used by the NASD Regulation Market Regulation staff as part of their ongoing market surveillance operations and should minimize the risk of any market manipulation or disruption related to the accumulation or disposition of large options positions.

The proposed rule change may raise concerns that it could motivate members to move their existing conventional equity options business to off-shore broker/dealer affiliates to avoid position limits entirely. In response to these concerns, NASD Regulation notes that the proposed rule change is limited to transactions ''effected pursuant to Exchange Act Rule 15a–6(a)(3)''—*i.e.*, trades negotiated between a foreign broker/dealer and a U.S. institutional investor or major U.S. institutional investor for which the U.S. broker/dealer is acting solely in the limited capacity prescribed by Rule 15a–6(a)(3). The proposed rule change would *not* allow a member to negotiate an option transaction with a U.S. institutional customer and then book such transaction with a foreign broker/dealer affiliate and thereby avoid position limits because such transaction would not be ''effected pursuant to Exchange Act Rule 15a–6(a)(3).''

2. Statutory Basis

NASD Regulation believes that the proposed rule change is consistent with the provisions of Section 15A(b)(6) of the Act[5] in that it promotes just and equitable principles of trade, removes impediments to and perfects the mechanism of a free and open market and a national market system, and is not designed to permit unfair discrimination between customers, issuers, brokers, or dealers.

*B. Self-Regulatory Organization's Statement on Burden on Competition*

The Association does not believe that the proposed rule change will impose any inappropriate burden on competition.

*C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others*

No written comments were either solicited or received.

## III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Within 35 days of the publication of this notice in the **Federal Register** or within such longer period (i) as the Commission may designate up to 90 days of such date if it finds such longer period to be appropriate and publishes its reasons for so finding or (ii) as to which the self-regulatory organization consents, the Commission will:

(A) By order approve the proposed rule change, or

(B) Institute proceedings to determine whether the proposed rule change should be disapproved.

## IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing. Persons making written submission should file six copies thereof with the Secretary, Securities and Exchange Commission, 450 Fifth Street, N.W., Washington, D.C. 20549. Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. § 552, will be available for inspection and copying at the Commission's Public Reference Room. Copies of such filing will also be available for inspection and copying at the principal office of the Exchange. All submissions should refer to File No. SR–NASD–97–80 and should be submitted by January 6, 1998.

For the Commission, by the Division of Market Regulation, pursuant to delegated authority.[6]

**Margaret H. McFarland,**

*Deputy Secretary.*

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[4] In a no-action letter dated April 9, 1997, 1997 SEC No-Act. LEXIS 525, the Commission expanded the exemption under Rule 15a–6 to include transactions with any entity that owns or controls in excess of $100 million in aggregate financial assets and modified the clearance and settlement requirements of an intermediating U.S. broker/dealer with respect to foreign securities and U.S. Government securities. Additionally, the no-action letter expanded the range of permissible contacts between foreign broker/dealers and U.S. institutional investors.

[5] 15 U.S.C. § 78*o*–3.

[6] 17 CFR 200.30–3(a)(12).

## SECURITIES AND EXCHANGE COMMISSION

**[Release No. 34–39413; File No. SR–PCX–97–37]**

## Self-Regulatory Organizations; Notice of Filing and Order Granting Accelerated Approval of Proposed Rule Change and Amendment Nos. 1 and 2 Thereto by the Pacific Exchange, Inc. Relating to Market Maker Outside Trading Accounts

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act''),[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on September 9, 1997, the Pacific Exchange, Inc. (''PCX'' or ''Exchange'') filed with the Securities and Exchange Commission (''SEC '' or ''Commission'') the proposed rule change as described in Items I and II below, which Items have been prepared by the self-regulatory organization. On October 31, 1997, the Exchange submitted Amendment No. 1 [3] and on November 6, 1997, the Exchange submitted Amendment No. 2 [4] to the proposed rule change. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons and to grant accelerated approval to the proposed rule change, as amended.

### I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange is proposing to amend its rules to eliminate the current requirements of routine submission by Market Makers of information relating to non-market-maker trading accounts (or ''outside'' accounts). The text of the proposed rule change is available at the Office of the Secretary, PCX, and at the Commission.

### II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the self-regulatory organization included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The self-regulatory organization has prepared summaries, set forth in Sections A, B, and C below, of the most significant aspects of such statements.

*A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change*

1. Purpose

The Exchange is proposing to amend its Rule 6.39, ''Securities Accounts and Orders of Market Makers.'' Specifically, the Exchange is amending Rule 6.39(a) regarding the identification of accounts, to eliminate the need for routine submission by Market Makers of information on non-market-maker trading accounts or ''outside accounts.'' Currently, Exchange Market Makers are required to identify and report to the Exchange all accounts in which the Market Maker may engage in stock, option and securities trading, directly or indirectly, or over which it has investment discretion. The Rule in its current form is broad enough to require Market Makers to report professional trading accounts held at clearing firms, as well as outside personal accounts such as brokerage accounts. The rule change will require Market Makers to report outside account information only when requested by the Exchange. The Exchange also proposes amending Rule 6.39(b) regarding the reporting of Market Maker orders. Currently, each Market Maker is required to report to the Exchange every order entered into by that Market Maker within the specifications of the Rule. The Exchange proposes amending Rule 6.39(b) to require the clearing firm that maintains the Market Maker's trading account, rather than the Market Maker personally, to report executed order information to the Exchange. The Exchange believes it is appropriate to limit the required order information to ''executed'' orders only, based upon its position that only marginal surveillance benefits are derived from gathering unexecuted order information on a routine basis.

Under the proposal, the Market Maker will be held responsible for the reporting requirements only if the clearing firm is not reporting executed order information to the Exchange and/or if the Exchange has requested that the Market Maker provide the information. Furthermore, the proposed rule change will clarify that this reporting requirement applies to all accounts carried for Market Makers who are the subject of a clearing firm Letter of Guarantee issued to the Exchange pursuant to Rule 6.36.

The clearing firm thus will be the primary source for the reporting of Market Maker-executed order information to the Exchange. However, all firms that represent and execute market-maker orders will continue to be responsible for maintaining and retaining executed and unexecuted order information as required by Rules 17a–3 and 17a–4 under the Act and by Exchange Rule 6.68.

Finally, in an effort to improve reporting and move toward electronic reporting in the future, the Exchange proposed to eliminate from Rule 6.39(b) the existing description of specific order information required to be reported.[5]

2. Statutory Basis

The basis under the Act for the proposed rule change is the Section 6(b)(5) [6] requirement that an Exchange have rules that are designed to promote just and equitable principles of trade, to remove impediments to, and perfect the mechanism of a free and open market and, in general, to protect investors and the public interest.

*B. Self-Regulatory Organization's Statement on Burden on Competition*

The PCX does not believe that the proposed rule change will impose any inappropriate burden on competition.

*C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received from Members, Participants or Others*

No written comments were solicited or received with respect to the proposed rule change.

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[1] 15 U.S.C. § 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] *See* Letter from Michael D. Pierson, Senior Attorney, PCX to David S. Sieradzki, Attorney, SEC, dated October 29, 1997 (''Amendment No. 1''). Amendment No. 1 clarifies what types of transactions the clearing firm must report to the Exchange under Rule 6.39(b). In addition, Amendment No. 1 adds language to Rule 6.39(b) that requires Market Makers to report executed orders, upon the request of the Exchange, in instances where the clearing firm does not report executed orders.

[4] *See* letter from Michael D. Pierson, Senior Attorney, PCX to David S. Sieradzki, Attorney, SEC, dated November 5, 1997 (''Amendment No. 2''). In Amendment No. 2, the Exchange represents that it will issue a regulatory circular to Members and Member Firms stating that all of the specific order information currently contained in Rule 6.39(b) will continue to be required to be reported pursuant to the Rule. In addition, the Exchange acknowledges that if it seeks to eliminate the required reporting of any specific information, such a change would require a rule filing pursuant to Section 19(b) of the Act. Finally, Amendment No. 2 makes a minor, non-substantive change to the Rule.

[5] This provision states that the report pertaining to orders must include the terms of each order, identification of the brokerage firms through which the orders were entered, the times of entry or cancellation, the time report of execution were received and, if all or part of the order was executed, the quality and execution price. The Exchange will continue to require the reporting of this information, but pursuant to a Regulatory Circular. *See* Amendment No. 2, *supra* note 4.

[6] 15 U.S.C. § 78f(b)(5).

## III. Commission's Findings and Order Granting Accelerated Approval of Proposed Rule Change

The Commission finds that the proposed rule change is consistent with the requirements of the Act and the rules and regulations thereunder applicable to a national securities exchange, and, in particular, with the requirements of Section 6(b) of the Act.[7] Specifically, the Commission believes the proposal is consistent with the Section 6(b)(5)[8] requirements that the rules of an exchange be designed to promote just and equitable principles of trade, to prevent fraudulent and manipulative acts, and, in general, to protect investors and the public interest.[9]

The Commission believes that the PCX's proposal to allow market-makers to provide outside account information upon request by the Exchange rather than providing such information on a routine basis is a reasonable revision to the Exchange's market-maker account reporting procedures. This conclusion is based on the Exchange's representation that outside account information provides little benefit to the Exchange's surveillance programs unless special circumstances exist. The Commission believes that the ability of the Exchange to request outside account information upon request should help preserve the Exchange's ability to conduct adequate surveillance.

The Commission believes that PCX's proposal to make a Market Maker's clearing firm the primary responsible source for reporting market-maker executed order information to the Exchange is a reasonable means of streamlining the order reporting process. Accordingly, the proposed change should result in more effective and efficient reporting of market-maker accounts and executed order information to the Exchange, thus promoting just and equitable principles of trade, perfecting the mechanism of a free and open national market system, and furthering investor protection and the public interest.

The Commission believes it is appropriate to limit the required submitted order information to ''executed'' orders only, based on PCX's representation that only minimal surveillance benefits are gained by gathering unexecuted order information on a routine basis. Where the clearing firm is not reporting the information to the Exchange and if the Exchange requests that the market-maker provide the information, the market-maker will be responsible for reporting executed order information. Moreover, while the clearing firm is the primary source for the reporting of market-maker executed order information, the firms representing and executing market-maker orders will continue to be responsible for maintaining and retaining executed and unexecuted order information pursuant to Rules 17a–3[10] and 17a–4[11] of the Act and Exchange Rule 6.68. These provisions offer further assurance that executed order information will be reported and records of executed and unexecuted orders will be maintained.

The Commission believes that the PCX's proposal to eliminate the existing description of specific order information required to be reported pursuant to Rule 6.39(b)[12] will provide the Exchange with greater flexibility in adding reporting requirements as needed. The Commission notes that the Exchange has agreed to issue a regulatory circular to its members reflecting that all of the specific order information currently contained in Rule 6.39(b) will continue to be required to be reported pursuant to the Rule.[13] If the PCX in the future seeks to eliminate the required reporting of any of the specific information, such a change would require the submission of a rule filing pursuant to Section 19(b) of the Act.[14]

The Commission finds good cause for approving the proposed rule change prior to the thirtieth day after the date of publication of notice of filing thereof in the **Federal Register**. The proposal, as amended, is virtually identical to a proposal by the Chicago Board Options Exchange approved by the Commission on February 13, 1997, following a full notice period during which no comments were received.[15]

## IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing. Persons making written submissions should file six copies thereof with the Secretary, Securities and Exchange Commission, 450 Fifth Street, NW., Washington, DC 20549. Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. § 552, will be available for inspection and copying at the Commission's Public Reference Room. Copies of such filing will also be available for inspection and copying at the principal office of the Exchange. All submissions should refer to File No. SR–PCX–97–37 and should be submitted by January 6, 1998.

## V. Conclusion

*It is therefore ordered,* pursuant to Section 19(b)(2) of the Act,[16] that the proposed rule change (SR–PCX–97–37) is approved.

For the Commission, by the Division of Market Regulation, pursuant to delegated authority.[17]

**Jonathan G. Katz,**

*Secretary.*

[FR Doc. 97–32756 Filed 12–15–97; 8:45 am]

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## SECURITIES AND EXCHANGE COMMISSION

**[Release No. 34–39409; File No. SR–PTC–97–04]**

## Self-Regulatory Organizations; Participating Trust Company; Notice of Filing and Immediate Effectiveness of Proposed Rule Change to Conform PTC's Rules to the Revised Articles 8 and 9 of the Uniform Commercial Code of the State of New York

December 5, 1997.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act''),[1] notice is hereby given that on October 10, 1997, the Participants Trust Company (''PTC'') filed with the Securities and Exchange Commission (''Commission'') the proposed rule change as described in Items I, II, and III below, which items have been prepared primarily by PTC. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

[7] 15 U.S.C. § 78f(b).

[8] 15 U.S.C. § 78f(b)(5).

[9] In approving this rule change, the Commission has considered the proposed rule's impact on efficiency, competition, and capital formation. 15 U.S.C. § 78c(f).

[10] 17 CFR 240.17a–3.

[11] 17 CFR 240.17a–4.

[12] *See supra* note 5.

[13] *See* Amendment No. 2, *supra* note 4.

[14] *Id.*

[15] *See* Securities Exchange Act Release No. 38286 (Feb. 13, 1997), 62 FR 8287 (Feb. 24, 1997) (order approving File No. SR–CBOE–96–70).

[16] 15 U.S.C. § 78s(b)(2).

[17] 17 CFR 200.30–3(a)(12).

[1] 15 U.S.C. 78s(b)(1).

**I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change**

The proposed rule change amends PTC's rules to make them consistent with the revisions to Articles 8 and 9 of the Uniform Commercial Code (''UCC'') of the State of New York.

**II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change**

In its filing with the Commission, PTC included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. PTC has prepared summaries, set forth in sections (A), (B), and (C) below, of the most significant aspects of such statement.[2]

*(A) Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change*

The purpose of the proposed rule change is to amend PTC's rules to make them consistent with the amendments to Article 8 and Article 9 of the UCC (collectively ''Article 8'') that are effective in the State of New York on October 10, 1997. According to PTC, the proposed amendments retain the meaning of PTC's existing rules under the new Article 8 format and terminology by deleting certain cross-references to the former Article 8 and replacing obsolete terminology.

PTC believes the proposed rule change is consistent with Section 17A(b)(3)(F) of the Act[3] and the rules and regulations thereunder because it calls for the prompt and accurate clearance and settlement of securities transactions and protects investors and the public interest, by conforming PTC's rules to changes in the New York State law in order to retain the meaning of PTC's existing rules.

*(B) Self-Regulatory Organization's Statement on Burden on Competition*

PTC does not believe that the proposed rule change imposes any burden on competition.

*(C) Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants or Others*

Participants have requested that PTC make the proposed rule change. PTC has not solicited nor received any written comments on the proposed rule change.

**III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action**

The foregoing rule change has become effective pursuant to Section 19(b)(3)(A)(i) of the Act[4] and pursuant to Rule 19b–4(e)(1)[5] promulgated thereunder because the proposal constitutes a stated policy, practice, or interpretation with respect to the meaning, administration, or enforcement of existing PTC rules. At any time within sixty days of the filing of such rule change, the Commission may summarily abrogate such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act.

**IV. Solicitation of Comments**

Interested persons are invited to submit written data, views, and arguments concerning the foregoing. Persons making written submissions should file six copies thereof with the Secretary, Securities and Exchange Commission, 450 Fifth Street, N.W., Washington, D.C. 20549. Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. § 552, will be available for inspection and copying in the Commission's Public Reference Section, 450 Fifth Street, N.W., Washington, D.C. 20549. Copies of such filing also will be available for inspection and copying at the principal office of PTC. All submissions should refer to File No. SR–PTC–97–04 and should be submitted by January 6, 1998.

For the Commission by the Division of Market Regulation, pursuant to delegated authority.[6]

[2] The Commission has modified the text of the summaries prepared by PTC.

[3] 15 U.S.C. 78q–1(b)(3)(F).

[4] 15 U.S.C. 78s(b)(3)(A)(i).

[5] 17 CFR 240.19b–4(e)(1).

[6] 17 CFR 200.30–3(a)(12).

**Margaret H. McFarland,**

*Deputy Secretary.*

[FR Doc. 97–32752 Filed 12–15–97; 8:45 am]

BILLING CODE 8010–01–M

## SMALL BUSINESS ADMINISTRATION

**[Declaration of Disaster #2993]**

### State of Mississippi (and Contiguous Parishes in Louisiana)

Pearl River County and the contiguous Counties of Forrest, Hancock, Harrison, Lamar, Marion, and Stone in the State of Mississippi, and St. Tammany and Washington Parishes in the State of Louisiana constitute a disaster area as a result of damages caused by a tornado which occurred on November 21, 1997. Applications for loans for physical damage as a result of this disaster may be filed until the close of business on January 30, 1998 and for economic injury until the close of business on September 1, 1998 at the address listed below or other locally announced locations: U.S. Small Business Administration, Disaster Area 2 Office, One Baltimore Place, Suite 300, Atlanta, GA 30308.

The interest rates are:

**For Physical Damage**

Homeowners with credit available elsewhere—7.625%

Homeowners without credit available elsewhere—3.812%

Businesses with credit available elsewhere—8.000%

Businesses and non-profit organizations without credit available elsewhere—4.000%

Others (including non-profit organizations) with credit available elsewhere—7.125%

**For Economic Injury**

Businesses and small agricultural cooperatives without credit available elsewhere—4.000%

The numbers assigned to this disaster for physical damage are 299312 for Mississippi and 299412 for Louisiana. For economic injury the numbers are 967300 for Mississippi and 967400 for Louisiana.

(Catalog of Federal Domestic Assistance Program Nos. 59002 and 59008.)

Dated: December 1, 1997.

**Ginger Lew**

*Acting Administrator.*

[FR Doc. 97–32725 Filed 12–15–97; 8:45 am]

BILLING CODE 8025–01–P

## SMALL BUSINESS ADMINISTRATION

**[Declaration of Disaster #2995]**

### State of Washington

Kitsap County and the contiguous Counties of Island, Jefferson, King, Mason and Pierce in the State of Washington constitute a disaster area as a result of damages caused by a fire which occurred on November 13, 1997 in the Kona Village Apartments in the City of Bremerton. Applications for loans for physical damages may be filed until the close of business on January 30, 1998 and for economic injury until the close of business on September 1, 1998 at the address listed below or other locally announced locations: U.S. Small Business Administration, Disaster Area 4 Office, P.O. Box 13795, Sacramento, CA 95853–4795.

The interest rates are:

**For Physical Damage:**

Homeowners with credit available elsewhere—7.625%

Homeowners without credit available elsewhere—3.812%

Businesses with credit available elsewhere—8.000%

Businesses and non-profit organizations without credit available elsewhere—4.000%

Others (including non-profit organizations) with credit available elsewhere—7.125%

**For Economic Injury**

Businesses and small agricultural cooperatives without credit available elsewhere—4.000%

The number assigned to this disaster for physical damage is 299505 and for economic injury the number is 967500.

(Catalog of Federal Domestic Assistance Program Nos. 59002 and 59008.)

Dated: December 1, 1997.

**Ginger Lew,**

*Acting Administrator.*

[FR Doc. 97–32724 Filed 12–15–97; 8:45 am]

BILLING CODE 8025–01–P

## OFFICE OF THE UNITED STATES TRADE REPRESENTATIVE

**[Docket No. WTO/D–22]**

### WTO Dispute Settlement Proceeding—U.S. Anti-Dumping Duties on Color Televisions From Korea

**AGENCY:** Office of the United States Trade Representative.

**ACTION:** Notice; request for comments.

**SUMMARY:** Pursuant to section 127(b)(1) of the Uruguay Round Agreements Act (URAA) (19 U.S.C. 3537(b)(1)), the Office of the United States Trade Representative (USTR) is providing notice that the Government of Korea has requested the establishment of a dispute settlement panel under the Marrakesh Agreement Establishing the World Trade Organization (WTO) to examine the continuing maintenance by the United States with respect to Samsung Electronics Co., Ltd. (Samsung) of an antidumping order on color television receivers (CTVs) from the Republic of Korea (Korea). According to the Government of Korea, Samsung's dumping margins for CTVs exported from Korea to the United States from 1985–1991 were *de minimis,* and Samsung has not exported CTVs from Korea to the United States since 1991. The Department of Commerce has initiated a changed circumstances review to determine whether the antidumping order should be revoked in part, i.e., with respect to Samsung. The Department of Commerce has also initiated anti-circumvention inquiries to determine whether Samsung is circumventing the antidumping order by exporting CTVs assembled in Mexico and Thailand to the United States. The Government of Korea is challenging the Department of Commerce's failure to revoke with respect to Samsung the antidumping order on CTVs from Korea, as well as its initiation of the circumvention inquiries.

**DATES:** Although USTR will accept any comments received during the course of the dispute settlement proceedings, comments should be submitted on or before January 12, 1998 to be assured of timely consideration by USTR in preparing its first written submission to the panel.

**ADDRESSES:** Comments may be submitted to Litigation Assistant, Office of Monitoring and Enforcement, Room 501, Attn: Korea Color Televisions Dispute, Office of the U.S. Trade Representative, 600 17th Street, N.W., Washington, DC 20508.

**FOR FURTHER INFORMATION CONTACT:** Audrey Winter, Office of the General Counsel, (202) 395–7305.

**SUPPLEMENTARY INFORMATION:** By letter dated November 6, 1997, the government of Korea requested the establishment of a panel to examine the continued imposition of anti-dumping measures on color television receivers from Korea. The WTO Dispute Settlement Body is likely to establish the panel no later than December 1997. Under normal circumstances, the panel, which will hold its meetings in Geneva, Switzerland, would be expected to issue a report detailing its findings and recommendations within six to nine months after it is established.

**Major Issues Raised by the Government of Korea and Legal Basis of Complaint**

In its request for the establishment of a panel, the Government of Korea challenges the Department of Commerce's continuing imposition of antidumping duties on Samsung's CTV exports from Korea pursuant to the Department's April 30, 1984 antidumping order. The Government of Korea also challenges the Department's initiation and conduct of the anti-circumvention inquiries. The Government of Korea alleges that these actions are inconsistent with several provisions of the WTO agreements, including the following specific allegations:

—The failure of the United States to review, on its own initiative, dumping and injury respectively and to revoke the order constitutes a violation of Article 11.1 combined with Article 11.2, as well as Article 5.8 of the Agreement on Implementation of Article VI of the General Agreement on Tariffs and Trade 1994 (Antidumping Agreement).

—The United States' rejection of Samsung's request for revocation review on the ground of the U.S. concern about lack of current data as a result of ''no shipment'' violates Article 11.2 of the Antidumping Agreement, which does not provide such a standard.

—The failure of the United States to revoke the order, coupled with the U.S. position that the outcome of the revocation review is dependent on the outcome of the anti-circumvention investigation, is in violation of Article 11.1 combined with Article 11.2 and Article 11.4 of the Antidumping Agreement because it introduces considerations not mentioned in Articles 11.1 and 11.2, and because the review exceeds the Article 11.4 time limit and the requirement that review investigations must be carried out expeditiously.

—The United States' requirement (19 C.F.R. 353.25(b)) that applicants file revocation requests only in ''the third and subsequent anniversary months'' is in violation of Article 11.2, which stipulates no time limit whatsoever for such requests.

—The conduct of the United States of the anti-circumvention inquiries violates Article VI of GATT 1994 and several provisions of the Antidumping Agreement.

—The initiation of the anti-circumvention inquiries violates Article VI of GATT 1994 and Articles

1, 2.1 and 3.1 of the Antidumping Agreement, because it may lead to the imposition of antidumping duties on imports of CTVs from Mexico and Thailand without findings of dumping and resulting injury ever having been made.

—The refusal by the United States to conduct a standing inquiry before initiating its anti-circumvention investigation violates Article 3.1, 3.6, 4.1 and 5.6 of the Antidumping Agreement.

—Failure by the United States to make a determination in the anti-circumvention inquiries for more than 22 months violates Article 5.10 of the Antidumping Agreement.

—The conduct of the United States in the revocation review and the anti-circumvention inquiries, when examined and compared, violates Article X.3 of GATT 1994 and Article 17.6(i) of the Antidumping Agreement because the United States has not established the facts properly nor has it evaluated the facts in an unbiased and objective manner.

**Public Comment: Requirements for Submissions**

Interested persons are invited to submit written comments concerning the issues raised in the dispute. Comments must be in English and provided in fifteen copies. A person requesting that information contained in a comment submitted by that person be treated as confidential business information must certify that such information is business confidential and would not customarily be released to the public by the commenter. Confidential business information must be clearly marked ''Business Confidential'' in a contrasting color ink at the top of each page of each copy.

Information or advice contained in a comment submitted, other than business confidential information, may be determined by USTR to be confidential in accordance with section 135(g)(2) of the Trade Act of 1974 (19 U.S.C. 2155(g)(2)). If the submitter believes that information or advice may qualify as such, the submitter—

(1) Must so designate that information or advice;

(2) Must clearly mark the material as ''Submitted in Confidence'' in a contrasting color ink at the top of each page of each copy; and

(3) Is encouraged to provide a non-confidential summary of the information or advice.

Pursuant to section 127(e) of the URAA (19 U.S.C. 3537(e)), USTR will maintain a file on this dispute settlement proceeding, accessible to the public, in the USTR Reading Room: Room 101, Office of the United States Trade Representative, 600 17th Street, N.W., Washington DC 20408. The public file will include a listing of any comments received by USTR from the public with respect to the proceeding; the U.S. submissions to the panel in the proceeding; the submissions, or non-confidential summaries of submissions, to the panel received from other participants in the dispute, as well as the report of the dispute settlement panel and, if applicable, the report of the Appellate Body. An appointment to review the public file (Docket WTO/D–22, ''U.S.—Anti-Dumping Duties on Color Televisions from Korea'') may be made by calling Brenda Webb, (202) 395–6186. The USTR Reading Room is open to the public from 9:30 a.m. to 12 noon and 1 p.m. to 4 p.m., Monday through Friday.

**A. Jane Bradley,**

*Assistant U.S. Trade Representative for Monitoring and Enforcement.*

[FR Doc. 97–32794 Filed 12–15–97; 8:45 am]

BILLING CODE 3190–01–M

## DEPARTMENT OF TRANSPORTATION

### Notice of Application for Certificates of Public Convenience and Necessity and Foreign Air Carrier Permits Filed Under Subpart Q During the Week Ending December 5, 1997

The following Applications for Certificates of Public Convenience and Necessity and Foreign Air Carrier Permits were filed under Subpart Q of the Department of Transportation's Procedural Regulations (See 14 CFR 302.1701 et seq.). The due date for Answers, Conforming Applications, or Motions to Modify Scope are set forth below for each application. Following the Answer period DOT may process the application by expedited procedures. Such procedures may consist of the adoption of a show-cause order, a tentative order, or in appropriate cases a final order without further proceedings.

*Docket Number:* OST–97–3187.

*Date Filed:* December 2, 1997.

*Due Date for Answers, Conforming Applications, or Motion to Modify Scope:* December 30, 1997.

*Description:* Application of Transportes Aereos Ejecutivos, S.A. de C.V., pursuant to 49 U.S.C. Section 41302 and Subpart Q of the Regulations, applies for amendment and re-issuance of its Foreign Air Carrier Permit issued to it by Order 95–3–11 to the extent necessary to permit TAESA to engage in scheduled air transportation of persons, property and mail on the following Mexico-U.S. scheduled combination routes: The coterminal points Guadalajara, Zacatecas; Mexico City; Leon (El Bajio); and Morelia, Mexico, on the one hand, and Fresno, California on the other hand.

*Docket Number:* OST–97–3177.

*Date Filed:* December 1, 1997.

*Due Date for Answers, Conforming Applications, or Motion to Modify Scope:* December 29, 1997.

*Description:* Application of Northwest Airlines, Inc., pursuant to 49 U.S.C. Section 41101, and Subpart Q of the Regulations, applies for renewal of Segment 1 of its Experimental Certificate of Public Convenience and Necessity for Route 378, which authorizes Northwest to engage in foreign air transportation of persons, property and mail between the terminal point Chicago, the intermediate points Los Angeles, San Francisco, Seattle or Honolulu, an intermediate point in Japan, and the coterminal points Shanghai, Guanzhou, and Beijing, China. Northwest requests renewal of Segment 1 of its Route 378 Certificate for a period of five years.

*Docket Number:* OST–97–3207.

*Date Filed:* December 5, 1997.

*Due Date for Answers, Conforming Applications, or Motion to Modify Scope:* January 2, 1998.

*Description:* Application of Delta Air Lines, Inc., pursuant to 49 U.S.C., Sections 41102 and 41108 and Subpart Q of the Regulations, requests a new or amended Certificate of Public Convenience and Necessity authorizing Delta to provide scheduled foreign air transportation of persons, property and mail between a point or points in the United States and a point or points in Panama. Delta further requests route integration authority to permit Delta to combine services that will be operated pursuant to the grant of this application with all other Delta services authorized by existing certificates and exemptions granted by the Department, to the extent permitted by applicable international agreements.

**Paulette V. Twine,**

*Documentary Services.*

[FR Doc. 97–32735 Filed 12–15–97; 8:45 am]

BILLING CODE 4910–62–P

## DEPARTMENT OF TRANSPORTATION

### Federal Aviation Administration

**[Docket No. 29088]**

### Airport Privatization Pilot Program

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

**ACTION:** Notice of acceptance for review: Preliminary application for Stewart International Airport, Newburgh, New York.

**SUMMARY:** The Federal Aviation Administration (FAA) has completed its review of the Stewart International Airport (SWF) preliminary application for participation in the airport privatization pilot program. The preliminary application is accepted for review, with a filing date of October 23, 1997. The New York State Department of Transportation (NYSDOT), the airport sponsor, may select a private operator, negotiate an agreement and submit a final application to the FAA for exemption under the pilot program.

49 U.S.C. Section 47134 establishes an airport privatization pilot program and authorizes the Department of Transportation to grant exemptions from certain Federal statutory and regulatory requirements for up to five airport privatization projects. The application procedures require the FAA to publish a notice in the **Federal Register** after review of a preliminary application. The FAA must publish a final application in the **Federal Register** for public review and comment for a sixty day period. The SWF preliminary application is available for public review in the Federal Aviation Administration, Office of Chief Counsel, Attention: Rules Docket (AGC–200), Docket No. 29088, 800 Independence Avenue, SW., Washington, DC 20591.

**FOR FURTHER INFORMATION CONTACT:** Benedict D. Castellano, Manager, (202–267–8728) or Kevin C. Willis (202–267–8741) Airport Safety and Compliance Branch, AAS–310, Federal Aviation Administration, 800 Independence Ave. SW., Washington, DC 20591.

**SUPPLEMENTARY INFORMATION:**

### Introduction and Background

Section 149 of the Federal Aviation Administration Authorization Act of 1996, Pub. L. No. 104–264 (October 9, 1996) (1996 Reauthorization Act), adds a new § 47134 to Title 49 of the U.S. Code. Section 47134 authorizes the Secretary of Transportation, and through delegation, the FAA Administrator, to exempt a sponsor of a public use airport that has received Federal assistance, from certain Federal requirements in connection with the privatization of the airport by sale or lease to a private party. Specifically, the Administrator may exempt the sponsor from all or part of the requirements to use airport revenues for airport-related purposes, to pay back a portion of Federal grants upon the sale of an airport, and to return airport property deeded by the Federal Government upon transfer of the airport. The Administrator is also authorized to exempt the private purchaser or lessee from the requirement to use all airport revenues for airport-related purposes, to the extent necessary to permit the purchaser or lessee to earn compensation from the operations of the airport.

On September 16, 1997, the Federal Aviation Administration issued a notice of procedures to be used in applications for exemption under Airport Privatization Pilot Program (62 FR 48693). That notice, and public comments received on a notice of proposed procedures issued in April 1997, are available for review in FAA Rules Docket No. 28895. A request for participation in the Pilot Program must be initiated by the filing of either a preliminary or final application for exemption with the FAA.

Final and preliminary applications were not accepted before December 1, 1997, unless an applicant has issued a request for proposal (RFP) on or before the date of the notice, September 16, 1997. Applicants that had already issued a RFP for proposals for the sale or lease of the airport on or before September 16, 1997 and had selected a private operator could submit a final application for review before December 1, 1997. Applicants that had issued the RFP but had not selected a private operator could file a preliminary application on or before December 1, 1997.

NYSDOT issued its RFP on June 19, 1997, for Stewart International Airport, Newburgh, New York and has not selected a private operator. It was, therefore qualified to submit a preliminary application prior to December 1, 1997. The filing date of the NYSDOT preliminary application is October 23, 1997, the date the preliminary application was received by the FAA. NYSDOT may select a private operator, negotiate an agreement and submit a final application to the FAA for exemption.

When a final application is reviewed by the FAA, a notice that the application is available for review will be published in the **Federal Register**, with a sixty day comment period.

Issued in Washington, DC on December 9, 1997.

**Susan L. Kurland,**

*Associate Administrator for Airports.*

[FR Doc. 97–32773 Filed 12–15–97; 8:45 am]

BILLING CODE 4910–13–M

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## DEPARTMENT OF TRANSPORTATION

### Federal Aviation Administration

**[Summary Notice No. PE–97–62]**

### Petitions for Exemption; Summary of Petitions Received; Dispositions of Petitions Issued

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

**ACTION:** Notice of petitions for exemption received and of dispositions of prior petitions.

**SUMMARY:** Pursuant to FAA's rulemaking provisions governing the application, processing, and disposition of petitions for exemption (14 CFR part 11), this notice contains a summary of certain petitions seeking relief from specified requirements of the Federal Aviation Regulations (14 CFR Chapter I), dispositions of certain petitions previously received, and corrections. The purpose of this notice is to improve the public's awareness of, and participation in, this aspect of FAA's regulatory activities. Neither publication of this notice nor the inclusion or omission of information in the summary is intended to affect the legal status of any petition or its final disposition.

**DATES:** Comments on petitions received must identify the petition docket number involved and must be received on or before January 6, 1998.

**ADDRESSES:** Send comments on any petition in triplicate to: Federal Aviation Administration, Office of the Chief Counsel, Attn: Rule Docket (AGC–200), Petition Docket No. _____, 800 Independence Avenue, SW., Washington, DC 20591.

Comments may also be sent electronically to the following internet address: 9–NPRM–CMNTS@faa.dot.gov.

The petition, any comments received, and a copy of any final disposition are filed in the assigned regulatory docket and are available for examination in the Rules Docket (AGC–200), Room 915G, FAA Headquarters Building (FOB 10A), 800 Independence Avenue, SW., Washington, DC 20591; telephone (202) 267–3132.

**FOR FURTHER INFORMATION CONTACT:** Angela Anderson (202) 267–9681 or Tawana Matthews (202) 267–9783, Office of Rulemaking (ARM–1), Federal

Aviation Administration, 800 Independence Avenue, SW., Washington, DC 20591.

This notice is published pursuant to paragraphs (c), (e), and (g) of § 11.27 of Part 11 of the Federal Aviation Regulations (14 CFR part 11).

Issued in Washington, DC on December 11, 1997.

**Donald P. Byrne,**

*Assistant Chief Counsel for Regulations.*

## Petitions for Exemption

*Docket No.:* 29057.

*Petitioner:* The Boeing Company.

*Sections of the FAR Affected:* 14 CFR 25.785(d), 25.807(c)(1), 25.857(e), 25.1447(c)(1).

*Description of Relief Sought:* To permit a McDonnell Douglas Model MD–11 Freighter Aircraft operating with a Class E Cargo compartment to carry up to five supernumeraries in a Courier Area (aft of the cockpit door and forward of the rigid cargo barrier).

*Docket No.:* 28999.

*Petitioner:* Intimate Air, Inc.

*Sections of the FAR Affected:* 14 CFR 119.3.

*Description of Relief Sought:* To permit the petitioner, an on-demand charter operator, to operate more than four round-trip scheduled operations per week under the on-demand rules in 14 CFR part 135 rather than the commuter rules in part 135. The petitioner desires to operate between Long Beach, California; Brown Field Municipal Airport, San Diego, California; and San Felipe, Mexico.

*Docket No.:* 28989.

*Petitioner:* Renown Aviation, Inc.

*Sections of the FAR Affected:* 14 CFR 121.434(g).

*Description of Relief Sought:* To allow each Renown pilot in command and second in command to substitute 50 hours of line-operating flight time and 50 takeoffs and landings for the required 100 hours of line-operating flight time required under 14 CFR 121.443(g) for the consolidated of knowledge and skills.

## Dispositions of Petitions

*Docket No.:* 28952.

*Petitioner:* Minebea Technologies PTE Ltd.

*Sections of the FAR Affected:* 14 CFR 119.5(h).

*Description of Relief Sought/ Disposition:* To permit the petitioner, the holder of a 14 CFR part 125 operating certificate, to conduct common carriage cargo operations.

*Denial, November 24, 1997, Exemption No. 6700.*

*Docket No.:* 28997.

*Petitioner:* Israel Aircraft Industries.

*Sections of the FAR Affected:* 14 CFR 25.813(a).

*Description of Relief Sought/ Disposition:* To permit an interior arrangement that does not provide the required passageway to the main entry door of the Astra SPX airplane.

*Grant, November 20, 1997, Exemption No. 6699.*

*Docket No.:* 28824.

*Petitioner:* Triad International Maintenance Corporation.

*Sections of the FAR Affected:* 14 CFR 25.807(c)(1) and 25.857(e).

*Description of Relief Sought/ Disposition:* To allow the accommodation of up to four supernumerary occupants forward of the main deck Class E cargo compartment on Boeing 767–200 aircraft converted by the petitioner from a passenger to an all-freighter configuration, and to deactivate the existing R1 passenger emergency escape exit.

*Grant, November 12, 1997, Exemption No. 6698.*

*Docket No.:* 23358.

*Petitioner:* Clarke Environmental Mosquito Management, Inc.

*Sections of the FAR Affected:* 14 CFR 91.313(c).

*Description of Relief Sought/ Disposition:* To permit the petitioner to carry passengers in its Bell 47G–4A and 47G–3B–1 helicopters, certificated in the restricted category, while performing aerial-site survey flights.

*Grant, November 21, 1997, Exemption No. 6701.*

*Docket No.:* 25624.

*Petitioner:* Boeing Commercial Airplane Group, Douglas Products Division.

*Sections of the FAR Affected:* 14 CFR 121.411(a)(2), (3), and (b)(2); 121.413(b), (c), and (d); and appendix H to part 121.

*Description of Relief Sought/ Disposition:* To permit Douglas Aircraft Company (DAC), without holding an air carrier operating certificate to train part 121 certificate holders' pilots and flight engineers in initial, transition, upgrade, differences, and recurrent training in FAA-approved simulators and in turbojet-powered airplanes manufactured by DAC, without DAC's instructors meeting all applicable training requirements of part 121, subpart N.

*Grant, December 1, 1997, Exemption No. 5117D.*

*Docket No.:* 29011.

*Petitioner:* Atlantic Coast Airlines.

*Sections of the FAR Affected:* 14 CFR 61.57(e), 121.433(c)(1)(iii), 121.441 (a)(1) and (b)(1), and Appendix F to part 121.

*Description of Relief South/ Disposition:* To permit the petitioner to conduct an FAA-monitored training program under which Atlantic Coast Airlines pilots in command and seconds in command meet ground and flight recurrent training and proficiency check requirement through a single visit training program.

*Grant, December 1, 1997, Exemption No. 5783C.*

*Docket No.:* 2899.

*Petitioner:* Sun 'N Fun Aviation Foundation Inc.

*Sections of the FAR Affected:* 14 CFR 91.413(a).

*Decription of Relief Sought/ Disposition:* To permit Sun 'N Fun members to use an air traffic control transponder specified in 14 CFR 91.215(a) without meeting the test and inspection requirements of the transponder every 24 calendar months, provided the transponder has been operationally checked within the last 30 days with an ATC facility and found to be functioning properly.

*Denial, December 4, 1997, Exemption No. 6703.*

## Petition for Exemption

*Docket No*: 29057.

*Petitioner*: The Boeing Company.

*Regulations Affected*: 25.785(d), 25.807(c)(1), (25.857(e), 25.1447(c)(1).

*Description of Petition:* To exempt The Boeing Company from the requirements of 14 CFR 25.785(d), 25.807(c)(1), 25.857(e), 25.1447(c)(1) to permit a McDonnell Douglas Model MD–11 Freighter Aircraft operating with a Class E Cargo compartment to carry up to five supernumeraries in a Courier Area (aft of the cockpit door and forward of the rigid cargo barrier).

[FR Doc. 97–32774 Filed 12–15–97; 8:45 am]

BILLING CODE 4910–13–M

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## DEPARTMENT OF TRANSPORTATION

### Federal Highway Administration

**[FHWA Docket No. 97–3161]**

### Notice of Request for Reinstatement of an Expired Information Collection; Transportation of Hazardous Materials, Highway Routing

**AGENCY:** Federal Highway Administration (FHWA), DOT.

**ACTION:** Notice and request for comments.

**SUMMARY:** In accordance with the Paperwork Reduction Act of 1995 (44 U.S.C. 3051, 3506(c)(2)(A)), the FHWA solicits comment on its intent to request the Office of Management and Budget

(OMB) to reinstate the expired information collection for FHWA's Transportation of Hazardous Materials, Highway Routing.

**DATES:** Comments must be submitted on or before February 17, 1998.

**ADDRESSES:** Signed, written comments should refer to the docket number that appears at the top of this document and must be submitted to the Docket Clerk, U.S. DOT Dockets, Room PL–401, 400 Seventh Street, S.W., Washington, D.C. 20590–0001. All comments received will be available for examination at the above address between 10 a.m. and 5 p.m., E.T., Monday through Friday, except Federal holidays. Those desiring notification of receipt of comments must include a self-addressed, stamped envelope or postcard. Interested parties are invited to send comments regarding any aspect of this information collection, including, but not limited to: (1) The necessity and utility of the information collection for the proper performance of the functions of the FHWA; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the collected information; and (4) ways to minimize the collection information. Comments submitted in response to this notice will be summarized and/or included in the request for OMB clearance of this information collection.

**FOR FURTHER INFORMATION CONTACT:** Mr. Kenneth Rodgers, Office of Motor Carrier Safety and Technology, Safety and Hazardous Materials Division, (202) 366–4016, Department of Transportation, Federal Highway Administration, 400 Seventh Street, SW., Washington, D.C. 20590–0001. Office hours are from 7:45 a.m. to 4:15 p.m., E.T., Monday through Friday, except Federal holidays.

**SUPPLEMENTARY INFORMATION:**

## Availability

An electronic copy of this document may be downloaded using a modem and suitable communications software from the **Federal Register** electronic bulletin board service (telephone number: 202–512–1661). Internet users may reach the **Federal Register's** web page at: http://www.access.gpo.gov/su__docs.

*Title:* Transportation of Hazardous Materials; Highway Routing.

*OMB Number:* 2125–0554.

## Background

Public comment is requested regarding the burden associated with this collection of information. The data for the Transportation of Hazardous Materials; Highway Routing designations are collected under authority of 49 U.S.C. 5112 and 5125, which places the responsibility on the Secretary of Transportation to specify and regulate standards for establishing, maintaining, and enforcing routing designations. The Federal Highway Administrator has the authority, as required in 49 CFR 397.73, to request that each State and Indian tribe, through its routing agency, provide information identifying hazardous materials routing designations within their respective jurisdictions. This information will be consolidated by the FHWA and published annually in whole or as updates in the **Federal Register**.

*Respondents:* The reporting burden is shared by the 50 States, the District of Columbia, Puerto Rico, American Samoa, Guam, Northern Marianas, and the Virgin Islands.

*Estimated Total Annual Burden:* The annual reporting burden is estimated to be 63 hours.

*Frequency:* The data is collected by the respondents and submitted to FHWA within 60 days after any routing designation changes occur.

**Authority:** 49 U.S. Code 5112 and 5125; Section 3506 (c)(2)(A) of Pub. L. 104–13; 49 CFR 1.48.

Issued on: December 3, 1997.

**George S. Moore,**

*Associate Administrator for Administration.*

[FR Doc. 97–32736 Filed 12–15–97; 8:45 am]

BILLING CODE 4910–22–P

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# DEPARTMENT OF TRANSPORTATION

## Federal Highway Administration

**[FHWA Docket No. MC–96–40; FHWA–1997–2287]**

## Motor Carrier Regulatory Relief and Safety Demonstration Project

**AGENCY:** Federal Highway Administration (FHWA), DOT.

**ACTION:** Extension of deadline for submission of applications.

**SUMMARY:** The FHWA is extending the deadline for motor carriers to submit applications to participate in the agency's Motor Carrier Regulatory Relief and Safety Demonstration Project (the Project). The Project will allow eligible motor carriers operating light- to medium-weight commercial motor vehicles in interstate commerce to qualify for an exemption from certain Federal Motor Carrier Safety Regulations (FMCSRs) for a three-year period.

**DATES:** Applications must be received on or before June 30, 1998.

**FOR FURTHER INFORMATION CONTACT:** Mr. Robert W. Miller, Office of Motor Carrier Field Operations, HMC–DC, (202) 523–0178, Federal Highway Administration, Union Center Plaza, Suite 750, 820 First Street, NE., Washington, DC 20002; or Mr. Charles E. Medalen, Office of the Chief Counsel, HCC–20, (202) 366–1354, Federal Highway Administration, 400 Seventh Street, SW., Washington, DC 20590. Office hours are from 7:45 a.m. to 4:15 p.m., e.t., Monday through Friday, except Federal holidays.

**SUPPLEMENTARY INFORMATION:**

## Background

On November 28, 1995, the President signed the National Highway System Designation Act of 1995 (Pub. L. 104–59, 109 Stat. 568) (the Act). Section 344 of the Act, codified at 49 U.S.C. 31136(e)(2), requires the Secretary to implement a commercial motor vehicle regulatory relief and safety pilot program to grant and to monitor exemptions from provisions of the Federal Motor Carrier Safety Regulations. The exemptions would be applicable to motor carriers operating commercial motor vehicles with a gross vehicle weight rating (GVWR) between 4,537 and 11,794 kilograms (10,001 and 26,000 pounds), inclusive. However, commercial motor vehicles designed to transport more than 15 passengers, including the driver, and vehicles transporting hazardous materials in a quantity requiring placarding are not covered under the Project.

On August 28, 1996 (61 FR 44385), the FHWA requested public comment on the implementation of section 31136(e)(2). In response to comments which raised the concerns about the relationship between the Project and existing State motor carrier safety regulations, a supplemental notice was published on October 29, 1996 (61 FR 55835). The supplemental notice requested comment on the use of the FHWA's preemption authority to resolve any conflicts between the Project and State regulations. The FHWA issued the notice of final determination for the Project on June 10, 1997 (62 FR 31655).

## Reason for Extending the Application Deadline

The FHWA has received numerous telephone calls from motor carriers interested in participating in the Project but uncertain about how to document the information that must be submitted with their requests to participate. These inquiries indicate there is need for additional information to assist motor carriers in understanding the criteria for

admission to, and the procedures for applying for, the Project. The agency will soon publish in the **Federal Register** additional information clarifying the eligibility criteria and application process. In the meantime, to ensure that all eligible motor carriers have an opportunity to submit the information required by the notice of final determination, the agency is extending the application period to June 30, 1998.

The FHWA notes that this extension of the deadline to submit applications does not alter the eligibility criteria for participating in the Project, or the information that must be submitted. Therefore, eligible motor carriers interested in participating in the Project must submit all of the information specified in the notice of final determination. If there are questions about the eligibility criteria or the application process, motor carriers should contact one of the individuals listed at the beginning of this notice.

**Authority:** 49 U.S.C. 31136, 31141, and 31502; 49 CFR 1.48.

Issued on: December 9, 1997.

**Kenneth R. Wykle,**

*Administrator.*

[FR Doc. 97–32737 Filed 12–15–97; 8:45 am]

BILLING CODE 4910–22–M

## DEPARTMENT OF TRANSPORTATION

## Federal Railroad Administration

**[FRA Docket No. 87–2]**

**RIN 2130–AB20**

## Automatic Train Control and Advanced Civil Speed Enforcement System; Northeast Corridor Railroads; Correction

**AGENCY:** Federal Railroad Administration (FRA), Department of Transportation (DOT).

**ACTION:** Correction.

**SUMMARY:** In proposed order document 97–30505 beginning on page 62097 in the issue of November 20, 1997, make the following corrections:

e. Missing transponder:

1. On page 62105 in the second column in line 13, the maximum speed for the North End should be changed to read 110 mph.

2. On page 62105 in the second column in line 14, the maximum speed for the South End should be changed to read 125 mph.

Dated: December 10, 1997.

**S. Mark Lindsey,**

*Chief Counsel, Federal Railroad Administration.*

[FR Doc. 97–32772 Filed 12–15–97; 8:45 am]

BILLING CODE 4910–06–M

## DEPARTMENT OF TRANSPORTATION

## Surface Transportation Board

**[STB Finance Docket No. 33413]**

## Trimax Holdings, Inc.—Corporate Family Transaction Exemption—Allegheny Valley Railroad Company and Southwest Pennsylvania Railroad Company

Trimax Holdings, Inc. (TMH), a noncarrier holding company, has filed a verified notice of exemption for the acquisition of control through stock ownership of the Allegheny Valley Railroad Company (AVR) and the Southwest Pennsylvania Railroad Company (SWP).[1] TMH is wholly owned and controlled by Russell A. Peterson (Peterson), a noncarrier individual. Prior to the transaction covered by the exemption, AVR and SWP were commonly controlled through stock ownership by Peterson, Philip C. Larson (P. Larson) and Dennis E. Larson (D. Larson), also noncarrier individuals.[2] TMH has acquired all of the outstanding stock of AVR that had previously been owned by P. Larson and D. Larson.[3] Following the issuance of stock to TMH by SWP's board of directors that is as anticipated to occur in the near future, TMH will own 92.69% of the stock of SWP.[4]

[1] AVR and SWP are Class III common carriers by rail operating in the State of Pennsylvania.

[2] In addition, Peterson, P. Larson, and D. Larson commonly control the Camp Chase Industrial Railroad Corporation (CCIR), a Class III common carrier operating in the State of Ohio. No changes in the ownership of CCIR are planned at this time.

[3] The stock of AVR is currently 50% owned by Peterson and 50% owned by TMH.

[4] At that time, TMH would own 92.69% of the stock of SWP, Peterson would own 3.67%, and P. Larson and D. Larson would each own 1.82%.

The transaction was to be consummated on or after the December 8, 1997 effective date of the exemption. TMH's acquisition of control of AVR and SWP is intended to create operating and management efficiencies for these entities.

This is a transaction within a corporate family of the type specifically exempted from prior review and approval under 49 CFR 1180.2(d)(3). The parties state that the transaction will not result in changes in service levels, operational changes, or a change in the competitive balance with carriers outside the corporate family.

Under 49 U.S.C. 10502(g), the Board may not use its exemption authority to relieve a rail carrier of its statutory obligation to protect the interests of its employees. Section 11326(c), however, does not provide for labor protection for transactions under sections 11324 and 11325 that involve only Class III rail carriers. Because this transaction involves Class III rail carriers only, the Board, under the statute, may not impose labor protective conditions for this transaction.

If the verified notice contains false or misleading information, the exemption is void *ab initio.* Petitions to reopen the proceeding to revoke the exemption under 49 U.S.C. 10502(d) may be filed at any time. The filing of a petition to reopen will not automatically stay the transaction.

An original and 10 copies of all pleadings, referring to STB Finance Docket No. 33413, must be filed with the Surface Transportation Board, Office of the Secretary, Case Control Unit, 1925 K Street, N.W., Washington, DC 20423–0001. In addition, a copy of each pleading must be served on Kevin M. Sheys, Esq., Oppenheimer Wolff & Donnelly, 1020 Nineteenth Street, N.W., Suite 400, Washington, DC 20036.

Decided: December 9, 1997.

By the Board, David M. Konschnik, Director, Office of Proceedings.

**Vernon A. Williams,**

*Secretary.*

[FR Doc. 97–32777 Filed 12–15–97; 8:45 am]

BILLING CODE 4915–00–P

federal register

Tuesday
December 16, 1997

# Part II

# Department of Agriculture

## Agricultural Marketing Service

## 7 CFR Part 205
## National Organic Program; Proposed Rule

**DEPARTMENT OF AGRICULTURE**

**Agricultural Marketing Service**

**7 CFR Part 205**

**[Docket Number: TMD–94–00–2]**

**RIN: 0581–AA40**

## National Organic Program

**AGENCY:** Agricultural Marketing Service, USDA.

**ACTION:** Proposed rule.

**SUMMARY:** The Agricultural Marketing Service (AMS) is seeking comments on a proposal to establish a National Organic Program (NOP or program). The program is proposed under the Organic Foods Production Act of 1990 (OFPA or Act), as amended, which requires the establishment of national standards governing the marketing of certain agricultural products as organically produced to facilitate commerce in fresh and processed food that is organically produced and to assure consumers that such products meet consistent standards. This program would establish national standards for the organic production and handling of agricultural products, which would include a National List of synthetic substances approved for use in the production and handling of organically produced products. It also would establish an accreditation program for State officials and private persons who want to be accredited to certify farm, wild crop harvesting, and handling operations that comply with the program's requirements, and a certification program for farm, wild crop harvesting, and handling operations that want to be certified as meeting the program's requirements. The program additionally would include labeling requirements for organic products and products containing organic ingredients, and enforcement provisions. Further, the proposed rule provides for the approval of State organic programs and the importation into the United States of organic agricultural products from foreign programs determined to have equivalent requirements.

**DATES:** Comments must be submitted on or before March 16, 1998.

**ADDRESSES:** Interested persons are invited to submit written comments on this proposal to: Eileen S. Stommes, Deputy Administrator, USDA–AMS–TM–NOP, Room 4007–So., Ag Stop 0275, P.O. Box 96456, Washington, DC 20090–6456. Comments also may be sent by fax to (202) 690–4632. Additionally, comments may be sent via the Internet through the National Organic Program's homepage at: http://www.ams.usda.gov/nop. See the **SUPPLEMENTARY INFORMATION** section for further details on submitting comments.

**FOR FURTHER INFORMATION CONTACT:** Michael I. Hankin, Senior Agricultural Marketing Specialist, USDA–AMS–TM–NOP, Room 2510-So., P.O. Box 96456, Washington, DC 20090–6456; Telephone: (202) 720–3252; Fax: (202) 690–3924.

**SUPPLEMENTARY INFORMATION:**

### Submission of Comments

Written comments submitted by regular mail and faxed comments should be identified with the docket number found in brackets in the heading of this document. Multiple page comments submitted by regular mail should not be stapled or clipped to facilitate the timely scanning and posting of these comments to the NOP homepage. Persons submitting written or faxed comments are requested to identify the topic and section number, if applicable, to which the comment refers: for example, for a comment regarding feed for organic livestock, reference Livestock and section 205.13. Topics should be selected from the following list: General, Proposed Effective Date, Regulatory Impact Assessment, Regulatory Flexibility Analysis, Paperwork Reduction Act, Definitions, Applicability (section 205.3), Crops, Livestock, Handling, National List, Labeling, Certification, Accreditation, State Programs, Fees, Compliance, Appeals, and Equivalency.

It is our intention to have all comments, whether mailed, faxed, or submitted via the Internet, available for viewing on the NOP homepage at http://www.ams.usda.gov/nop in a timely manner. Comments submitted in response to this proposal will be available for viewing at the USDA–AMS, Transportation and Marketing, Room 2945-South Building, 14th and Independence Ave., S.W., Washington, D.C., from 9:00 a.m. to 1:00 p.m., and from 2:00 p.m. to 4:30 p.m., Monday through Friday (except official Federal holidays). Persons wanting to visit the USDA South Building to view comments received in response to this proposal are requested to make an appointment in advance by calling Martha Bearer at (202) 720–8037.

### Purpose and Background of the National Organic Program

Members of organic industries across the U.S. 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 33 private and 11 State organic certification agencies (certifiers), each with their own standards and identifying marks. Some existing private certifying agencies are concerned that States might impose registration or licensing fees which would limit or prevent the private certifiers from conducting certification activities in those States. Labeling problems have confronted manufacturers of multi-ingredient organic food products containing ingredients certified by different certifiers because reciprocity agreements have to be negotiated between certifiers. Consumer confusion may exist because of the variety of seals, labels, and logos used by certifiers and State programs. Also, there is no industry wide 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 farmers and handlers from 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, the organic industry trade association attempted to establish a national voluntary organic certification program. However, the industry could not develop a consensus on the standards that should be adopted. Thereafter, Congress was petitioned by the organic industry trade association to establish a mandatory national organic program. Congress, in 1990, enacted the Organic Foods Production Act of 1990, as amended (7 U.S.C. 6501 *et seq.*). 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 Standards Board

Pursuant to section 2119 of the OFPA (7 U.S.C. 6518), the Secretary of Agriculture, hereafter referred to as the Secretary, established a National Organic Standards Board (NOSB or Board). The NOSB has assisted the Secretary in developing a National List of substances to be used in organic production and handling and has advised the Secretary on other aspects

of implementing the National Organic Program.

The Act establishes what the composition of the Board should be. In accordance with the Act, the Secretary appointed 14 members in January 1992 that included 4 organic farmers, 2 organic handlers, 1 owner or operator of a retail establishment with significant trade in organic products, 3 experts in environmental protection and resource conservation, 3 representatives of public interest or consumer interest groups, and 1 expert in the field of either toxicology, ecology, or biochemistry. The 15th member, an accredited certifier, would be appointed after certifying agents are accredited by the Secretary. The Act also provides that members of the NOSB be appointed for 5 year terms and that the original members be appointed to staggered terms of 3, 4 and 5 years to provide continuity of membership on the Board.

The NOSB has held 12 full Board meetings and 5 joint committee meetings since the appointment of its members in 1992. To make recommendations regarding specific issues, the Board formed 6 working committees: Crops Standards; Livestock (and Livestock products) Standards; Processing, Packaging and Labeling Standards; Materials; Accreditation; and International Committees. Each committee reviewed the provisions of the OFPA and standards previously established by other organic organizations to determine for which subject areas position papers would be developed. Based on the position papers developed, public input given by persons at NOSB meetings, and an extensive review and comment process used to develop draft recommendations, the Board provided recommendations to the Secretary about various matters. The recommendations included ones regarding production and handling standards, labeling, accreditation, product residue testing, and emergency spray programs.

The Board has provided recommendations regarding which synthetic substances should be permitted to be used in organic production and handling and which non-synthetic substances should be prohibited for use, in order to recommend to the Secretary whether they should be placed on the National List as synthetic substances approved for use or non-synthetic substances not approved for use. The Board has reviewed approximately 170 substances, including botanical pesticides as required in section 2119(k)(4) of the OFPA (7 U.S.C. 6518(k)(4)), for possible placement on the National List, and the Board used technical advisory panels to provide scientific evaluation of the materials considered in its review of the substances.

The NOSB's initial recommendations were presented to the Secretary on August 1, 1994. The NOSB has continued to make recommendations and has submitted 30 addenda to its initial recommendations. A copy of the NOSB recommendations may be viewed on the NOP home page at: http://www.ams.usda.gov/nop, or obtained by writing to: Maria Strother, Agricultural Marketing Specialist, USDA–AMS–TM–NOP, Room 2510-So., P.O. Box 96456, Washington, DC 20090–6456.

All of the NOSB recommendations were considered by AMS in developing the proposed regulation for the National Organic Program. The discussions and public input involved in generating the recommendations have been invaluable in assisting AMS to become aware of the complexity of various issues and to arrive at solutions that represent the interests of farmers, handlers and consumers. We have written a proposed regulation that incorporates to the greatest extent possible the organic principles and specifics contained in the NOSB recommendations. Many of the recommendations were restructured, reordered, or combined to be compatible with the format of the proposed rule. In the few instances where a section of our proposed rule does not reflect the NOSB recommendation, we explain the variation in the preamble for the specific section.

The NOSB recommendations and discussions on the following topics were especially helpful to AMS in developing the proposed rule: accreditation; labeling; importation; organic farm and handling plans; split operations; planting stock policies; emergency pest or disease treatments; livestock feed and health care; commercial availability; drift of synthetic substances; small farmer exemption; phase-in of NOP implementation; fiber processing; and the National List substance review process.

## Public Input

In addition to the NOSB recommendations, AMS has received considerable input from interested persons regarding establishment of the National Organic Program and this proposed rule.

Section 2110(g) of the OFPA (7 U.S.C. 6509(g)) requires the Secretary to hold public hearings to obtain information to guide the implementation of standards for livestock products. Four such hearings were held during 1994: January 27–28 in Washington, DC; February 10 in Rosemont, Illinois; February 24 in Denver, Colorado; and March 22 in Sacramento, California. Oral and written testimony was received from more than 70 persons, including livestock producers, veterinarians, certifying agents, processors and members of the NOSB. Comments covered livestock production and product marketing, antibiotic use, livestock living conditions, feed availability, provisions for conversion to organic production, and label requirements. These comments have been beneficial in developing this proposed rule.

Prior to publication of this proposed rule, public comment also was received at public events attended by NOP staff members. Public comment was received at the 12 full Board and 5 joint committee meetings. NOP staff made presentations and received comments at local and regional organic conferences and workshops and at national and international organic and natural food shows. Comments also were received at: a national organic certifiers meeting held on July 21, 1995, to discuss accreditation issues; a meeting of State officials held on February 26, 1996, to discuss the role of States in the NOP; training sessions for organic inspectors; and numerous speaking engagements of the AMS Administrator, the NOP program manager, and the NOP staff where the public had an opportunity to participate in question and answer sessions.

## Proposed Effective Date of the Regulation

We have received inquiries about when the various provisions of a final rule will be effective.

The final rule would establish a procedure and a time frame for designating private persons and State officials as accredited certifying agents under the program. One option would be to require organizations desiring to be included on the initial list of certifying agents accredited under the National Organic Program to submit their applications within approximately two months after publication of the final regulation. Applications submitted later than two months after publication of the final rule would not be considered for inclusion on the initial list of certifying agents, but would be reviewed as soon as possible after publication of the initial list of accredited certifying agents. Subsequent lists of accredited certifying agents would be published as they are developed.

If we adopted this option, we would publish an initial list of accredited certifiers in the **Federal Register** after

reviewing the applications received during the first two months after publication of the final regulation. We will publish subsequent lists of accredited certifying agents as new applicants become accredited. We would expect publication of the initial list to occur within six months after publication of the final rule. Only after publication of that list would the provisions of the regulation applicable to certification become effective. Thus, the provisions in the proposal that address the application process for, and decisions to be made about, the certification of farms, wild crop harvesting operations, and handling operations, would become effective only after certifiers have become accredited. Certifiers would begin certifying individual operations under the NOP six months after publication of the final rule.

In order for accredited certifying agents to begin certifying operations under the NOP six months after publication of the final rule, we believe we would need, as we previously indicated, to have accreditation applications submitted within two months after publication of the final regulation. We believe that the initiation of certification activities by accredited certifying agents six months after publication of the final rule would permit the implementation of the national standards for organic products within a reasonable time frame after publication of the final rule.

We request comments from all interested parties, particularly small businesses that want to obtain accreditation as certifying agents, as to whether a two month time frame after publication of the final rule for submission of applications for accreditation is a sufficient time period, or whether an extended time period, such as three or four months after publication of the final rule, should be permitted for those who want to be listed on the initial list of accredited certifiers. Any such extension, of course, would lengthen the implementation schedule.

In this implementation option, we would expect to allow a 12-month period of time after publication of the initial list of certifying agents for operations to become certified under the relevant provision of the final regulation. Thus, all provisions of the NOP would be implemented 18 months after publication of the final rule. On that date, which will be stated in the final rule, all organic operations required to be certified will have to be certified in order to sell or label their products as organic. Operations that are certified prior to 18 months after publication of the final regulation would be permitted to use the USDA organic seal upon certification by a USDA accredited certification organization.

We would like comments, particularly from small farm or handling operations, as to whether the 12-month period of time we anticipate allowing for farm, wild crop harvesting, and handling operations to become certified is a reasonable period of time for such operations to become certified. We are particularly interested in learning whether there are any economic or other factors that would create difficulties in obtaining certification within the 12-month time period we expect to provide for obtaining certification.

Several people have raised questions about what the impact of the rule would be when it is effective. Some farmers whose operations are currently certified as organic under private or State standards have asked what the status of their certified farming operations would be if a substance allowed for use under their current private or State certification is not on the National List, and, therefore, not allowed under the National Organic Program.

The OFPA requires that a product sold or labeled as an organically produced agricultural product must, except as otherwise provided in the Act and excluding livestock, be produced on land to which no prohibited substances, including synthetic chemicals, have been applied during the three years immediately preceding harvest of the agricultural product. We have incorporated this prohibition in our proposal. Thus, a farm would not be able to become certified under the National Organic Program until three years after the time any prohibited substance was last applied. Therefore, at the time the final rule becomes effective, such farming operations previously certified under private or State programs would not be able to sell or represent their products as organically produced if they could not satisfy the three year period established for nonuse of a prohibited substance.

Petitions, however, to amend the National List may be submitted immediately after publication of the final rule by using the petition process proposed in section 205.28 of subpart B. It may be possible, therefore, for a person who submits a petition immediately after publication of the final rule to the NOSB for review of a new synthetic substance to be included on the National List, to have this substance approved for use by the Secretary prior to the effective date of the program. If this were to occur, then prior use of the substance would not prevent the products from being sold or represented as organically produced.

Processors also have asked what impact the program's requirements would have on their existing product and label inventories. With regard to existing product and label inventories, we believe that our intended 18-month delayed effective date for the complete rule would provide ample time for handlers to use up existing product and label inventories required under their existing organic certification program before the rule becomes effective.

States also have asked what effect the rule would have on their current organic regulations. With regard to current State organic regulations, we also believe that the anticipated 18-month delayed effective date should provide State officials with ample time to make the necessary changes to their State regulations and submit their State proposed organic program to the Secretary for approval.

Because it is the intent of AMS to provide a final rule which facilitates trade and which is the least disruptive as possible for the production, handling and marketing of organic products, we request comment on our intended schedule of effective dates for the provisions of the rule. We also request comments on any problems that organic farmers and handlers, States, and others may encounter when adjusting their operations to meet the requirements of the National Organic Program, including the OFPA requirement of a 3-year period prior to the harvest of organic products from land to which a prohibited substance is applied. A time-table for implementation of the program would be published in the final rule.

**Prior Documents in This Proceeding**

The following notices related to the National Organic Standards Board and the development of this proposed regulation have been published in the **Federal Register**. Four notices of nominations for membership on the National Organic Standards Board were published between April 1991 and July 1996 (56 FR 15323, 59 FR 43807, 60 FR 40153, 61 FR 33897). 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). Twelve notices of meetings of the National Organic Standard Board were published between March 1992 and August 1996 (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). One notice of public hearings on organic livestock and livestock products was published on December 30, 1993 (58 FR 69315). One notice specifying a procedure to submit names of substances for inclusion on the National List was published on March 27, 1995 (60 FR 15744).

**Executive Order 12988**

This proposal has been reviewed under Executive Order 12988, Civil Justice Reform. This rule is not intended to have retroactive effect.

States and local jurisdictions are preempted under section 2115 of the 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 the 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 towards 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 proposal 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.

**Executive Order 12866**

This proposed rule has been determined to be economically significant for the purposes of Executive Order 12866 and, therefore, has been reviewed by the Office of Management and Budget (OMB). When proposing a regulation which has been determined to be economically significant, agencies are required to: assess the costs and benefits of available regulatory alternatives; base regulatory decisions on the best reasonably obtainable technical, economic, and other information; avoid duplicative regulations; and tailor regulations to impose the least burden on society consistent with obtaining regulatory objectives. Therefore, to assist in fulfilling the objectives of Executive Order 12866, and the Unfunded Mandates Reform Act of 1995, the USDA has prepared a Regulatory Impact Assessment (RIA) which is attached as an appendix to this proposed rule and from which the following summaries of the costs and benefits of the proposed National Organic Program have been taken.

Ideally, the net benefits of the proposed rule would be estimated by employing a quantitative analysis using information about the cost structure of the industry, the demand for organic food, and projected shifts in supply and demand resulting from the various factors discussed in the assessment. However, although researchers have conducted numerous small-scale studies to determine consumer willingness to pay for organic products and to identify reasons why conventional food buyers do not choose organic food products, the available data are insufficient to support a quantitative assessment of this type. At this time, USDA invites public input to provide additional data that may aid in the development of a quantitative assessment. This data should be submitted in response to the questions included in the Conclusion section of the RIA. These questions are intended to solicit information needed to develop baseline data about the potential program participants, the costs of organic production, revenues from organic sales, and the impact of the program on market growth.

**Summary of the Costs of the Proposed Rule**

The proposed rule would impose direct costs in the form of fees charged to certifiers for USDA accreditation and to farmers, wild crop harvesters and handlers for support of the National Organic Program. The proposed rule also would impose administrative costs, such as submission of information, recordkeeping, and access to records that may constitute an additional burden. The actual amount of the additional administrative costs that would be imposed by the final rule is expected to be different for those entities who currently are active in the organic industry, as compared to those new entities who would begin their activities only after the national program is implemented. Certifiers, farmers, wild crop harvesters 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.

Farmers, wild crop harvesters and handlers would be required to produce and handle products in accordance with the standards set forth in the rule and provide certifiers with the required information necessary to verify certification requirements. Farmers, wild crop harvesters, and handlers would be charged a fee by the certifying agent for these certification services. We were not able to estimate the exact cost of certification fees that would be charged by certifying agents after implementation of the national program because these fees currently vary widely among existing certifiers: some existing private certifying agents are non-profit; some States who currently conduct certification activities subsidize these activities from other revenue sources; some existing certifying agents include the cost of inspection and, in some cases, laboratory testing, in their certification fee; and some existing larger certifying agents may charge lower fees because they are able to spread their fixed costs over a larger number of clients.

Farmers, wild crop harvesters, and handlers may experience certain costs to comply with the final regulations. For example, there may be costs associated

with the proposed requirement that organic products not come in contact with prohibited substances, or with the proposed requirement that pest control substances be used only if pest prevention measures are ineffective. However, since the proposed rule is a synthesis of existing State and private organic certification programs and the NOSB recommendations, we believe that farmers, wild crop harvesters and handlers who currently participate in existing State or private organic certification programs would experience little or no increased compliance costs as a result of implementation of the National Organic Program. Additionally, farmers and handlers who would be exempted or excluded under the rule, but who choose to become certified in order to receive the benefits of certification, would be subject to the additional cost of certification and recordkeeping. USDA requests data on the costs of organic production and the revenues from organic farming, and on a comparison of these costs and revenues to conventional systems.

The following are the upper-bound estimates of the cost of initial certification under the National Organic Program:

**Estimated Cost to Farmers and Wild Crop Harvesters for Initial Certification**

| | | |
|---|---|---|
| Certification fee * | $413 | |
| USDA fee | 50 | |
| Total fees | 463 | |
| Paperwork reporting burden | [1] 381 | |
| Paperwork recordkeeping burden | 34 | |
| Total reporting and recordkeeping | 415 | |
| ESTIMATED COST TO FARMERS AND WILD CROP HARVESTERS FOR INITIAL CERTIFICATION | | $878 |

**Estimated Cost to Handlers for Initial Certification**

| | | |
|---|---|---|
| Certification fee * | $943 | |
| USDA fee | 500 | |
| Total fees | 1,443 | |
| Paperwork reporting burden | [2] 433 | |
| Paperwork recordkeeping burden | 34 | |
| Total reporting and recordkeeping | 467 | |
| ESTIMATED TOTAL COST TO HANDLERS FOR INITIAL CERTIFICATION | | $1,910 |

* The estimated certification fee is based on the average of fees charged by a representative group of certifying agents: private non-profit, private for-profit and a State agency. Most certifying agents in our representative group include the cost of inspection and, if applicable, required laboratory testing in the certification fee.

[1] For new organic producers.

[2] For new organic handlers.

USDA requests data on certification fees currently paid by existing organic farmers, wild crop harvesters, and handlers in order to better assess the impact of the proposed program.

After implementation, all organic certification agencies, whether private or State, would be accredited by USDA and would pay fees for the following services provided by USDA: application review, annual report review, site evaluation visits, and administrative duties. A certifier who currently is accredited by a private accreditation organization might pay USDA lower site evaluation visit fees than a certifier who is not currently accredited, because of measures that are implemented by the certifier to receive its private accreditation. Additionally, as required by the OFPA, a private certifying agent would have to furnish reasonable security for the purpose of protecting the rights of farms and handling operations certified by the agent. The amount and type of security would be established through future rulemaking.

States that currently perform organic certification activities under their own regulations, or that have laws pertaining to the certification of organically produced and handled products, or that plan to have an organic program in the future, may incur some additional costs. For example, States with existing organic programs or regulations may be required to supplement or revise them in order to meet the criteria of the OFPA, including the provisions set forth in section 2107 of the OFPA (7 U.S.C. 6506). A State without an existing organic program that initiates a new State organic program would be expected to incur greater costs to establish its program.

The following are the upper-bound estimates for the cost of initial accreditation under the National Organic Program:

**Estimated Cost to Certifying Agents for Initial Accreditation**

| | | |
|---|---|---|
| Accreditation application fee | $640 | |
| Site evaluation fee * | 3,500 | |
| USDA Administrative fee | 2,000 | |
| Total fees | 6,140 | |
| Paperwork reporting burden | [1] 23,931 | |
| Paperwork recordkeeping burden | 60 | |
| Total reporting and recordkeeping | 23,991 | |
| ESTIMATED TOTAL COST FOR INITIAL ACCREDITATION | | $30,131 |

*Each certifying agent would have a site-evaluation to confirm accreditation, and thereafter a subsequent renewal evaluation at least every 5 years following confirmation of accreditation. In some cases, a pre-confirmation site visit may be necessary. We anticipate that the frequency of site evaluations would be based on the performance of the certifying agent and would be higher during the initial years of the program.

[1] For new organic certifiers.

The USDA requests data on the fees currently paid by existing organic certifying agents for accreditation in order to better assess the impact of the proposed program.

The requirement in the proposed rule for qualified certification personnel to be used to evaluate certification applications and contribute to certification decisions may result in an increase in labor and training costs for some existing certifiers. The amount of additional costs to these certifiers would depend on the level of expertise among current certification personnel, the extent to which certifiers currently rely on volunteers, and the costs of training these persons. Our proposed inspector training requirements conform to current established practice in the industry and are not expected to impose an additional burden on existing certifiers who utilize inspectors.

We also have identified non-quantifiable costs that may result. Some certifiers consider the loss of independence in setting certification standards under a national program as imposing a cost. Other certifiers consider the establishment of uniform national standards and an accreditation program as a benefit in that the risk of potentially costly disputes over acceptance of other certifier's standards (reciprocity) is eliminated. We anticipate that the net impact would be positive because the reciprocity dispute problems would be eliminated.

Another non-quantifiable cost could result from the proposed requirements that certifiers provide access to all their records to the Secretary and the applicable governing State official, and provide access to laboratory analyses and certification documents, other than

confidential business information, to the general public. Although not quantifiable, these requirements may represent a change in the way some existing certifiers currently maintain these records.

**Summary of Benefits of the Proposed Rule**

In the absence of a nationally recognized definition of organic, consumers may be mislead by labels on products claiming to be organic, or claiming to contain organic ingredients, when in fact some of the products or ingredients may not have been organically produced. Because many consumers are willing to pay price premiums for organic food, producers have an economic incentive to label their products organic. But consumers generally are unable to distinguish organic products from conventionally produced products by sight inspection; hence, consumers rely on verification methods such as certification by private entities or verification by retailers. The USDA requests data to determine the extent to which mislabeling of non-organically produced products as organic occurs and the market impacts of mislabeling in terms of quantities of organic goods sold and the prices for organic goods.

Individual ingredients in multi-ingredient processed products may be certified under different standards of organic production, thus making it difficult for a consumer to determine the production standards under which each of the ingredients was produced. The proposed standards for organic production, enforced through accreditation of certifiers, would assure consumers that the organic ingredients were produced under one national standard. Furthermore, USDA regulation of labeling claims for organic food would allow the USDA and other federal agencies whose jurisdiction includes ensuring the veracity of labeling claims to prosecute those who mislabel products sold as organic.

Establishing a national definition for organic would be expected to increase the supply and variety of organic products, especially meat and poultry, available to consumers. The Food and Drug Administration (FDA) and the Bureau of Alcohol, Tobacco and Firearms (ATF) currently allow use of the word organic on most food and alcohol labels, but USDA has withheld approval for the use of organic labels on meat and poultry pending the outcome of this rule making. Without the regulation, however, FDA may decide to disallow use of the term organic on labels and USDA may continue their current restrictions on the use of organic on meat and poultry labels. The increased variety of organic products, especially meat and poultry, that might be marketed after implementation of the final rule may increase the variety of available organic products so as to parallel the variety of non-organic products. The USDA requests data and analyses which would support projections of the demand for organic meat and poultry.

By providing for the accreditation of certifiers, the proposed rule would establish the requirements and enforcement mechanism to protect producers and handlers from inconsistent certification services, lack of reciprocity between certifiers, and competition from fraudulent products, which can increase costs or reduce revenue for organic farmers and handlers. In the absence of the National Organic Program, the certifier of a final product may not be required to recognize the certification of an intermediate organic product used in the final product. Thus, both farmers and primary food processors face a risk of being unable to sell an organic product identified as certified when more than one certifier is involved. Monitoring by USDA of certification inspections and certifier personnel training and qualifications would help to ensure the quality of the certification, the use of consistent criteria for certification, and the use of certification personnel who are knowledgeable and free from conflicts of interest.

National organic standards and the assurance provided by the USDA accreditation of certifiers would benefit farmers and handlers by opening access to international markets. The trade restrictions that currently exist would be resolved if foreign countries who import organic products recognize the National Organic Program as equivalent. Farmers and handlers in the United States may expect larger growth in exports of organic products to follow implementation of the final rule.

The contributions of national organic standards to increased domestic demand and to expanded international markets for organic products may provide opportunities for current organic producers to expand the scale of their operations. Increased organic production also may provide incentives for input industries to develop new technologies which could lower producers' costs of organic production. Input costs also may decline as a result of economies of scale being achieved in input industries producing for the organic market. Expanded markets could encourage additional farmers and handlers to enter the marketplace, resulting in a potential decline of certifiers' average costs of operation as fixed costs are spread over a growing number of clients. The USDA requests information to determine whether the organic industry and consumers of organic goods have benefitted from industry growth resulting in economies of scale and production and marketing efficiencies, and whether industry participants anticipate such benefits from this rule.

There are three ways in which certifiers' administrative costs could be reduced as a result of the regulation. First, certifiers' costs of maintaining access to organic markets for their clients should be reduced because costs associated with determining equivalency between certifiers would be reduced or eliminated. Accreditation and uniform national standards would alleviate the need to negotiate individual reciprocity agreements with other certifiers. Furthermore, USDA oversight of certifiers would simplify the process of certifying multiple ingredient products, thus reducing certification costs. The responsibility for meeting production and certification requirements of each ingredient would rest with the certified producers and accredited certifying agents of the individual ingredients. National standards also would eliminate costly equivalency disputes between States which may affect interstate commerce.

Second, certifiers would no longer have to pay private organizations for the accreditation required to gain access to some international markets. This would be of particular benefit to the smaller certifiers who may have been unable to enter these markets because of the high cost of international accreditation. A portion of the administrative fees paid by each certifying agent would support USDA activities to negotiate equivalency of organic standards in world markets so that producer clients of all USDA accredited certifiers could have access to these markets.

Third, in the long run, uniform standards of production, certification and accreditation should reduce the cost of training certification staff. Industry-wide training costs may increase initially, but should decline as the pool of trained certifiers and certification personnel increases and the corresponding cost of training new certification personnel decreases, especially in those instances where personnel transfer from one certifier to another. Standardized materials, such as compliance guides and training manuals, also should contribute to a reduction in the cost of training

certification staff. In addition, USDA accreditation of certifiers would present opportunities for sharing information about standards, practices and the general requirements of the program through the National Organic Program staff.

**Unfunded Mandates Reform Act**

The Unfunded Mandates Reform Act (Pub. L. 104–4) requires (in Section 202) that agencies prepare a qualitative and quantitative assessment of the anticipated costs and benefits before proposing any rule that may result in annual expenditures by State, local, and tribal governments, in the aggregate, or by the private sector, of $100,000,000 (adjusted annually for inflation) in any one year. As discussed in the preceding section entitled ''Executive Order 12866'', USDA has prepared a Regulatory Impact Assessment (RIA) to assess the costs and benefits of this proposed rule. As explained in the RIA, which is attached as an appendix to this proposed rule, USDA was unable to provide a quantitative assessment of the costs and benefits of the proposed rule, except for the cost of fees and recordkeeping that would result from the proposed rule, because of insufficient data available to support a quantitative assessment. The cost of fees resulting from this proposed rule is estimated to be $1,000,000 during the first year of program implementation, and the cost of recordkeeping is estimated not to exceed $4,700,000 during any one of the first three years of program implementation. The RIA does, however, provide a qualitative assessment of the proposed rule's costs and benefits.

The USDA has posed a list of questions in the RIA to assist in the development of a quantitative assessment for the final RIA that will be published as part of the final rule for the National Organic Program. We will utilize public input received in response to these questions and to other provisions of this proposed rule, as well as other resources available to USDA before publication of the final rule, to develop a quantitative assessment of the costs and benefits of the final rule.

Although USDA has not determined whether this proposed rule would result in annual expenditures by State, local, and tribal governments, in the aggregate, or by the private sector, of $100,000,000, USDA has sought to meet the objectives of the Unfunded Mandates Reform Act. In addition to its qualitative cost/benefit assessment, USDA has identified in the RIA three regulatory alternatives to the proposed rule. We also discuss in the preamble sections entitled ''Paperwork Reduction Act of 1995'' and ''The Regulatory Flexibility Act and the Effects on Small Businesses'', the analysis we have employed in reaching a determination that this proposed rule is the least costly and least burdensome to the regulated parties, in that we have designed the proposed rule to be as consistent as possible with existing industry practices, while satisfying the specific requirements of the OFPA.

Additionally, we have had numerous occasions to communicate with State governments during the development of the proposed rule. Representatives of various State governments participated in several public meetings of the NOSB and they have provided valuable input to the NOSB for its recommendations on standards and the National List. USDA also hosted a meeting on February 26, 1996, to discuss with many State officials the status of the proposed rule and to listen to concerns about such topics as fees, enforcement, certifier logo use, and the range of additional requirements that States may include in their State programs. On numerous other occasions, AMS staff has had discussions with a wide array of State officials on subjects related to this proposed rule or the establishment of, or amendment to, State organic certification programs. USDA will continue to provide effective opportunities for the broadest possible input by States and all interested parties throughout the rulemaking process.

**The Regulatory Flexibility Act and the Effects on Small Businesses**

Pursuant to the requirements set forth in the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*), the Agricultural Marketing Service (AMS) has considered the economic impact of the proposed rule on small entities. The AMS' analysis, as required by the RFA, considers the impact of this proposed regulation on small entities and evaluates 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 organic market. The following Initial Regulatory Flexibility Analysis was written with guidance from the Small Business Administration (SBA).

The size of the organic industry has risen dramatically in recent years from a low of $78 million in 1980, to $1 billion in 1990, to a total retail sales level of $3.5 billion in 1996. Certified organic cropland production has expanded from 473,000 acres to 667,000 acres in the period 1992 to 1994, and is expected to reach 2 million acres by the year 2000. Despite this rapid growth, it should be noted that the organic industry represents a very small percentage of total agricultural production and sales, and that organic certifiers, farmers and handlers tend to own smaller operations rather than larger ones.

Currently, organic certification is voluntary and self-imposed. According to the most complete data available to the AMS, there are 33 private and 11 State certifying agencies certifying approximately 4,000 farmers and 600 handlers in the United States. Over half of the private and State agencies certify both farm and handling operations, while the others certify only farms. Over three-fourths of State and private agencies each certify fewer than 150 farms and 20 handlers. Based on a review conducted by AMS of 16 certifiers, who provided information on the organic sales of products produced on certified farms, most of the farms certified have less than $25,000 in gross sales.

A national organic program would benefit farmers by opening access to international markets. U.S. exports of organic products totaled $203 million in 1994 or about 9 percent of the organic output. Export markets may become more substantial and offer price premiums for organic products with increased world-wide consumption of organically produced food. For example, the organic market share in the European Union (EU) has been projected to reach 2.5 percent of total food consumption expenditures by 1998. Austria expects its organic market share to equal one third of all food sales by the year 2000. In 1994, France and Germany combined had total retail sales of organic foods equal to that of the United States in the same year (approximately $2 billion). Japan's retail sales for that year were estimated to be $688 million. Other EU countries report growth rates equal to or greater than the current growth rate in the United States of about 20 percent per year.

The reason for regulatory action is fully explained in the Regulatory Impact Assessment which is attached as an appendix to this proposed regulation. In short, the organic market may be precluded from reaching its full potential until there is a definition of the term organic, which would be achieved by implementation of this proposed regulation that provides regulations for production, handling, labeling, certification and accreditation of U.S. certifiers. Domestic and international trade in organic products may also be hampered by the need to negotiate reciprocity agreements because of the differing standards of

production and handling that currently exist; meat and poultry, including processed products containing meat and poultry as ingredients, cannot be labeled organic; and few enforcement mechanisms exist to protect consumers against fraudulent organic labeling.

The statutory authority for this proposed rule is the OFPA, which in section 2104(a) (7 U.S.C. 6503(a)) requires the Secretary of Agriculture to develop a national organic program. In general, the Secretary must establish an organic certification program for farmers and handlers of agricultural products that have been produced using organic methods as provided for in the OFPA. In addition, section 2115 of the OFPA (7 U.S.C. 6514) requires the Secretary to establish and implement a program to accredit a governing State official and any private person who meets the requirements of the OFPA and the regulations in part 205 as a certifying agent for the purpose of certifying a farm or handling operation as being in compliance with the standards set forth in this proposed regulation.

The purpose of the RFA is to fit regulatory actions to the scale of business subject to the actions in order that small businesses would not be unduly or disproportionately burdened. To accomplish this purpose, it first is necessary to define a small business. According to the Standard Industrial Codes (SIC) (13 CFR Part 121) which are developed by an inter-agency group, published by the Office and Management and Budget (OMB), and used by the SBA to identify small businesses, nearly all of the entities affected by this proposed regulation would be considered small businesses. According to the SIC, a small business in the agricultural services sector, such as certifiers, includes firms with revenues of less than $3.5 million (SIC Division A Major Group 07). In crop production, the SIC definition of a small business includes all farms with annual gross sales under $500,000 (SIC 0111–0191). (Most of the farms currently certified have less than $25,000 in gross sales of organic production. However, many farms combine organic and conventional production on the same operation, some with total sales that may exceed $500,000). In handling operations, according to the SIC, a small business is defined as having fewer than 500 employees (SIC Division D Major Group 20). (The workforce data needed to determine whether any organic handling operations exceed 500 employees is not available, but anecdotal information leads us to believe that no organic handling operations employ more than 499 persons).

We consulted with the SBA Office of Advocacy regarding the use of size standards different from those in 13 CFR 121. For the purpose of identifying those entities who would be most affected by this proposed regulation, alternative definitions were established for the purpose of this analysis. The alternative definition of a small certifier which we established for this analysis is one with total revenue from certification of less than $25,000. The alternative definition of a small farm which we established is one with a maximum of $5,000 in gross sales of agricultural products, as is set forth in section 2106(d) of the OFPA (7 U.S.C. 6505(d)). Additionally, for this analysis, we established the alternative definition of a small handling operations to be one whose sales are $50,000 or less.

Development of regulations for the National Organic Program began with the premise that the industry should be burdened as little as possible by the OFPA regulation. To accomplish the goal of regulation with minimal burden, we initially determined that most of the information needed for organic farmers and handlers to become certified, and for certifiers to become accredited, already exists for those entities currently operating. The challenge was to create a regulation which complied with the OFPA mandates and which embodied the customary and usual business practices already being carried out by the industry. No new forms have been proposed and few additional documents would be required in this proposed regulation. Certifiers may need to create some of the documents proposed for the application process; farmers may have to keep records for longer periods of time; and handlers may need to refine recordkeeping to ensure a clear audit trail. However, they would be allowed the flexibility to use the easiest and least expensive means available to provide information, as long as the required information is adequate to ensure compliance with the regulations.

Small and large farmers, handlers, and certifiers would be affected by additional fees resulting from implementation of the National Organic Program. Certifiers may be burdened with the accreditation requirements for business related activities, such as the requirement for a financial audit. However, because no particular form is required, current business records may be sufficient to provide the necessary information. The requirements to keep personnel records, explain administrative procedures, and evaluate personnel may be burdensome to small certification businesses. Yet, we have received the comment from at least one small business that requirements such as these can increase efficiency and make a small business more cost effective.

Section 2112(d) of the OFPA (7 U.S.C. 6511(d)) requires farmers and handlers to maintain records for five years, and section 2116 (c)(1) of the OFPA (7 U.S.C. 6515(c)(1)) requires certifiers to maintain records for ten years. Our research of the industry indicates that farmers and handlers already maintain records for five years and certifiers do not discard historical documents. This regulation, therefore, should not significantly increase the record retention burden beyond current industry practice. However, under the requirements of the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3506 and 3507), a burden is created when a law or regulation requires the storage of information. The burden to the industry is calculated on the time required to file a document. Under the PRA we are required to estimate and account for this burden.

No other burdens are expected to fall upon the organic industry as a result of overlapping Federal rules. This proposed regulation would not duplicate, overlap or conflict with any existing Federal rules. In preparing this proposed regulation, AMS consulted other Federal agencies such as the FDA, EPA, ATF, and the USDA's Food Safety and Inspection Service (FSIS) to ensure that this proposed regulation would complement existing regulations.

Whether using the SIC definitions for small businesses or the alternative definitions created for this analysis, our proposed regulation would have a significant impact on a substantial number of small businesses. However, we have considered several options with the intention of mitigating negative economic impacts. The following options were considered by AMS prior to and during the development of the proposed regulation.

**Regulatory Options**

*Option 1: The Organic Market in the Absence of Regulation*

We have explored the alternative of no government regulation of the organic industry. However, current problems in the organic industry would continue to affect small entities as well as large ones. In fact, it is likely that the effect of no regulation would negatively impact small businesses to a greater degree than larger ones. For example, without regulation, smaller certifiers

entering the industry with growth expectations based on implementation of the OFPA through Federal regulation would be negatively affected to a greater degree than larger certifiers who can spread fixed costs over a larger number of clients. Larger businesses do not depend as heavily on industry growth to maintain their business operations.

Organic farmers who have integrated livestock into their agricultural operation are negatively impacted in two ways without regulation of the organic industry. First, they do not receive the price premium for organic meat and poultry because at the present time FSIS does not allow for the use of the term organic on meat and poultry labels. This would impact small farmers to a greater extent because they have fewer animals from which to profit from a price premium. Second, to feed their livestock, farmers either must pay a higher price for organically produced livestock feed or raise the feed on their own land which otherwise could be used to produce organic cash crops. Smaller farmers are disproportionately impacted because the ratio of the number of livestock per acre of land is limited by the number of acres they must use for organic crop production in order to be a profitable business. Larger farmers face the same decision of whether to purchase organic feed or raise their own, but they have more acres over which to spread the cost of either choice.

Without Federal regulation, small certifiers and farmers wishing to export agricultural products are negatively impacted to a greater degree than larger organizations by a lack of resources and influence over foreign market systems. Also, completing the paperwork required for exporting products is disproportionately costly to small entities because of their limited resources. The burden of completing this paperwork can be eased if the certifier has attained private, third-party accreditation. We are aware that certifiers currently may pay in excess of $15,000 for accreditation by a private organization. Smaller certifiers cannot afford these fees, and therefore, potential clients wishing to export organic products choose to be certified by the larger, privately-accredited organizations.

Finally, we are required by the OFPA to regulate the industry through the National Organic Program. In fact, we have received requests from many small businesses, certifiers, farmers, and handlers, to move forward with implementation of a national program as quickly as possible. Therefore, we believe that regulating the organic industry would be the most appropriate action to help small businesses.

*Option 2: Exemption of Small Certifiers From Accreditation*

We considered the option to exempt small certifiers from accreditation requirements, just as small farmers and handlers are exempt from certification. However, the OFPA does not provide for such an exemption and this, therefore, would require a legislative amendment. Additionally, we do not believe that exempting small certifiers would be in the best interest of the industry or the small certifiers.

The exemption of small farmers carries with it limitations which may discourage some small farmers from claiming exemption, preferring instead to become certified. In this proposed regulation, small farmers who are not certified and who use the term organic to identify their products must comply with the USDA standards, yet they may not display the USDA seal or a certifying agent's logo on the labels or the labeling of their products. Furthermore, organic agricultural products produced on small farms that claim exemption from certification requirements cannot be labeled as organic ingredients in products processed by a certified operation. As a result, consumers and processors may not wish to pay a price premium for organic products from a non-certified operation.

The exemption of small certifiers from accreditation would carry with it limitations resulting from the absence of Federal oversight. Interstate and international trade would be hampered because it would likely be limited to products certified by accredited certifiers. Distinguishing exempt certifiers from accredited ones might require that product labels of accredited certifiers' clients include the USDA logo and lead to consumer confusion over labels in the marketplace.

Protecting consumers from fraudulent certification claims on labels would be difficult at the Federal level since AMS and other enforcement agencies, such as the FDA, ATF, and FSIS, would have to distinguish accredited certifiers from those who are exempt. Costly spot checks or site visits would be required by AMS to verify that products sold or labeled as organic are produced under systems that are consistent with the national program. To accomplish this, a mechanism would have to be established to charge exempt certifiers for spot checks or site visits and these charges might be more costly than becoming accredited.

One of the purposes of the OFPA is to assure consumers that organically produced products meet a consistent standard. Without the assurance provided by Federal oversight of certifiers through USDA accreditation, there is no way to ensure that one national standard of production and handling for organic agricultural products would be employed. The result could be the continuation of costly reciprocity agreements among small, exempt certifiers and large, USDA accredited certifiers. This could prove to be more costly to small entities than accreditation. For all of these reasons, we have determined that option 2 is not a viable alternative.

*Option 3: The Proposed Regulation*

The regulation we propose is a synthesis of existing organic standards and certification programs. We have done extensive outreach which is explained in the **SUPPLEMENTARY INFORMATION** section entitled ''Public Input''. After gathering the necessary information, we developed this proposed regulation to ensure industry integrity and help the organic industry grow. In this section, we will discuss how this proposed Federal regulation of the organic industry would: eliminate costly administrative tasks now necessary under current industry practice and thus mitigate the financial burden of USDA accreditation; level the playing field, enabling small entities to better compete in the industry; and benefit all farmers and handlers through industry growth. Finally, this proposed regulation includes three factors that would decrease its overall burden by providing flexibility in compliance and fees.

Certification organizations currently develop and interpret their own standards of production and handling. The consensus of our outreach to the industry is that one national standard with interpretation, decision making, and enforcement authority at the Federal level would eliminate the need for certifiers to develop and amend standards. Federal regulation also would provide a consistent process for certifying operations that produce and handle products bearing an organic label. Smaller certifiers would benefit to a greater degree than larger certifiers because the resources saved from creating and interpreting their own standards could be directed toward improving their business operations and offsetting any additional burden imposed by accreditation.

One national standard would eliminate the need to negotiate costly reciprocity agreements and thus save

certifiers' resources used to negotiate the agreements, while also expanding markets for organic farmers and handlers certified by smaller organizations which currently do not have, or have a limited number of, such agreements. Eliminating the need for accreditation by private organizations prior to export would relieve certifiers of current financial and paperwork burdens while leveling the playing field for large and small organic entities wishing to export organic agricultural products.

An expanded market caused by the introduction of organic meat and poultry, added consumer confidence backed by consistent standards of production and handling, and additional export volumes of organic agricultural products would benefit all of the organic industry.

Another benefit of this proposed regulation to smaller certifiers would be an extended network of information exchange. Presently, information dissemination occurs on a one-to-one basis and through participation in industry groups, meetings, workshops and international trade fairs. Participation in these activities, which often are dominated by issues of the larger certifiers, is costly and frequently prohibitive to smaller entities. This proposed regulation would facilitate providing certifiers with information about the program, including standards, practices and general requirements. Small certifiers would have access to the same information at the same time as large certifiers, which could be passed on to their clients, typically small farmers and handlers.

In our previously discussed implementation option, we consider allowing a 6-month period of time after publication of the final rule for certifying agents to gain initial accreditation, followed by a 12-month period of time for farm, wild crop harvesting, and handling operations to become certified under the relevant provision of the final regulation. Thus, we intend that the provisions of the NOP would be implemented approximately 18 months after publication of the final rule. On that date, which will be stated in the final rule, all organic operations required to be certified in order to sell or label their products as organic would have to be certified. Operations that are certified prior to 18-months after publication of the final regulation would be permitted to use the USDA organic seal upon certification by a USDA accredited certification organization.

We would like comments, particularly from small farm or handling operations, as to whether the 12-month period of time we anticipate allowing for farm and handling operations to become certified is a reasonable period of time for such operations to become certified. We are particularly interested in learning whether there are any economic or other factors that would create difficulties in obtaining certification within the 12-month time period we expect to provide for obtaining certification.

Small certifiers have expressed concern that they may not have the expertise necessary to become accredited by USDA or to carry out the responsibilities associated with accreditation. However, we believe that this proposed regulation is consistent with, and builds upon, current industry practice. It was designed to allow existing certifiers, farmers and handlers to continue to operate within the organic industry.

In developing our proposal, we considered requiring that accreditation be renewed annually by large certifiers and bi-annually by small certifiers. However, annual or bi-annual preparation of accreditation application materials and the review of applications would be burdensome to accredited certifiers and the NOP staff, respectively. Therefore, in this regulation we have proposed that rather than extending the length of accreditation for small certifiers, we would require that all certifiers submit annually only information about their operation that had changed from the previous year. This requirement would eliminate the burden of certifiers annually refiling all of the information submitted in the initial accreditation. Renewal of accreditation would occur every fifth year.

Finally, this proposed regulation has three elements of flexibility that are advantageous to small entities: performance based production and handling standards and certifier requirements; production and handling standards that contain a range of allowable practices; and certifier site-evaluation fees that would reflect actual costs incurred in connection with the site-evaluation.

The standards in this proposed regulation are performance standards based on the results of a management system, rather than prescriptive or design standards that prescribe specific technology or a precise procedure for compliance. Performance standards allow for flexibility in compliance, which is especially important to organic farmers, handlers and certifiers with limited resources. Performance standards promote innovation and the development of new technologies which would help the industry as a whole be more efficient. Finally, they provide a less costly means of compliance than design standards. Small entities, in particular, benefit because compliance with performance standards allows for the adaptation of existing systems without costly capital investment.

The proposed rule allows for flexibility by providing a range of farming and handling practices that can be used when necessary to maintain the organic integrity of the operation. The use of a practice or substance that is allowable only when necessary must be described in the organic plan, as set forth in section 205.205 of subpart D of this proposed regulation, as a record for consideration by the certifier during a certification review. The benefit in providing a range of practices is that a farmer or handler would not lose their investment in an organic operation because of certain conditions, such as adverse weather or commercial unavailability. This is especially important to small farmers and handlers who depend on the organic price premium to a greater extent than larger firms.

Section 2107(a)(10) of the OFPA (7 U.S.C. 6506(a)(10)) authorizes the collection of reasonable fees from farmers, handlers, and certifying agents who participate in the national organic program. When developing this proposed rule, two alternative fee models were considered. The fee for direct services model proposed in sections 205.421 through 205.424 of this proposed regulation combines a fixed fee for all farmers, handlers and certifiers with a variable fee for certain direct services provided by AMS in the accreditation of certifiers. The second model considered, but not used in this proposal, was the fee per certification model which would have based accreditation fees on the numbers of farmers and handlers certified.

The fee for direct services model proposes to distribute program costs for services to certified farmers and handlers through fixed fees of $50 and $500, respectively. The difference between farmer and handler fees is designed to account for the greater overhead and staff time devoted to handler and processed product issues as compared to farmer and raw product issues. A more extensive explanation of farmer and handler fees is provided in the **SUPPLEMENTARY INFORMATION** section entitled ''Fees''. Additionally in this model, certifiers would be required to pay a fee of $640 when applying for accreditation and submitting annual reports to cover staff time needed to

process the application or review the report, and an annual administrative fee of $2,000 for program costs that cannot be allocated to a specific certifier. The balance of accreditation costs would be billed to certifiers on a time rate for direct services. A certifier would have to collect sufficient funds from the farmers and handlers it certifies to cover these program fees. Due to the fixed components of the fees in this model, large farmers and handlers, as well as large certifiers, would have the ability to spread their costs over a larger base and, consequently, lower their fixed costs per unit.

Under the fee for direct services model, labor hours, travel, and per diem costs for the site inspections required for accreditation would be included in the variable fee for direct services. AMS estimates the average cost to conduct an accreditation site visit to be $3,500 per visit. The travel cost component of this figure would vary based on the certifier's distance from Washington, D.C., because site visits would be conducted by the National Organic Program staff working away from program headquarters. An alternative method of distributing travel costs would be to estimate an average annual cost per trip, given the expected number of trips and the geographic distribution of certifiers, and charge that amount for all site visits regardless of location.

The advantage of the fee for direct services model is that it incorporates a measure of size in the fee structure, i.e., the time spent on each accreditation by National Organic Program staff. The variable portion of the fee would distribute program costs among certifiers according to the resources actually consumed in providing the accreditation service. The disadvantage of this model is that it introduces a source of variation in fees for which the derivation is not wholly transparent or predictable. With several National Organic Program staff conducting accreditation evaluations, a complaint about the efficiency of an individual accreditation would be difficult to resolve on the basis of objective measures.

Under the fee per certification model that we did not use in this proposal, in which certifiers would pay a fee to the USDA for each certification performed, the smallest one half of certifiers, who certify about 10 percent of organic operations, would pay about 10 percent of the estimated costs associated with accreditation. The largest 10 percent of certifiers, who certify about 45 percent of organic operations, would pay about 45 percent of accreditation costs. The remaining 40 percent of certifiers in the middle would pay 45 percent of the costs. The fee per certification would be fixed, regardless of the size of the operation being certified. This feature has the potential to create a barrier to market access for the smaller operations. Certifiers who charge farmers and handlers for certification based on size and scope of the operation would maximize their profits by certifying only the larger farmers and handlers from whom they would realize a higher return. If certifiers were to discriminate in this manner in favor of larger operations, smaller farmers and handlers would find the certification services available to them to be relatively limited and possibly more expensive than under the fee for direct services model that includes a variable fee for site visits. A fixed fee per certification also would not take into account, in the distribution of costs, the large difference in size between processors and primary producers. Processors are generally much larger than primary producers in terms of both total output and total revenue.

Even with the flexibility proposed in the regulation and the expanded market opportunities brought about by implementation of the National Organic Program, some small organic certifiers, farmers and handlers may choose not to continue because of the proposed fees. We invite comments concerning the expected benefits and costs to small entities as presented in this analysis.

**Paperwork Reduction Act of 1995**

This proposed rule contains recordkeeping and submission requirements that are subject to public comment and to review by the Office of Management and Budget under the Paperwork Reduction Act of 1995 (44 U.S.C. 3506 and 3507). Therefore, in accordance with 5 CFR Part 1320, we are providing a description of the reporting and recordkeeping requirements and an estimate of the annual burden on the organic industry. The proposed requirements would not become effective prior to OMB approval.

*Title:* National Organic Program.

*OMB Number:* New collection.

*Expiration Date of Approval:* Three years from date of approval.

*Type of Request:* New.

*Abstract:* The information collection requirements in this proposed regulation are essential to carry out the mandate of the Organic Foods Production Act of 1990 (OFPA or Act). The OFPA requires the Secretary of Agriculture to establish and implement a program to accredit a governing State official, or any private person, who meets the requirements of the Act and the proposed regulations, as a certifying agent for the purpose of certifying a farm, wild crop harvesting, or handling operation as being in compliance with the standards set forth in the Act and this proposed regulation. After implementation of the National Organic Program, any agricultural product labeled as organic or made with certain organic ingredients would have to originate from an operation that is certified by an accredited USDA certifier.

The OFPA requires certified farms, wild crop harvesting operations and handling operations to maintain records for 5 years and certifying agents to maintain records for 10 years. The OFPA exempts from certification farm operations with gross agricultural sales of less than $5,000, and the proposed regulation also exempts handling operations with gross agricultural sales of less than $5,000. We propose that each exempt operation would be required to maintain records for one year that verify that such sales are less than $5,000. We also propose that operations that handle only multi-ingredient agricultural products that only represent the organic nature of ingredients in the ingredients statement would not have to be certified. These operations would be required to maintain records for one year that verify the source of organic products received and the operations to whom final organic products are sold. The OFPA also exempts from certification any retail operation, or portion of a retail operation, that only handles organically produced agricultural products, but does not process them. The exemptions and exclusions from certification requirements proposed in this regulation are discussed in the supplementary information provided for section 205.202 of subpart D.

Other information collection requirements proposed in this regulation include: petitioning the NOSB to review a substance for inclusion on the National List; developing labels; preparing inspector and peer review panel reports; documenting methods to prevent commingling of organic with non-organic products; notifying the proper authority in the case of non-compliance with the regulations or the possible violation of food safety laws; and submitting State organic certification programs to the Secretary for approval.

The USDA conducted extensive research while developing this proposed regulation so as to minimize disruption to the customary and usual business practices of certifiers, farms, wild crop harvesting operations and handling

operations. The research included consultation with administrators of existing certification agencies; a review of certifiers' publications, recordkeeping forms, and business characteristics; discussions at meetings with State and private certifiers about their concerns regarding accreditation; communications with the organic industry trade association; and a review of the National Organic Standards Board recommendations that were presented to the Secretary after extensive public input. This research helped us determine that certifiers conduct their certification of farms, wild crop harvesting operations and handling operations in a similar manner and have similar recordkeeping systems and business operating practices. We also determined that most of the information we would require to conduct accreditation could be collected from certifiers' existing materials without creating new forms, and that the information currently used by certifiers to certify farmers, wild crop harvesters and handlers could be adapted to comply with this proposed regulation.

We are required under the PRA to report the amount of time necessary for participants to comply with the proposed regulation as if there were no previously existing documents. The PRA requires that our total reporting (creation and submission of documents) burden cover the greatest amount of reporting burden that might occur for any single creation or submission of a document during any one of the first three years following program implementation, i.e: 1999, 2000, and 2001. Therefore, our total estimated reporting burden reflects the greatest possible burden for each reporting activity that might occur during this three year period. We also are required by the PRA to measure the recordkeeping burden. The recordkeeping burden is the amount of time needed to store and maintain records. For the purpose of measuring the recordkeeping burden for our proposed rule, we use the burden for the year 2001, the reporting year for which we estimated that the largest number of records might be stored and maintained.

The USDA estimated the number of program participants who would be required to either create, submit, or store documents as a result of the proposed rule. To determine the number of organic farmers and handlers, we conducted an analysis of existing certified organic farmers and handlers in the United States for 1994, (Dunn, Julie Anton. 1995. ''Organic Food and Fiber: An Analysis of 1994 Certified Production in the United States.'' U.S. Department of Agriculture, Agriculture) and examined an analysis of data collected for the California Department of Food and Agriculture Organic Program concerning registered organic farms and handling operations in that state (Klonsky, Karen, and Laura Tourte. September 1995. ''Statistical Review of California's Organic Agriculture, 1992–93''. Cooperative Extension, Department of Agricultural Economics, University of California, Davis). Our analysis indicated that an estimated 4,000 farms and 600 handling operations were certified by 33 private and 11 State certifiers. The data collected in the USDA analysis indicated that the number of certified organic farmers increased at an average rate of 12 percent in the period from 1991 to 1994, and the number of certified organic handlers increased at an average rate of 11 percent over the same 3 years. Based on this rate of growth, we estimate that 7,049 farmers and 1,011 handlers will seek certification in the year 1999 and that these numbers would increase to 8,843 farmers and 1,245 handlers in the year 2001. We also estimate, based on our inquiries to existing certifiers, that in the year 1999: 50 percent of certified organic farms will include livestock, 25 percent of certified organic farms and 75 percent of certified organic handling operations will be split operations, and 150 wild crop harvesting operations will seek certification.

Data from the California Department of Food and Agriculture study indicated that 50 percent of registered organic farmers in California had incomes below $10,000 in 1994. For the purposes of this burden analysis, we estimated for the year 2001 that 25 percent of all organic farmers and handlers would have an income of less than $5,000 from the sale of agricultural products and, therefore, would be exempt from certification. Based on our estimated rate of growth for organic farmers and handlers, we anticipate that there would be a total of 11,788 non-certified and certified organic farms and a total of 1,660 non-certified and certified organic handling operations in the year 2001. Of these farms and handling operations, we estimated that 25 percent (2,947 farms and 415 handling operations) could be exempt from certification. As proposed in this regulation, each exempt operation would be required to maintain records to verify that its gross sales of agricultural products is below $5,000. We request data and public input that would assist us to better determine the percentage of certified organic farms with livestock and the percentage of certified operations that may be split operations, the percentage of organic farms and handling operations that may be exempt from certification because they have sales less than $5,000, and the number of wild crop harvesters.

Our inquires to several existing certifiers indicated that of the total number of operations seeking certification, approximately 5 percent of farms and handling operations are denied certification; most of the farms and handling operations denied certification received certification after they reapply. Additionally, approximately 25 percent of certified operations were identified by certifiers during an annual review as having some deficiency; most of these operations retained their certification status.

Other than farmers and handlers, we have made burden estimates for other entities who will create, submit or maintain records as a result of the proposed National Organic Program. For instance, we expect to receive 5 petitions annually for substances to be reviewed by the NOSB for inclusion on the National List. We estimated a low number of petitions because prior to proposing the National List the NOSB researched and determined which substances are currently in use in the organic industry, and because the NOSB itself will be identifying new substances for inclusion on the National List.

We also estimated the time spent to develop product labels for products sold, labeled, or represented as organic or made with certain organic ingredients, or which use the term organic to modify an ingredient in the ingredients statement. The time spent deciding about use of the USDA seal, a State emblem, or the seal of a private certifier also is included in this burden. Our research indicated that operations using product labels containing the term organic handle an average of 19.5 product labels. Additional research indicated that there are currently about 16,000 products with the term organic used on the product label and that the number has been increasing by 250 products annually, based on marketing data from 1994, 1995 and 1996. We estimate, therefore, that by the year 2001, 17,000 products will be marketed with the label term organic.

Regarding operations that handle products that only represent the organic nature of ingredients in an ingredients statement, or that handle prepackaged organic products and do not remove them from the packaging (such as a warehouse or terminal market), the proposed rule contains certain recordkeeping requirements in addition to the requirement to document the procedures to prevent the commingling

of organic with non-organic products and the exposure of organic products to prohibited substances. These recordkeeping requirements are that documentation is to be maintained for 1 year to verify the source and quantity of organic products received and to verify the destination and quantity of products shipped from the operation. At this time, we do not have information as to the number of such operations, nor can we identify a means of collecting this information. We request public input to assist us in determining the number of such operations.

We estimated that the number of certifying agents would remain constant during the years 1999, 2000, and 2001 because our research indicates that the total number has remained unchanged since 1994. Although we predicted in the Regulatory Flexibility Analysis that some of the smallest entities may cease operation as a result of the NOP, we know of new certifying agents that have begun certifying operations, and others who intend to begin so after implementation of the NOP. We also know of existing certifiers who have ceased their operations. We further estimated that the number of organic inspectors would increase by the year 2001. We based this estimate on information obtained from a private organic inspector organization which indicated that each inspector performed approximately 35 inspections in 1996. Using this average of 35 inspections per inspector, we estimate that 293 inspectors would be required in the year 2001 to inspect the estimated 10,238 operations to be certified.

The proposed regulation has certain requirements for laboratory testing of products that are produced on certified organic farms or wild crop harvesting operations and handled through certified handling operations. These tests would be required to be conducted of certified operations not less frequently than every five years; therefore, approximately 20 percent of the total number of certified operations would have products tested each year. Based on our estimate that 10,238 operations would be certified in the year 2001, we estimate that 2,048 operations would have products tested in that year. Other residue testing may be conducted randomly of products at any point of production or distribution. Pre-harvest tissue testing is proposed to be conducted of crops grown on soil suspected of harboring a contaminant. We estimate that certifiers would be required to collect a combined total of 32 samples as part of this random and pre-harvest testing, and would report violations of food safety laws to the appropriate health agencies in 10 instances. We also propose that producers, handlers, and wild crop harvesters report to their certifier any instance of an application of a prohibited substance. We estimate that 25 such instances would be reported to a certifier.

We estimate that approximately 30 foreign programs would submit their programs to USDA in the year 1999 for review in order to seek equivalency with the NOP. These programs are important to handlers of multi-ingredient organic products, especially for the spices and flavoring agents that cannot be produced in the U.S. We also estimate that 15 approved foreign programs would be reviewed again by the Secretary for continued equivalency in the year 2001 and that 5 approved programs would submit substantive program amendments to the Secretary also in the year 2001.

ESTIMATED ANNUAL REPORTING BURDEN

| Burden element | Respondents | Number of responses | Average hours per response | Total hours | Total cost |
|---|---|---|---|---|---|
| Monitor for measurable degradation of soil and water. | Farmers/handlers, harvesters. | 2,560 | 4.00 | 10,238.00 | $102,380 |
| Petition to add to the National List | Interested parties | 5 | 10.00 | 50.00 | 500 |
| Development of a label | Farmers/handlers, harvesters. | 17,056 | 2.00 | 34,113.00 | 682,260 |
| Application for certification | Farmers/handlers, harvesters. | 8,210 | 1.00 | 8,210.00 | 82,100 |
| Farm organic plan (crops) [1] | Farmers | 7,049 | 14.75 | 103,972.75 | 1,039,730 |
| Farms with livestock [2] | Farmers | 3,525 | 3.00 | 10,575.00 | 105,750 |
| Split farms [2] | Farmers | 1,762 | 2.50 | 4,405.00 | 44,050 |
| Wild crop organic plan | Harvesters | 150 | 9.50 | 1,425.00 | 14,250 |
| Handler organic plan | Handlers | 1,011 | 13.00 | 13,143.00 | 131,430 |
| Handler split operation [2] | Handlers | 759 | 5.00 | 3,795.00 | 37,950 |
| Statement of compliance to USDA regulations | Farmers/handlers, harvesters. | 8,210 | 0.50 | 4,105.00 | 41,050 |
| Inspector report | Inspectors | 10,240 | 4.00 | 40,960.00 | 409,640 |
| Determination of certification status [3] | Certifying agents, farmers/handlers, harvesters. | 8,254 | 1.24 | 10,209.10 | 102,090 |
| Annual continuation of certification | Farmers/handlers, harvesters. | 10,238 | 3.78 | 38,648.70 | 386,490 |
| Notification to certified operation of non-compliance | Certifying agents | 2,561 | 2.23 | 5,711.44 | 114,220 |
| Certifying agent notification of Administrator [4] | Certifying agents | 12,769 | 0.85 | 10,848.20 | 216,960 |
| Accreditation requirements (other than record-keeping) [5]. | Certifying agents | 8,272 | 03.06 | 25,344.00 | 506,880 |
| Accreditation application | Certifying agents | 44 | 1.67 | 73.50 | 1,480 |
| Evidence of ability to certify | Certifying agents | 44 | 23.28 | 1,024.50 | 20,500 |
| Statements of agreement | Certifying agents | 44 | 0.69 | 30.25 | 600 |
| Peer review panel [6] | Panel members, certifying agents. | 72 | 11.00 | 792.00 | 15,840 |
| Annual continuation of accreditation | Certifying agents | 44 | 10.36 | 456.00 | 9,120 |
| Transfer of records to Secretary | Certifying agents | 2 | 40.00 | 80.00 | 1,600 |
| Suspended certifying agent submits new application | Certifying agents | 1 | 16.00 | 16.00 | 320 |
| State program application | State officials | 11 | 42.73 | 470.00 | 9,400 |
| Periodic sampling for compliance | Certifying agents | 2,048 | 3.00 | 6,144.00 | 122,880 |

ESTIMATED ANNUAL REPORTING BURDEN—Continued

| Burden element | Respondents | Number of responses | Average hours per response | Total hours | Total cost |
|---|---|---|---|---|---|
| Additional sampling and residue testing | Certifying agents | 22 | 3.00 | 66.00 | 1,320 |
| Report residue and pre-harvest test results | Certifying agents | 20 | 0.50 | 10.00 | 200 |
| Report application of prohibited substances | Certifying agents, farmers/handlers, harvesters. | 25 | 0.15 | 3.75 | 80 |
| Equivalency of foreign programs | Foreign program officials | 30 | 128.33 | 3,850.00 | 77,000 |
| Total | | | | 338,771.00 | 4,278,034 |

[1] We do not have information to estimate the number of livestock operations that do not produce crops; therefore, it is not possible to estimate the burden hours for such an operation.

[2] Estimated hours for farms with livestock and split operations are in addition to the hours needed to complete a farm plan for crops or a handler plan.

[3] Respondents in the determination of certification status include 44 certifying agents who determine to grant or deny certification to 8,210 applicants. The time elements include the exchange of information necessary for a certifying agent to decide whether to grant or deny certification, issuance of a certificate, and notification of the Administrator when certification is denied and when applicants do not reapply.

[4] Notification of certification status includes notification of the Administrator by the certifier of both the operations that have been certified and those operations not in compliance. We estimate that about 25 percent of all operations will not be in compliance, and would be granted a continuation of certification with restrictions.

[5] The burden elements accounted for in this entry are not mentioned in other sections of the proposed rule. These include the time necessary to provide information to persons seeking certification and to establish a State or certifying agent logo, seal or identification.

[6] We estimate that 72 persons (50 peer review pool members and 22 certifying agents) would participate in the peer review panel process.

ESTIMATED ANNUAL REPORTING BURDEN

| Burden element | Respondents | Number of responses | Average hours per response | Total hours | Total cost |
|---|---|---|---|---|---|
| Exempt and excluded operations | Farmers/handlers, harvesters. | 3,362 | 1.00 | 3,362.0 | $33,620 |
| Production records | Farmers/handlers, harvesters. | 10,238 | 3.41 | 34,905.5 | 349,055 |
| Certification records | Certifying agent | 44 | 3.00 | 132.0 | 2,640 |
| Total | | | | 38,399.5 | 385,315 |

*Annual Reporting and Recordkeeping Burden:*

*Estimated number of respondents:* 13,967.

*Total annual hours:* 377,171.

*Total Cost:* $ 4,663,349.

It is important to note that the burden being reported is an estimate of the amount of time that would be required of program participants. It is not a measurement of the burden that would be required of existing certifying agents and currently certified farmers, harvesters and handlers in addition to the reporting and recordkeeping activities that they currently perform. In writing the proposed regulation, we carefully reviewed existing industry practice and made every effort to incorporate the documents and practices currently being used within the industry as a means of minimizing reporting and recordkeeping costs when the program begins full operation.

The USDA encourages farmers, handlers and certifiers to use any electronic means available to them to create, submit and store records, including: keeping data base records of crops or livestock produced on operations that are certified; lists of farm and handling operations and their location; creating certification or training documents; maintaining business accounting records; and sending documents by fax or over the Internet. Research of the industry indicates that most certifiers use electronic data creation and storage, fax machines, and the Internet. Some farm and handling operations use computers and word processors for their recordkeeping. Based on this information, we estimated that 25 percent of the collection of information would be performed by automated, electronic, mechanical, or other technological means. We request comments to help assess the number of organizations using computers, word processors, and other electronic equipment to create and store documents, as well as the extent to which the Internet is used to exchange information.

Additionally, comments are invited on: (1) whether the proposed collection of information is necessary for the proper performance of the functions of the USDA, including whether the information would have practical utility; (2) the accuracy of the USDA'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 those who are to respond, including the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology. Comments should be sent to: Office of Management and Budget, New Executive Office Building, 725 17th Street, N.W., Room 725, Washington, DC 20503, Attention: Lisa Grove, Desk Officer. Comments also should be sent to: Don Hulcher, Clearance Officer, USDA–OICO, Room 404W, Jamie Whitten Building, Ag Stop 7602, P.O. Box 96456, Washington, DC 20090–6456. Additionally, comments may be sent by fax to (202) 690–4632 or submitted via the Internet through the National Organic Program's homepage at: http://www.ams.usda.gov/nop.

Comments are best assured of having full effect if they are received within 30 days after publication of the proposed rule in the **Federal Register**.

**National Organic Program Overview**

Pursuant to the OFPA, this rule proposes regulations for the production, handling and marketing of organically produced agricultural products and for the management of the National Organic Program. The major components of the national organic program are summarized below. A reference to the placement of the regulatory text of the summarized topic is entered at the end of each program component's summary.

*Definitions:* Various terms used in the proposal are defined to ensure that regulatory requirements that must be met are clear. Subpart A.

*Production and handling requirements:* The OFPA requires that national standards be established for the organic production and handling of agricultural products. Agricultural products are any agricultural commodity, whether raw or processed, including any commodity or product derived from livestock that is marketed in the United States for human or livestock consumption. To establish consistent national standards for organic production and handling of agricultural products, this proposed rule provides for the implementation of a system of organic farming and handling that is consistent with the provisions of the OFPA. The standards proposed would apply to the production of crops and livestock and the harvesting of wild crops, and to fresh or processed agricultural products that are, or that are intended to be, sold, labeled, or represented as organically produced or as containing organic ingredients.

The proposed regulation provides for flexibility in the application of the proposed national organic standards and takes into account specific conditions that may occur at different production and handling sites. Under the proposal, each organic farmer and handler would be required to develop an organic plan for their operations. The plan would be evaluated and approved by an accredited certifying agent if it were determined to meet the requirements of the OFPA and the regulations promulgated under the OFPA. The performance of each farmer and handler in meeting the approved practices in their organic plans would be monitored by their certifiers. Subpart B.

*National List:* This proposal includes a National List of allowed synthetic substances that can be used, and provides for the development of a list of non-synthetic substances that cannot be used, in the production and handling of organically produced agricultural products. The NOSB provided recommendations to the Secretary with regard to synthetic substances it believed should be permitted to be used and the non-synthetic substances it believed should be prohibited for use. The Act establishes the criteria that must be considered before a synthetic substance can be placed on the National List of substances approved for use, and criteria that must be considered before a non-synthetic substance can be placed on the National List of substances prohibited for use. A procedure for petitioning the Secretary and the NOSB to have changes made to the National List of substances approved or prohibited for use is incorporated in the proposed regulations. Subpart B.

*Labeling:* This rule proposes regulations for the label, labeling, and market information for organically produced agricultural products. The proposal applies to agricultural products that contain various percentages of organic ingredients. The proposal also provides for the use of the USDA organic seal, States' organic seals, and a certifying agent's name, seal or logo, under certain conditions. Subpart C.

*Certification:* The proposed rule provides the requirements and procedures for farms, wild crop harvesting operations, and handling operations applying for organic certification under the NOP. The proposed rule would permit Indian tribes that as an entity operate a farm, a wild crop harvesting operation, and/or a handling operation, as well as individual tribal members who carry out such operations, to apply for organic certification for these operations. The application process for certification and the requirements that must be met to obtain certification, including the submission of an organic plan, are in the proposed regulations. The proposed regulations provide, in accordance with the Act, that the determination of whether a farm, wild crop harvesting, or handling operation should be certified as an organic farm, wild crop harvesting, or handling operation, would be made by certifying agents accredited by the Secretary. If a certifying agent initially determines that certification should not be granted, the proposed rule allows the applicant for certification to reapply under certain conditions. Additionally, the proposed rule provides for the denial of an application for certification and the termination of certification. It also provides for notice of these actions to the applicant or certified operation and an opportunity for the applicant or certified operation to respond to the notice prior to the denial or termination action. Subpart D.

*Accreditation:* This proposed rule establishes an accreditation program for persons who want to be accredited as a certifying agent. Persons who could become accredited if they meet the OFPA's requirements for accreditation would include Indian tribes or individual tribal members. Accredited certifying agents would be authorized to certify operations that meet the requirements of the OFPA and the regulations in part 205 as certified farms, certified wild crop harvesting operations, and certified handling operations. State governing officials and private persons may apply for and be accredited by the Secretary as certifying agents. Qualifications needed to obtain and to maintain accreditation are specified in the proposed rule. Procedures for denying, terminating, and suspending accreditation also are proposed. Subpart E.

*State organic programs:* This proposal permits States to establish or continue to operate their own organic programs, provided that the program reflects the requirements of the OFPA and its implementing regulations, and is approved by the Secretary.

In order for a State program to be approved as meeting the general requirements set forth in section 2107 of the OFPA (7 U.S.C. 6506), the program must have regulatory provisions that meet the following requirements: (1) provide that an agricultural product to be sold or labeled as organically produced must be produced only on certified organic farms and handled only through certified organic handling operations in accordance with the OFPA's requirements and be produced and handled in accordance with such program; (2) require that producers and handlers desiring to participate under such program establish an organic plan as provided for in section 2114 of the OFPA (7 U.S.C. 6513); (3) provide for procedures that allow producers and handlers to appeal an adverse administrative determination under this Act; (4) require each certified organic farm, certified organic wild crop operation, and each certified organic handling operation to certify to the governing State official, on an annual basis, that such farmer or handler has not produced or handled any agricultural product sold or labeled as organically produced except in accordance with this title; (5) provide for annual on-site inspection by the certifying agent of each farm, wild crop

harvesting, and handling operation that has been certified under the OFPA requirements; (6) require periodic residue testing by certifying agents of agricultural products that have been produced on certified organic farms and handled through certified organic handling operations to determine whether such products contain any pesticide or other nonorganic residue or natural toxicants and to require certifying agents, to the extent that such agents are aware of a violation of applicable laws relating to food safety, to report such violation to the appropriate health agencies; (7) provide for appropriate and adequate enforcement procedures; (8) protect against conflicts-of-interest; (9) provide for public access to certification documents and laboratory analyses that pertain to certification; (10) provide for the collection of reasonable fees from producers, certifying agents and handlers who participate in the program; and (11) require such other terms and conditions as may be determined by the Secretary to be necessary.

Once a State program is approved, farm, wild crop harvesting, and handling operations in that State that wish to sell, label, or represent their product as organically produced would have to be approved as a certified operation under the State program. The determination as to whether or not a farm, wild crop harvesting, or handling operation meets a State's certification requirements would be made by an agent accredited by the USDA under the National Organic Program. The accredited agent who would make this determination either can be a private person who has been accredited by the USDA or a governing State official who has been accredited by the USDA.

In order to be certified under the State program, an operation would have to meet the State certification requirements. These certification requirements, as discussed previously, must reflect the requirements in the National Organic Program. Thus, certified operations in States that have their own program would be producing products that are represented as organically produced in accordance with the requirements of the National Organic Program that have been included in the State program, in accordance with section 2107 or the OFPA (7 U.S.C. 6506). Therefore, the provisions set forth in our proposal in part 205 would be applicable to operations that are located in States that have their own programs since these provisions would be included in programs that are approved by the Secretary.

States, however, could have requirements that are in addition to those of the NOP if they are approved by the Secretary and meet the statutory criteria for approval. This means that if a State has applied for, and received, approval from the Secretary for requirements in its program that are in addition to those in the NOP, farm, wild crop harvesting, and handling operations that operate in that State would have to comply with these additional requirements that have been approved. However, a State would not be allowed to require farm, wild crop harvesting, and handling operations in other States to comply with any additional requirements that the Secretary has approved for use by that State.

*Fees:* The proposed rule establishes a system of fees to be paid by farmers, wild crop harvesters, handlers, and certifying agents based on the services provided to them by the USDA. The fees collected from applicants for accreditation and from accredited certifying agents would be for reviewing applications and annual reports, performing administrative services for the benefit of all accredited certifying agents, and for conducting site evaluations to evaluate the certifying agent's performance. The fees collected from farmers, wild crop harvesters, and handlers would be assessed as a fixed fee for each category. Farmers, wild crop harvesters, and handlers operating under a State organic program would pay fees directly to USDA. Subpart F.

*Compliance review and other testing:* This proposal establishes a system for sampling and testing organically produced and handled products. It provides for pre-harvest tissue testing and residue testing to aid in enforcement of the regulations. Subpart F.

*Appeals:* The OFPA provides for the Secretary to establish an expedited administrative appeals procedure under which persons may appeal an action of the Secretary or a certifying agent under this title that adversely affects such person or is inconsistent with the organic certification program established under this title. This proposal provides a procedure for the appeal of these actions. Subpart F.

*Equivalency of imported organic products:* This proposal, in accordance with the OFPA, permits organic products produced and handled in foreign countries to be imported into the United States, and represented as organically produced, under certain conditions. These products would have to be produced and handled under an organic certification program that provide safeguards and guidelines that are at least equivalent to the requirements of the OFPA and the National Organic Program. Under this proposal, the Secretary would review and approve, if equivalent, the foreign organic programs. Subpart F.

*Subpart A—Definitions*

A number of the definitions provided in this proposed rule are terms defined in the Act, and for these definitions we have used the language provided in the Act. Some definitions are discussed in other parts of the supplementary information and other definitions provided are self-explanatory. However, for certain definitions, we have discussed below our reasons for establishing these definitions to help ensure that appropriate and consistent procedures are followed in complying with other requirements proposed here.

*Active ingredient* is a term found in section 2118(c)(1)(B)(i) of the OFPA (7 U.S.C. 6517(c)(1)(B)(i)). This section describes categories of substances that may include active synthetic ingredients that may be considered to be included on the National List. Although the Act does not specifically define the term active ingredient, EPA does define this term in section 2(a) of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) (7 U.S.C. 136(a)), as amended. The EPA defines the term active ingredient to be pesticides, herbicides, and other substances covered by the FIFRA. We have included the EPA definition of active ingredient as one of our definitions for this term, i.e., the definition that covers active ingredients in pesticide formulations.

The EPA definition, however, does not cover the full scope of all active synthetic substances that the Act would authorize for inclusion on the National List. Therefore, our other proposed definition for active ingredients, ''active ingredients in any input other than pesticide formulations'', covers these other substances. One type of substance that is included in this definition of active ingredient is a substance used in any aspect of organic production or handling that becomes chemically functional within an agroecosystem. A chemically functional substance is one that would be absorbed by plants or that would affect soil chemistry when used as permitted under this proposal, such as a micronutrient or a cation balancing agent. Substances or materials that do not fit this description, such as plastic mulches, sticky barriers or row covers, thereby would not be considered as

active ingredients under this definition. Our proposed definition also covers substances required to be listed as ingredients or additives on food labels, but it does not include incidental additives and processing aids that are not required to be listed on food labels.

The *agroecosystem* is a term that encompasses all the elements of a system of organic farming and handling, and as such is the primary focus of the proposed organic crop and livestock production standards. Section 2119(m)(5) of the OFPA (7 U.S.C. 6518(m)(5)) specifically indicates that the effects of a substance on the agroecosystem is a criterion that must be evaluated before a synthetic substance can be included on the National List of substances allowed for use.

*Biodegradable* refers to a specific quality of a material or substance that is used on or applied to the soil that makes the material or substance susceptible to biological decomposition. Most biodegradable materials are organic matter obtained from plant or animal sources. A material such as plastic that is not biodegradable will resist decomposition and persist in the soil, and may enter into unknown chemical interactions with soil and water. While chemical degradation of non-biodegradable materials into simpler compounds eventually occurs, this process happens very slowly compared to biological decomposition. The use of non-biodegradable materials as production inputs is considered to be incompatible with a system of organic farming or handling because they may leave residues of synthetic substances in the soil.

*Chapter* is defined here with reference to our proposal for the accreditation of certifying agents in subpart E. We are aware of two existing certifying agents that each operate as a single certification body through a system of chapters. We believe that this is an acceptable practice. Such chapters would, however, be expected to comply with the Act and the regulations in this part.

*Commercially available* is a term that was the subject of extensive deliberation by the NOSB, and our proposed definition reflects their recommendation. We believe that this definition is essential in order for producers and handlers to make appropriate decisions about whether it is necessary to use certain materials, such as the use of non-organically produced planting stock or livestock feed. It also is necessary to help certifying agents evaluate whether the use of such materials is justified or should be discontinued.

*Contaminant* is a term used in section 2112(b) of the OFPA (7 U.S.C. 6511(b)) with reference to substances that persist in the environment, that may be suspected to be present in soil, and which may necessitate a preharvest tissue test of crops grown on that soil to determine the level of the contaminant in an organically produced crop.

*Cytotoxic mode of action* is used in sections 205.9(f) and 205.21(a) of subpart B to describe the activity of a type of synthetic substance that is prohibited for use in organic production. Substances of this type chemically interact with plant and animal cells and interfere with normal cell functions. Our definition describes synthetic substances that are cytotoxic and that, therefore, would be prohibited for use.

*Degradation* is defined to allow organic producers, handlers and certifying agents to accurately identify when the use of a practice or substance that is otherwise permitted under this proposal should be ended or modified. This would occur when it results in measurable degradation of soil or water quality. For example, if nitrate levels in an adjacent well are found to increase over two or more crop years following application of a highly soluble mined source of nitrogen to soil, as set forth in proposed section 205.7 (c)(2) of subpart B, then the practice would have to be terminated or modified to prevent further adverse effects on water nitrate levels.

*Detectable residue level* (DRL) is proposed for the purposes of this part as being a residue of a pesticide or other prohibited substance that is five percent or greater than the established EPA tolerance level for the product that was tested, provided that if there is no tolerance level established but an action level has been established, the DRL will be the action level established by the FDA for the product tested. EPA tolerance levels, expressed in terms of parts of a pesticide residue per million parts of the food (ppm), refer to the amount of a pesticide residue that may be present in or on a raw agricultural commodity, processed food or processed feed. These tolerance levels are listed in 40 CFR Part 180 (raw agricultural commodities), Part 185 (processed foods) and Part 186 (processed feed). The FDA action levels are used to regulate the occurrence of very low levels of pesticide residues that result from the persistence of a pesticide in the environment and for which there is no tolerance level established by EPA. The action levels for certain pesticides found as residues in agricultural commodities, processed foods or processed feeds are listed in the FDA publication entitled ''Action Levels for Poisonous or Deleterious Substances in Human Food and Animal Feed.'' Certain pesticide residues may not be detectable by available residue testing techniques at a level as low as five percent of the EPA tolerance level; in these cases, we would consider the detectable residue level to be the lowest level measurable by available techniques.

The purpose of defining the DRL at the proposed levels is to establish a practical level for determining when to conduct an investigation, as required in section 2112(c)(2)(B) of the OFPA (7 U.S.C. 6511(c)(2)(B)), to determine when a residue is the result of an intentional application or when it is justified by site-specific unavoidable residual environment contamination due to the persistence of the detected substance. The proposed DRL should help eliminate unnecessary investigations and test procedures and is within the range of tolerance levels developed by existing State and private organic programs. As discussed with reference to unavoidable residual environmental contamination, the Secretary would establish on a case by case basis the residue levels which would indicate that a prohibited substance had been intentionally applied.

*Fertilizers* are addressed in section 2109(b)(1) of the OFPA (7 U.S.C. 6508(b)(1)), which prohibits the use in organic production of fertilizers that contain synthetic ingredients or any commercially blended fertilizers that contain prohibited substances under the Act or a State program. Although the Act does not define the term fertilizers, we have proposed a definition in order to clarify the kinds of synthetic soil amendment substances that may be considered for inclusion on the National List. Our proposed definition of fertilizers is consistent with those used by various State agencies that regulate the labeling of fertilizers, and refers to materials that supply the major plant nutrients nitrogen, phosphorus and potassium. Synthetic mineral substances, such as micronutrients and cation balancing agents, which do not supply quantities of the three major plant nutrients, would not be considered fertilizers under this definition and could, therefore, be considered for inclusion on the National List because they are not prohibited under section 2109(b)(1) of the OFPA (7 U.S.C. 6508(b)(1)).

*Incidental additive* is defined so that handlers clearly know that the substances included in this category may be used in handling organic

products, even though the incidental additive itself may not be included on the National List.

*Inert ingredient* refers to any substance or group of structurally similar substances if designated by the EPA, other than an active ingredient that is intentionally included in a pesticide or formulated product. Inert ingredients used in pesticides are specifically regulated by EPA and have been classified by EPA with respect to their relative toxicity. This EPA classification of inert ingredients is referred to in Section 2118(c)(1)(B)(ii) of the OFPA (7 U.S.C. 6517(c)(1)(B)(ii)) and has been used in this proposal to indicate the types of inert ingredients that may be used in any pesticide product allowed for use on a certified farm or handling operation.

However, the EPA definition does not cover the full scope of inert ingredients that may be used in formulated products allowed for use in organic farming. Our proposed definition of this term also includes inert ingredients intentionally included in any product used in organic crop production, such as fertilizers or foliar sprays.

*Non-agricultural ingredient* is a term we use in various sections of this proposal to delineate the type and category of substances allowed for use as ingredients in or on organically produced agricultural products if the substance is included on the National List in section 205.26 of subpart B. As discussed in the supplementary information section in reference to the National List, we have used this term in order to accurately describe those substances that would satisfy the provisions of section 2118(c)(1) of the OFPA (7 U.S.C. 6517(c)(1)) related to handling.

*Non-synthetic* is a term used throughout our proposal to describe those substances that are not synthetic. As discussed in the supplementary information for the National List, we determined that this term is more appropriate than the word natural, which is not defined in the Act and which has other regulatory and marketing meanings.

*Packaging* is defined here as any material used to wrap, cover, or contain an agricultural product, and also includes wax applied directly to an edible surface of an agricultural product. This definition is proposed in response to the public input that expressed concerns that waxes that contain synthetic fungicides or preservatives may be used on organic products, such as fresh produce or cheese. We believe that this definition is needed to implement the prohibition against the use of packaging materials containing such prohibited substances, as set forth in section 2111(a)(5) of the OFPA (7 U.S.C. 6510(a)(5)), to any material that contacts an edible surface of an organic product.

*Production aid* is any substance, material, device or structure, but not an organism, that is used to produce an agricultural product. A production aid may or may not be synthetic, and may or may not function as an active ingredient. Examples of production aids are provided in section 2118(c)(1)(B)(i) of the OFPA (7 U.S.C. 6517(c)(1)(B)(i)) and include netting, tree wraps and seals, insect traps, sticky barriers, row covers, and equipment cleansers. Any production aid that is determined to be active and synthetic must appear on the National List in either sections 205.22 or 205.24 of subpart B before it may be used in organic farming.

*Putrefaction* is defined in order to clarify the reasons why plant and animal materials that are prone to putrefaction are less preferable for use in proper manuring practice than those materials that are not prone to putrefaction, as proposed in section 205.7 of subpart B.

*Soil quality* is a term that serves as a central performance standard for the use of any method or substance in an organic farming system, in that such use may not result in measurable degradation of soil or water quality, as proposed in section 205.3(b)(1). In order to determine whether a given operation is in compliance with the regulations, farmers and certifiers must have a clear understanding of what soil quality is and how it may be measured. Our proposed definition of this term encompasses physical, chemical and biological soil quality indicators that could readily be measured or observed at a given location. Examples of soil quality indicators commonly measured in organic farming systems include erosion, aggregation, compaction, drainage, organic content, nutrient content, pH, cation balances, presence of contaminants, leaf tissue analysis, presence of indicator weed species, presence of pathogens, earthworm populations, and legume nodulation.

*Subtherapeutic* is a term used in section 2110(d)(1)(A) of the OFPA (7 U.S.C. 6509(d)(1)(A)) to refer to a dosage level of antibiotics that is prohibited for administration to organically managed livestock. Our proposed definition of this term indicates one of the circumstances in which use of an antibiotic is prohibited.

*System of organic farming and handling* is a term used throughout our proposal to refer to the general set of principles and objectives of the Act. This term also serves as the foundation of the organic production and handling provisions proposed here, and is discussed more fully in the supplementary information that introduces Subpart B.

*Unavoidable residual environmental contamination* (UREC) is a term used in section 2112(c)(2)(B) of the OFPA (7 U.S.C. 6511(c)(2)(B)) which we define as the residue level of a prohibited substance that could be expected to exist in the soil at, or in a product originating from, a specific production site to which the prohibited substance had not been applied for a minimum of three years. If a residue test of an organically produced product originating from a specific certified site reveals a detectable residue level of a prohibited substance, then the UREC level for the specific certified site would be determined by the Secretary in consultation with the applicable governing State official, and the appropriate environmental regulatory agency. A product found to contain a detectable residue level exceeding the UREC level for the specific site may not be sold or labeled as organic.

*Subpart B—Organic Crop and Livestock Production and Handling Requirements*

*Introduction*

USDA's proposed requirements for organic farming and handling, encompassed in subpart B, sections 205.3, 205.5 through 205.9, and 205.11 through 205.28, set forth the requirements for organic crop production, wild crop harvesting, organic livestock production, organic handling, and for products and substances allowed and prohibited in organic farming and handling. These requirements are proposed to implement the purposes of the Act as set forth in section 2102 of the OFPA (7 U.S.C. 6501) to establish national standards governing the marketing of organically produced agricultural products; to assure consumers that organically produced products meet a consistent standard; and to facilitate interstate commerce in fresh and processed food that is organically produced. Section 2106 of the OFPA (7 U.S.C. 6505) requires that any agricultural product that is sold or labeled as organically produced be produced and handled in accordance with the standards established under the Act. Section 2118 of the OFPA (7 U.S.C. 6517) requires that a National List of substances approved and prohibited for use in organic farming

and handling established by the Secretary be included in the standards. Active synthetic substances must appear on the National List as approved substances in order to be used in organic production, and a non-synthetic (natural) substance may not be used if it appears on the National List of substances prohibited for use.

We would like to point out that the word substance is used in a variety of ways in this docket. When the word substance refers to a material that meets the OFPA's definition of a synthetic substance, it is described as a ''synthetic substance''. When the word substance refers to a non-synthetic material (i.e., natural material), which is one that does not come within the OFPA's definition of a synthetic substance, it is described as a ''non-synthetic substance.'' When the word substance refers to a material prohibited for use in the organic program, whether it be synthetic or non-synthetic (i.e., natural), it is described as a ''prohibited substance.'' An example of such a prohibited material is a synthetic substance that does not appear on the National List of synthetic substances permitted for use in organic farming and handling. When the word substance is used without any modifiers, it is used to describe all materials (substances), regardless of whether such substances are synthetic or non-synthetic, or prohibited or allowed for use in organic farming and handling.

We have crafted this subpart to be consistent with the requirements of the Act, including its principles for organic farming and handling systems. Although the Act does not specifically define what a system of organic farming and handling is, it does refer in sections 2103(4) and (5) of the OFPA (7 U.S.C. 6502(4) and (5)) to a system of organic farming and a system of organic handling, respectively, as described in the Act. In order to establish consistent national standards for organic production and handling, we have determined that it is necessary to define what a system of organic farming and handling is, and to describe those practices that are consistent with such a system. Another purpose of this definition will be to provide an explicit point of reference for the organic industry to make determinations as to whether various practices and substances are consistent with organic farming and handling. We further expect the proposed definition of a system of organic farming and handling to serve as a reference point for program matters it is determined need further development.

We have defined a system of organic farming and handling to be: a system that is designed and managed to produce agricultural products by the use of methods and substances that maintain the integrity of organic agricultural products until they reach the consumer. This is accomplished by using, where possible, cultural, biological and mechanical methods, as opposed to using substances, to fulfill any specific function within the system so as to: maintain long-term soil fertility; increase soil biological activity; ensure effective pest management; recycle wastes to return nutrients to the land; provide attentive care for farm animals; and handle the agricultural products without the use of extraneous synthetic additives or processing in accordance with the Act and the regulations in this part.

Our proposed definition has been derived from the underlying premises of what constitutes organic farming and handling systems, as reflected in various provisions of the Act. This definition also is consistent with the definitions and principles established by the existing public and private organic programs that we have reviewed and the definitions and principles of organic agriculture and production systems adopted by the National Organic Standards Board. The principles reflected in our definition of a system of organic farming and handling are incorporated in the regulations we are proposing.

The concept of maintaining the integrity of organic agricultural products is established by one of the purposes of the Act, stated in section 2102(2) of the OFPA (7 U.S.C. 6501(2)), to assure consumers that organically produced products meet a consistent standard. The Act generally delineates methods and substances that may or may not be used in organic farming and handling in furtherance of this purpose. Additionally, in section 2104 of the OFPA (7 U.S.C. 6503) it specifically provides for an organic certification program for producers and handlers of organic agricultural products. Such a program helps to ensure the integrity of organic products.

There is a preference for the use of cultural, biological and mechanical methods wherever possible, as opposed to using substances, in organic farming and handling. Examples of methods that do not involve the use of any substances are the planting of green manure crops instead of applying fertilizer substances, and the use of crop rotations and disease resistant plant varieties instead of applying disease-suppressing substances. Section 2105(1) of the OFPA (7 U.S.C. 6504(1)) provides that an organically produced agricultural product must be produced and handled without the use of synthetic chemicals, except as otherwise provided for in the Act. Further, the Act provides in section 2118 (7 U.S.C. 6517) a detailed scheme and criteria for determining whether a particular active synthetic substance may be exempted from the general prohibition on the use of synthetic chemicals, and further provides in that section for the prohibition of the use of certain substances that are not synthetic. Also, the Act specifically directs in section 2119(m)(6) of the OFPA (7 U.S.C. 6518(m)(6)) that the NOSB consider the use of practices or other available materials as alternatives to a synthetic substance being included on the National List. Furthermore, the use of certain substances in organic crop and livestock production and organic handling is specifically prohibited in several provisions of the Act, such as portions of sections 2109, 2110, and 2111 of the OFPA (7 U.S.C. 6508, 6509 and 6510). Therefore, we are proposing in our definition of a system of organic farming and handling that, where possible, cultural, biological and mechanical methods, as opposed to using substances, are preferred. These provisions support the concept that both non-synthetic substances and methods that do not involve the use of any substances, such as cultural, biological, and mechanical methods, are preferred alternatives to the use of synthetic chemicals.

The tenets of maintaining long-term soil fertility and increasing soil biological activity are established in section 2114(b)(1) of the OFPA (7 U.S.C. 6513(b)(1)), which requires that an organic plan contain provisions designed to foster soil fertility, primarily through the management of the organic content of the soil. The Act further addresses soil biological activity in section 2119(m)(5) of the OFPA (7 U.S.C. 6518(m)(5)) when it requires that the physiological effects of a synthetic substance on soil organisms be taken into consideration before the substance is allowed for use in organic production.

The need for effective pest management methods in an organic farming system is established in section 2109(c) of the OFPA (7 U.S.C. 6508(c)) which prohibits the use of certain substances and materials for the control of pests, weeds, and diseases. This section, considered together with the Act's prohibition of the use of most synthetic chemicals in organic production systems, necessitates that crop pest management methods be implemented that avoid the need to use

synthetic substances and materials. In addition, the inclusion of crop rotation practices in an organic plan, as set forth in section 2114(b)(1) of the OFPA (7 U.S.C. 6513(b)(1)), is critical to implementing effective pest management strategies and soil fertility management in an organic farming system.

Recycling wastes to return nutrients to the land is a principle expressed in the language of section 2114(b)(1) of the OFPA (7 U.S.C. 6513(b)(1)) which requires the fostering of soil fertility and which provides for proper manuring to be used to manage soil organic content, and in section 2114(b)(2) of the OFPA (7 U.S.C. 6513(b)(2)) which delineates more specific requirements for the application of manure to crops. Although the use of livestock manure is one means of complying with this requirement, our proposed definition of proper manuring also includes the use of other plant or animal wastes to improve soil organic content and provide crop nutrients.

Attentive care for farm animals is implicit in the provisions of sections 2110(c) and (d) of the OFPA (7 U.S.C. 6509(c) and (d)), which specify what may or may not be fed to organically managed livestock, prohibit certain health care practices, and require the NOSB to recommend additional standards for the care of organic livestock. The alternative to using the methods and practices prohibited under this section of the Act is expressed by the concept of attentive care which is essential when relying on management methods, rather than substances such as medications, to maintain livestock health.

This proposed rule also incorporates the principle that organic agricultural products are to be handled without the use of extraneous synthetic additives and processing. Examples of extraneous additives are synthetic preservatives, coloring agents and flavors. These are not allowed because the Act, in section 6510(a)(1), prohibits the addition of any synthetic ingredient during the processing or postharvest handling of an agricultural product. Extraneous processing generally involves the use of additional substances during and after the processing. Extraneous processing would entail, for example, unnecessarily subjecting a product to temperatures that degrade its inherent antioxidant content, thereby requiring supplementation with an antioxidant to maintain the product's stability.

Our proposed program encompasses all agricultural products, as defined in section 2103 of the OFPA (7 U.S.C. 6502), and all aspects of their production and handling, ranging from soil fertility management to the packaging and labeling of the final product. Our requirements address the systems used to produce an agricultural product rather than the physical qualities of the product itself. No distinctions should be made between organically and non-organically produced products in terms of quality, appearance, or safety.

We believe that an effective regulatory scheme, which has to be applicable to diverse types of operations and geographic regions must be as flexible as possible and take into account site-specific conditions. We accordingly have developed this proposal to provide, within the parameters of the Act, provisions that take into account site specific conditions without impairing the organic integrity of the product produced. In creating this proposal, we examined various examples of, and ideas for, such provisions, including standards developed by existing organic programs, guidelines of international organic interest groups and standards setting organizations, recommendations of the NOSB, and suggestions provided in public input received in the course of NOSB meetings and as response to NOSB draft documents.

Existing organic certification programs, both State and private, have grappled with the need to provide flexibility in their allowed standards and procedures. One method that existing organic programs have used is to distinguish in their standards between practices that they consider to be acceptable for use without restrictions, those that they consider to be acceptable for use only in certain conditions (i.e., restricted practices), and those that they do not consider to be acceptable for use under any circumstance. An example of restricted use is illustrated by the case of botanical pesticides, which most organic practitioners consider to be a last resort for pest control, and which are considered acceptable for use only under certain circumstances. Many existing organic certification programs have thus included such substances within the area of restricted practices that must be closely evaluated and justified by site-specific needs.

We have approached this need for flexibility by incorporating two types of regulatory provisions into our proposed standards. The first type of regulatory provision establishes, where appropriate, an order of preference for selecting practices or materials. For example, we propose in section 205.7(b) of subpart B an order of preferred selection of five types of materials that would be acceptable for use in proper manuring. We also propose in section 205.9 of subpart B an order of preferred selection for the use of practices and substances to prevent and control crop pests, weeds, and diseases. We would like to solicit public comment as to whether or not the establishment of orders of preference would impose an unnecessary burden on organic producers.

The second type of regulatory provision we propose would permit the use of certain practices or substances only if necessary. The producer or handler would base their determination of the need to use a particular method or substance on site specific circumstances. The basis for a producer or handler determining that a certain practice or substance is necessary would be described in the organic plan, or update to the organic plan, and would be reviewed and evaluated by the certifying agent. An example of a practice that we are proposing be used only if necessary is the use of non-organically produced feedstuffs as a portion of an animal's feed ration, as proposed in section 205.13(a) of subpart B.

A number of the regulations are written as performance standards. Performance standards are generally written in terms of the results expected, rather than the specific actions that must be taken to achieve the desired result. An example of a performance standard is the requirement proposed in section 205.3(b) of subpart B that the use or application of any practice or substance must not result in measurable degradation of soil or water quality. This proposed provision requires that practices used in an organic operation be implemented in a manner that maintains soil and water quality, but does not specify the practices that have to be used.

*Subpart B—Regulatory Overview*

Subpart B of part 205 consists of USDA's proposed organic production and handling requirements, and a proposed list of (1) synthetic substances allowed and non-synthetic (natural) substances prohibited for use in organic crop and livestock production and (2) non-agricultural substances and non-organically produced agricultural products allowed in or on processed organic products. The proposed requirements for organic production and handling, and the provisions for the proposed National List and use of substances, have been integrated as a unified whole consistent with our

proposed definition of a system of organic farming and handling.

Section 205.3 (applicability) of subpart B delineates proposed general requirements and conditions for organic production and handling. Section 205.3 of subpart B includes the general requirement that the use of any method or substance not result in measurable degradation of soil or water quality. This section is followed by the sections that set forth the requirements for organic crop production (sections 205.5 through 205.9), wild crop harvesting (section 205.11), organic livestock management (sections 205.12 through 205.15), and organic handling (sections 205.16 through 205.19). Following the sections on production and handling, sections 205.20 through 205.28 contain the proposed National List. The proposed National List regulations consist of sections that describe the active synthetic substances that are allowed for use in organic crop and livestock production, the non-synthetic (natural) substances that are prohibited for use in organic crop or livestock production, and the non-agricultural and non-organically produced ingredients allowed in or on processed organic products. (The OFPA does not require non-synthetic (natural) substances allowed for use in organic crop and livestock production, or non-organically produced products prohibited for use in or on processed organic products, to be included in the National List). Sections 205.20 and 205.21 summarize all of the categories and types of substances allowed and prohibited for use in organic farming and handling, as provided under the Act and the proposed regulations in Subpart B.

*Applicability—Section 205.3*

In paragraph (a) of this section, we propose to establish the requirement that any agricultural product that is sold, labeled or represented as organic be produced in compliance with the relevant proposed crop, wild crop, livestock and handling requirements, including those of the National List. Crops and livestock would have to be produced or harvested on a certified organic farming operation and handled by a certified organic handling operation under a system of organic farming and handling.

We propose in paragraph (b) of this section that any use or application of a method or substance under these proposed requirements must be used in accordance with all applicable requirements of part 205 and must not result in measurable degradation of soil or water quality. This provision is proposed to clarify that all methods and substances used in a certified operation shall be consistent with a system of organic farming and handling, the purposes of the Act, and any other requirements in the regulations in part 205. This provision also is consistent with the recognition in the Act of the relation between organic practices and soil and water quality.

In most instances we are not proposing to require that any specific indicators of soil or water quality be monitored for compliance with this provision. Rather, we expect that appropriate and reliable indicators of soil or water quality would be chosen according to site-specific considerations, such as the nature of the crops or livestock being produced, the location and scale of the operation, and the kinds of practices being used. By not requiring monitoring of specific indicators, except in certain cases, we thus intend to leave the decision as to whether to monitor the effects of a method or substance, as well as the choice of indicators to be monitored, to the producer or handler in consultation with the certifying agent. We would expect any such monitoring activities to be described in the applicable organic plan, and therefore subject to approval by the certifying agent, who might require changes.

For example, if a certifying agent had some concerns about the impact on soil quality of any practice, such as the planting of a sloping field prone to erosion with corn or sorghum, the certifying agent might require the producer to monitor erosion in that field to ensure that soil quality was not being degraded. This could occur following a review of an organic plan or any required annual inspection of a certified operation. This provision also would address the requirement set forth in section 2114(b)(1) of the OFPA (7 U.S.C. 6513(b)(1)) that soil fertility be addressed in an organic farm plan for crop production. Additionally, a certifier who was concerned about the compliance of a cattle feeding operation with the manure management requirements proposed in section 205.15(c) might require that the producer monitor nitrate levels in a nearby well to show that cattle holding areas were not discharging manure-laden runoff into groundwater. A wild crop harvester similarly might be required by a certifier to estimate the population of the harvested plant species that remain in a given area after each harvest, to ensure that the harvesting was being done in compliance with section 2114(f) of the OFPA (7 U.S.C. 6513(f)), which requires that harvesting does not deplete the plant species being harvested (as proposed in section 205.11(b)).

Other indicators of soil or water quality that might be appropriate to monitor, depending on the situation, would include: residues in soil or water of substances prohibited for use in organic farming; soil biological activity as indicated by earthworm populations; soil organic matter and nutrient content; or soil compaction. It should be noted that much of this monitoring activity is widely practiced in the course of managing a farm or handling operation, and in many cases would coincide with measurements, assessments or observations already being undertaken routinely by a producer.

Although not required by statute, the NOSB recommended that irrigation and water management be addressed within an organic farm plan. At this time, however, we are not proposing regulations specifically for the quality of irrigation water.

Section 205.3(b)(2) further would require that, if the same function within an organic farming or handling operation may be fulfilled by either a commercially available non-synthetic substance or an allowed synthetic substance equally suitable for the intended use, then the producer or handler must choose the non-synthetic substance in preference to the synthetic substance if there is no discernable difference between the two in terms of impacts on soil or water quality. We recognize that such choices may seldom have to be made in any operation. However, we are proposing this provision to further reinforce the preference for the use of non-synthetic substances, as opposed to synthetic substances, that is implicit in the Act, as previously discussed. Any allowed synthetic substance will have been evaluated by the NOSB according to section 2119(m)(6) of the OFPA (7 U.S.C. 6518(m)(6)), regarding alternative practices and available materials, and our proposed requirement makes clear the choice producers and handlers must make in a situation where an equally suitable non-synthetic alternative is available.

**Organic Crop Production Requirements**

*Land Requirements—Section 205.5*

This proposed section addresses overall land management practices that we have determined are needed to ensure that the area on which organic crops are produced meets the requirements of the Act and the proposed regulations in subpart B. We have proposed in paragraph (a) of this

section, in accordance with section 2105 of the OFPA (7 U.S.C. 6504), that land not have had any prohibited substances applied to it for at least three years prior to harvest of an organically produced crop.

We are proposing further that any land on which organic crops are produced have clearly defined and identifiable boundaries, as provided under section 2107(b)(1)(A) of the OFPA (7 U.S.C. 6506(b)(1)(A)). We believe that this requirement should apply to all land on which crops are grown under organic management for two reasons. First, organically managed fields must be clearly identifiable so that an inspector may verify that the observed conditions on a farm operation are consistent with the information provided by the producer in the application for certification. Secondly, organically managed fields need to be clearly identifiable to anyone who may be using prohibited substances on adjoining lands in order to help prevent unintentional application of prohibited substances to organically managed areas.

Paragraph (b) of this section would apply to any organically managed land area that adjoins land that is not organically managed, and would require that a producer implement, or propose a plan to implement, some means to prevent the possibility of unintended application of prohibited substances to land and contact of a prohibited substance with the land from which organically produced crops are to be harvested. This could be done through establishment of physical barriers, diversion of runoff, buffer zones, or other means, in accordance with section 2107(b)(1)(A) of the OFPA (7 U.S.C. 6506(b)(1)(A)). Existing State and private organic standards have customarily required producers to establish and maintain adequate buffer zones between adjoining organic and non-organic field units and usually specify the minimum size of a buffer area. The information we have reviewed indicates that such specific minimum size requirements should not be included in our proposal because they would not be applicable to every situation and could impose unnecessary burdens on some organic producers.

*Crop Rotation—Section 205.6*

Crop rotations, or other means of ensuring soil fertility and effective pest management, are the cornerstone of successful organic crop production. They are essential considerations in establishing and maintaining an organic farm system because they help to prevent pest, weed and disease problems; disrupt crop pest, weed, and disease cycles; provide habitat for beneficial organisms; stimulate positive biological and chemical interactions in the agroecosystem; and maintain soil and water quality in a manner that diminishes the need for the use of synthetic substances.

Section 2114(b)(1) of the OFPA (7 U.S.C. 6513 (b)(1)) requires a crop production farm (organic) plan to foster soil fertility through practices that include crop rotation. Although the Act includes a provision for crop rotations as a means of improving soil fertility, crop rotations also serve additional critical functions in an organic farming system. Primary among these functions are: the prevention of weed, pest and disease problems by the planting of species that do not support the pest organisms or that provide food or habitat for beneficial insects; the stimulation of populations of beneficial soil organisms, such as mycorrhizal fungi and predacious nematodes; and the occurrence of alellopathic effects that suppress weed growth.

Such functions similarly may be accomplished by techniques other than crop rotation. Additionally, crop rotation practiced in the production of annual crops, such as corn or soybeans, may not be feasible in the production of perennial crops, such as tree fruits or hay. Therefore, we are providing for alternative practices to crop rotations that also serve the purposes of ensuring soil fertility and effective pest management.

Examples of alternative practices which a producer might use include the following: one method would be to establish or preserve non-agricultural areas such as hedgerows, wetlands, native prairies and woodland, adjacent to or adjoining a farm or field, to serve, for example, as habitat for beneficial organisms. A second related method would be to plant species that serve this same function adjacent to or between rows of crops. A third related method would be the use on pasture areas of rotational or intensive grazing methods in which animals are moved frequently to fresh pasture in order to optimize nutritional content of the forage and extend the pasture season. Other methods commonly used in managing perennial plantings, which cannot be rotated from field to field, include interplanting, alley cropping, strip cropping and introduction of livestock into perennial systems.

As proposed in section 205.2, a crop rotation is defined as 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 during two or more crop years. This rotation might include the use of sod, legumes or other nitrogen-fixing plants, or green manures in alternation with cultivated crops. These crops are universally recognized in the applicable literature as highly desirable methods of improving soil organic matter content and long-term fertility, as well as conferring other benefits associated with crop rotation.

However, a producer could repeatedly plant the same species or family in a given field over more than two crop years, provided that practices which ensure soil fertility and effective pest management, and which do not result in measurable degradation of soil or water quality, as proposed in section 205.3(b)(1), are used. For example, use of living mulches, such as clover interplanted between rows of carrots, could accomplish the same result as a more frequent rotation of carrots with other crops. Other examples of practices that might be used in place of the rotation of annual crops are the application of large amounts of leaf mulch or compost to beds in which the same crop family is grown several seasons in succession by a small-scale vegetable producer, and a grain operation in which early annual weeds may serve as a green manure crop that replenishes soil fertility and provides the other beneficial effects of crop rotations despite the continual commercial production of a single species in a field.

*Soil Fertility and Crop Nutrient Management—Section 205.7*

Section 2114(b) of the OFPA (7 U.S.C. 6513(b)) requires that an organic plan provide for the management of soil organic content through proper tillage, crop rotation and manuring, thereby acknowledging the importance of soil fertility for organic crop production. A fundamental tenet of organic management systems is that the primary objective of soil management is to nourish soil organisms which will in turn ensure soil fertility and properly balanced crop nutrition. We have incorporated this concept in drafting this proposal.

We consider the term proper manuring as used in section 2114(b) of the OFPA (7 U.S.C. 6513(b)) to mean any use or application of plant or animal materials, including green manure crops, to improve soil fertility, especially its organic content. The use of compost and other recycled organic wastes, whether or not they contain

livestock manure, are therefore considered to be part of proper manuring. Any practice, however, that could contribute significantly to water contamination by nitrates and bacteria, including human pathogens, or otherwise result in measurable degradation of soil or water quality, would accordingly not be considered proper manuring.

Section 2109(b) of the OFPA (7 U.S.C. 6508(b)) specifically addresses prohibitions on the use of certain materials as fertilizers and soil amendments; these provisions also are addressed in this section of the proposal. The practices we propose for fertility and nutrient management are also relevant to and essential for the prevention of pest, weed and disease problems that might otherwise have to be controlled through the use of synthetic substances.

Section 205.7(a) would require that any tillage or cultivation implements and practices be selected and used by an organic producer in a manner that does not result in measurable degradation of soil quality. Soil physical qualities include soil structure, aggregation, aeration, drainage and erodibility, all of which are indicators of soil fertility. While we have not proposed to prohibit any specific tillage or cultivation implement or practice, our proposal would require producers to select tools and practices that do not harm soil quality. For example, excessive use of rototillers has been shown to damage soil structure and lead to accelerated loss of organic content, while improper moldboard plowing may induce soil compaction. We would expect an organic producer to manage such tools or practices so that no measurable degradation of soil quality resulted.

*Proper Manuring—Section 205.7(b)*

In section 205.7(b) we propose the types of plant and animal wastes that may be used in an organic system. These materials would represent the methods, in conjunction with crop rotations and green manure crops, that can be used to build soil organic matter and provide essential crop nutrients in accordance with section 2114(b) of the OFPA (7 U.S.C. 6513(b)). The practices proposed are stated in an order of preference for choosing among available alternatives because we believe that these preferences most accurately reflect the concept of proper manuring. As proposed here, the preferred choices in this order of preference are for the practices that are least likely to result in measurable degradation of soil or water quality. For example, the application of compost, as provided in paragraph (b)(1) of this section, is least likely to contribute to contamination of water by nitrates and bacteria, including human pathogens, whereas uncomposted materials having a high soluble nutrient content, as provided in paragraph (b)(3) of this section, are more likely to adversely affect water quality. Because section 2114(b)(2)(C) of the OFPA (7 U.S.C. 6513(b)(2)(C)) requires manuring practices to not significantly contribute to water contamination by nitrates or bacteria, this section also would require that any application of plant or animal waste materials does not do so.

The first choice of materials, as stated in paragraph (b)(1) of this section, would be certain composted materials; these include materials such as livestock manure, food processing wastes, crop residues, spoiled hay and similar materials. The use of composted plant and animal matter recycles nutrients and builds soil organic content with minimal concern for measurable degradation of soil or water quality, and is fully compatible with our proposed definition of a system of organic farming and handling. This practice does not include composts made with certain materials that may pose greater concerns for soil or water quality, which are addressed in paragraphs (b)(4) and (b)(5) of this section.

Paragraph (b)(2) of this section includes plant or animal materials that are neither susceptible to anaerobic decomposition (which presents potential odor and pathogen problems) nor high in soluble nutrients (that may pollute water) and which therefore are suitable for application to soil without first being composted. These materials are the second best choice because applying them directly to soil permits them to decompose and contribute to soil organic content and fertility, thereby functioning in a manner similar to composted materials. This choice also is consistent with the proposed definition of a system of organic farming and handling because it furthers the use of methods in preference to substances. Paragraph (b)(2) of this section would cover materials such as seaweed, sawdust, peat, earthworm castings, leaves, rice hulls and similar dry, stable substances. Well-aged and fully decomposed animal manure that has not been subjected to a composting process might also be used under proposed paragraph (b)(2) of this section.

We propose in section 205.7(b)(3) to allow the use of agricultural waste materials that are known to be susceptible to anaerobic decomposition or that are high in soluble nutrients. These materials are the third choice because they require care in use and application in order to avoid causing measurable degradation of soil or water quality. However, we believe that their use should still be permitted because they are a potentially valuable source of soil organic content and crop nutrients. Examples of such materials include food processing wastes, such as fruit peelings or culls, slaughterhouse by-products, fish wastes, whey, and highly nitrogenous plant concentrates like alfalfa or soybean meal. This category also would include the use of raw animal manure.

Section 2114(b) of the OFPA (7 U.S.C. 6513(b)) permits the application of raw manure to any green manure crop, any perennial crop, and any crop not for human consumption. This section of the OFPA also restricts the use of raw manure, in that raw manure may only be applied to a crop intended for human consumption if the crop is harvested after a reasonable period of time determined by the certifying agent to ensure the safety of the crop, but in no event may the period be less than 60 days after the application of raw manure. Furthermore, section 2114 (b)(2)(C) of the OFPA (7 U.S.C. 6513 (b)(2)(C)) prohibits raw manure from being applied to any crop in a way that significantly contributes to water contamination by nitrates or bacteria.

Over recent months and years, there has been an increase in the incidence of food borne illness caused by certain human pathogens found in animal manure. In consideration of this increased incidence of illness, this proposed regulation does not address in detail the use of raw animal manure in crops intended for human consumption because of the need to develop more and better scientific data regarding the safety of the crop after application of raw manure. Although we acknowledge that the use of animal manure, whether applied directly to the field or composted, is common in organic agriculture, there is inadequate data to make the determinations necessary regarding the safety of the crop after application of raw manure. Similarly, data are needed to make the determinations necessary to ensure that livestock exposure to pathogens does not occur in cases where raw manure is used.

We are soliciting public comment and scientific and technical data in regard to the minimum time which must pass before a crop raised for human consumption on land to which raw manure has been applied may be harvested. Such technical information might include differentiating the type of crops to which differently treated manure can be applied with safety and,

in addition, suitable time and temperature standards for composting animal manures. The Act specifies that when raw manure has been applied to land used to raise a crop intended for human consumption, at least 60 days must pass between application and harvesting to ensure the safety of the crop. If and when regulations regarding the safety of any food grown on land to which raw manure has been applied are promulgated by FDA, EPA and/or USDA, these regulations would be applicable to the use of raw manure in organic agriculture.

We also would like to obtain public comment and scientific and technical data as to whether there are any situations where composted manure would have essentially the same characteristics as raw manure, thus necessitating special measures to ensure the safety of the food. We would like to receive data as to whether under any circumstances, and if so which circumstances, the application of composted material to crops, or the method of preparation of composted material which is intended to be applied to crops, would create any human health or food safety concerns.

On October 2, 1997, President Clinton announced a plan to further ensure the safety of the nation's food supply. The plan, entitled ''Initiative to Ensure the Safety of Imported and Domestic Fruits and Vegetables,'' is geared towards increasing assurances that fruits and vegetables, whether produced domestically or imported, are safe. As part of this initiative, the President directed the Secretary of Health and Human Services, in partnership with the Secretary of Agriculture, and in close cooperation with the agricultural community, to issue guidance on good agricultural practices (GAP's) and good manufacturing practices (GMP's) for fruits and vegetables.

In response to this directive, FDA and USDA are developing guidance to minimize microbial food safety hazards for fresh fruits and vegetables. The guidance is intended to assist growers and handlers in continuing to improve the safety of domestic and imported produce. The agencies have identified several potential vehicles or mechanisms for pathogenic contamination of fruits and vegetables, including but not limited to: (1) Water; (2) the application of manure and municipal wastewater; (3) worker and field sanitation and hygiene; and (4) transportation and handling. The agencies will be publishing draft general guidance for public comment shortly.

Proposed paragraph (b)(4) of this section addresses the use of plant and animal waste materials containing a non-active residue of a substance. We define a non-active residue in section 205.2 as: any synthetic substance that does not appear on the National List of synthetic substances allowed for use, any non-synthetic substance that does appear on the National List of non-synthetic substances prohibited for use, or any non-synthetic (natural) poison (such as arsenic or lead salts) that has long-term effects and persists in the environment, and which occurs in a very small quantity as a non-active substance in a production input or water. This provision would apply to plant or animal waste materials resulting from industrial food or fiber processing, municipal solid waste streams, and similar sources in which the materials have been treated or mixed with other substances. These kinds of materials include non-organically produced cotton gin trash, cocoa hulls, and confinement livestock manure from animals that are known to have been treated with synthetic substances. Municipal yard wastes, including leaves, grass trimmings and prunings, also might fall into this category.

As discussed in the supplementary information to the National List, plant or animal materials that only have been treated or mixed with synthetic substances, but not chemically altered by such treatment, are not considered synthetic under the definition provided by section 2103(21) of the OFPA (7 U.S.C. 6502(21)), and are therefore not prohibited under the Act. Additionally, any non-active residues of substances found on such materials would have minimal or no impact on the organic agroecosystem and therefore the residues are not consistent with the definition of an active substance or ingredient when found in a compost feedstock. Furthermore, the residues themselves are not used to produce an organic crop since they occur as unintended additives that are not intentionally applied and do not perform nor interfere with any function in the agroecosystem.

Such materials would therefore be permitted for use as compost feedstock in organic crop production, but we are proposing that their use be restricted by the requirements that they be composted prior to application to soil, and that levels of any non-active residues detected in the raw plant or animal waste materials not increase in soil. Although certain synthetic substances resist decomposition or may persist if composting is incomplete, most residues present in these materials will decompose sufficiently when subjected to proper composting processes so as to be of negligible concern. A producer using these composted waste materials would be expected to use them in such a way that any persistent residues did not increase in the soil or accumulate to a level that caused measurable degradation to soil or water quality.

In paragraph (b)(5) of this section, we propose to permit the use of plant and animal waste materials that have been chemically altered (by the industrial process), and which are therefore considered active synthetic substances under section 2103(21) of the OFPA (7 U.S.C. 6502(21)), and can only be used if they appear on the National List of active synthetic substances allowed for use in organic farming. Unlike non-synthetic materials that may contain synthetic substances as non-active residues as permitted under paragraph (b)(4) of this section, this provision refers to materials derived from a process that chemically changes the material. Such materials might include leather meal, newspaper and kiln dust. Although this type of material would not have to be composted prior to application, a farmer using such substances in a system of organic farming would be expected to use them in such a way so that measurable degradation of soil or water quality did not occur.

*Providing Mineral Nutrients—Section 205.7(c)*

In section 205.7(c), we propose that certain mineral substances could be used as a means of fostering soil fertility by providing major nutrients or micronutrients. While use of proper rotations and recycled plant and animal wastes can often provide all the mineral nutrients required by crops, supplemental sources of these nutrients sometimes are needed. We have divided paragraph (c) into two subsections, which represent two broad types of mineral substances that may be used. The first two types consist of non-synthetic substances of low solubility and salinity, including mined substances such as lime, greensand and rock phosphate, and substances extracted from a plant or animal substance, such as liquid seaweed extracts, or from a mined mineral. Such substances historically have been accepted in organic production, and because they are not synthetic chemicals their use is consistent with the Act and with a system of organic farming and handling. It should be noted that, as we discuss in the supplemental information to the National List, we do not consider the extraction method to be consequential

when used to obtain substances from non-synthetic sources that are used in crop production. The extraction method alone would not cause the substance to be considered synthetic nor would we expect the resultant substances to have detrimental effects on biological and chemical interactions in the agroecosystem or cause any measurable degradation of soil or water quality. Fish emulsion products which contain synthetic stabilizers also would not be considered to be synthetic under this proposal because the stabilizers are not active synthetic ingredients, as discussed in the supplementary information to the National List.

The use of ash derived from the burning of a plant or animal material, such as wood or sunflower hulls, is also included in this category of non-synthetic mineral nutrient sources, except for certain instances. The use of ash would be prohibited if the ash is obtained from a practice prohibited under paragraphs (d)(2) or (3) of this section or if the ash appears on the National List of prohibited non-synthetic substances or if the material burned to create the ash had been treated or combined with a prohibited substance. It should be noted that a product of the combustion of an inorganic or mineral substance, such as sulfur or calcium carbonate, would be considered a synthetic substance under this proposal.

The second category of substances that could be used as sources of crop nutrients comprises any highly soluble or synthetic substance, which we propose may be added to soil to correct a known nutrient deficiency provided that its use does not result in measurable degradation of soil or water quality. These substances have historically been permitted by most organic certification programs we have reviewed, but with restrictions placed on their use. We would like to receive comment as to whether or not further restrictions on the use of any of these substances would be appropriate. Such restrictions might, for example, include designating this type of substance as representing a lower order of preference than substances included in paragraph (c)(1) of this section, or might include permitting their use only if necessary.

The three types of substances that would be covered by this second category include synthetic micronutrient substances, non-synthetic minerals that are highly soluble and have a high salt index, and cation balancing agents. Synthetic micronutrient minerals, such as soluble boron and chelated trace minerals (e.g. zinc, manganese, iron, and copper), may often be the most effective and practical choice for correcting soil deficiencies of these essential nutrients, and when properly used can be considered a beneficial practice in an organic soil management system. Their proposed use is restricted because, in addition to being synthetic substances, misuse or overuse of these substances can cause measurable degradation of soil or water quality. Synthetic micronutrients, which are minerals that we propose to consider as active ingredients in an organic system, are proposed in section 205.22(f) for inclusion on the National List as allowed synthetic crop production substances. However, the NOSB has recommended, and we agree, that it is not acceptable to use any of these substances in a way that takes advantage of their herbicidal nature which could result in measurable degradation of soil quality.

Other substances in this category include highly soluble and saline non-synthetic mined minerals, such as sodium (Chilean) nitrate or potassium nitrate (niter), which may be applied as a source of nitrogen, as well as potassium chloride (muriate of potash), langbeinite (sulfate of potash magnesia), and potassium sulfate, which are sometimes used to balance the soil cation nutrient content. Such substances are usually available as non-synthetic mined minerals, but are proposed to be restricted to cases of known nutrient deficiency because of their potential to degrade soil quality by contributing to soil salinization when excessively applied. While the Act makes no mention of these specific materials, section 2109(b)(2) of the OFPA (7 U.S.C. 6508(b)(2)) indicates that certain mineral nutrients and nitrogen should not be permitted if they are inconsistent with the applicable organic certification program. Soil amendment substances, such as langbeinite and potassium sulfate, used to balance cation nutrients are more widely considered to be acceptable adjuncts to an organic fertility management system, but are included in this category due to their high solubility and salinity, which could cause measurable degradation of soil quality if overused. As previously stated, a producer could use these substances only to correct a known nutrient deficiency.

As proposed and discussed in section 205.22(c) for allowed synthetic crop substances, certain cation balancing agents, such as potassium sulfate, may be available on the market either as non-synthetic mined minerals or as synthetic by-products of an industrial process. In cases where the origin of such a substance cannot be determined from readily available information, such as a label or labeling accompanying the product, the mineral is presumed to be synthetic and must appear on the National List as an allowed synthetic crop production substance before it may be used. This presumption would prevent the inadvertent application of a prohibited substance when the producer cannot readily determine the origin of a cation balancing agent.

Finally, we propose in paragraph (d) of this section to prohibit: the use of any fertilizers or commercially blended fertilizers that contain an active synthetic ingredient not allowed for use in crop production as provided for in section 205.22, or that contains an active prohibited substance; the use of ash obtained from the disposal of manure by burning; and burning as a means of disposal of manure or of crop residues produced on the farm. The first prohibition is proposed in accordance with section 2109(b)(1) of the OFPA (7 U.S.C. 6508(b)(1)) which requires that such a prohibition be established. The second and third prohibitions are proposed in agreement with the recommendations received from the NOSB. Burning these materials is not an appropriate method to use to recycle organic wastes and would not be considered as a proper method in a manuring program because burning removes the carbon from these wastes and thereby destroys the value of the materials for restoring soil organic content. Burning as a disposal method of these materials would therefore not be consistent with section 2114(b)(1) of the OFPA (7 U.S.C. 6513(b)(1)).

*Selection and Use of Seeds, Seedlings and Planting Stock—Section 205.8*

Section 2109(a) of the OFPA (7 U.S.C. 6508(a)) prohibits an organic producer from applying materials to or engaging in practices on seeds or seedlings that are inconsistent with the program established under the Act. Therefore, we are proposing that all seeds and planting stock, including annual seedlings and transplants, be organically produced. However, we recognize that at the present time this is impractical for many farms because organically produced seeds and planting stock are not widely commercially available; thus, we are proposing to permit exceptions to this requirement. It is our expectation that our requiring organic producers to use organic seed and planting stock except in limited circumstances will stimulate increased organic production of these essential farm inputs.

This proposal would permit the use of non-organically produced seeds and planting stock in producing an organic

crop only when an equivalent organically produced variety is not commercially available. Planting stock includes, as we define it, any plant material used for plant reproduction, except seeds, and includes such materials as seedlings, cuttings, tubers, roots, slips, rhizomes, crowns, and plantlets derived through tissue culture techniques. Our proposal also would require that untreated planting stock be selected in preference to treated planting stock whenever there is a choice. With the exception of annual seedlings, most organic farm operations are not equipped to produce planting stock on the farm. In addition, certain planting stock, such as berry plants and tubers, are required by some State regulations to be treated with pesticides to prevent the introduction of plant diseases and other pests.

Although we have received some input in favor of prohibiting all uses of non-organically produced annual seedlings, we believe that the inclusion of such annual seedlings under this proposed rule is justified. The flexibility of allowing the use of non-organically produced annual seedlings would permit a farmer who lost a crop due to unanticipated or emergency circumstances shortly after transplanting to replant with a similar non-organically produced variety that was either treated or untreated. It should be noted that any annual seedlings that are produced and replanted on the same certified organic farm are considered transplants and could not be treated with prohibited substances, as proposed in section 205.8(c).

We are proposing that treated seeds could only be used if untreated seeds of the same variety are commercially unavailable or it is infeasible to obtain untreated seeds due to unanticipated or emergency circumstances. As discussed in the supplementary information for the National List, we are not proposing any seed treatment substance to be included on the National List because we are not proposing to allow a producer to use any seed treatment on a certified organic farm. Treated seeds under our proposal are not an active synthetic ingredient in the organic farming system and therefore are not required to appear on the National List. A producer could not use the treated seed in order to take advantage of the functional application of the seed treatment (this would be using the seed treatment as an active ingredient) or to use up treated seed remaining from the previous year if the appropriate untreated seed had since become available.

Because a full range of untreated non-organically produced crop seeds is widely available, the circumstances under which this exception would be justified are limited. These circumstances might include situations in which untreated seeds are not obtainable due, for example, to the fact that untreated seeds must sometimes be ordered well in advance of expected delivery or the fact that it may not be possible to order very small amounts of untreated seed of a new seed variety that a producer wishes to use on a trial basis. Emergency or unanticipated circumstances would include loss of a crop to flood or frost and untreated seeds were no longer available for replanting.

In section 205.8(b) we propose the requirements for how non-organically produced planting stock used as planting stock to produce a perennial crop could be sold, labeled or represented as organic. We propose this provision, as authorized by section 2107(a)(11) of the OFPA (7 U.S.C. 6506(a)(11)), in order to provide the means by which a nursery operation that operates in accordance with the Act and our proposed regulations in part 205 could purchase planting stock from a non-organic operation and later resell this stock as organically produced. This proposal would permit perennial planting stock to be represented as organic after it had been maintained under organic management on a certified organic farm for a period of at least one crop year. For example, a certified organic nursery operation could purchase non-organic dwarf apple rootstock and graft it with locally adapted varieties, then sell the resultant planting stock as organically produced after raising it organically for at least one year. We have proposed the one year period because we do not consider nursery stock that is held on a certified operation for less than a year before it is resold to have been organically produced. This provision is intended to stimulate a wider availability of key organic production inputs and thus make the ability to comply with the requirement that organic sources of planting stock be used, as set forth in proposed section 205.8(a), more feasible for organic producers.

In section 205.8(c), we propose to prohibit the use of transplants treated with a prohibited substance, as provided for in section 2109(c)(3) of the OFPA (7 U.S.C. 6508(c)(3)). It should be noted that we have defined a transplant as an annual seedling produced on an organic farm and transplanted to a field on the same farm operation to raise an organically produced crop. This definition also is consistent with section 2109(a) of the OFPA (7 U.S.C. 6508(a)) which prohibits farm producers from applying substances to seeds or seedlings that are contrary to or inconsistent with the proposed program. We do not propose to prohibit the use of seedlings or other planting stock that may have been treated with synthetic substances before reaching the organic farm since the treatment itself is not applied on, or intended to be used on, the organic farm.

While the OFPA mandates that the Secretary develop organic standards, it is silent on the issue of genetically engineered organisms (GEOs) and their products. However, the accompanying Senate report language states that ''* * * as time goes on, various scientific breakthroughs, including biotechnology techniques, will require scrutiny for their application to organic production. The committee is concerned that production materials keep pace with our evolving knowledge of production systems.''

In the time since the OFPA was passed, GEOs and their products have assumed a more significant role in agricultural production. The policy of the United States Government is that GEOs and their products should be regulated based on risk, not on how they are produced. The NOSB has recommended to the Secretary as a policy matter that GEOs should not be allowed in organic farming and handling.

Public comment is invited with respect to the use of GEOs or their products in a system of organic farming and handling. The USDA specifically invites comments on whether the use of GEOs or their products in organic farming and handling should be permitted, prohibited, or allowed on a case-by-case basis. Comments should detail the basis for the commenter's recommendations, including the agricultural, technical, or scientific factors involved. Comments should also identify the criteria that should be applied to case-by-case determinations.

*Prevention and Control of Crop Pests, Weeds, and Diseases—Section 205.9*

Section 2109(c) of the OFPA (7 U.S.C. 6508(c)) sets forth practices, such as the use of natural poisons that persist in the environment, or plastic mulches, that are prohibited or restricted in the control of pests, weeds and diseases in organic crops. Section 2118(c)(1)(B)(i) of the OFPA (7 U.S.C. 6517(c)(1)(B)(i)) lists the following categories of active synthetic substances (used for pest, weed, and disease control) that may be considered for exemption if they are

included on the National List: copper and sulfur compounds; toxins derived from bacteria; pheromones, soaps, horticultural oils, vitamins and minerals, and production aids including netting, tree wraps and seals, insect traps, and sticky barriers.

This section is designed to implement these two provisions of the Act and is consistent with the NOSB recommendations and public comments received by the NOSB, as well as being consistent with the proposed definition of a system of organic farming and handling. The structure of this section reflects an order of preference, in which the first choice is the use of management methods to prevent the occurrence of weeds, pests, and diseases, and the second choice is the use of methods and certain substances to control occurrences that may develop. This section is consistent with the definition of a system of organic farming and handling and with the NOSB recommendations because it requires that methods be chosen in preference to substances and that toxic substances, whether allowed synthetic substances or non-synthetic substances, be permitted only as a last resort.

In section 205.9(a), we propose to require that preventive measures be used by an organic producer for the prevention of pest, weed and disease problems in crops, including, but not limited to: crop rotations or other practices provided for by section 205.6; replenishment and maintenance of soil fertility, as proposed in section 205.7; appropriate sanitation measures, such as composting plant debris to remove disease vectors, weed seeds and pest habitat; cultural practices such as irrigation or timing of plantings to enhance crop health and avoid peak pest hatchings; and selection of species and varieties for traits such as disease resistance and suitability to local climate conditions.

When prevention is inadequate, sections 205.9(b) through (d) of our proposal would provide for a range of practices that could be used to control pest, weed, and disease problems. These methods are consistent with the section 2105(1) of the OFPA (7 U.S.C. 6504(1)) requirement that organic production not include the use of synthetic chemicals unless otherwise provided for in the Act. Although a preventive management approach, as exemplified in proposed section 205.9(a), would be preferable, we recognize that once pests or weeds are present they must be controlled in order to avoid economic or otherwise significant damage to crops. Pest control practices, as proposed in section 205.9(b), are: augmentation or introduction of predators or parasites, such as trichogramma wasps and ladybugs; mechanical or physical controls, such as pest barriers or traps; and use of non-synthetic and non-toxic controls, such as repellants or lures. All of these methods are fully consistent with a system of organic farming, as defined in section 205.2, and do not entail the use of any active synthetic substance.

Practices proposed in section 205.9(c) that could be used for weed control when preventive measures are not effective are: mulching with fully biodegradable materials, which include plant-derived matter such as straw, bark, leaves and paper, but do not include plastics that disintegrate but do not biodegrade; livestock grazing to reduce weed competition; any mechanical or physical controls, such as weeding and cultivation techniques; and, in accordance with section 2109(c)(2) of the OFPA (7 U.S.C. 6508(c)(2)), plastic or other synthetic mulches provided that they are removed from the field at the end of the growing or harvest season. It should be noted that the use of cultivation to control weeds under this proposal also would have to be consistent with the provisions proposed in section 205.7(a) for protecting soil quality.

In paragraph (d) of this section, we propose that practices that are intended to prevent the spread of diseases, such as steam sterilization to eliminate disease organisms from greenhouse growing media, could be used if disease preventive measures are not effective. Plant diseases, once they occur, are difficult to control with existing organic technologies, although some success has been demonstrated with the use of compost preparations that actively suppress plant pathogens, a practice that would be included in this provision.

In paragraph (e) of this section, we are proposing to permit the use of certain methods and substances to control pests, weeds, and diseases in an organic farming system if the practices proposed in paragraphs (a) through (d) are not effective, provided that their use does not result in measurable degradation of soil or water quality. Although the use of the proposed substances is often necessary, the use of these substances may pose concerns for soil or water quality when overused. Therefore, a producer who used any substance proposed for use in paragraph (e) of this section would have to describe in the organic plan how use of the substance was not resulting in measurable degradation of soil or water quality.

Botanical pesticides are specifically addressed in section 2119(k)(4) of the OFPA (7 U.S.C. 6518(k)(4)) as requiring a special review to determine whether any of them should be placed on the National List of prohibited natural substances. This review was undertaken by the NOSB at its meeting in Rohnert Park, California, in October, 1994. Considerable public input also has been received concerning the use of botanical pesticides in organic production. Some public input expressed concern as to whether organic farmers should be permitted to use any pesticide sprays, even if they are non-synthetic. Many organic practitioners who acknowledged the need to use botanical pesticides stated that they used them only after more ecologically compatible alternatives proved to be unsuccessful. Our review of existing organic programs and public input also indicated that non-synthetic substances used as biological controls may pose concerns for soil and water quality if used indiscriminately. Concerns also have been expressed that the use of these substances may impact biological and chemical interactions in the agroecosystem, including the possibility of inducing accelerated resistance in pest populations.

While many producers may not need to use botanical pesticides, prohibiting these materials entirely would severely restrict the availability of a wide range of organically produced crops. After concluding its technical review process, the NOSB recommended that neem, pyrethrums, rotenone, ryania, and sabadilla be allowed for use in organic agriculture. We agree with the NOSB recommendations on the basis of the aforementioned public input, and therefore provide in section 205.9(e) for the use of botanical pesticides under certain circumstances, provided that the botanical substance is not included as a prohibited non-synthetic (natural) substance on the National List.

Our proposal also would allow the use of any synthetic weed, pest, or disease control substance that is included on the National List as a crop production substance, such as dormant oils, vitamin-D based rodenticides, pheromones, and copper or sulfur fungicides. In addition, non-synthetic, biologically based materials, such as bacterial toxins, that are used to kill pests, weeds or plant diseases also would be included under this paragraph of our proposal.

This paragraph of section 205.9 also would permit the use of allowed synthetic substances for the purpose of cotton defoliation. We have determined that this provision should be proposed

after reviewing testimony from organic cotton producers and scientific evidence that the substances in question, which are mineral compounds having a high salt index and solubility (and usually synthetically derived) are ordinarily not used in amounts that could cause concern for adverse impacts on soil fertility.

*Prohibited Pest, Weed and Disease Control Practices—Section 205.9(f)*

In section 205.9(f), we propose to prohibit the use of a synthetic carbon-based compound that kills insects, weeds, diseases or other pests through a cytotoxic mode of action. We have defined the phrase cytotoxic mode of action to mean having a toxic effect by means of interference with normal cell functions. We believe this proposal is appropriate because section 2118 (c)(1)(B)(i) of the OFPA (7 U.S.C. 6517(c)(1)(B)(i)) does not delineate this category of substances as a category of active synthetic substances that could be considered for inclusion on the National List of permitted synthetic substances. In addition, these substances are prohibited under all existing State, private and international organic programs that we reviewed, and public input received from organic producers and other members of the public has raised frequent concerns that such substances potentially might be allowed for use in organic production. We therefore have determined that the use of any substance in this category would be inconsistent with a system of organic farming, as defined under proposed section 205.2, and with the organic certification program established under the Act.

*Wild Crop Harvesting—Section 205.11*

Wild crops are generally not produced and managed on a farming operation, but rather are harvested from public or private lands; therefore, most of the farming and management practices and materials described in this proposal, such as soil management practices or weed, pest and disease control, would not be applicable. However, because wild crops are addressed in section 2114(f) of the OFPA (7 U.S.C. 6513(f)) and because they are used extensively as ingredients in many organic products, we are proposing in this section provisions for the harvesting of organic wild crops. We note here that if management practices such as cultivation or fertilization are undertaken prior to the harvest of a wild crop, the wild crop would be considered as a managed agricultural product and would be subject instead to the relevant requirements proposed for organic crop production. This idea is reflected in our proposed definition of a wild crop as being harvested from an area of land that is not maintained under cultivation or other agricultural management. It should be noted that this section would apply only to crops harvested from the wild, and that game animals harvested from the wild are not addressed in this proposal.

As required under section 2105(2) of the OFPA (7 U.S.C. 6504(2)) and section 2114(f)(2) of the OFPA (7 U.S.C. 6513(f)(2)), we propose in section 205.11(a) that the land from which wild crops are harvested for sale as organic must have had no prohibited substances applied to it for the three years immediately preceding the harvest of the wild crop and any time thereafter. Our proposal requires that wild crop harvesting be done in a manner that would not be destructive to the environment and which would sustain the growth and production of the wild crop, as required under section 2114(f)(3) of the OFPA (7 U.S.C. 6513(f)(3)).

*Organic Livestock Production Requirements*

Section 2110 of the OFPA (7 U.S.C. 6509) sets forth certain requirements and prohibitions for organic animal production. It requires the Secretary to hold public hearings to guide the implementation of standards for livestock products. It also states that the NOSB shall recommend additional standards for livestock health care to ensure that such livestock is organically produced. Accordingly, the Secretary held public hearings in Washington, DC, on January 27–28, 1994; Rosemont, IL, on February 10, 1994; Denver, CO, on February 24, 1994; and Sacramento, CA, on March 22, 1994 on this matter. Additionally, the NOSB provided recommendations to the Secretary on August 1, 1994 and subsequently, as required in the Act. We have developed the provisions proposed in sections 205.12 through 205.15 in accordance with section 2110 of the OFPA (7 U.S.C. 6509), the input received at the public hearings, and the NOSB recommendations.

*Origin of Livestock—Section 205.12*

Livestock as defined in section 2103(11) of the OFPA (7 U.S.C. 6502(11)) are cattle, sheep, goats, swine, poultry, equine animals used for food or in the production of food, fish used for food, wild or domesticated game, or other nonplant life. Organically raised livestock should be the offspring of organically raised parents and live under organic management beginning with their first day of life. We propose in paragraph (a) of this section that livestock raised on a certified organic farm for the production of meat, milk, eggs, or other products to be sold, labeled, or represented as organically produced be under organic management from birth or hatching, or be the offspring of parents that have been under organic management, except in certain cases. These exceptions are based on the provisions of section 2110 of the OFPA (7 U.S.C. 6509) that provides that breeder stock, poultry from which meat or eggs are derived, and dairy animals from which milk and milk products are derived, can be purchased from non-organic sources and subsequently raised as organic livestock.

Paragraphs (a)(1) through (3) of this section are proposed in accordance with section 2110 of the OFPA (7 U.S.C. 6509). Paragraph (a)(1) of this section would permit the purchase of livestock from any source for use as breeder stock of organic livestock, except that a gestating mammal would have to be brought onto a certified facility prior to the last third of pregnancy. Paragraph (a)(2) of this section would permit dairy animals from which milk or milk products will be sold, represented, or labeled as organically produced to be brought onto a certified facility beginning no later than 12-months prior to the production of milk or milk products that are to be sold, represented, or labeled as organic. Paragraph (a)(3) of this section would permit the purchase of poultry from any source for use as organic slaughter stock (meat) or for organic egg production provided that the poultry are brought onto a certified facility no later than the second day of life.

We have proposed other provisions that cover what the practices are for bringing other types of livestock, such as bees, fish, and mammalian livestock designated as organic slaughter stock, into an organic operation to produce such products as fiber, honey, meat and caviar. These provisions are based on public input received at the USDA livestock hearings, NOSB meetings and public response to NOSB draft recommendations.

In section 205.12(a)(4) we propose that livestock may be designated for the production of non-edible organic products, such as hides, feathers, fur and fiber, if the animal is raised in compliance with one of the other provisions proposed in paragraph (a) of this section, as appropriate to the species. Additionally, we propose that livestock not raised under organic management from birth or hatching,

such as male breeder stock purchased from non-organic sources and subsequently raised as organic livestock for the production of certain non-edible products, shall have been maintained under organic management no less than 90 days prior to harvest of the organic product. For example, wool from a buck sheep designated as organic breeder stock in accordance with paragraph (a)(1) of this section could be sold or represented as organically produced only after the buck had been maintained under organic management for at least 90 days prior to the time of shearing. This time period is proposed in order to ensure that non-edible products, such as wool or hides, from breeder animals brought under organic management could not be represented as organically produced until the producer had included the livestock in the overall farm management system.

In section 205.12(a)(5) we are proposing how livestock types such as fish, crustaceans, mammalian livestock designated as organic slaughter stock, and other species not addressed in the previous four provisions, could be introduced onto an organic operation for the production of edible organic products.

We specifically propose in paragraph (a)(5)(i) that bees may be brought onto a certified facility at any stage of life. We propose this because we determined that the production of honey depends on the nature of the forage available to the bees at the time of honey flow. Additionally, because of the ephemeral life cycle of individual bees, previous locations of the hive would be inconsequential to the honey harvested at the certified organic facility.

We propose in paragraph (a)(5)(ii) of this section that, if necessary, mammalian livestock from any source could be used as organic slaughter stock for the production of meat if it is brought onto a certified facility no later than the 15th day of life. This proposed provision would allow producers a reasonable length of time to integrate animals from non-organic sources into their organic operation, while still ensuring that the animal is brought onto the certified facility early enough in life to develop primarily and substantially under organic care. Allowing a mammal up to 15 days to be introduced onto the certified facility would provide adequate time for the young stock to receive its mother's first milk, gain strength and be transported over any distance to the organic farm.

As noted, a producer could use non-organic sources of mammalian livestock to be designated as organic slaughter stock only if the use of non-organic livestock is necessary. The determination of necessity would be based on site-specific conditions that would be described by a producer in an organic plan, or updates to an organic plan, and reviewed by the certifying agent. Examples of site specific conditions that may serve as a basis for supporting the determination to purchase livestock from non-organic sources are: commercial unavailability of livestock from organic sources, and unanticipated or emergency circumstances that prevent the purchase of commercially available organic livestock.

We are requesting public comment as to the conditions under which non-organic mammalian livestock may be used as organic slaughter stock. For example, we would like public comment as to whether specific conditions, such as commercial unavailability of organic livestock or an emergency situation, should be a prerequisite for allowing mammalian livestock of non-organic origin to be designated as organic slaughter stock and, if so, what these conditions should be. We also request comment as to whether we should provide for the use of mammalian livestock of non-organic origin in the production of organic meat.

We propose in paragraph (a)(5)(iii) that all livestock types other than those described in paragraphs (a)(1) through (5)(ii) may be brought onto a certified facility no later than the earliest commercially available stage of life. Other livestock types represent a wide range of life spans and levels of commercial availability, and there is no basis for proposing specific time limits for their introduction into an organic facility. Sufficient time is required to raise the young of any such species from its earliest commercially available stage to reach marketable size; this time period will ensure that the stock is raised primarily under organic management.

*Prohibited Practices for Origin of Livestock—Section 205.12(b)*

In section 205.12(b)(1), we propose that producers be prohibited from moving animals in and out of organic care for the purpose of circumventing the proposed requirements. This provision addresses our concerns that the leeway provided by proposed paragraph (a)(1) of this section for the purchase of non-organic breeder stock might be misused by a producer who might, for example, repeatedly bring a pregnant mammal onto a certified farm just prior to the last third of pregnancy, remove the mammal from organic care after the offspring is born, and then reintroduce her to organic management again just before the last third of the next pregnancy. Paragraph (b)(2) of this section is consistent with section 2110(c)(3) of the OFPA (7 U.S.C. 6509 (c)(3)), which prohibits the use of hormones to stimulate the growth or production of organically produced livestock. In paragraph (b)(2) of this section we propose that the use of hormones for any breeding purposes be prohibited.

*Livestock Feed—Section 205.13*

Organically produced feed is one of the foundations of organic livestock management. Section 2110(c)(1) of the OFPA (7 U.S.C. 6509(c)(1)) requires producers of organic livestock to provide organically produced feed that meets the requirements of the Act to their livestock. Therefore, we propose in paragraph (a) of this section that the total feed ration for organically raised livestock be organically produced. This requirement would include all pasture or rangeland on which the livestock are grazed. Forage from rangeland would be considered a wild crop and, thus, would be considered to be organically produced if it complied with the proposed wild crop harvesting requirements proposed in section 205.11. Purchased feed supplements, such as soybean protein concentrates, would have to be produced in compliance with the Act and the regulations in subpart B to be considered organically produced.

During the livestock hearings conducted by USDA, producers expressed concerns that unless an allowance was provided for non-organic animal feed, the organic status of livestock could be jeopardized by unavoidable circumstances that would cause or prevent livestock from consuming non-organic feed. Some of the circumstances cited by the producers were poor growing conditions, severe weather, commercial unavailability and fence jumping. We believe that these concerns are valid and, therefore, propose in paragraph (a)(1)(i) through (iv) of this section to permit, if necessary, that livestock under organic management be allowed to receive other than a total feed ration that is organically produced. We believe that our additional proposed provisions are consistent with a system of organic farming and handling and that they will not result in a compromise of the integrity of organic products.

We propose in paragraph (a)(1)(i) of this section that an animal be allowed to receive up to twenty percent non-organic feed as part of its total feed ration in a given year. Paragraph

(a)(1)(ii) of this section proposes that in emergency situations which affect the commercial availability of organic feed, such as weather related disasters, the Administrator could authorize the use of non-organic feed greater than the twenty percent non-organic feed allowed in paragraph (a)(1)(i) of this section.

As noted, a producer could use non-organic sources of feed if the use of non-organic feed is necessary. As previously described in regard to the use of non-organic sources of mammalian livestock to be designated as organic slaughter stock, determination of necessity would be based on site-specific conditions that would be described by a producer in an organic plan, or updates to an organic plan, and reviewed by the certifying agent.

We are requesting public comment as to conditions under which non-organic feed may be used. For example, we would like public comment as to whether specific conditions, such as commercial unavailability of organic feed, regional environmental factors, or an unanticipated situation, should be a prerequisite for allowing non-organic feed and, if so, what these conditions should be. We also request comment as to whether we should provide for the use of feed of non-organic origin in the production of organic livestock on certified organic farms.

In paragraph (a)(1)(iii) of this section, we propose an exemption that would allow an entire, distinct dairy herd, that is converted to organic management for the first time, to be fed non-organic feed up to 90 days prior to the production of milk or milk products labeled, sold, or represented as organic. In testimony received at the USDA public hearings, milk producers expressed concern that purchasing organic feed for twelve months prior to selling the milk as organic could hinder or prevent a producer from deciding to make the transition from non-organic to organic production. They further explained that the twelve-month period for feeding organic feed grown on the farm could not be initiated until after the farm was certified as organic, which might be three years after the producer first decided to make the transition to organic production so as to comply with section 2105(2) of the OFPA (7 U.S.C. 6504(2)) regarding prohibited substances applied to the land.

Our proposal would permit use of this exception only one time for any given discrete dairy herd. This exception applies only to feed; producers still would have to comply with all other organic livestock management requirements for the 12-month period prior to selling the milk or milk products from these animals as organic, as required in section 2110(e)(2) of the OFPA (7 U.S.C. 6509(e)(2)).

We propose in section 205.13(a)(1)(iv) that bees from which organic honey and other products are harvested be provided with access to enough organically managed forage to provide them with a predominant portion of their needs. The NOSB received many comments about organic honey production and considered several suggestions without making a recommendation to the Secretary. One suggestion considered by the NOSB was that the producers monitor their honey bees to ensure that only organic forage was accessed by the bees; honey producers maintain that it is infeasible to monitor and control all bee forage areas. Another suggestion considered was to require the hive to be surrounded by organic forage areas for the total radius of the distance for which bees are known to fly. However, this radius may vary and is impractical in most regions because the estimated two mile radius that bees are known to cover would entail more than 12.5 square miles of continuous organic forage area surrounding each hive.

In creating the proposed provision for bee forage areas, we considered the applicability of the proposed provision in paragraph (a)(1)(i) of this section for twenty percent non-organic feed. However, we decided that it would not be possible for a producer or certifier to ascertain the exact forage percentages for bees. We expect that producers of organic honey would meet our proposed requirement that bee forage areas be predominantly organic by actively managing on-farm plantings, including crops, buffer zones, biological islands, roadsides or other available areas during honey flows. A producer also could satisfy this provision by moving hives to other organically managed areas to take advantage of organic off-farm acreage.

The NOSB received public comments regarding the addition of vitamin and mineral supplements to an organic feed ration to prevent deficiency diseases. In their deliberations, the NOSB recognized that producers cannot easily determine whether an animal's nutritional requirements are being satisfied solely by the organically grown feed provided to them, especially in the case of grazing animals.

The NOSB subsequently recommended that organic feed be allowed to be supplemented with vitamins and minerals, as needed, to ensure an animal's health. Deficiency diseases, such as milk fever, may not be recognized until an animal becomes debilitated; moreover, allowing any animal to become weakened because of vitamin and mineral deficiencies may lead to more serious health problems. Accordingly, we propose in paragraph (a)(2) of this section that the use of non-agricultural products as vitamin and mineral supplements to satisfy the health requirements of livestock be permitted, provided that any synthetic supplement used in organic livestock production is included as an allowed synthetic on the National list in section 205.24. In accordance with section 2118(c)(1) of the OFPA (7 U.S.C. 6517(c)(1)), trace minerals and dietary supplements are included in proposed section 205.24 as synthetic substances permitted for use in organic livestock production.

We propose in section 205.13(a)(3) that producers be allowed to use synthetic amino acid additives as necessary for the purpose of fulfilling the nutritional requirements of the livestock, if the synthetic amino acid used is included as an allowed synthetic on the National list in section 205.24. During the USDA public hearings and NOSB meetings, organic livestock producers stated that it is sometimes necessary to add amino acid (protein) additives to feed rations to ensure optimal health and growth. They explained that producers cannot control, even by diversifying the feed ration, the quantity and type of protein available in organic feedstuffs. For example, the lysine content of many feedstuffs is known to be inadequate.

Tests to analyze the essential amino acid content in feed are inexpensive, and the National Research Council's Committee on Animal Nutrition publishes nutrient requirements for domestic animals, including requirements for essential amino acids, where applicable. These levels could be used as guidelines for producers and certifying agents to ensure that the amino acids were not used at levels high enough to artificially stimulate growth or production in the animal, which is proposed to be prohibited under section 205.13(b)(2). An analysis of feed showing that it required use of amino acid supplementation would constitute a site-specific condition that could be used to demonstrate that its use was necessary to fulfill the nutritional requirement of the livestock.

*Prohibited Livestock Feeding Practices—Section 205.13(b)*

Sections 2110(c)(2) and (3) of the OFPA (7 U.S.C. 6509(c)(2) and (3)) prohibit the use of plastic pellets for roughage; manure refeeding; feed formulas containing urea; and the use of

growth promoters and hormones, including antibiotics and synthetic trace elements to stimulate growth or production. We therefore propose in paragraphs (b)(1) through (3) of this section that these materials and practices be prohibited. It should be noted that this proposal differs from the language given in the Act for the purpose of clarifying the intent of this prohibition. This clarification is necessary because synthetic trace elements and other feed supplements, which are stated in the Act as prohibited when used to stimulate livestock growth or production, are proposed to be permitted, as allowed by the Act, in section 205.13(a) when used only to provide essential nutritional elements to supplement livestock feed. In accordance with section 2118(c)(1) of the OFPA (7 U.S.C. 6517(c)(1)), trace minerals and nutritional supplements are proposed to be included as synthetic substances permitted for use in organic livestock production in section 205.24 of the proposed National List.

*Livestock Health Care—Section 205.14*

In developing our proposed organic livestock health care requirements, we considered information from a number of sources. This research was necessary because the Act does not provide affirmative requirements for the health care of livestock in an organic operation. The primary sources of information we used were the NOSB recommendations, provided in accordance with section 2110(d)(2) of the OFPA (7 U.S.C. 6509(d)(2)), and public input received during the USDA organic livestock hearings held in accordance with section 2110(g) of the OFPA (7 U.S.C. 6509(g)). We also reviewed comments from the public provided during input sessions at NOSB meetings and in response to NOSB draft recommendations. And, finally, we reviewed the livestock production standards of the existing State and private certification organizations in an effort to learn as much as possible about the practices currently being used.

As a result of the research we did, we determined that health care in organic livestock production should be based on the prevention of diseases and should include the provisions of adequate feed, living conditions and attentive care so as to ensure a healthful living environment and prevent the occurrence of disease and injury.

We propose in paragraph (a) that the practice for maintaining livestock health would be a preventive management system. Preventive management includes providing diverse feedstuffs while minimizing conditions favorable to disease, illness, injury and parasites. Techniques such as providing isolation facilities for sick animals, rotating pastures, and introducing species that disrupt parasite reproduction would be appropriate for a certified operation. Sanitation practices, such as the use of antiseptics to cleanse wounds, and the removal of manure, spilled fodder, and soiled bedding material, would be suitable practices to prevent the occurrence and spread of infectious organisms.

We further propose to permit the use of veterinary biologics, such as vaccines and inoculants, as well as vitamins and minerals, to effectively prevent disease or injury. In fact, Federal and State regulations may require the use of vaccines and inoculants, and organic livestock producers would be expected to comply with any applicable regulations regarding mandatory vaccinations. Additionally, the practice of breeding animals for adaptability to site-specific conditions, including resistance to local diseases and parasites, also would play an important role in a system of organic farming.

The OFPA does not contain affirmative requirements for administering animal drugs in the event of illness or injury; section 2110(d)(1) of the OFPA (7 U.S.C. 6509(d)(1)) prohibits administering medications, other than vaccinations, in the absences of illness. This suggests that the use of medications in organic livestock production may be permitted. In determining the appropriate use of medications in organic livestock production, we reviewed the NOSB recommendations, public input received at NOSB meetings, livestock hearings testimony, and existing State and private standards. The result of this research indicated that there is little agreement about the kinds of medications that are appropriate in organic livestock production and how they should be used. There was agreement, however, that even with the best preventive management, animals sometimes become ill, injured or infested with parasites and that producers should be provided with a means of administering medications to sick or injured animals. We have used the term *animal drug* to include three of the terms used in the Act: ''medication, antibiotic and parasiticide'', since animal drug is the term commonly used by the Center for Veterinary Medicine of the FDA in referring to these substances.

In section 205.14(b) we propose that, in a situation where the preventive measures provided for in paragraph (a) were not effective in maintaining livestock health, animal drugs, except as prohibited in paragraph (d) of this section, may be administered to organic livestock and that they may be used at any life stage; restrictions are provided only for mammals and other stock intended for slaughter stock.

Our research indicated that it is appropriate in organic livestock health care to administer parasiticides either internally or externally to any animal at any life-stage, provided that the producer complies with the prohibition against routine use of a synthetic internal parasiticide, set forth in section 2110(d)(1)(B) of the OFPA (7 U.S.C. 6509(d)(1)(B)). Routine use is defined in section 205.2 as administering a parasiticide to an animal without cause. While some public comment favored prohibiting the use of internal parasiticides and the NOSB recommended a restricted use of parasiticides, many producers stated that parasites can threaten animal health at any life-stage and that the use of parasiticides is essential in certain regions of the country. Even under highly controlled situations, some parasites endemic to certain regions can be carried by wild birds, water, or feed. Concerns for the overall health of an animal would indicate that parasiticides be used as soon as possible after determining the presence of parasites at a level that would affect the health of the infected livestock.

Our review of information concerning organic livestock health care revealed a good deal of difference in the use of antibiotics. We found that most of the concern about this drug use in animals was with the subtherapeutic use of antibiotics, which is prohibited by the Act. The NOSB recommended prohibiting the use of antibiotics in the production of organic slaughter stock and restricting the use of antibiotics for other livestock. Public comment suggested that the health of organic livestock might benefit from receiving antibiotics. We would like to solicit public comment on the use of animal drugs in the production of organic livestock, including organic slaughter stock.

Based on the above reasons and after careful consideration of the information available, we propose to restrict the use of animal drugs in animals intended as organic slaughter stock. We propose in sections 205.14(b)(1) and (2) that animal drugs, other than those administered topically and parasiticides, could be administered to mammals intended as slaughter stock only during the first 21 days of life, and to all other slaughter stock only during the first 7 days after arrival at the certified facility. Animal drugs administered topically and

parasiticides could be administered at any time of life.

We propose to permit this limited allowance for the use of animal drugs in slaughter stock due to the concerns about the vulnerability of newly born or hatched livestock brought onto a certified operation from a non-organic source. Newborn animals are particularly vulnerable to diseases, such as diarrhea and pneumonia, during the time immediately following transport, as a result of the stress of adapting to a new environment. Allowing the use of animal drugs would be an appropriate safety net for young organic livestock during their first week of organic management. Since mammals may be as old as 15 days of age when brought onto an organic operation, as proposed in section 205.12(a)(5)(ii) dealing with the sourcing of animals, mammals could receive animal drugs up to the 21st day of life, or 7 days after the last possible date after arrival at the certified facility. This is consistent with the 7-day time period in which animal drugs may be administered to non-mammals after their arrivals onto an organic facility. We believe that restricting the use of animal drugs in organic slaughter stock production is consistent with a system of organic farming and handling which uses prevention methods, rather than substances, to optimize health.

Proposed section 205.14(c) restricts the sale of products from organic livestock to which an animal drug has been administered. We propose in this paragraph that the products from treated livestock could be obtained and thereafter sold, labeled, or represented as organic only after the producer has determined that the animal had fully recovered from the conditions being treated, but in no case sooner than the applicable withdrawal period stated on the label or labeling of the animal drug or as required by the veterinarian. This proposal was developed after a lengthy and extensive review of significant amounts of public input. Also, the NOSB submitted to the Secretary a subsequent addenda to their recommendations on the use of antibiotics and parasiticides in livestock used to produce milk and eggs, which stated:

> Just as soil health must be restored after the use of restricted materials, animals whose health has been threatened by illness or infection must be allowed adequate time to recuperate after administration of an antibiotic or parasiticide. The restoration of health is effected through adequate recovery management. Products from both restored soil and restored animals may then be labeled as organically produced.

In determining when animal health has been restored, a producer might observe the somatic cell counts in milk, the resumption of normal weight gain in a young animal, or an increase of egg production in a laying flock. Under this proposal, an organic producer might reasonably decide to withhold a product from the organic market beyond the withdrawal period specified on the label based on observations of the animal's health.

Some of the input received by the NOSB and the USDA requested extending FDA withdrawal period after internally administering animal drugs, particularly antibiotics or parasiticides, to organic livestock. The extended withdrawal periods suggested by the public input ranged from twice the FDA withdrawal time to a minimum of 90 days. However, our proposal does not make such a requirement because an extended withholding time does not further the goals of a system of organic farming and handling. We wish to point out that under our proposal, animals used for breeding or as a source of other products could later be sold as organic slaughter stock only if the animal complied with all of the other requirements for organic slaughter stock.

*Prohibited Livestock Health Care Practices—Section 205.14(d)*

Section 2110(d) of the OFPA (7 U.S.C. 6509(d)) prohibits producers from using subtherapeutic doses of antibiotics, synthetic internal parasiticides on a routine basis, or medications, other than vaccinations, in the absence of illness. Accordingly, we propose in paragraph (d) of this section to prohibit administering any medication, other than vaccinations, in the absence of illness; the routine use of synthetic internal parasiticides; and the subtherapeutic use of antibiotics.

*Livestock Living Conditions and Manure Management—Section 205.15*

Living conditions play a significant role in livestock health and production. At the USDA hearings and NOSB meetings, extensive testimony was received addressing the issue of livestock living conditions. As provided for under section 2110(d)(2) of the OFPA (7 U.S.C. 6509(d)(2)), the NOSB developed specific recommendations for additional standards for livestock living conditions, including manure management. This proposal is consistent with the NOSB recommendations.

In section 205.15(a), we propose to require that the following living conditions be provided, as appropriate to the species, to promote livestock health: protection from the elements; space for movement; clean and dry living conditions; and appropriate access to the outdoors, food and clean water. These conditions would provide a healthful environment to raise organically produced livestock and reduce or eliminate the need to administer animal drugs.

We propose in section 205.15(b) that, if necessary, animals could be maintained under conditions that restrict the available space for movement or access to outdoors, provided that other living conditions are adequate to maintain the animals' health without the use of animal drugs, except as provided in 205.14(b). In developing this proposal, we considered public input regarding the effects of climate, geographical location and physical surroundings on the ability of animals to have access to the outdoors. The premise that organic management is soil based and that animals should be allowed, as appropriate, access to the soil was considered in balance with animal health issues, such as prevention of exposure to harmful organisms carried by wild animals and the need to keep animals indoors during extended periods of inclement weather. The flexibility provided by the provisions of 205.15(b) would allow operations without facilities for outdoor access to be certified for organic livestock production and also would permit animals to be confined during critical periods such as farrowing.

As noted, the producer could maintain animals under conditions that restrict the available space for movement or access to outside only if the practice is appropriate and necessary. As previously discussed in regards to the use of non-organic sources of livestock feed and mammalian livestock designated as organic slaughter stock, the determination of necessity would be based on site-specific conditions that would be described by the producer in an organic plan, or updates to an organic plan, and reviewed and evaluated by the certifying agent.

We are requesting public comment as to the conditions under which animals may be maintained so as to restrict the available space for movement or access to outdoors. Examples of site-specific conditions which might serve as a basis for maintaining animals under conditions that restrict the available space for movement or access to outdoors are: emergency or unanticipated circumstances and site-specific soil, climate, animal health, or other environmental factors. We also

request comment as to whether we should allow practices that restrict the available space for movement or access to outdoors.

*Manure Management—Section 205.15(c)*

In section 205.15(c), we propose that in any area where livestock are housed, pastured or penned, manure would have to be managed in a way that does not cause measurable degradation of soil quality; does not significantly contribute to contamination of water by nitrates and bacteria, including human pathogens; optimizes nutrient recycling; and does not include burning or any practice inconsistent with section 205.14(a) of this subpart which addresses prevention of livestock health problems. These provisions are consistent with sections 2114(b)(1) and (2) of the OFPA (7 U.S.C. 6513(b)(1) and (2)) that address proper manuring and methods for applying livestock manure to soil. The proper management of manure requires that it be used in a way that optimizes nutrient recycling to be consistent with a system of organic farming. As discussed in the supplementary information for proposed section 205.7(d)(3), the disposal of manure by burning cannot be considered proper manuring.

**Organic Handling Requirements**

*Product Composition—Section 205.16*

This section of our proposal addresses the requirements and prohibitions for ingredients used in products that would be permitted to use the word organic in some manner on a label or labeling of an agricultural product. These provisions are in accordance with: section 2106(a)(1)(A) of the OFPA (7 U.S.C. 6505(a)(1)(A)) which requires that any product that is sold, labeled, or represented as organic must be produced and handled in accordance with the Act; section 2111(a)(4) of the OFPA (7 U.S.C. 6510(a)(4)) which provides for an organic product to contain up to 5 percent by total weight of the finished product, exclusive of water and salt, of non-organically produced ingredients that are on the National List; and sections 2106(c)(1) and (2) of the OFPA (7 U.S.C. 6505(c)(1) and (2)) which permit certain exemptions for agricultural products that contain more than 5 percent non-organically produced ingredients.

In paragraph (a)(1) of this section, we propose that an agricultural product, including a raw agricultural product, sold, labeled, or represented as organic, contain only organically produced agricultural ingredients, exclusive of water or salt, except in one circumstance. This exception is based on section 2111(a)(4) of the OFPA (7 U.S.C. 6510(a)(4)) which allows an organically produced agricultural product to contain up to 5 percent non-organically produced ingredients that are on the National List. Accordingly, we propose in paragraphs (a)(1)(i) and (ii) of this section that a product sold, labeled, or represented as organic could contain non-organically produced agricultural products and non-agricultural ingredients that are included on the National List, up to 5 percent of the total weight of the finished product, exclusive of water or salt. As proposed and discussed in the supplementary information to the National List section 205.27 for non-organic agricultural products, all non-organically produced agricultural products are proposed to be included on the National List, and therefore would be permitted for use in an organic product in accordance with section 2111(a)(4) of the OFPA (7 U.S.C. 6510(a)(4)).

We propose in paragraph (a)(2) of this section the order of preference by which all ingredients used in an organic product would have to be selected. We have determined that the provisions of paragraph (a)(2) of this section are needed to ensure the integrity of products sold, labeled, or represented as organic and to ensure that organic products are handled in accordance with a system of organic farming and handling, as defined in proposed section 205.2 of subpart A. Accordingly, we propose in paragraph (a)(2)(i) that a handler would have to select commercially available organically produced agricultural products as ingredients in preference to non-organic agricultural products and non-agricultural ingredients. For example, in a bread that contains 97 percent organically produced flour and also sesame seeds, a handler would have to use organically produced sesame seeds whenever they were commercially available.

We propose in paragraph (a)(2)(ii) that a handler would have to choose a commercially available non-organically produced agricultural product as an ingredient in preference to a non-agricultural ingredient. For example, a thickener such as corn starch or arrowroot, if commercially available, would need to be selected as an ingredient in a salad dressing in preference to a non-agricultural ingredient, such as disodium phosphate. Paragraphs (i) and (ii) of this section together would direct a handler toward the use of an organically produced agricultural product whenever possible for a given function in the product. The provisions of these two paragraphs are consistent with the NOSB recommendation that organic ingredients be used in a multi-ingredient product to the extent possible.

We propose in paragraph (a)(2)(iii) of this section that a non-organically produced agricultural product or non-agricultural ingredient that is extracted without the use of a synthetic volatile solvent, or which does not contain propylene glycol as a carrier, if commercially available, must be used as an ingredient in preference to a non-organically produced agricultural product or non-agricultural ingredient that is extracted with a synthetic volatile solvent or which contains propylene glycol as a carrier.

Although the NOSB recommended that substances extracted with a synthetic volatile solvent (such as hexane) or that contain propylene glycol as a carrier be prohibited for use in organic products, we believe our proposal to allow their use only when alternative substances or products are not commercially available does not affect the integrity of organically produced products.

Section 2106(c)(1) of the OFPA (7 U.S.C. 6505(c)(1)) authorizes products that contain at least 50 percent (but less than 95 percent) organically produced ingredients to use the word organic on the principal display panel of the product to describe those ingredients that are organically produced. Accordingly, the Secretary, in consultation with the NOSB and the Secretary of Health and Human Services, is proposing in subpart C of this part to allow the statement made with certain organic ingredients to appear on the principal display panel of this type of product.

We propose in paragraph (b) the composition requirements for a product labeled as made with certain organic ingredients. These proposed requirements are that the total weight of the finished product that is not comprised of organic agricultural products, excluding water and salt, shall consist of some combination of non-organically produced agricultural products and non-agricultural ingredients included on the National List. This is consistent with the proposed composition requirement for non-organic ingredients in products labeled as organic and is consistent with the composition requirements of section 2111(a)(4) of the OFPA (7 U.S.C. 6510(a)(4)).

Proposed paragraph (b)(3) of this section would require that products sold, labeled, or represented as made with certain organic ingredients have been produced in compliance with sections 205.16 through 205.19 of this proposal, with the exception of sections 205.16 (a) and (c) of this subpart. Section 205.16(a) applies to agricultural products, including raw agricultural products, that are labeled as organic. Section 205.16(c) applies to multi-ingredient agricultural products that only represent the organic nature of such ingredients in the ingredients statement and which themselves are not sold, labeled or represented as organic or made with certain organic ingredients. The provisions of proposed paragraph (b)(3) are necessary to assure consumers that products in which the predominant portion of ingredients are represented as organically produced have been produced and handled in accordance with a consistent standard, as provided under section 2102(2) of the OFPA (7 U.S.C. 6501(2)).

We note that processed agricultural products sold, labeled, or represented as made with certain organic ingredients are exempted by section 2106(c)(1) of the OFPA (7 U.S.C. 6505(c)(1)) from complying with the provisions of the Act, except as required by the Secretary in consultation with the NOSB and the Secretary of HHS. Therefore, handlers of this type of product can be exempted from complying with certain provisions of this proposal, provided that the exemptions do not affect the integrity of the organic ingredients in the product. Accordingly, as proposed and discussed in the supplementary information for section 205.201(b) of subpart D regarding an exemption for handlers of this type of product from the requirement set forth in section 205.3(b)(2) of subpart B that a commercially available non-synthetic substance be selected in preference to an allowed synthetic substance, we note that a handling operation that produces products sold, labeled, or represented as made with certain organic ingredients also would not be subject to the provisions in section 205.16(a) and (c) with respect to the handling of this type of product. For example, a manufacturer of a product sold, labeled, or represented as made with certain organic ingredients could use a non-organic agricultural ingredient instead of a commercially available organic agricultural ingredient, as is required in proposed section 205.16(a)(2) for the manufacturer of a product to be sold, labeled or represented as organic. However, the handling operation would be required to be certified and to demonstrate in the organic plan compliance with the applicable handling requirements in subpart B. We believe that these provisions will help assure the integrity of the organic ingredients in this type of product without imposing undue requirements on the handlers who produce them.

Paragraph (c) of this section is proposed in accordance with section 2106(c)(2) of the OFPA (7 U.S.C. 6505(c)(2)) and would exempt a multi-ingredient product that only represents the organic nature of such ingredients in the ingredients statement, and which itself is not sold, labeled or represented as organic or made with certain organic ingredients, from complying with the requirements proposed in this subpart. It is not critical for either the purposes of the Act or the integrity of the organic ingredients if a finished product that cannot be sold, labeled, or represented as organic or as made with certain organic ingredients on its principal display panel is not subject to the provisions of this subpart. We note, however, that although a finished product that contains less than 50 percent organically produced ingredients, or any other multi-ingredient product that represents the organic nature of ingredients in the ingredients statement and which is not labeled as organic or made with certain organic ingredients, need not be handled by a certified organic handling operation, the ingredients represented as organic in such a product must have been produced and handled in accordance with all the applicable provisions of the Act and the regulations of this part. In addition, while handling operations which handle only this type of product would not be required to become certified under the provisions proposed in section 205.202 of subpart D, this proposal would still require such operations to maintain records to show that any organic ingredients listed on product labels were obtained from operations that were certified in compliance with the Act and the regulations of this part.

Paragraph (d) of this section would prohibit the use of organic and non-organic forms of the same agricultural ingredient if the ingredient is listed as organic in the ingredients statement. We believe that such a provision is needed in order to avoid any possibility of confusion concerning the source and percentage of the organic ingredients in the product.

Paragraph (e) of this section would prohibit, in accordance with sections 2111(a)(3) and (7) of the OFPA (7 U.S.C. 6510(a)(3) and (7)), the addition of sulfites, nitrates, or nitrites to an organic food product, or the addition to the food of water that does not meet the Safe Drinking Water Act requirements (42 U.S.C. 300f *et seq.*).

*Processing Practices—Section 205.17*

In paragraph (a) of this section we propose that biological methods, such as fermentation, or mechanical methods, such as grinding, pressing, heating or drying, be used to process an agricultural product intended to be sold, labeled, or represented as organic or made with certain organic ingredients for the purpose of retarding spoilage or otherwise preparing an agricultural product for market. However, an incidental additive, except for the prohibition on the use of volatile synthetic solvents proposed in section 205.17(b)(3), may be used, if necessary, to process an agricultural product intended to be sold, labeled, or represented as organic or made with certain organic ingredients. An incidental additive used in the processing of agricultural products is defined in proposed section 205.2 as an additive present in an agricultural product at an insignificant level and that does not have any technical or functional effect in the product, and is therefore not considered an active ingredient. As discussed in the supplementary information for section 205.26 of subpart B, incidental additives may be used in organic handling without inclusion on the National List. Section 205.17(a) is consistent with the principles stated in our proposed definition of a system of organic farming and handling (section 205.2) and as further discussed in the introduction to the supplementary information for subpart B.

The NOSB recommended that handlers document that a food could not be processed without the use of a synthetic incidental additive and that the handler demonstrate progress to replace the synthetic incidental additive over time. The NOSB language is consistent with our proposal to permit the use of such substances only if necessary. By including several synthetic incidental additives in its National List recommendations, the NOSB also recognized that a wide range of currently available organic products could not be manufactured feasibly without the use of incidental additives, such as defoaming agents, adjuvants, clarifiers, filtering agents and equipment cleansers.

As noted, a producer could use an incidental additive if the use of the additive is necessary. As previously

described in the supplementary information for sections 205.12, 205.13, and 205.15 of subpart B regarding livestock production, determination of necessity would be based on site-specific conditions that would be described by a producer in an organic plan, or updates to an organic plan, and reviewed by the certifying agent.

We are requesting public comment as to the conditions under which incidental additives may be used. For example, we would like public comment as to whether specific conditions, such as the inefficacy or unavailability of mechanical or biological methods, should be a prerequisite for using an incidental additive and, if so, what these conditions should be. We also request comment as to whether handlers who handle only products sold, labeled, or represented as made with certain organic ingredients should be exempted from the restriction of using incidental additives only if necessary.

Paragraph (b) of this section proposes several practices that would be prohibited for the processing and preparation of any raw agricultural product, and on a finished agricultural product, sold, labeled, or represented as organic or as made with certain organic ingredients.

Paragraphs (b)(1) and (b)(2) of this section are proposed in accordance with sections 2111(a)(5) and (6) of the OFPA (7 U.S.C. 6510(a)(5) and (6)) and would prohibit the use of storage containers or bins, including packages and packaging materials that contain synthetic fungicides, preservatives or fumigants, and also would prohibit the use or reuse of any bag or container that previously had been in contact with any substance that could compromise the organic integrity of its contents. Our proposed definition of packaging set forth in section 205.2 encompasses waxes used in contact with an edible surface of an agricultural product.

Proposed paragraph (b)(3) of this section would prohibit the use of a volatile synthetic solvent. Volatile synthetic solvents, such as hexane or isopropyl alcohol, are used in processing and extraction. This proposed prohibition is made under the authority of section 2107(a)(11) of the OFPA (7 U.S.C. 6506(a)(11)) which authorizes this program to require such terms and conditions as are determined necessary. The prohibition of the use of a volatile synthetic solvent is in agreement with the NOSB recommendation that the use of a volatile synthetic solvent is not essential, and therefore should not be permitted in the handling of an organically produced product or a product sold, labeled, or represented as organic or made with certain organic ingredients.

As previously discussed in regard to the use of raw manure in organic crop production (section 205.7 of subpart B), there has been an increase in the incidence of food borne illness caused by certain pathogens. The application of ionizing radiation as a sanitation or preservation treatment currently is permitted by FDA for a wide range of agricultural products. Additionally, a request to permit the use of ionizing radiation on red meat products was recently approved by FDA. The NOSB has recommended to the Secretary that the practice of ionizing radiation should not be allowed in organic handling, and its use is prohibited by most existing organic certification programs which we have reviewed.

Public comment is invited with respect to the compatibility of the use of ionizing radiation with a system of organic farming and handling. The USDA also invites comments on whether there are effective alternatives to ionizing radiation, such as sanitary practices, heat pasteurization and incidental additives, that are compatible with a system of organic farming and handling, and, if so, how they are compatible. Additionally, we are soliciting comment as to whether the use of ionizing radiation is considered an essential standard industry practice, or good manufacturing practice, in the processing of any agricultural product: for example, in the sanitary handling of herbs and spices.

*Prevention and Control of Facility Pests—Section 205.18*

We are proposing provisions to safeguard the integrity of organic products that are handled in facilities in which pest control substances may be used. The NOSB recommendations and our review of most existing organic programs indicate that this area needs to be addressed. We have accordingly determined, as authorized by section 2107(a)(11) of the OFPA (7 U.S.C. 6506(a)(11)), which authorizes this program to require such terms and conditions as are determined necessary, that the proposed requirements for facility pest management in an organic handling operation are necessary and appropriate for an organic certification program.

As is true with crop production and livestock health care, prevention of pest occurrences should be the first strategy used by an organic handler. This is also consistent with the goal of maintaining the integrity of organic products by avoiding the need to use pest control substances in handling facilities, as reflected in our definition of a system of organic farming and handling. We propose in paragraph (a) of this section that the best practice for control and prevention of facility pests would be a preventive management system. This system would include measures to remove pest habitat and to prevent pests from gaining entrance to the handling facility, as well as managing environmental factors inside the facility such as temperature, light, air circulation and humidity to discourage proliferation of pest populations.

If prevention measures are not effective and pests do appear in organic handling facilities, we propose in paragraph (b) of this section for facility pest control to permit the use of pest control techniques, which include: mechanical controls such as traps or barriers; augmentation and introduction of predators and parasites for the pest species; and non-toxic, non-synthetic substances such as lures and repellants. Pest prevention and control is further discussed in the supplementary information provided in section 205.9 for crop pests, weeds and diseases.

However, if pest prevention or control measures provided in paragraph (a) and (b) of this section are not effective, we propose in paragraph (c) of this section to permit the use of any substance to control pests, provided the substance is approved for its intended use by the appropriate regulatory authority and the substance is applied in a manner that prevents such substance from contacting any ingredient or finished product intended to be sold, labeled, or represented as organic or made with certain organic ingredients. We have proposed paragraph (c) in recognition of the fact that handling facilities are subject to federal, state, and local regulations concerning food safety. The use of the practices in paragraph (c) of this section would entail maintaining adequate safeguards to protect organic products and ingredients from being contacted by any pest control substance.

As noted, proposed paragraph (c) would allow the use of any substance to control pests, provided such substances were used only when methods to prevent or control pests were not effective. Additionally, any substance used must be applied in a manner that prevents such substance from contacting any ingredient or finished product intended to be sold, labeled, or represented as organic or made with certain organic ingredients. Because eradication of a pest infestation may necessitate the use of substances, we are proposing to allow the use of any

substance approved for use by the appropriate Federal, State or local regulatory agency to assure that organic handling operations have sufficient practices available to deal effectively with severe pest infestations. Structural pest control is unique in that substances used for this purpose are not considered to be used in the production and handling of organic crops, and are not applied to land used in the production of organic crops.

Many existing certification programs restrict synthetic substances used to control pests in certified handling facilities to substances reviewed and allowed for use by the certification agency. We request comment as to whether only those substances included on the National List of active synthetic substances allowed for use in organic crop production, as set forth in section 205.22, should be permitted to be used to control pests in certified handling facilities. Additionally, if the use of synthetic substances in structural pest control should not be restricted solely to those synthetic substances included on the National List of active synthetic substances, we request comment as to whether handlers should be required to use synthetic substances included on the National List of active synthetic substances (or a non-synthetic biological or botanical substance) before the use of synthetic substances not included on the National List.

*Prevention of Commingling and Contact With Prohibited Substances—Section 205.19*

There are two primary threats to organic integrity: the possibility of commingling organic products with similar products that were not organically produced, and the possibility of the organic product coming into contact with a prohibited substance. Since there is no apparent physical difference between an organically produced product and a non-organic product, commingling is a serious concern and an organic handling operation must make every effort to provide adequate measures to ensure that commingling does not occur, in addition to adopting measures to protect organic products from contacting prohibited substances.

Sections 2107(b)(1)(C) and 2111(b) of the OFPA (7 U.S.C. 6506(b)(1)(C) and 6510(b)) specifically provide for the prevention of commingling of organic and non-organic products, especially meat, in any operation that handles both types of products, and the implementation of practices that protect organic products from contact with prohibited substances. Therefore, we propose in this section that a certified handling operation, and a handling operation that is exempt or excluded from certification in accordance with section 205.202(a)(3) or section 205.202(b) of subpart D, shall be required to establish appropriate safeguards during handling, storage and transportation to both prevent the commingling of organic and non-organic products and to assure that organic products are protected from contact with prohibited substances.

These safeguards could take many forms depending on the nature of the products and the certified handling operation, and should encompass each step of the manufacturing or handling process, including storage and transportation. A certified handling operation that receives certification under our proposal might consist of disparate locations and facilities, including some that handle both non-organic and organic products. The public input we have received indicates that many certified handling operations use subcontractors to perform certain processing functions, such as dehydrating or freezing, rather than performing the function within the facilities maintained by the certified operation. Our primary concern in these instances is that adequate safeguards are maintained by the certified operation and the subcontractor to ensure that commingling and contact of organic products with prohibited substances did not occur. A certified handling operation that subcontracted with different facilities for cold storage, for example, would have to make sure that its products were clearly segregated from non-organic products and that an inspector examined all such subcontracted facilities as a part of the site visit to the certified operation. A certified handling operation also would have to take appropriate measures to ensure that organic products or ingredients were transported under conditions that protected their integrity. We note that the best method to prevent commingling or contact with prohibited substances would be to eliminate the possibility of such occurrences, such as when a certified operation handles only organic products and uses no prohibited pest control substances.

*Subpart B—National List*

*Purpose and Basis of the Proposed National List*

The National standards for organic production, provided for in section 2105 of the OFPA (7 U.S.C. 6504), include the requirement that an organically produced agricultural product shall have been produced without the use of synthetic chemicals, except as otherwise provided for in the Act. The exemptions to which section 2105 refers are specifically delineated in section 2118 of the OFPA (7 U.S.C. 6517), which provides for the establishment of a National List of substances that may be allowed for use in an organic farming or handling operation that are otherwise prohibited for use under the Act. This section also provides for the establishment of a National List of non-synthetic substances, that are otherwise allowed under the Act, that may not be used in organic farming or handling.

Section 2118(a) of the OFPA (7 U.S.C. 6517(a)) provides that the Secretary shall establish the National List of approved and prohibited substances, and section 2118(d)(1) of the OFPA (7 U.S.C. 6517(d)(1)) provides that the National List shall be based upon a proposed national list developed by the NOSB. In accordance with section 2119 of the OFPA (7 U.S.C. 6518), the NOSB conducted the prescribed review process, and solicited public comment at meetings, before recommending an initial proposed national list to the Secretary. The NOSB recommendations were based on at least one technical advisory panel review of each substance in question, as required in section 2119(k)(3) of the OFPA (7 U.S.C. 6518(k)(3)). The NOSB also reviewed available information from the Environmental Protection Agency, the National Institute of Environmental Health Studies, and other appropriate sources, as required in section 2119(l)(1) of the OFPA (7 U.S.C. 6518(l)(1)), to assist it in evaluating each substance under consideration in accordance with the criteria delineated in section 2119(m) of the OFPA (7 U.S.C. 6518(m)). The criteria that were considered for each substance are: the potential of the substance for detrimental chemical interactions with other materials used in organic farming systems; the toxicity and mode of action of the substance and of its breakdown products or any contaminants, and their persistence in the environment; the probability of environmental contamination during manufacture, use, misuse or disposal of the substance; its effects on human health; the effects of the substance on biological and chemical interactions in the agroecosystem; the alternatives to using the substance; and the compatibility of the substance with a system of sustainable agriculture. The NOSB recommendations, along with the results of the required evaluation and technical advisory panel review for each

substance, were considered by the Secretary in accordance with the requirements of section 2118(d) of the OFPA (7 U.S.C. 6517(d)).

**Basis for Inclusion of Substances and Ingredients on the National List**

*Basis for Inclusion of Specific Synthetic Substances on the National List of Synthetic Substances Allowed for Use in Organic Farming and Handling*

Section 2118(c)(1) of the OFPA (7 U.S.C. 6517(c)(1)) provides three sets of criteria upon which determinations to allow the use of substances that are otherwise prohibited by the Act must be based. The first set of criteria, in section 2118(c)(1)(A) of the OFPA (7 U.S.C. 6517(c)(1)(A)), requires that the Secretary, in consultation with the Secretary of the Department of Health and Human Services and the Administrator of EPA, determine that: use of the substance would not be harmful to human health or the environment; the substance is necessary to the production or handling of an agricultural product because of the unavailability of wholly natural substitute products; and the use of the substance is consistent with organic farming and handling.

The second set of criteria in section 2118(c)(1)(B) of the OFPA (7 U.S.C. 6517(c)(1)(B)) describes the types of substances that may be considered for use if they are included on the National List. The first type of substance is one that is used in production and contains an active synthetic ingredient that falls into one of the following categories: copper and sulfur compounds; toxins derived from bacteria; pheromones; soaps; horticultural oils; fish emulsions; treated seed; vitamins and minerals; livestock parasiticides and medicines; and production aids, including netting, tree wraps and seals, insect traps, sticky barriers, row covers, and equipment cleansers. The Secretary has accordingly reviewed each substance proposed in sections 205.22 and 205.24 for inclusion on the National List to determine that it is an active synthetic ingredient or includes an active synthetic ingredient. The second type is a substance that is used (in a formulation) in production and (the formulation) contains synthetic inert ingredients that the Administrator of the EPA has not classified as inerts of toxicological concern; and the third type of substance is one that is used in handling and is non-synthetic but is not organically produced.

The third criterion in section 2118(c)(1)(C) of the OFPA (7 U.S.C. 6517(c)(1)(C)) is that each specific exemption be developed according to the procedure described in section 2118(d) of the OFPA (7 U.S.C. 6517(d)) for establishing and amending the National List. This procedure includes basing the proposed National List on the recommendations received from the NOSB, and publishing such proposed National List in the **Federal Register** for public comment before establishing the National List. The same procedure must be used in developing any amendments to the National List.

After receiving the NOSB's recommendations, the Secretary determined, in consultation with the Secretary of HHS and the Administrator of the EPA that the use of each substance or ingredient being considered for inclusion on the proposed National List of synthetic substances allowed for use in organic farming would meet the first set of criteria. We then examined the second set of criteria to make determinations concerning substances being considered for inclusion on the National List of allowed synthetic substances. For each substance considered, it was first necessary to determine whether the substance is synthetic according to the definition provided by the Act. The Act defines a synthetic substance to be ''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.''

The language in section 2118(c)(1)(B)(i) of the OFPA (7 U.S.C. 6517)(c)(1)(B)(i)), which provides one set of criteria for placing a substance on the National List, makes it clear that only synthetic substances that contain active ingredients need to be on the National List in order to be permitted for use in organic production. This provision only encompasses active synthetic ingredients that are used in production and that come within certain categories. We have accordingly proposed a definition of an active ingredient or substance (in any input other than pesticide formulations) to include any substance that, when used in a system of organic farming or handling, becomes a chemically functional part of that system, or is otherwise of significant consequence to the production, handling and integrity of an organically produced product. This definition excludes substances that are present in insignificant amounts in the agroecosystem, such as equipment cleansers; do not chemically interact with the system, such as plastic mulches or row covers; or are otherwise inconsequential to the performance of any function within the system.

It should be noted that a formulated product that contains a substance that is an active synthetic ingredient and which also contains a synthetic inert ingredient may only be used if the active synthetic ingredient is included in one of the proposed allowed synthetic categories. Section 2118(c)(1)(B)(ii) of the OFPA (7 U.S.C. 6517(c)(1)(B)(ii)) does not require that inert ingredients be included as a separate category of the National List in order to be permitted for use in organic production. Rather, the Act requires only that the inert ingredients not be classified by the Administrator of the EPA as inerts of toxicological concern in order for the substance to be permitted for use. Our proposal for evaluating formulations that contain synthetic inert ingredients is included and discussed in proposed sections 205.20 through 205.21 and the corresponding supplementary information.

The discussions held by the NOSB as they evaluated substances under consideration, and their recommendations for their proposed National List, served as the primary basis for our determinations as to whether or not a particular substance is active and synthetic, and if so, whether to include it as an allowed synthetic substance on the proposed National List. A discussion of those substances that we have determined to be synthetic, but not active, and which therefore are not required to be included on the National List in order to be used in organic farming and handling, is included in the supplementary information to section 205.20 of this proposal, which sets forth all the categories of substances and ingredients that can be used in organic production and handling.

*Basis for Including Specific Natural (Non-synthetic) Substances on the National List of Non-synthetic Substances Prohibited for Use in Organic Farming and Handling*

In this proposal the word non-synthetic is used to address substances that are described in the Act as either natural or non-synthetic. No definition is provided in the OFPA for the word natural. There is also a great deal of ambiguity currently surrounding the use and meaning of the term in regard to production inputs, nutritional supplements, cosmetics and other products. The use of the term non-synthetic in section 2118 of the OFPA (7 U.S.C. 6517) provides us with the basis for using this term in our proposed rule to describe substances that are not

synthetic. By using this one term to describe substances that are not determined to be synthetic, we hope to avoid the uncertainty that surrounds the current use of the term natural in the marketplace. Therefore, in agreement with the recommendations provided by the NOSB, we will use the word non-synthetic in this and all other provisions of this proposal to address substances that are described in the Act either as natural or non-synthetic substances.

Natural (non-synthetic) substances are generally allowed under the Act for use in organic farming and handling and thus do not have to be included on the National List in order to be used. However, the Act does provide for specific natural (non-synthetic) substances to be prohibited for use in organic farming and handling if certain criteria are met. The Act also provides that the specified natural (non-synthetic) substances which are prohibited for use in organic farming and handling are to be put on the National List of prohibited substances.

Section 2118(c)(2) of the OFPA (7 U.S.C. 6517(c)(2)) delineates the criteria upon which the decision to prohibit the use of a specific natural substance is to be based. These criteria require that the Secretary determine, in consultation with the Secretary of HHS and the Administrator of the EPA, that the use of the substance would be harmful to human health or the environment, and that its use would be inconsistent with organic farming or handling and the purposes of the Act.

*Basis for Inclusion of Non-agricultural Substances and Non-organically Produced Agricultural Products on the National List as Substances Permitted for Use as Ingredients In or On Processed Organic Products.*

One criterion provided by section 2118(c)(1)(A)(ii) of the OFPA (7 U.S.C. 6517(c)(1)(A)(ii)) for inclusion of a substance on the National List of synthetic substances permitted to be used is that it must be necessary to the production or handling of the agricultural product because of the unavailability of wholly natural substitute products. Thus, synthetic substances used in handling an organic product may be considered for inclusion on the National List of substances permitted to be used. Such substances, however, must be evaluated according to the same criteria as synthetic substances permitted to be used in crop or livestock production, in accordance with section 2118(c)(1)(A) of the OFPA (7 U.S.C. 6517(c)(1)(A)). Section 2118(c)(1)(B)(iii) of the OFPA (7 U.S.C. 6517(c)(1)(B)(iii)) permits the consideration of the inclusion of non-synthetic non-organically produced substances on the National List for use in handling organic processed products if they meet the same criteria set forth for synthetic substances in section 2118(c)(1)(A) of the OFPA (7 U.S.C. 6517(c)(1)(A)). Because a substance that is not an agricultural product is considered to be non-organically produced, this OFPA provision requires that the NOSB and the Secretary evaluate non-synthetic non-agricultural substances according to the same criteria and procedure as an active synthetic substance used in crop or livestock production or handling. For these reasons, we are proposing in section 205.26 a National List category of non-agricultural substances allowed as ingredients in or on organic processed products, that consists of both synthetic and non-synthetic substances. A separate category of non-organically produced agricultural products allowed as ingredients in organic processed products is proposed in section 205.27, also in accordance with section 2118(c)(1)(B)(iii) of the OFPA (7 U.S.C. 6517(c)(1)(B)(iii)).

*Summary of the National List and Petition Process for Adding New Substances*

Sections 205.20 and 205.21 of subpart B provide a summary of all the categories of substances, ingredients and formulated products that are either allowed or prohibited for use in organic farming and handling. These sections are proposed in order to make clear the status of any substance that may be considered for use in a certified operation. The following are the categories of substances that we propose comprise the National List: active synthetic substances allowed for use in organic crop production (section 205.22); non-synthetic substances prohibited for use in organic crop production (section 205.23); active synthetic substances allowed for use in organic livestock production (section 205.24); non-synthetic substances prohibited for use in organic livestock production (section 205.25); non-agricultural substances allowed as ingredients in or on processed products labeled as organic or as made with certain organic ingredients (section 205.26); and non-organically produced agricultural products allowed as ingredients in or on processed products labeled as organic or as made with certain organic ingredients (section 205.27).

The six categories of substances we propose for the National List delineate the substances that can and cannot be used in organic crop production, in organic livestock production, and in processed products labeled as organic or made with certain organic ingredients. Accordingly, only a substance that appears in more than one category, such as synthetic mineral nutrients that are proposed for use in both crop production and as livestock feed supplements, may be used for more than one purpose.

Proposed section 205.28 delineates the process by which a person may petition the NOSB to add new substances to the National List in any of the six aforementioned categories, which entails the submission of specified information to USDA.

*Relationship of the National List to the Organic Production and Handling Requirements*

Section 2118(a) of the OFPA (7 U.S.C. 6517(a)) requires the Secretary to establish a National List to be included in the standards for organic production and handling established under the Act. We have accordingly developed the proposed production and handling requirements (sections 205.3 through 205.19) and the National List (sections 205.22 through 205.28) as a unified whole. The practices delineated within the proposed requirements for organic production and handling include appropriate restrictions and conditions on the use of substances, while the National List delineates what substances may or may not be used. These standards also are intended to be consistent with our proposed definition of a system of organic farming and handling, which, as discussed previously, was created in order to provide a concise summary of the underlying principles implicit in the Act. Under this proposal, any substance that is permitted to be used in organic farming or handling must be used in compliance with the regulations delineated in sections 205.5 through 205.19 of subpart B and must also meet the requirements proposed in section 205.3(b)(1) that its use not result in any measurable degradation of soil or water quality. We believe that the provisions proposed here for the appropriate use and application of substances is consistent with the provisions of the Act that address the National List and with the definition of a system of organic farming and handling.

*General Rules for Categories of Substances and Ingredients Permitted for Use in Organic Farming and Handling—Section 205.20*

Section 205.20 has been proposed to make it clear that a substance or

ingredient on the National List of substances permitted to be used in organic farming and handling may have its use restricted under other proposed regulatory provisions.

In section 205.20(a) we propose that all active synthetic substances or non-organically produced ingredients that are included on the National List in sections 205.22, 205.24, 205.26, or 205.27, and therefore permitted to be used in organic farming and handling, would have to be used in compliance with the Act and all the regulations we are proposing. In paragraph (b) of this section we propose that any other substance that may be used in a system of organic farming and handling also would have to be used in compliance with the Act and the regulations. Thus, any substance or ingredient that is permitted for use only could be used if its use complied with any applicable restrictions on its use that are provided for in other sections of the proposed regulations. For example, section 205.7(c)(2)(i) permits the use of synthetic micronutrients to produce organic crops provided that the micronutrients are not applied in a manner intended to be herbicidal, and section 205.16(a) permits the use of non-organically produced ingredients in a product labeled as organic provided that the ingredients comprise less than 5 percent of the total weight of the product, excluding water and salt. Of course, all substances used in organic farming or handling also must be used in accordance with any other applicable Federal, State, or local regulations.

In section 205.20(b) we propose three categories of substances that are not required to be included on the National List in order to be permitted for use in the production or handling of organic products. A substance that does not appear on the National List would have to be included in one of these categories in order to be used in organic farming or handling, as applicable.

The first category of substances permitted for use in organic farming or handling, as proposed in paragraph (b) of this section, comprises non-synthetic substances that are not included on the National List in section 205.23 or section 205.25 as a non-synthetic substance prohibited for use. Section 2118(c)(2) of the OFPA (7 U.S.C. 6517(c)(2)) provides for a non-synthetic substance to be prohibited in organic farming and handling only when it is included as a prohibited substance on the National List. Also, section 2113 of the OFPA (7 U.S.C. 6512) states that a production or handling practice is permitted under the Act unless it is prohibited or otherwise restricted, or is determined to be inconsistent with the certification program established under the Act.

The following list contains various substances that we have reviewed in consultation with the NOSB and determined to be both non-synthetic and as not meeting the Act's criteria that would prohibit their use. Therefore, these substances are permitted for use in organic crop production. This list is not intended to be inclusive of all non-synthetic substances allowed for use. It is, however, based on lists of substances historically permitted for use in organic production by existing certification programs and is included here as a reference guide.

**A List of Natural (Non-Synthetic) Substances Reviewed for Use in Organic Crop Production (Non-Inclusive, for Reference Only)**

*Animal substances or byproducts:*
- Blood meal
- Bone meal and bones
- Feather meal
- Fish emulsions
- Fish hydrolysate
- Fish products (fish meal, fish bones, and fish powder)
- Fish solubles
- Guano, bat or bird
- Hoof and horn meal
- Insect extracts
- Manures, animal
- Manure tea
- Oyster shells and other sea shells
- Oyster shell lime
- Sea animal wastes
- Tankage
- Whey, dairy
- Worm castings

*Beneficial organisms*
- Algae
- Bacteria [including *Bacillus thuringiensis* (Bt)]
- Fungi
- Higher animals
- Higher plants
- Insects
- Microbial soil, compost, plant and seed inoculants
- Mites
- Nematodes
- Protozoa
- Viruses

*Fermented or bio-processed substances and composts (see animal, plant and mineral categories for compost feed stocks):*
- Alcohol-from natural sources only (Ethyl)
- Biodynamic preparations
- Compost
- Compost tea
- Gibberellic acid
- Leaf mold
- Mushroom compost
- Vinegar

*Mined minerals and other mined substances:*
- Basalt
- Borate and boron products
- Calcium sulfate (gypsum)
- Chilean nitrate (sodium nitrate, nitrate of soda)
- Clays
- Colloidal phosphate
- Cryolite (sodium fluoaluminate)
- Diatomaceous earth
- Dolomite
- Feldspar
- Granite dust
- Greensand
- Humates, mined sources
- Humic acid derivatives
- Kieserite
- Lignite
- Limestone
- Marl
- Muriate of potash
- Niter (potassium nitrate)
- Peat moss
- Perlite
- Phosphate rock, raw
- Potassium sulfate
- Pumice
- Rock dust
- Sand
- Sulfur
- Sulphate of potash magnesia (langbeinite)
- Sodium bicarbonate
- Vermiculite

*Plant substances or byproducts:*
- Alfalfa pellets, or meal
- Aquatic plant extracts
- Citrus products
- Citrus oil
- Cocoa bean hulls
- Cotton gin trash
- Cottonseed meal
- Food processing wastes
- Garlic
- Grape and other pomaces
- Herbal preparations
- Hay
- Kelp or seaweed, unprocessed, meal, extracts or other derivatives
- Leaves
- Molasses
- Neem and Neem extracts
- Peanut meal
- Peanut hulls
- Plant extracts
- Propolis
- Pyrethrums
- Rice hulls and other residues
- Rotenone
- Ryania
- Sabadilla
- Saw dust, bark, wood chips and other wood wastes
- Soybean meal
- Straw
- Tobacco, and tobacco by-products
- Wood ash
- Vegetable waste, cannery waste

We consider a non-synthetic substance that is an industrial by-product to be synthetic only if the substance becomes chemically altered as a result of a manufacturing process. This is consistent with section 2103(21) of the OFPA (7 U.S.C. 6502(21)) which defines a synthetic substance as one that is formulated or manufactured by a chemical process or by a process that chemically changes the substance. Examples of industrial by-products that are synthetic substances are: paper

manufacturing wastes, kiln dust, and leather meal. Whey solids and sawdust are examples of industrial by-products that are not chemically altered and are therefore non-synthetic.

We do not consider non-synthetic substances that have been treated with a s ynthetic substance, but which have not been chemically altered by a manufacturing process, to be synthetic under the definition given in the Act. This is because the residues of synthetic substances that may be present in these materials do not chemically combine with or change the chemical composition of the original substance. Additionally, the presence of these residues has no significant effect on biological and chemical interactions in the agroecosystem, including physiological effects on soil organisms, crops and livestock, nor would the residues cause measurable degradation to soil or water quality. The synthetic residues therefore are not considered to be active synthetic ingredients or substances under the definition we have proposed. Examples of non-synthetic substances that may have been treated with a synthetic substance, but not chemically altered, include municipal yard wastes and processing wastes from non-organically produced crops, such as cotton gin trash or cocoa hulls.

We also do not consider certain categories of substances that are delineated in section 2118(c)(1)(B)(i) of the OFPA (7 U.S.C. 6517(c)(1)(B)(i)), which provides one set of criteria for substances which may be included on the National List of synthetic substances allowed for use in organic farming and handling, as synthetic substances according to the definition of synthetic given in the Act. We are therefore proposing to allow the use of the following substances in organic production and handling without being included in the National List of active synthetic substances allowed for use in organic farming.

Toxins derived from bacteria are not synthetic and the use of non-synthetic toxins as pest control substances in organic crop production would be regulated under section 205.9(e)(1). We note, however, that toxins derived from genetically engineered microorganisms are included in this document as a separate listing on the proposed National List of active synthetic substances allowed for use in crop production, as set forth in section 205.22(d) of subpart B. We have included toxins derived from genetically engineered bacteria on the proposed National List primarily so that we can receive comment on the proper classification of these substances, and on whether they should be allowed, prohibited, or approved on a case-by-case basis.

Fish emulsions are non-synthetic, although they may contain synthetic preservatives or stabilizers. These preservatives or stabilizers would be considered as inert ingredients, as defined in section 205.2, because they are not active ingredients in the formulated product. Also, these preservatives or stabilizers do not chemically alter the non-synthetic fish emulsion; therefore, their presence in a formulated product would not make the fish emulsion synthetic under the definition in the Act. However, if the level of a synthetic stabilizer in the fish emulsion is higher than necessary to stabilize the product, the stabilizer would then be considered as a synthetic fertilizer and thus prohibited under section 2109(b)(1) of the OFPA (7 U.S.C. 6508(b)(1)).

Treated seed, i.e., seed treated with pesticides, itself is not a synthetic substance because seed is an agricultural product and the treatment does not chemically alter or combine with the seed. When a treated seed is used as permitted in proposed section 205.8(a), the seed treatment does not function as an active ingredient for its intended use, nor do we consider it as causing measurable degradation of soil or water quality; therefore, the seed treatment is incidental or inconsequential when treated seed is used in organic production.

The second category, proposed in paragraph (b)(2) of this section, includes those substances or devices that are not active synthetic ingredients or substances, as defined in section 205.2, in a system of organic farming and handling. This category encompasses certain production aids used in crop and livestock production, such as plastics or other synthetic materials used as mechanical devices, treatments used for structures, and substances that otherwise do not enter into chemical interactions in the agroecosystem under normal conditions of use. It also includes certain production aids and other substances used in handling that are considered to be incidental additives, as is consistent with FDA and FSIS regulations governing ingredients that must be included on product labels.

The following list of substances or categories of substances have been determined by us to fall into this category because they are aids, devices, or incidental additives that do not contain active synthetic ingredients and do not meet the proposed definition of active ingredient or substance, and are therefore permitted for use in organic production or handling without inclusion on the National List. Included in this listing are some categories of substances delineated in section 2118(c)(1)(B)(i) of the OFPA (7 U.S.C. 6517(c)(1)(B)(i)), which establishes one set of criteria for substances that may be included on the National List, as well as additional substances that were considered by the NOSB for inclusion on the National List. This discussion is not intended to be an all-inclusive listing of non-active substances that may be used in organic production or handling.

Production aids such as netting; tree wraps and seals; sticky barriers; row covers; equipment cleaners; flocculants; pelletizers; adjuvants; and surfactants and other substances added to water to change its physical properties do not contain or function as active ingredients under our proposed definition of active ingredient because proper use of these substances has no consequential effects on biological and chemical interactions in the agroecosystem and does not cause measurable degradation of soil or water quality. Agricultural plastics, whether used as insect barriers, mulch, irrigation pipe, season extenders, or similar purposes, cannot be said to enter into chemical interactions in the agroecosystem. Substances used to adjust the texture of dry materials (e.g., flocculants or pelletizers) or to change the physical qualities of water (e.g., adjuvants or surfactants) are considered to be inconsequential additives rather than active ingredients in fertilizer, pest control, tank mixes, or other types of product formulations.

Synthetic substances used in insect or rodent traps are not active synthetic ingredients because they are not integrated into an organic production or handling system and do not interact chemically with any element of the agroecosystem. They are, additionally, prohibited from directly contacting an organic product or crop and therefore would not affect the integrity of an organic product.

We do not consider wood that is treated with synthetic preservatives and used in buildings, trellises and fences to have a significant potential to cause degradation of soil or water quality because the wood preservatives do not chemically interact with, or affect the integrity of, any aspect of the agroecosystem when used for structures, even structures that are used in contact with the soil. However, in certain situations, treatments used to preserve wood have been shown to have effects on biological and chemical interactions in the agroecosystem that would cause the treated wood to be considered an

active substance under our proposed definition. These situations are conditions that bring the wood into prolonged contact with soil that has a very high organic content, as is commonly found in compost bins and containers used for greenhouse potting mixes. We therefore would consider treated wood to be an active synthetic substance in any such situation, and thus prohibited for use in conditions of prolonged contact with soil that has a very high organic content. Further, as discussed in the supplementary information for section 205.21, if treated wood were to be used as a bin or container for an organic product, its use would be prohibited under section 2111(a)(5) of the OFPA (7 U.S.C. 6510(a)(5)), which prohibits the use for the handling of organic products of any storage containers or bins that contain synthetic fungicides, preservatives or fumigants.

An incidental additive used in the processing of agricultural products, which we define as an additive present in an agricultural product at an insignificant level and that does not have any technical or functional effect in the product, does not therefore meet our definition of an active ingredient. As discussed in the supplementary information for section 205.26, incidental additives may be used in organic handling without inclusion on the National List, but their use is regulated in section 205.17(a).

In section 205.20(b)(3), we propose that formulated products containing inert ingredients may be used in a certified organic farming operation if the formulated product does not contain an active synthetic ingredient that is prohibited for use in organic farming, and any synthetic inert ingredient contained in the formulation is not classified by EPA as an inert of toxicological concern. In order for a formulated product to be used in organic crop production, each active ingredient it contains must be a substance that is permitted under the Act and subpart B of part 205.

Additionally, the Act in section 2118(c)(1)(B)(ii) of the OFPA (7 U.S.C. 6517(c)(1)(B)(ii)) specifically prohibits products containing substances classified by EPA as inerts of toxicological concern. We have determined that this prohibition applies only to EPA List 1 inerts (Inerts of Toxicological Concern), as explained in the supplementary information for section 205.21(d). Accordingly, formulations containing synthetic inert substances included on EPA List 2, Potentially Toxic Inerts; EPA List 3, Inerts of Unknown Toxicity; and EPA List 4, Inerts of Minimal Concern would be permitted in organic production under our proposal.

*General Rules for Categories of Substances and Ingredients Prohibited for Use in Organic Farming and Handling—Section 205.21*

Section 205.21 delineates five general categories of substances that would be prohibited for any use in organic production or handling. The first of these, proposed in paragraph (a) of this section, would be an active synthetic substance that is not included as an active synthetic substance permitted for use in either organic crop or livestock production in sections 205.22 or 205.24 of the National List. This category is proposed, as stated previously, in accordance with sections 2105(1) and 2118(c)(1)(B)(i) of the OFPA (7 U.S.C. 6504(1) and 6517(c)(1)(B)(i)) which prohibit the use of any active synthetic substance in organic production unless it is on the National List. Our proposed category specifically includes any synthetic carbon based substance that has a cytotoxic mode of action, as defined in section 205.2. These synthetic carbon based substances are discussed in the supplementary information for section 205.9(f). They are not one of the categories of substances that is identified in section 2118(c)(1)(B)(i) of the OFPA (7 U.S.C. 6517(c)(1)(B)(i)) as a possible category of synthetic substances that may be put on the National List, thus allowing their use. It should be noted that any active synthetic substance that does not belong to any of the categories of substances identified in this section of the Act could not be included on the National List and thus could not be permitted for use in organic farming or handling.

Paragraph (b) of this section would prohibit the use of a non-agricultural substance used as an ingredient in or on a processed product that is labeled as organic or as made with certain organic ingredients if the substance is not included in section 205.26 as an allowed non-agricultural substance. This category, as previously discussed, is proposed in accordance with section 2118(c)(1)(B)(iii) of the OFPA (7 U.S.C. 6517(c)(1)(B)(iii)), which permits the use of a non-organically produced ingredient in handling an organic product only if the substance is included on the National List.

The third category, proposed in paragraph (c) of this section, would include any prohibited non-synthetic substance included in either sections 205.23 or 205.25. The absence of any prohibited non-synthetic substances in this proposal is discussed in the supplementary information for proposed section 205.23.

The fourth category of substances prohibited under this proposal, in section 205.21(d), is in accordance with section 2118(c)(1)(B)(ii) of the OFPA (7 U.S.C. 6517(c)(1)(B)(ii)), which prohibits the use of formulated products that contain any synthetic inert ingredient that is classified by the Administrator of the EPA as an inert of toxicological concern. Inert ingredients of toxicological concern are those inert ingredients included on the EPA List 1 Inerts of Toxicological Concern (54 FR 48314, November 22, 1989). Our proposed provision would prohibit the use of any formulation containing an inert ingredient included on the EPA List 1, even if that product contained an active ingredient that was otherwise allowed in this subpart. Formulated pesticidal products that contain EPA List 1 inerts can be identified by organic producers and handlers because the EPA requires the phrase ‘‘This product contains the toxic inert ingredient . . .’’ to appear on the label of such products.

Paragraph (e) of this section would prohibit the use of any fertilizer or commercially blended fertilizer that contains an active synthetic ingredient not allowed for use in crop production as provided for in section 205.22, or that contains an active prohibited substance. This prohibition is consistent with section 2109(b)(1) of the OFPA (7 U.S.C. 6508(b)(1)) and would apply in this proposal only to substances or products which meet the definition of fertilizer which we propose in section 205.2. Under our proposal, the provisions of paragraph (e) of this section would not apply to substances used as micronutrients, foliar nutrients, soil cation balancing agents, soil conditioners, or substances with similar functions which do not meet our proposed definition of fertilizer as a single or blended substance applied to the soil to supply any of the three primary plant nutrients, nitrogen (N), phosphorus (P) and potassium (K), needed for the growth of plants. Micronutrients and these substances with similar functions are permitted for use in organic crop production in most of the existing organic programs we have reviewed, and to include them within the category of synthetic fertilizers, which are prohibited under the Act, would unnecessarily restrict the options available to organic farmers for providing essential plant nutrients and maintaining soil fertility.

*The National List of Active Synthetic Substances Allowed for Use in Organic Crop Production—Section 205.22*

This section of the proposed regulation lists the active synthetic substances that have been reviewed for use in organic crop production and which the Secretary proposes be allowed for such use because each meets the criteria in the Act that permits their use. These substances have been reviewed by the NOSB as required by the Act, and have been determined by the Secretary to contain or function as an active ingredient in one of the categories the Act permits for inclusion on the National List as a substance permitted for use.

Any synthetic substance included on the National List appears only according to its generic or most commonly used name. In some cases, we have indicated other commonly-known terms for certain substances, such as horticultural oils. A farmer or handler is expected to request clarification from the applicable certifying agent in the case of uncertainty about the generic name of a particular brand-name substance, or about the use of any substance for which there might be any other questions.

Section 205.22, the list of active synthetic substances allowed for use in organic crop production, is organized into groups according to the functions for which the substances may be used. These groups are: horticultural oils used as insect pest smothering or suffocating agents; soaps used as insecticides, algicides, de-mossers, large animal repellants, and herbicides; production aids; toxins derived from genetically engineered bacteria (that are not released live into the agroecosystem) for use as pesticides; copper and sulfur compounds used as pesticides; minerals used as micronutrients; and minerals used as defoliants in fiber production.

Most of the substances included in this section of the National List are proposed in accordance with the recommendations provided by the NOSB. There are, however, a few cases in which we have determined it necessary to amend the NOSB recommendations concerning a particular substance in consideration of the Act, public input, and other information, including evaluations by the technical advisory panels. The following are substances for which the NOSB recommendations differ from our proposed list in section 205.22.

The NOSB recommended restricting the use of herbicidal soaps (proposed in section 205.22(b)) to non-field applications. We determined, however, that the uses of herbicidal soaps allowed by EPA would not be harmful to human health or the environment and are consistent with the other criteria provided by the Act, and thus do not need to be restricted to non-field applications. The available evidence suggests that these soaps are not persistent in the agroecosystem and would not cause measurable degradation of soil or water quality or have discernable effects on biological and chemical interactions in the agroecosystem.

The NOSB recommended allowing certain specific antibiotics as pesticides in crop production, but did not recommend to allow others for this use, particularly Avermectin. Based on a review of the technical information for these substances, we determined that all the antibiotics labeled for use as pesticides by EPA are of equally minimal consequence in their effects on biological and chemical interactions in the agroecosystem and would not cause measurable degradation of soil or water quality when properly used according to label instruction and use restrictions, and there are no other criteria specified in the Act that any specific substance in this category fails to meet.

The synergist piperonyl butoxide (PBO) (proposed in section 205.22(c)(9)) was not recommended by the NOSB for inclusion on the National List; the vote to approve PBO failed by only one vote to achieve the two-thirds majority required for approval. PBO is extracted from a non-synthetic substance, but is modified synthetically in the process of extraction and refining; it does not appear to persist in the environment or otherwise have significant effects on biological and chemical interactions in the agroecosystem or cause measurable degradation of soil or water quality, and is consistent with the other criteria specified in the Act. It also functions in a manner that significantly reduces the amounts required of some botanical pesticides that may be applied. In consideration of the benefits of reducing the amount of botanical pesticides used in an organic farming operation, which the scientific evidence clearly indicates is more likely to effect biological and chemical interactions in the agroecosystem than the PBO, we have determined that PBO should appear as an allowed synthetic substance on the proposed National List.

The NOSB did not recommend to include on the proposed National List killed microbial pesticides (toxins derived from genetically engineered bacteria that are not released live into the agroecosystem), such as the *Bacillus thuringiensis* toxin (proposed in section 205.22(d)). However, several technical experts to the NOSB reviewed these substances positively, and did not raise concerns about their effects on biological and chemical interactions in the agroecosystem when these substances are properly used. We have included toxins derived from genetically engineered bacteria that are not released live into the agroecosystem on the proposed National List.

Our research indicates that the genetically engineered bacteria from which the toxins proposed for inclusion on the National List in section 205.22(d) are derived are not released live into the agroecosystem and therefore do not have the potential to reproduce. Our research, however, indicates that the toxins themselves if overused may have the potential to induce accelerated resistance of pest populations. In this regard, we would like to receive public comment and technical and scientific data as to the effects of the use of toxins derived from genetically engineered bacteria that are not released live into the agroecosystem on the biological and chemical interactions in the agroecosystem.

The NOSB recommended that minerals used as defoliants in organic fiber production (proposed in section 205.22(g)) should be restricted according to their use and source because of their potential to cause measurable degradation of soil and water quality. However, technical information we reviewed about the use of these substances indicates that they are unlikely to result in measurable degradation of soil and water quality in the amounts applied for the defoliation of fiber crops. We have, therefore, listed calcium chloride, magnesium chloride, sodium chlorate, and sodium chloride as allowed synthetic substances used to defoliate fiber crops. In accordance with proposed section 205.3(b)(2), a non-synthetic substance, such as sodium chloride extracted from brine, would have to be chosen in preference to any synthetic defoliant, whenever possible. However, we determined that all four substances reviewed should appear on the National List because they are relatively indistinguishable with respect to their potential for measurable degradation of soil and water quality. In addition, all these minerals are available in both synthetic and non-synthetic forms that are not readily distinguishable, and thus would have to appear on the National List in order to be permitted for use.

The NOSB has reviewed amino acids (proposed in section 205.22(b)(5)) but has not yet made a recommendation as to whether to include them on the

National List as allowed synthetic crop production substances. However, the NOSB did vote to allow the use of certain vitamins, which are similar to amino acids in their use as a crop production aid and their effects on soil and water quality. We did not find any scientific evidence that amino acids, which are synthetically derived but chemically identical to substances that are normally found in soil organic matter, pose any concern for measurable degradation of soil and water quality and they meet all the other criteria established in the Act. We therefore have included amino acids on the proposed National List for use as an organic crop production aid.

The NOSB recommended the following substances for inclusion on the National List of allowed synthetic substances, but we have not included them on the proposed National List because we determined that they were non-synthetic. Therefore, they may be used in organic farming without being included on the National List.

Fish products, aquatic plant extracts, and humic acid and its derivatives are not included because, as discussed previously, we determined that they are non-synthetic. Although the NOSB also had concerns about synthetic extractants used to produce these non-synthetic substances, we determined that the extraction methods for substances used in crop production are inconsequential in their effects on biological and chemical interactions in the agroecosystem or to measurable degradation of soil and water quality. Additionally, the addition of small amounts of synthetic stabilizers or preservatives to these products is of minimal concern and, as discussed in the supplementary information for section 205.20 of this proposal, the inclusion in a formulated product of synthetic inert ingredients that are not of toxicological concern does not cause the product to be prohibited for use in organic production. However, we are aware that synthetic stabilizers sometimes may be added to such products at levels higher than necessary to stabilize the formulation in order to increase its fertilizer value. In such cases, the stabilizers would be considered to be synthetic fertilizers, which are prohibited for use in organic production by section 2109(b)(1) of the OFPA (7 U.S.C. 6508(b)(1)) and proposed section 205.7(d)(1). A certified producer or handler is expected to request clarification from the certifying agent in the case of uncertainty about whether a specific product would be prohibited according to this definition.

Elemental sulfur also was recommended by the NOSB for inclusion in proposed section 205.21. However, we consider elemental sulfur to be non-synthetic regardless of its source.

Potassium nitrate (niter) was reviewed by the NOSB as a synthetic substance and was not recommended for inclusion as an allowed synthetic substance for organic crop production. However, we reviewed information that potassium nitrate also exists as a natural mineral deposit that may be mined for agricultural use. Although we agree with the NOSB and do not consider synthetic potassium nitrate to meet the criteria for inclusion as a synthetic substance on the National List, niter in the form of a non-synthetic mined product would be allowed for use in organic production under the Act and the proposed regulations in subpart B of this part.

The following substances were recommended by the NOSB for inclusion as allowed synthetic substances for organic crop production. We have not included them on the National List because we consider them not to be active substances or ingredients in the applications for which they are used and therefore, as previously discussed, are substances that may be used in a certified organic operation without inclusion on the National List:

Plastic mulches and row covers do not interact chemically with the agroecosystem and are specifically permitted under section 2109(c)(2) of the OFPA (7 U.S.C. 6508(c)(2)) if they are removed at the end of each harvest season.

Disinfectants, such as alcohols, hydrogen peroxide and chlorine bleach that are used to clean equipment; sticky traps and barriers; and ammonium carbonate used as bait in traps are not used directly on soil or crops and thus are not active because they have no significant consequence to the organic production system.

Lignin sulfonate, which is used as a dust suppressant or as a chelating agent, is not active in either use because, in the former instance it is not applied to soil used for crop production and, in the latter instance, it is not an active ingredient in a formulated (micronutrient) product.

Detergents and other emulsifiers used as surfactants or adjuvants often are added in very small quantities directly to tank mixes used for spraying and are considered to be non-active, just as inert ingredients within a formulated product are. Similar considerations apply to sodium silicate and other substances used to affect the surface tension of water, as is sometimes done to improve the buoyancy of tree fruit during packing.

The NOSB also recommended that lumber treated with arsenates not be included on the National List as an allowed synthetic substance. However, as previously discussed, we determined that a substance used to treat lumber that is used for such purposes as buildings, fences and trellises cannot be considered to be an active ingredient under our definition of an active ingredient. However, evidence we have reviewed indicates that arsenates and other synthetic lumber preservatives may become active when in contact with soil having a very high organic content, such as soil used in greenhouse beds or compost bins. Because arsenates and other synthetic substances used to preserve lumber are not proposed by us to be included on the National List as active synthetic substance, and because section 2109(c)(1) of the OFPA (7 U.S.C. 6508(c)(1)) specifically prohibits the use of arsenic or lead salts in organic crop production, the use of arsenates and other synthetic lumber preservatives in any manner that might be considered an active use would be prohibited under the Act and this proposal. Furthermore, section 2111(a)(5) of the OFPA (7 U.S.C. 6510(a)(5)) prohibits the use of storage containers or bins that contain any synthetic fungicides or preservatives in handling organic products and this would include bins constructed of arsenate treated lumber.

Finally, the NOSB recommended that biosolids, or municipal sludge, should be classified as synthetic and were not appropriate for use in organic crop production. The EPA defines biosolids as the primarily organic residuals, produced by current wastewater treatment processes that treat domestic sewage, that can be beneficially recycled. Under current EPA regulations, such recycling can include land application of biosolids to provide primary plant nutrients and micronutrients to crops and vegetation produced in agriculture and to improve soil characteristics by providing necessary moisture and/or organic matter to enhance soil tilth. Over the years, EPA, USDA, and FDA have issued joint policy statements that have endorsed the beneficial utilization of biosolids on land for purposes that include the production of fruits and vegetables. However, to prevent potential problems, the guidance contains steps that must be taken relative to issues such as the amount of cadmium and lead that can be applied to the soil, the amount of PCBs in the biosolids, and the relative accumulation

of heavy metals into edible plant parts. Under these and other restrictions contained in 40 CFR Part 503, biosolids can be safely used in conventional agriculture. However, we are requesting comments to assess the extent to which biosolids may be used in organic production. The USDA specifically invites comments on whether the use of biosolids (municipal sludge) should be permitted or prohibited in organic production. The USDA also invites comments on the classification of biosolids as a synthetic rather than a non-synthetic substance. Comments should detail the basis for the commenter's recommendation, including the agricultural, policy, technical, or scientific factors.

*The National List of Non-Synthetic (Natural) Substances Prohibited for Use in Organic Crop Production—Section 205.23*

The NOSB has recommended that the rodenticide strychnine, the fertilizer ingredient manure ash, and the pesticide sodium fluoaluminate, which are non-synthetic (natural) substances, be prohibited for use in organic farming and handling. As stated previously, in order for the Secretary to prohibit the use of a non-synthetic (natural) substance in an organic farming or handling operation, it must be determined that the use of such substance both would be harmful to human health and the environment and inconsistent with organic farming or handling. Further, the Secretary of HHS and the Administrator of EPA must be consulted.

The Secretary of HHS and the Administrator of EPA, respectively, have the authority to regulate crop production substances according to human health and safety and environmental protection. These two agencies have the responsibility to review and establish appropriate restrictions on the use of any substance as a pest control, food, feed or drug, and the applicable agency must determine that allowed use of the substance poses no threat to human health and the environment before permitting a substance to be used in agricultural production or handling. In consulting with these agencies, they concluded that their review of these substances showed that, when used according to the requirements established by these agencies, the substances do not meet the criteria in the Act for inclusion on the National List of prohibited non-synthetic (natural) substances. In concurrence with this conclusion, we have determined that there can be no non-synthetic substance that meets both of the OFPA criteria for being designated as a prohibited non-synthetic substance, and we did not accept the NOSB's recommendation for the prohibition of strychnine, manure ash, and sodium fluoaluminate. We only include sections 205.23 and 205.25 in our proposal so that appropriate substances may be included on the National List in the future should this be determined to be necessary.

*The National List of Active Synthetic Substances Allowed for Use in Organic Livestock Production—Section 205.24*

The substances proposed for inclusion in this section of the National List are listed as the following six categories: trace minerals; nutrients and dietary supplements; feed additives (provided they are also included in section 205.26); animal drugs and other animal health care substances; vaccines and biologics; and pest control substances (provided they also are included in section 205.22).

This section would permit any active synthetic substance permitted by FDA, EPA and USDA in the specified categories to be allowed for use in organic livestock production when used in accordance with the restrictions specified by the approving agency and the restrictions specified in this section. We have proposed these active synthetic substances to be permitted for use after reviewing the NOSB recommendations for livestock substances to be included on the National List, and their recommendations for the use of vitamins, minerals, inoculants, vaccines, antibiotics and parasiticides in livestock production. Our proposed list is consistent with sections 2110 and 2118 of the OFPA (7 U.S.C. 6509 and 6517), which delineate feeding and health care practices to be used in organic livestock production and the categories of synthetic substances related to livestock production that may be included in the National List.

Section 2110(d) of the OFPA (7 U.S.C. 6509(d)) prohibits certain uses of veterinary medications, specifically subtherapeutic doses of antibiotics and routine administration of synthetic internal parasiticides, in organic livestock production. The use of other veterinary medications, except vaccines, is prohibited only in the absence of illness. This indicates that therapeutic doses of antibiotics, non-routine use of synthetic internal parasiticides, any use of vaccines, and administration of any veterinary medication to treat an illness are all permitted under the Act, without the need to include these substances on the National List of synthetic substances permitted to be used. However, because livestock parasiticides and medicines are also included among the categories of active synthetic substances in section 2118(c)(1)(B)(i) of the OFPA (7 U.S.C. 6517(c)(1)(B)(i)) that would need to be included on the National List in order to be permitted to be used, we have included animal drugs (veterinary medications) in this section of the proposed National List in order to clarify that their use is permitted.

All of the categories proposed for inclusion in this section of the National List, other than animal drugs and other animal health care substances and vaccines and biologics, have been explicitly reviewed by the NOSB itself and proposed for inclusion as either crop production substances in section 205.22 or as ingredients allowed in processed products in section 205.26. We are including the categories of animal drugs and animal health care substances and vaccines and biologics in the National List because these substances have already been evaluated by the applicable regulatory agency that approves them for general use by criteria similar to those in section 2119(m) of the OFPA (7 U.S.C. 6518(m)) that are to be used by the NOSB in evaluating a substance.

A representative of the FDA's Center of Veterinary Medicine (CVM) addressed the NOSB in Rohnert Park, California, in October 1994, to explain in detail the review process conducted by CVM in reviewing veterinary drugs and establishing withdrawal times. The NOSB voted at its meeting in Austin, Texas, on October 31, 1995, to accept the FDA evaluations of antibiotics, parasiticides, vitamins and minerals and the USDA evaluations of inoculants and vaccines as equivalent to the substance review process established for the NOSB in sections 2119(k), (l) and (m) of the OFPA (7 U.S.C. 6518 (k), (l) and (m)). However, in doing so, the NOSB did indicate that it would: defer the initial technical advisory panel review of synthetic vitamins and minerals for a period of two years unless a specific vitamin or mineral is identified in the interim as being in conflict with organic principles and therefore requires an immediate review; defer the initial review of vaccines and inoculants for a period of two years, except in the case of a substance that may be in conflict with organic principles and therefore requires an immediate review; and establish a priority ranking of antibiotics and parasiticides to be used by producers when administering animal drugs. To date, the NOSB has not yet established a priority ranking for preferred use of the antibiotics and parasiticides approved by FDA.

*The National List of Non-Synthetic Substances Prohibited for Use in Organic Livestock Production—Section 205.25*

As previously discussed with reference to proposed section 205.23, no substances are proposed in this section because we have determined that no non-synthetic substances meet the criteria provided in section 2118(c)(2) of the OFPA (7 U.S.C. 6517(c)(2)) for prohibiting their use.

*The National List of Non-agricultural Substances Allowed as Ingredients in or on Processed Products Labeled as Organic or Made With Certain Organic Ingredients—Section 205.26*

We propose in § 205.26 the National List category of non-agricultural substances allowed as ingredients in or on processed products labeled as organic or made with certain organic ingredients. As discussed previously, this section of the National List is proposed to satisfy the provision in section 2118(c)(1)(B)(iii) of the OFPA (7 U.S.C. 6517(c)(1)(B)(iii)) that a non-organically produced substance used in handling be evaluated as if it were synthetic, and therefore the use of such a substance is prohibited unless it appears on the National List.

The inclusion of both synthetic and non-synthetic non-agricultural substances in this category is necessary because, as was indicated in the NOSB's deliberations, it is often very difficult to decisively classify many non-agricultural ingredients as synthetic or non-synthetic. For example, citric acid is a naturally occurring substance that may be obtained from citrus fruits. However, after reviewing and discussing the process by which virtually all commercially available citric acid is formulated, the NOSB was almost evenly divided in its vote as to whether or not this process rendered the substance synthetic under the definition provided in section 2103 of the OFPA (7 U.S.C. 6502).

We have not, however, proposed to include in this section of the National List any substance (ingredient) that does not meet our definition of an active ingredient. Substances that are not active ingredients are considered to be incidental additives, and such substances are not consistent with the FDA and FSIS requirements for substances that must be listed on a product label. As previously discussed, because incidental additives are not active ingredients, they are not otherwise prohibited by the Act and may thus be used in handling organic products without having to be included on the National List. We are accordingly including only substances that do meet the definition of an active ingredient, and that therefore are required by the FDA and FSIS to be listed on a product label, in the National List of non-agricultural substances allowed as ingredients in or on processed organic products.

Proposed § 205.26 contains an alphabetical listing of the generic name of the non-agricultural substances which meet the Act's criteria for inclusion on the National List as substances permitted to be used. These substances have been reviewed by the NOSB and included in recommendations made by them to the Secretary regarding substances to be included on the proposed National List. In most cases, substances are listed individually, such as ammonium bicarbonate or lactic acid, but in many cases categories of substances, such as cultures (dairy, non-synthetic) or nutrient supplements, are listed. When a category is listed, the use of any substance that belongs to that category is allowed.

This section diverges from certain recommendations provided by the NOSB. As discussed with respect to allowed synthetic substances used in crop production, proposed in § 205.22, certain substances that the NOSB recommended be included on the National List of substances allowed for use as ingredients in or on processed organic products are not active, and are thus not included in this section. These substances, which may be used without inclusion on the National List, are diatomaceous earth, clays including kaolin and bentonite, nitrogen, oxygen, ozone, chlorine bleach, perlite, sodium hydroxide, ethylene, hydrogen peroxide, and potassium hydroxide.

Kelp was reviewed and recommended by the NOSB as a permitted non-agricultural substance in processed products. We have not included kelp as a non-agricultural substance permitted for use because kelp and other seaweeds are plants harvested from the wild, and so are considered agricultural products as opposed to non-agricultural products when used as ingredients in processed organic products. Kelp also might be considered a nutrient supplement when used as a source of iodine in food meant for human consumption and as a source of iodine and trace minerals in livestock feed.

The NOSB recommended the plant derived waxes carnauba wax and wood rosin for inclusion on the proposed National List. (Wood rosin also is referred to as lac-resin, shellac-based wax, or resin). We have included carnauba wax and wood rosin in this proposed section and additionally propose to include candelilla wax and beeswax as allowed non-agricultural substances. Candelilla wax is a plant derived wax that is commonly used, as is beeswax, in coatings for fresh produce. We consider both waxes to be necessary to the handling of agricultural products and as meeting the other requirements of section 2118(a) of the OFPA (7 U.S.C. 6517(a)) that must be met before such substances may be permitted to be used. In accordance with section 2111(a)(5) of the OFPA (7 U.S.C. 6510(a)(5)), which prohibits the use of any packaging materials that contain synthetic fungicides or preservatives, any wax used as a coating on fresh produce could not contain synthetic preservatives or fungicides.

The NOSB recommended the inclusion of unmodified cornstarch as a permitted substance and postponed a decision on other unmodified starches. Unmodified starches are agricultural ingredients because they are manufactured from agricultural products through methods that do not meet the Act's definition of synthetic. Their use would therefore be permitted as non-organic agricultural ingredients in proposed § 205.27.

The NOSB reviewed whey protein and did not recommend it for inclusion on the National List of allowed non agricultural ingredients. We consider whey protein to be necessary to the handling of certain agricultural products because of the unavailability of wholly natural products, which use is then provided for in section 2118(c)(1)(A)(ii) of the OFPA (7 U.S.C. 6517(c)(1)(A)(ii)). This substance also meets the other criteria in the Act for inclusion on the National List, and we accordingly propose that it be included as an allowed non-agricultural ingredient as part of our category whey and its fractions.

The NOSB also recommended not to include magnesium carbonate, potassium phosphate, magnesium stearate, and potassium iodide on their proposed National List of non-agricultural ingredients allowed in agricultural products labeled as organic. However, the NOSB recommended that these four substances be permitted in products labeled as made with certain organic ingredients. Because our proposed National List is applicable to both types of labeled products, we propose to include magnesium carbonate, potassium phosphate, magnesium stearate and potassium iodide in this section and allow their use in products labeled organic and made with certain organic ingredients.

(Potassium iodide is not listed separately because it is included within the nutrient supplement category).

Chymosin is an enzyme that occurs naturally in animals and currently is being produced through genetically engineered microorganism in quantities suitable for cheese production. The NOSB recommended that chymosin not be included on the proposed National List of non-agricultural substances because it is derived from a genetically engineered microorganism. We have included chymosin on the proposed National List so as to solicit public comment.

The NOSB recommended that enzymes derived from bacteria which were not genetically engineered are appropriate for use as non agricultural ingredients in agricultural products labeled as organic or made with certain organic ingredients. Although the NOSB has not completed its review of sources of non-synthetic enzymes, such as plant, animal, and micro-organisms other than bacteria, we have included the category of enzymes, non-synthetic in this section of the proposed National List for the purpose of receiving comment during the period that the NOSB completes its review and develops its recommendation. When they have completed their review, appropriate notice will be provided. We would consider animal-derived rennet to be included in the category of non-synthetic enzymes.

The NOSB classified calcium sulfate as synthetic and did not recommend it for inclusion on the proposed National List of non-agricultural substances permitted to be used. However, we are aware of at least one source of mined gypsum (non-synthetic) that is refined to food grade calcium sulfate. Also, we received comments from some manufacturers of tofu who stated their preference for calcium sulfate over other coagulants. Non-synthetic calcium sulfate could serve in some cases as a wholly natural alternative to the use of synthetic tofu coagulants, and otherwise meets the Act's criteria for inclusion on the National List of non-agricultural substances permitted to be used. We have therefore included calcium sulfate in this section of the proposed National List.

Some substances included in this proposed section 205.26 as non-agricultural substances are manufactured from feed stocks that are agricultural products, such as corn. Some persons may thus consider these substances to be agricultural products, and therefore not appropriate for inclusion in this section of the National List. We have included these substances because they are not easily recognizable as agricultural products, or because there is some likelihood that the processing methods used to purify these substances would render them synthetic as defined under the Act. The inclusion of these substances in this section is based on our definition of a non-agricultural ingredient (proposed in section 205.2) as a substance that is extracted, isolated from, or is a fraction of an agricultural product, so that the identity of the agricultural product is unrecognizable in the extract, isolate or fraction. Examples of these proposed substances include: ascorbic acid, beeswax, citric acid, candelilla wax, carnauba wax, carrageenan, non-synthetic colors, lactic acid, lecithin, mono and diglycerides, pectin, potassium acid tartrate, tartaric acid and whey and its fractions. Since many of these substances originate from agricultural products, it is possible that these substances could be available in the future as organic agricultural products.

*Non-organically Produced Agricultural Products Allowed as Ingredients In or On Processed Products Labeled as Organic or Made With Organic Ingredients—Section 205.27*

Non-organically produced agricultural ingredients are permitted for use in processed organic products under section 2111(a)(4) of the OFPA (7 U.S.C. 6510(a)(4)), provided that they comprise less than five percent by weight of the finished product, exclusive of water and salt, and are included on the National List. Section 2118(c)(1)(B)(iii) of the OFPA (7 U.S.C. 6517(c)(1)(B)(iii)) requires non-organically produced substances to be evaluated according to the same criteria used for active synthetic ingredients in order to be permitted for use as ingredients in organic products. In its review of non-organically produced agricultural products, the NOSB concluded that all agricultural products, considered as a category, meet the criteria for including substances on the National List, as set forth in sections 2118(c)(1)(A) and 2119(m) of the OFPA (7 U.S.C. 6517(c)(1)(A) and 6518(m)). In concurrence with the NOSB, we are proposing in this section that all non-organically produced agricultural products be allowed as ingredients in organic processed products. Under this proposal, any agricultural product could be used if such use complied with the provisions proposed in section 205.16.

*Amending the National List—Section 205.28*

Section 2119(n) of the OFPA (7 U.S.C. 6518(n)) requires the establishment of a petition procedure by which interested parties may request the NOSB to evaluate substances for inclusion on the National List. We accordingly have proposed in section 205.28 a process by which an interested party may petition the NOSB to review a substance and make a recommendation as to whether the substance should be included in the National List as an allowed active synthetic substance, a prohibited non-synthetic substance, or a non-agricultural substance allowed to be used as an ingredient in or on processed organic products.

This section also proposes the information that, to the extent it is available to the petitioner, should be included in the petition to assist the NOSB review of the substance and the Secretary's determination as to its inclusion on the National List. The information requested by proposed paragraph (d) of this section would provide information relevant to the issues that are to be examined when considering placing a substance on the National List. This would include information that would enable the Secretary to determine whether a substance functions as, or contains, an active synthetic ingredient, and whether it falls into one of the categories of active synthetic substances that may be included on the National List of approved substances. This would also include information needed to evaluate the health, environmental, and agroecosystem effects of the substance.

This proposed section also would require regulatory information, such as registration of the substance in question with EPA or FDA. Other required information would include a description of the manufacturing process of the substance, product characteristics, safety information relating to the substance, and bibliographies of scientific literature relating to the substance that may be available to the petitioner to be submitted. The petitioner would be requested to submit information that describes alternative substances or alternative cultural methods that could be utilized in place of the substance, and that summarizes the effects on the environment, human health, and farm ecosystem that might support the use of the substance. This information is needed to help determine whether a substance is an active synthetic ingredient in one of the categories that the Act, in section 2118(c)(1)(B)(i) of the

OFPA (7 U.S.C. 6517(c)(1)(B)(i)), permits to be used if it is on the National List and whether allowance of a synthetic substance is justified by the lack of a suitable non-synthetic or cultural alternative, as required under section 2118(c)(1)(A)(ii) of the OFPA (7 U.S.C. 6517(c)(1)(A)(ii)). Other information required to be submitted is needed to determine whether a non-synthetic substance will be prohibited for use under the criteria specified in section 2118(c)(2) of the OFPA (7 U.S.C. 6517(c)(2)).

Section 2118(d) of the OFPA (7 U.S.C. 6517(d)) includes provision for the procedure by which amendments may be made to the National List. Following receipt of a petition, as proposed in this section, the Secretary would determine whether the substance is within one of the categories of the National List. If the substance is within one of the defined categories, it would be reviewed by the NOSB in accordance with the criteria provided in the Act.

After the NOSB submits its recommendations concerning a petitioned substance to the Secretary, the Secretary would then determine whether the substance satisfies the criteria listed in section 2118(c) of the OFPA (7 U.S.C. 6517(c)) regarding the inclusion of substances on the National List as an allowed or prohibited substance. If the Secretary determines that the substance does meet these criteria, the addition of the substance to the National List would then be proposed as an amendment to the National List according to the procedure established in section 2118(d) of the OFPA (7 U.S.C. 6517 (d)), which includes publication in the **Federal Register** of a proposed amendment to the National List and an opportunity for public comment.

As provided for in section 2118(e) of the OFPA (7 U.S.C. 6517(e)), the NOSB also would review any substance on the National List within five years of the substance being allowed or prohibited for use, and would provide the Secretary with recommendations as to whether the substance should remain on the National List. The Secretary would decide whether to renew each allowance or prohibition in order for an allowed or prohibited substance to remain on the National List. The Secretary's decisions concerning this then would be published in the **Federal Register**.

*Subpart C—Labels, Labeling, and Market Information*

Sections 2106(a)(1)(A) and (B) of the OFPA (7 U.S.C. 6505(a)(1)(A) and (B)) state that persons may sell or label agricultural products as organically produced only in accordance with the Act, and that persons may affix a label to and provide other market information concerning organically produced agricultural products only when the products are produced and handled in accordance with the Act.

In accordance with the Act, we are proposing in subpart C of this part provisions regarding labels, labeling, and marketing information for agricultural products that are organically produced and for any agricultural products that contain organically produced ingredients. Additionally, provisions also are included for the use of the USDA seal on labels, labeling, and other market information as authorized by section 2106(a)(2) of the OFPA (7 U.S.C. 6505(a)(2)), and this subpart also addresses the use of products that originate from operations that sell no more than $5,000 annually in value of agricultural products. These operations are exempt from certain provisions of the Act.

*Agricultural Products in Packages Sold, Labeled, or Represented as Organic—Section 205.100*

In accordance with section 2106 of the OFPA (7 U.S.C. 6505) which provides for selling and labeling a product as organically produced, we propose in section 205.100 of this subpart our labeling provisions for agricultural products in packages described in section 205.16(a) that are sold, labeled, or represented as organic. These are finished products that contain at least 95 percent organically produced ingredients, by weight, excluding water and salt, hereafter referred to as ''products that contain at least 95 percent organic ingredients''. The percentage of the product that is not organic must be made of some combination of non-agricultural ingredients and/or non-organically produced agricultural products included on the National List. Packages are defined in our proposal as a container or wrapping that bears a label and which encloses an agricultural product, except for agricultural products in bulk containers, shipping containers, or shipping cartons.

In paragraph (a) of this section, we propose the terms that may be used on agricultural products described in section 205.16(a) that are sold, labeled, or represented as organic, (i.e., products that contain at least 95 percent organic ingredients). We propose to allow the term organic to be used on the principal display panel to modify the name of the product and in the ingredients statement to modify the name of each ingredient organically produced and handled in accordance with the Act and the regulations in this part. We have defined the principal display panel to be that part of a label that is most likely to be displayed, presented, shown or examined under customary conditions of display for retail sale. The ingredients statement is defined as the listing of the ingredients contained in a product listed by their common or usual names in the descending order of predominance. The ingredients statement is usually located on the information panel of products other than meat and poultry products and is often located on the principal display panel of meat and poultry products, but may be placed on other package panels because of package restrictions.

We are proposing to allow the term organic to appear on the principal display panel to ensure a clear, consistent and conspicuous identification of organically produced agricultural products for consumers. Examples of the use of this term are organic grapes, organic beef, organic peppermint tea, organic vegetable soup, organic whole wheat bread, and organic ice cream. We are proposing to allow the term organic to be used in the ingredients statement to modify the name of each organically produced ingredient in order to provide consumers with a means of knowing which ingredients have been organically produced. Many consumers would consider information about the specific organic ingredients contained in a product to be essential information to have as a part of their purchasing decision.

Section 2106(a)(2) of the OFPA (7 U.S.C. 6505(a)(2)) provides for products that meet USDA standards for organic production to incorporate the USDA seal on such agricultural products. Additionally, section 2108 of the OFPA (7 U.S.C. 6507) provides for a State to establish a State organic program that meets the requirements of the national organic program. If a State does so, and its program is approved by USDA, we believe it is appropriate to allow the State to have a seal representing its program, and to allow agricultural products produced under such a State program to bear a State seal. Accordingly, we propose in paragraph (a)(3) of this section that a USDA seal, and a State seal that represents a State organic program approved by the Secretary, as provided for in section 205.402 of subpart F, may be used on the principal display panel of packages of agricultural products labeled as organic. These seals would reflect that

the product was produced and handled in accordance with the Act and the regulations in this part, and if applicable, the requirements of a State organic program approved by the Secretary.

We think that the terms and marks used on the principal display panel, which is the most visible panel, should be those terms and marks which simply and clearly present information about the organic nature of the agricultural product and its compliance with the national organic program requirements and, if applicable, the requirements of an approved State organic program. This is consistent with the purposes stated in sections 2102(2) and (3) of the OFPA (7 U.S.C. 6501(2) and (3)) to assure consumers that organically produced products meet a consistent standard and to facilitate commerce.

We propose in paragraph (a)(4) of this section the terms and marks which may appear on the information panel of products in packages that are sold, labeled, or represented as organic (i.e., products that contain at least 95 percent organic ingredients). We have defined the information panel to be that part of the label immediately contiguous and to the right of the principal display panel as observed by an individual facing the principal display panel, unless an allowance has to be made for another section of the label to be designated as the information panel because of size or other limitations. Many meat and poultry products do not have an information panel.

Most of the terms and marks proposed to be permitted to be used on the information panel of products that contain at least 95 percent organic ingredients are the same terms and marks previously proposed to be allowed to be used on the principal display panel: the term organic, the USDA seal, and a State seal representing a State organic program approved by the Secretary. Additionally, we propose to permit on the information panel the use of a certifying agent's name, seal, logo or other identification which represents that the farm, wild crop harvesting, or handling operation that produced or handled the finished product is a certified operation. We are proposing here to allow only the identification of the certifying agent that certified the operation that produced or handled the finished product. We believe that allowance of the use of multiple identification of certifying agents who certify any operation involved in the production or handling of the product would be unwieldy and confusing to the consumer. We invite comments on this issue.

The NOSB received some public comment which requested that identification of a certifying agent on product labels be prohibited. Other public comments, however, indicated that the identification of a certifying agent should be required on product labels to inform consumers of the specific organization that performed the certification of the operation. Additionally, some public comments requested that the identification of a certifying agent be optional, so that each individual producer and handler could decide whether to include this identification on their label.

After evaluating the public comments, we agree that the decision as to whether to include the certifying agent's identification on a label should be optional. We believe that inclusion of the identification of the certifying agent who certified the operation that made the finished product is not essential. Therefore, we have included this identification of a certifying agent in our proposal as optional information that may be included on the information panel of a label of products that contain at least 95 percent organic ingredients.

We propose to allow the placement of the identification of the certifying agent on the information panel, but not on the principal display panel, because we want the principal display panel to include only those terms or marks that would be important to everyone, i.e., those terms or marks that present information about the organic nature of the agricultural product, its compliance with the national organic program requirements and, if applicable, the requirements of an approved State organic program; we do not feel that the identification of a certifying agent is this type of information. We propose to allow the placement of the identification of the certifying agent on the information panel, rather than restricting its use to other less prominent panels, because we agree with the public input we received that stated that this information would be important to some consumers in their purchasing decisions.

In paragraph (a)(5) of this section, we propose that the terms or marks that may appear on the information panel for products sold, labeled, or represented as organic (i.e., products that contain at least 95 percent organic ingredients) also may be used on any package panels of the product, excluding the principal display panel. Additionally, we are proposing that these same terms and marks may be used on the product's labeling and on market information about the product. We have defined labeling to be written, printed or graphic material accompanying a product at any time or displayed about the product at the retail store. Market information has been defined to be any written, printed, audio-visual or graphic information, including advertising, pamphlets, flyers, catalogues, posters, and signs, that are used to assist in the sale or promotion of a product. This provision is consistent with section 2106(a)(1)(B) of the OFPA (7 U.S.C. 6505(a)(1)(B)), which provides for labels and market information to be provided for and affixed on agricultural products that are produced and handled in accordance with the Act and the regulations in this part.

*Agricultural Products in Packages Sold, Labeled, or Represented as Made With Certain Organic Ingredients—Section 205.101*

Section 2106(c)(1) of the OFPA (7 U.S.C. 6505(c)(1)) authorizes the Secretary, in consultation with the NOSB and the Secretary of Health and Human Services, to allow the use of the word organic on the principal display panel of an agricultural product that contains at least 50 percent organically produced ingredients by weight, excluding water and salt, only for the purpose of describing the organically produced ingredients. Our proposed section 205.16(b) makes it clear that this type of product is one containing at least 50 percent, but less than 95 percent, organically produced ingredients. The Secretary has consulted with the Secretary of Health and Human Services and reviewed the NOSB recommendations for this matter. We are proposing to allow the word organic to appear on the principal display panel of products described in section 205.16(b) as discussed below, hereafter referred to as ''products that contain between 50 and 95 percent organic ingredients''.

We propose, in paragraph (a) of this section, the terms that must be used on agricultural products sold in packages, described in section 205.16(b), that are sold, labeled, or represented as made with certain organic ingredients, (i.e., products that contain between 50 and 95 percent organic ingredients). We propose in paragraph (a)(1) of this section that the statement made with certain organic ingredients must be used on the principal display panel of a product described in section 205.16(b). We believe that allowing the word organic to appear on the principal display panel of these products only when used within the statement made with certain organic ingredients would enable consumers to easily distinguish this type of product from a product that

contains at least 95 percent organic ingredients, on which the term organic must appear on the principal display panel to modify the name of the product.

We request comments from industry, consumers, consumer interest groups, and all other interested persons on our proposed use of the statement made with certain organic ingredients on the principal display panel of products that contain between 50 and 95 percent organic ingredients. We are soliciting information as to whether there are alternative label proposals, and if so, a description of them, that would accomplish our purpose of clearly distinguishing on the principal display panel between products that contain at least 95 percent organic ingredients and those that contain between 50 and 95 percent organic ingredients.

We also propose in paragraph (a)(2) of this section to require that the term organic be used in the ingredients statement to modify organically produced ingredients. We are proposing this in order to provide consumers with a means of knowing which ingredients have been organically produced.

We propose in paragraph (b) of this section the terms and marks that may, but that are not required to, be used on agricultural products described in section 205.16(b) that are sold, labeled, or represented as made with certain organic ingredients (i.e., products that contain between 50 and 95 percent organic ingredients). In paragraph (b)(1) of this section, we propose to allow the statement made with certain organic ingredients to appear on the information panel. We believe this would further assist consumers in readily identifying products that contain between 50 and 95 percent organic ingredients, and additionally may be useful in certain retail display situations where the view of the principal display panel may be obscured from the consumer. We also propose in paragraph (b)(1) of this section to allow the identification on the information panel of the certifying agent who certified the farm, wild crop harvesting, or handling operation that produced or handled the finished product. Our reasons for allowing the optional inclusion of the certifying agent's identification on the information panel and the prohibition of its placement on the principal display panel for these type of products, are the same ones we previously discussed with regard to products that contain at least 95 percent organic ingredients.

In paragraph (b)(2) of this section, we propose that any of the terms and marks proposed to be allowed to be used on the information panel may also be used on labeling, market information and any package panel, excluding the principal display panel, of products labeled as made with certain organic ingredients. The allowed terms or marks would be the statement made with certain organic ingredients and the certifying agent's identification. This provision is consistent with section 2106(a)(1)(B) of the OFPA (7 U.S.C. 6505(a)(1)(B)), which provides for labels and market information to be provided for and affixed on agricultural products that are produced and handled in accordance with the Act and the regulations in this part.

*Multi-ingredient Agricultural Products That Only Represent the Organic Nature of Such Ingredients in the Ingredients Statement—Section 205.102*

Section 2106(c)(2) of the OFPA (7 U.S.C. 6505(c)(2)) authorizes the Secretary, in consultation with the NOSB and the Secretary of Health and Human Services, to allow products that contain less than 50 percent organically produced ingredients by weight of the finished product, excluding water and salt, to include the word organic on the ingredient listing panel to describe those ingredients that are organically produced. The Secretary has consulted with the Secretary of Health of Human Services and reviewed the NOSB recommendations on this matter. We propose the following provisions for the use of the word organic in the ingredients statement of multi-ingredient agricultural products that only represent the organic nature of such ingredients in the ingredients statement.

We propose in section 205.102 that the term organic may be used in the ingredients statement of this type of product to modify the name of an ingredient organically produced and handled in accordance with the Act and the regulations in this part. We also propose in section 205.102 that agricultural products that are composed of more than one ingredient may represent in an ingredients statement that the ingredients are organic without the finished product having to be produced and handled in a certified operation, if certain conditions are met. One of the conditions that must be met is that the producer or handler of the finished product would have to maintain certain records that are required for non-certified operations. The second condition that must be met is that the only representation made about the organic nature of the product is a statement in the ingredients statement that identifies organic ingredients.

We also propose in paragraph (b) of this section that the term organic may be used on labeling, marketing information and package panels of labels other than the principal display panel and information panel, to describe the organic ingredients in products discussed above. We are permitting the identification of organic ingredients under these conditions for a variety of organic products in order to allow the organic industry flexibility in the production and marketing of organic products.

*Use of Terms or Statements That Directly or Indirectly Imply That a Product is Organically Produced and Handled—Section 205.103*

Section 2106(a)(1)(B) of the OFPA (7 U.S.C. 505(a)(1)(B)) provides that a person may affix or provide a label or other market information about an agricultural product, including an ingredient, that directly or indirectly implies that the product is organically produced and handled only when the product has been produced and handled using organic methods in accordance with the Act. Accordingly, we propose in this section that labels, labeling or market information that directly or indirectly imply organic production and handling practices may be provided for or affixed only on agricultural products produced and handled in accordance with the Act and the regulations in this part.

Our proposed regulations would authorize the use on a label, labeling, or market information of the term organic and other terms and phrases that directly or indirectly imply that the product was organically produced and handled. Therefore, under our proposal, any terms or phrases that directly or indirectly imply that a product has been organically produced or handled would be prohibited from being used on the label, labeling, or market information of products that are not produced in accordance with the Act and the regulations in this part.

We considered putting in our proposed requirement a specific list of the terms and phrases that we believe would directly or indirectly imply that a product was organically produced and handled. We have not done this because we are uncertain as to what terms and phrases should appropriately be placed on such a list. We request comment from the public as to what terms or phrases, other than organic or made with certain organic ingredients, they believe could directly or indirectly imply that a product was organically produced and handled and the rationale for the allowance of their use. Examples

of terms or phrases which we consider may imply directly or indirectly that a product is organically produced and handled and about which we specifically request comment include: ''produced without synthetic pesticides''; ''produced without synthetic fertilizers''; ''raised without synthetic chemicals''; ''pesticide-free farm''; ''no drugs or growth hormones used''; ''raised without antibiotics''; ''raised without hormones''; ''no growth stimulants administered''; ''ecologically produced''; ''sustainably harvested''; and ''humanely raised''.

*Informational Statements Prohibited—Section 205.104*

We are proposing in this section to prohibit certain informational statements from being included on the principal display panel and ingredients statement of any products containing organically produced ingredients because we believe such statements might mislead consumers. Because these are the areas that consumers generally examine to obtain information about the nature of the product they are purchasing, we believe that these areas should therefore contain only terms or phrases that are familiar to consumers and are readily understood by them.

In paragraph (a) of this section, we propose to prohibit the phrase one hundred percent, stated in letters, numbers or symbols, when used as part of any phrase or sentence that includes the term organic, on the principal display panel and in the ingredients statement of a product that is sold, labeled, or represented as organic. Examples of phrases that would be prohibited by this paragraph are: our ingredients are one hundred percent organic; 100% organic whole wheat; and we only use 100 percent organic methods.

In paragraph (b) of this section, we propose to prohibit the placement of a statement of the percentage of organic ingredients on the principal display panel and in the ingredients statement of any product containing organic ingredients. Our proposal would not prohibit a statement of the percentage of organic ingredients from being used on labeling materials, market information and any panel other than the principal display panel.

The NOSB received comments from manufacturers both in favor and in opposition to allowing the inclusion of a statement of the percentage of organic ingredients on product labels. The NOSB recommended to the Secretary that a percentage statement be allowed on the principal display panel only for products containing one hundred percent organic ingredients. For all other products, the NOSB recommended that a percentage statement be restricted to the information panel.

We agree with the NOSB that a percentage statement should be permitted, and accordingly propose to allow a statement of the percentage of organic ingredients on a product label for the benefit of consumers who believe that this information is important to them as part of their purchasing decisions. However, we propose to prohibit its placement on the principal display panel and in the ingredients statement. We propose this prohibition on the placement of the percentage statement because we do not consider a percentage statement to be essential program information. Its use on the principal display panel and ingredients statement would be inconsistent with our proposed labeling scheme, as previously explained, which provides for placing only essential program information on the principal display panel and ingredients statement. We request comment on our proposal to allow a statement of the percentage of organic ingredients on a product package and on our proposal to prohibit its use on the principal display panel and in the ingredients statement.

In paragraph (c) of this section, we propose to prohibit the use of the phrase organic when available, or a term of similar meaning or intent, on the principal display panel and in the ingredients statement of products containing organic ingredients.

*Agricultural Products in a Form Other Than Packages That are Sold, Labeled, or Represented as Organic or Made With Certain Organic Ingredients—Section 205.105*

We propose in paragraphs (a) and (b) of this section the terms and marks that may be used on products in a form other than packages that are sold or represented as organic or made with certain organic ingredients, in order to prevent the possibility of mixing organic and nonorganic products. Products in a form other than packages are those products that either are not enclosed in a container or wrapping or are products labeled as bulk food items in containers. Products in other than package form include such products as bulk food items, unpackaged fruits and vegetables for sale in a retail store, raw agricultural products such as grains, and products in shipping containers for further processing.

We propose in paragraph (a)(1) of this section that agricultural products that contain at least 95 percent organic ingredients that are sold or represented as organic may use the term organic on a retail display label (or labeling) or display container to modify the name of the product. We propose in paragraph (a)(2) of this section that the term organic may be used in the ingredients statement to modify the name of an ingredient organically produced and handled in accordance with the Act and the regulations in this part. The proposals made in paragraphs (a)(1) and (a)(2) of this section would be applicable to organic products in other than package form at the time of retail sale and, thereby, would provide for organic products sold in retail stores in bulk or other non-package form to be identified by the same terms as we propose to be used on organic products in package form.

We propose in paragraph (a)(3) of this section that shipping containers for organic products in other than package form may bear a clearly recognizable organic identification mark(s) or term(s) in plain view on the shipping container. The mark(s) or term(s) are proposed to be chosen from the following: the term organic used to modify the name of the product; the USDA seal; a seal representing an approved State organic program; and the certifying agent's name, seal, logo, or other identification representing certification of the operation that produced or handled the product. We believe that this provision would assist those handlers who handle both organically produced and non-organically produced products to readily identify and separate the products and prevent their commingling, as required in proposed section 205.19.

We propose in paragraph (b) of this section the labeling requirements for agricultural products in other than package form that are sold or represented as made with certain organic ingredients. We believe that agricultural products in a form other than packages that are sold or represented as made with certain organic ingredients need to meet specific labeling requirements that are similar to the requirements proposed for agricultural products in other than package form that are sold, labeled, or represented as organic. These labeling requirements are needed to ensure that these products can be readily identified and to assist handlers in preventing the possibility of commingling products sold, labeled, or represented as made with certain organic ingredients with non-organically produced products. Accordingly, we propose in paragraph (b)(1) of this section that agricultural products that are sold or represented as made with certain organic ingredients

that are described in section 205.16(b) shall use the statement made with certain organic ingredients on a retail display label (or labeling) or display container to modify the name of the product. We propose in paragraph (b)(2) of this section that the term organic be used in the ingredients statement to modify the name of an ingredient organically produced and handled in accordance with the Act and the regulations in this part. Finally, we propose in paragraph (b)(3) of this section that agricultural products in a form other than packages would use the statement made with certain organic ingredients located in plain view on the shipping container, which may be accompanied by the certifying agent's name, seal, logo, or other identification. The rationale for the provisions proposed in paragraph (b) of this section are discussed in the supplementary information for paragraph (a) of this section regarding organic products in a form other than packages.

*Agricultural Products Produced on an Exempt Farm or Handling Operation—Section 205.106*

Section 2106(d) of the OFPA (7 U.S.C. 6505(d)) provides an exemption from the compliance requirements of section 2106(a)(1) of the OFPA (7 U.S.C. 6505(a)(1)), which does not permit a person to sell or label an agricultural product as organically produced unless it has been produced and handled in accordance with the Act. This exemption applies to a person who sells no more that $5,000 annually in value of agricultural products, unless such person voluntarily chooses to be certified. In § 205.202(a)(1) of subpart D, we propose that a farm, handling operation, or wild crop harvesting operation that produces, handles or harvests agricultural products, but which annually sells no more than $5,000 in value of agricultural products, would be exempt from the certification requirements of the Act and the regulations set forth in subpart D of this part. Consistent with section 2107(a)(11) of the OFPA (7 U.S.C. 6506(a)(11)), however, which allows the Secretary to require such other terms and conditions determined to be necessary, we propose in paragraphs (a) and (b) of this section certain labeling requirements for agricultural products that are produced on these exempt operations that have not been certified. We propose these labeling prohibitions in order to help ensure that consumers are not misled when they purchase agricultural products from them, and in order to assure that products and ingredients sold, labeled, or represented as meeting the requirements of the OFPA in fact have been produced and handled in accordance with the Act.

In paragraph (a) of this section, we propose to prohibit the displaying of the USDA seal or any certifying agent's name, seal, logo, or other identification of certification referring to the requirements of the Act and the regulations of this part. The purpose of this provision would be to ensure that only agricultural products that meet the proposed requirements for organic production and certification in part 205 could have a label or other market information that incorporated the USDA seal or certification identification, either of which would indicate compliance with the Act and the regulations in this part. Additionally, the provision proposed in paragraph (a) of this section would assist consumers in distinguishing between an organic product from an exempt operation and an organic product from an operation certified to national or State program requirements.

In paragraph (b) of this section, we propose that an agricultural product that is produced or processed on an exempt farm or handling operation that annually sells no more than $5,000 in value of agricultural products and which has not been certified could not be identified as an organic ingredient in a product produced or processed on a farm or handling operation that annually sells more than $5,000 in value of agricultural products. We propose this prohibition for the purpose of prohibiting organic agricultural products that originate from exempt uncertified operations from being commingled with organic agricultural products that originate from operations that are certified to national or State program requirements. This provision as proposed would help promote clarity for consumers in identifying when an agricultural product was produced and handled in accordance with the Act and the regulations in this part.

*The USDA Seal—Section 205.107*

Section 2106(a)(2) of the OFPA (7 U.S.C. 6505(a)(2)) allows labels affixed to, or market information provided for, domestic agricultural products that meet the USDA standards for organic production to incorporate the USDA seal. In accordance with this section of the OFPA, we propose in paragraph (a) of this section that the USDA seal could be used only on those agricultural products (raw or processed) labeled as organic (i.e., products that contain at least 95 percent organic ingredients), as described in § 205.16(a), that are produced in the U.S. and are produced and handled on a certified operation. This provision as proposed would permit a product produced in the U.S. which contained imported organic ingredients obtained from a program determined by the Secretary to be equivalent to the national program to display the USDA seal.

In paragraphs (b) and (c) of this section, we propose the form and design of the USDA seal. We propose to require the reproduction of the mark in a dark color on a light background, or in a light color on a dark background, or in a standard four color label. We propose that the USDA seal consist of an interior globe with continents displayed and a diagonal line across the globe (continents) with the word organic on the diagonal. The globe with continents would be surrounded by concentric circles with arrows containing the words meets USDA requirements. A triangle would enclose the globe and the concentric circles.

The use of the globe with continents is intended to represent the principles of organic production upon which the national organic program is founded. These principles are oriented toward the nurturing of a healthy agroecosystem as part of the biosphere, represented by the globe. The concentric circles with arrows represent the basic practice of recycling nutrients and materials which is essential to a system of organic farming. The triangle represents the stability of a healthy agroecosystem based upon the stewardship of soil, water and air as its components.

We believe that this seal, which may be used at the option of the producer or handler in accordance with the provisions of subpart C of this part, would allow consumers to readily identify that the organic product met the requirements of the National Organic Program as proposed in the regulations of this part. We request comment on the design of the USDA seal and its use as proposed in this subpart as to whether the proposed design will readily identify an organic product as one that meets the requirements of the National Organic Program.

In particular, we would like to receive examples of alternative designs for the USDA seal that would be effective in allowing consumers to readily identify that an organic product meets the requirements of the organic program. We would appreciate it if any alternative designs submitted are accompanied by an explanation about how the alternative design suggested would more effectively make organic products readily identifiable as being produced under the National Organic Program than the proposed design for

the USDA seal. In addition, we would like comments from all interested persons as to whether the proposed design for the USDA seal would create any burdens for its use.

We have provided a chart of what is required to be reflected on the labels and labeling of various types of organic products, as well as what is required to be reflected on certain types of market information provided about organic products. The chart also indicates where required information is to be placed on labels, on labeling, and on certain types of market information. Additionally, the chart indicates what type of information may, but is not required, to be placed on labels, on labeling, and on certain types of market information for various types of organic products. Further, the chart indicates what type of information may not be placed on the labels, labeling, and market information of various types of organic products, and where it is prohibited from being placed.

SUBPART C—LABELS, LABELING, AND MARKET INFORMATION

| Required | Discretionary | Prohibited |
|---|---|---|
| **Agricultural products in packages sold, labeled or represented as organic** | | |
| **Principal display panel:** | | |
| • None | • The term organic to modify the name of the product.<br>• USDA seal<br>• State seal | • Certifying agent's name, seal, logo, or other identification.<br>• One hundred percent stated in letters, numbers, or symbols, used with any phrase or sentence that includes the term organic.<br>• Statement of the percentage of organically produced ingredients contained in a product.<br>• Phrase: organic when available (or term of similar meaning or intent). |
| **Ingredients Statement:** | | |
| • None | • The term organic to modify the name of an ingredient organically produced and handled. | • One hundred percent stated in letters, numbers, or symbols, used with any phrase or sentence that includes the term organic.<br>• Statement of the percentage of organically produced ingredients contained in a product.<br>• Phrase: organic when available (or term of similar meaning or intent). |
| **Information panel:** | | |
| • None | • Organic with product name<br>• USDA seal.<br>• State seal.<br>• Certifying agent's name, seal, logo, or other identification. | • None. |
| **Agricultural products in packages sold, labeled, or represented as made with certain organic ingredients** | | |
| **Principal display panel:** | | |
| • Statement: made with certain organic ingredients. | • None | • One hundred percent stated in letters, numbers, or symbols, used with any phrase or sentence that includes the term organic.<br>• Statement of the percentage of organically produced ingredients contained in a product.<br>• Phrase: organic when available (or term of similar meaning or intent).<br>• USDA seal.<br>• State seal.<br>• Certifying agent's name, seal, logo, or other identification |
| **ingredients statement:** | | |
| • The term organic to modify the name of an ingredient organically produced and handled.. | • None | • One hundred percent stated in letters, numbers, or symbols, used with any phrase or sentence that includes the term organic.<br>• Statement of the percentage of organically produced ingredients contained in a product.<br>• Phrase: organic when available (or term of similar meaning or intent). |
| **Information panel:** | | |
| • None | • Statement: made with certain organic ingredients.<br>• Certifying agent's name, seal, logo, or other identification. | • USDA seal.<br>• State seal. |
| **Multi-ingredient agricultural products that are not produced by certified operations and that only represent the organic nature of such ingredients in the ingredient statement and which are not sold, labeled, or represented as organic or made with certain organic ingredients** | | |
| **Principal display panel:** | | |
| • None | • None | • The term organic to modify the name of the product.<br>• Statement: made with certain organic ingredients.<br>• USDA seal.<br>• State seal. |

SUBPART C—LABELS, LABELING, AND MARKET INFORMATION—Continued

| Required | Discretionary | Prohibited |
|---|---|---|
| | | • Certifying agent's name, seal, logo, or other identification.<br>• One hundred percent stated in letters, numbers, or symbols, used with any phrase or sentence that includes the term organic.<br>• Statement of the percentage of organically produced ingredients contained in a product.<br>• Phrase: organic when available (or term of similar meaning or intent). |
| **Ingredients statement:**<br>• None | • Organic to modify the name of an ingredient that is organically produced and handled. | • One hundred percent stated in letters, numbers, or symbols, used with any phrase or sentence that includes the term organic.<br>• Statement of the percentage of organically produced ingredients contained in a product.<br>• Phrase: organic when available (or term of similar meaning or intent). |
| **Information panel:**<br>• None | • None | • The term organic to modify the name of the product.<br>• Statement: made with certain organic ingredients.<br>• USDA seal.<br>• State seal.<br>• Certifying agent's name, seal, logo, or other identification. |
| **Agricultural products in other than package form that are sold, labeled or represented as organic or made with certain organic ingredients.** | | |
| **Retail display label or display container:** | | |
| For organic products:<br>• None | • For organic products:<br>• The term organic to modify the name of the product.<br>• USDA seal.<br>• State seal.<br>• Certifying agent's name, seal, logo, or other identification.. | • None. |
| For made with certain organic ingredients products:<br>• Statement: made with certain organic ingredients. | For made with certain organic ingredients products:<br>• Certifying agent's name, seal, logo, or other identification. | None |
| **Ingredients statement:** | | |
| For organic products:<br>• None. | For organic products:<br>• The term organic to modify the name of an ingredient organically produced and handled.. | • None. |
| For made with certain organic ingredients products:<br>• The term organic to modify the name of an ingredient organically produced and handled. | For made with certain organic ingredients products:<br>• None | • None. |
| **Shipping container:** | | |
| For organic products:<br>• None | For organic products, one or more of the following:<br>• The term organic to modify the name of the product; or<br>• USDA seal; or.<br>• State seal; or.<br>• Certifying agent's name, seal, logo, or other identification.. | • None. |
| For made with certain organic ingredients products:<br>• Statement: made with certain organic ingredients. | For made with certain organic ingredients products:<br>• Certifying agent's name, seal, logo, or other identification. | • None. |

*Subpart D—Certification*

Section 2104(a) of the OFPA (7 U.S.C. 6503(a)) requires that the Secretary establish an organic certification program for producers and handlers of agricultural products that have been produced using organic methods, and that this program be implemented through certifying agents. Section 2107(a) of the OFPA (7 U.S.C. 6506(a)) requires that all agricultural products sold or labeled as organically produced be produced on a farm and handled through a handling operation that has been certified, and delineates a number of other provisions that must be included in a certification program established under the Act. The Act,

however, provides for certain exemptions from certification. In this subpart we propose the certification provisions of the National Organic Program, which includes the requirements that must be met by farm, wild crop harvesting, and handling operations that want to be certified, and the procedures that must be followed by certifying agents in evaluating and making determinations concerning operations seeking certification. Subpart E of this part delineates our proposed accreditation program for organic certifying agents, as required by section 2115(a) of the OFPA (7 U.S.C. 6514(a)), including the requirement that a certifying agent must conduct certification activities in accordance with the procedures proposed in subpart D of this part to maintain its accredited status.

The certification process is needed to ensure that products labeled as organic and made with certain organic ingredients are produced and handled in accordance with the requirements proposed in subpart B of this part. Numerous private organizations and States already have developed experience and expertise in organic certification procedures. In developing this proposal, we have consulted with and examined the programs developed by existing private and State certifying agencies, considered the NOSB's recommendations, and considered comments received from the public. We also have reviewed the guidelines for the certification or registration of quality systems and for the assessment or accreditation of certifying bodies, as promulgated by the International Organization for Standardization. Other information we have reviewed includes guidelines for inspection, certification and accreditation established by other countries, international organic interest groups, and standards setting organizations, such as the International Federation of Organic Agricultural Movements.

This proposal is consistent with the provisions of the Act and incorporates, to the extent possible, the current practices of the organic certification community. We have designed the proposed regulations to minimize the burdens placed on organic producers and handlers, ensure that decisions made by certifying agents are well founded and fair, and provide sufficient guidance and oversight to protect the integrity of the organic label. We also have developed this proposal to utilize the expertise that exists in the organic community, which encompasses a broad range of producers, handlers and geographic locales, and to allow for differences in size, scope and organizational style represented by existing and anticipated private and State certification programs.

*Synopsis of Proposed Certification Program*

The provisions of sections 205.201 through 205.206, and sections 205.216 through 205.217(a), address the certification of farm, wild crop harvesting and handling operations that produce agricultural products, including livestock, that are, or are intended to be, sold, labeled or represented as organic or as made with certain organic ingredients. These proposed sections delineate the types of operations that must be certified; the types of operations that would be exempt or excluded from the certification requirement; the general requirements that must be met to obtain and maintain certification; and the information that must be submitted when applying for certification, including the provisions of an organic plan. Certification applicants would have to submit a statement agreeing to comply with the proposed production and handling requirements and would have to allow access to their facilities and records by a certifying agent, representatives of the Secretary, and the applicable governing State official in the case of operations located in a State that operates an approved State program. An operation whose request for certification was approved would have to operate in compliance with the requirements proposed in Subpart B, maintain records of its operations to show that it was complying with those requirements, and submit updated information annually.

Sections 205.207 through 205.215, and sections 205.217(b) through 205.220, propose the procedures that a certifying agent must follow in determining the certification status of a certification applicant or a certified operation, including the procedure for conducting on-site inspections; the basis for approving an application for certification; the procedure for notifying an operation of, along with an opportunity to correct, non-compliance with the Act and the regulations; and the procedure for recommending that the certification of an operation or a portion of an operation be denied or terminated by the Administrator, after providing notice and an opportunity to be heard. The final section of this subpart proposes the notifications that a certifying agent would have to provide to the Administrator concerning operations that it certified.

It should be noted that, in a State that establishes an approved State program, as provided for and discussed in sections 205.401 through 205.403 of subpart F, the certifying agent also would have to provide these notifications to the applicable governing State official. Additionally, the certifying agent would be required to verify that an applicant for certification in a State that establishes an approved state program was complying with any additional requirements provided under the State program. Proceedings to deny or terminate certification, and an opportunity to appeal such actions, would be initiated and conducted in accordance with the approved State program regulations.

*What Has to be Certified—Section 205.201*

Section 2106(a)(1) of the OFPA (7 U.S.C. 6505(a)(1)) requires that agricultural products that are sold or labeled as organically produced, including products for which other market information is provided that directly or indirectly implies that the products have been produced and handled using organic methods, must comply with the requirements of the Act. Therefore, we propose that, except as discussed below in proposed section 205.202, any farming, wild crop harvesting, or handling operation, or portion of any of these operations, that intends to sell, label or represent an agricultural product as organic, or as made with certain organic ingredients, would have to comply with all the applicable production and handling requirements set forth in subpart B of this part and be certified in accordance with the regulations of this subpart.

We further propose in section 205.201(a) that any operation that provides handling services to fewer than 3 certified entities that produce or handle agricultural products that are, or that are intended to be, sold, labeled or represented as organic or made with certain organic ingredients, would not be required to be separately certified apart from the operations for which it provides such services. This provision is proposed because, as is sometimes the case in existing certification programs we have examined, a certified operation may comprise facilities owned by different entities that it contracts with to provide handling services, such as washing and packing fresh produce, freezing multi-ingredient products, or warehousing. In such cases, the facilities that provide these services would be included in the certification obtained by the contracting operation, and therefore considered certified with respect to the handling of any products to be sold, labeled or represented as

organic or made with certain organic ingredients. Such a facility would, for the purposes of this proposal, also be considered to be a distinct portion of the operation for which it provides the handling services. However, as proposed in this section, if such a facility were to provide handling services under contract to three or more certified handling operations, it would then have to obtain a separate certification. For example, a facility that provided washing and packing services to one or two organic produce growers could be included in the growers' certifications as a portion of each of their operations, but if it were to then provide packing services for a third organic produce grower it would have to obtain its own separate certification. Comment is invited concerning the potential impact of this proposed requirement on handling operations that currently contract for handling services or that currently provide such services.

Section 2106(c) of the OFPA (7 U.S.C. 6505(c)) exempts products that contain at least 50 percent (but less than 95 percent) organic ingredients from complying with the requirements of the Act, but allows the Secretary, in consultation with the NOSB and the Secretary of HHS, to permit such products to be labeled on the principal display panel as containing certain organically produced ingredients. In section 205.101 of subpart C, we propose that such products could be labeled as made with certain organic ingredients on the principal display panel. In section 205.201(b) we propose that a handling operation, or portion of a handling operation, that handles only agricultural products that are, or that are intended to be, sold, labeled or represented as made with certain organic ingredients would have to be certified but would be exempt from complying with the requirement proposed in section 205.3(b)(2) of Subpart B, which requires that a commercially available non-synthetic substance be selected in preference to an allowed synthetic substance.

Products labeled as made with certain organic ingredients would not, in accordance with section 2106(c) of the OFPA (7 U.S.C. 6505(c)), have to be handled by a certified organic handling operation. However, the organically produced ingredients contained in such products would not be exempt from the Act's certification requirement. Therefore, because the preponderance of the ingredients in such a product would be organically produced, we believe that the level of oversight provided by the certification process is needed in order to safeguard the integrity of the organically produced ingredients and to assure consumers that these ingredients comply with consistent national standards. Because this type of product would be able to use the word organic on its principal display panel within the statement made with certain organic ingredients, we believe that consumers will generally expect that such products are in compliance with the Act and the regulations in this part. However, because the product itself is not represented as an organic product, we are proposing that such products need not comply with the requirement to select non-synthetic substances in preference to allowed synthetic substances. Such products would still have to comply with all other applicable provisions, including selecting only non-agricultural ingredients that are included on the National List.

*Exemptions and Exclusions—Section 205.202*

In accordance with section 2106(d) of the OFPA (7 U.S.C. 6505(d)), paragraph (a)(1) of this section would exempt producers and handlers that produce, handle or harvest agricultural products who sell no more than $5,000 annually in value of agricultural products from complying with the certification requirements set forth in this subpart. However, we propose in subpart C to prohibit the products produced on these exempt operations from being represented as originating from a certified operation, displaying the USDA seal, or being identified as an organic ingredient in a product processed or produced on an operation that sells more than $5,000 in value of agricultural products. These prohibitions are necessary to ensure that the organically produced ingredients contained in products that originate from certified operations are accurately represented. These prohibitions would not apply to an otherwise exempt operation that voluntarily chose to become certified under the Act and the regulations.

As indicated above, the exemption from certification proposed in the regulations for producers and handlers who sell no more than $5,000 annually of agricultural products is what is provided for in section 2106(d) of the OFPA (7 U.S.C. 6505(d)). During the course of public input given at NOSB meetings, various commenters suggested that the exemption from certification should include producers and handlers who annually sell no more than $10,000 of agricultural products, as opposed to $5,000. In order to provide for such an exemption in our regulations, we would need to have the OFPA amended. We would appreciate comments 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 is appropriate. In addition, we would like data as to the number of operations that may be exempt under the current $5,000 limitation for exemption, and the number of operations that may be exempt under any new monetary amount suggested.

In paragraph (a)(2) of this section, we propose to exempt retail operations, or portions of such operations, that handle organically produced agricultural products but do not process them. This is consistent with the definition of handling operation as set forth in section 2103(10) of the OFPA (7 U.S.C. 6502(10)). An exclusion for certain retail operations that do process organic agricultural products is proposed in paragraph (b)(3) of this section.

Section 2106(c) of the OFPA (7 U.S.C. 6505(c)) states that the provisions of section 2106(a) (7 U.S.C. 6505(a)) regarding compliance with the requirements of the Act do not apply to two types of processed agricultural products that contain less than 95 percent organic ingredients. This section of the Act exempts products that contain less than 50 percent organically produced ingredients from compliance with the regulations proposed in this part, and we have accordingly proposed, in paragraph (a)(3) of this section, to exempt any handling operation, or portion of a handling operation, that handles only agricultural products that contain less than 50 percent organic ingredients from all the requirements proposed in this part except the applicable labeling provisions proposed in subpart C and the provisions proposed in section 205.19 of subpart B for the prevention of commingling and contact of organic products by prohibited substances with regard to any organically produced ingredients used in this type of product. We believe that these requirements are necessary for a handler of this type of product in order to safeguard the integrity of the organic ingredients used in any such product, and to ensure that any use of the word organic in the ingredient listing is in accordance with our proposed labeling provisions.

In section 205.202(b), we propose that certain types of operations or portions of operations be excluded from compliance with the certification requirements in subpart D. After careful consideration of the NOSB recommendations, public input, and

information received from representatives of various types of handling and retail operations, we believe that it would be burdensome to require certification of the types of handling operations addressed in this section and, furthermore, that such a requirement is unnecessary because it would not contribute to assuring the integrity of an organically produced product. Accordingly, we propose that three types of handling operations, or portions of operations, not be required to be certified.

In section 205.202(b)(1) we propose that a handling operation, or portion of a handling operation, would be excluded from compliance with the proposed regulations in this part, except for the requirements for the prevention of commingling and contact by an organic product with prohibited substances in section 205.19 of subpart B, if it handles only products labeled as organic or as made with certain organic ingredients that meet two criteria. These two criteria are that the products are packaged or otherwise enclosed in a container prior to being received by the operation, and that the products remain in the same package or container and are not processed while in the control of the operation. This exclusion would avoid creating an unnecessary barrier for handlers who distribute non-organic products and who want to include a selection of organic products in their offerings. However, in order to protect the integrity of the organically produced products, we do not propose to exempt this type of handling operation from the requirements set forth in section 205.19 of subpart B regarding the prevention of commingling and contact with prohibited substances with respect to any organically produced products.

In section 205.202(b)(2) we propose to exclude restaurants and other food-service type establishments that process ready-to-eat organic agricultural products but which do not enclose the food in a container labeled or represented to the consumer as organic or made with certain organic ingredients. As further explained below in paragraph (b)(3) of this section, we are not proposing to require certification of operations that process food as part of their normal retail operations if they do not repackage the food in containers that are labeled or represented by the operation as organic or as made with certain organic ingredients. We consider the act of preparing ready-to-eat food by restaurants to be part of their normal retail operations.

We propose in section 205.202(b)(3) to exclude a retail operation, or portion of a retail operation, that processes products labeled as organic or as made with certain organic ingredients in the course of its normal retail operations, but does not repackage products under its own organic label. A retail operation, or portion of a retail operation, excluded under this proposal in paragraph (b)(3) of this section would have to satisfy two requirements. First, the operation would have to process only products that were previously labeled as organic or made with certain organic ingredients before being acquired by the retailer. Second, the products would have to be processed by the operation in the course of its normal retail business solely for the purpose of presenting or offering the product to a consumer. These requirements mean that the product offered to the consumer by the retail operation could not be one that was created by the retailer by combining two or more ingredients into a single product that is then labeled or represented by the retail operation as organic or as made with certain organic ingredients, and it could not be a product that is repackaged by the operation and newly labeled or represented as organic or made with certain organic ingredients. We do not consider either creating a new product from two or more ingredients, or repackaging and relabeling a product, to be normal retail business practices for retail operations solely for the purpose of presenting or offering a product to a consumer. It should be noted that a weight label is not included within our proposed definition of label as set forth in section 205.2 of subpart A; therefore, we would not consider a retail operation applying a weight label to a product repackaged from a bulk container or sliced from a larger quantity to be a repackaging activity that would require certification because applying weight labels is an activity that we consider to be within normal retail business practices for retail operations.

Examples of retailer processing activities that would be excluded and which therefore would not require that the retail operation be certified are washing and sorting fresh produce for display in bulk; cutting cheese from a bulk wheel and placing weight labels on the cheese packages; repackaging two pound bags of organic brown rice from a 50 pound sack and placing weight labels on the two pound bags; and allowing consumers to package their own bags of organic grain from a bulk container. Examples of retailer processing activities that would not be excluded and which therefore would require that the retail operation be certified are baking organic bread; preparing an organic pasta salad for sale at the deli counter; repackaging a series of products such as grains or pastas under the retailer's own label that identifies the products as organic; and preparing a private label pizza labeled as made with certain organic ingredients for customers to purchase from a refrigerated display case for baking at home. We invite further comment concerning the exclusions proposed in this section.

In section 205.202(c) we propose that farm or handling operations that are either exempt from certification under section 205.202(a), or excluded from certification under section 205.202(b), would still be required to maintain certain records and to make those records available to authorized representatives of the Secretary and the applicable governing State official. Small operations that are exempt pursuant to paragraph (a)(1) of this section would have to keep records for no less than one calendar year to substantiate that the operation did not sell more than $5,000 in agricultural products in the previous calendar year, and therefore met the requirements for exemption of small operations provided by section 2106(d) of the OFPA (7 U.S.C. 6505(d)).

Handlers of products that contain less than 50 percent organic ingredients who are exempt under section 205.202(a)(3), or handlers who are excluded under section 205.202(b)(1), would have to maintain records for no less than one year from the date of receiving a product labeled as organic or made with certain organic ingredients, that are adequate to verify the source and quantity of the product and that the product or ingredient was handled in accordance with section 205.19 to prevent commingling and contact with prohibited substances. Records also would have to be maintained for no less than one year from the date of shipping a product that contains organic ingredients so as to verify the destination and quantity of the product shipped. The recordkeeping requirements proposed in paragraph (c)(2) of this section are necessary to assist in enforcement of the national organic program and to verify that the operation is adequately safeguarding the integrity of organically produced products and organically produced ingredients.

We would like comments on the various exemptions from certification we have proposed, as well as on any other exemptions from certification that should be proposed, keeping in mind that legislative changes may have to be

sought to provide additional exemptions from certification.

*General Requirements for Certification—Section 205.203*

This section of our proposal delineates the six general requirements with which an organic farm, wild crop harvesting, or handling operation must comply in order to receive and maintain certification. These proposed provisions summarize the requirements provided in the Act and various sections of the regulations proposed in this part, so that a person seeking organic certification can determine all the requirements which must be met by the operation to be certified.

The first requirement, proposed in paragraph (a) of this section, is to comply with the applicable organic production and handling requirements of the Act and the regulations in this part. Paragraph (b) of this section would require that the operation establish and implement an organic plan that is submitted to an accredited certifying agent, as required by section 2107(a)(2) of the OFPA (7 U.S.C. 6506(a)(2)), and updated annually. The provisions that must be in the organic plan are proposed in section 205.205. The third requirement, proposed in paragraph (c) of this section in accordance with section 2107(a)(5) of the OFPA (7 U.S.C. 6506(a)(5)) is that an annual on-site inspection by the certifying agent must be permitted. In paragraph (d) of this section we propose that a certified operation must maintain all records applicable to the organic operation for a period of not less than five years from the date of creation of the record, and allow the Secretary, the applicable governing State official if the operation is in a State where there is an approved State program, and the certifying agent, access to such records, as proposed in section 205.216. This provision is proposed because we believe it is necessary in order to determine the operation's compliance with the Act and the regulations in this part for the purpose of providing adequate enforcement procedures, as required in section 2107(a)(7) of the OFPA (7 U.S.C. 6506(a)(7)). Section 205.203(e) of this proposal requires that a certified operation submit the required fees to the certifying agent, as proposed in section 205.422 of subpart F in accordance with section 2107(a)(10) of the OFPA (7 U.S.C. 6506(a)(10)).

In section 205.203(f) we propose that a certified operation must immediately notify the certifying agent about any application of a prohibited substance to any field, farm unit, site, facility, livestock, or product that is part of the certified operation, and about any other change in a certified operation, or any portion of the operation, that may affect its compliance with the Act and the regulations in this part. This provision is necessary in order to ensure that an operation that is approved for certification would notify the certifying agent in the event that anything occurs that would change the operation's compliance with the requirements proposed in subpart B. This provision therefore would require notification of the certifying agent if an operation was subject to a Federal or State emergency pest or disease treatment program as described in proposed section 205.432 of subpart F and provided for in section 2107(b)(2) of the OFPA (7 U.S.C. 6506(b)(2)).

*Applying for Certification—Section 205.204*

As proposed in this section, a certification applicant would have to submit an organic plan, as proposed in section 205.205, and a statement agreeing to comply with the Act and the regulations, as proposed in section 205.206, to an accredited certifying agent. An applicant also would need to submit basic contact information, such as phone and fax numbers, for the operation for which certification is sought. In paragraph (c) of this section, we further propose that the applicant submit the name or names of any organic certifying agent to which any application for certification previously has been made, including the year or years of the application and the outcome of each application. It should be noted that, if the certification applicant previously had applied to a different certifying agent who issued a notification of non-compliance as proposed in section 205.215(a), the applicant also would have to submit documentation that shows that the defects in compliance identified in that notice had been corrected, in accordance with proposed section 205.215(b). Knowledge of previous certifications or applications for certification is needed in order to determine if information about implementation of an organic plan or other updated information, as proposed in section 205.217(a), should be provided. It also would enable a certifying agent to verify whether any new applicant for certification was previously issued a notification of non-compliance by another certifying agent.

*Organic Plan—Section 205.205*

Section 2114 of the OFPA (7 U.S.C. 6513) requires a producer or handler who wants certification to submit an organic plan to the certifying agent, and provides for certain provisions that should be in the plan to foster the production and handling of agricultural products in accordance with the Act. Section 2103(13) of the OFPA (7 U.S.C. 6502(13)) defines an organic plan as a plan of management of an organic farming 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, including crop rotation and other practices required under the Act and the regulations in this part. The specific organic crop production and wild crop harvesting practices required by sections 2114(b) and (f) of the OFPA (7 U.S.C. 6513(b) and (f)) are addressed in this proposal in section 205.6 (crop rotation), section 205.7 (soil fertility and crop nutrient management), and section 205.11 (wild crop harvesting). The required provisions of the organic plan proposed here are consistent with the OFPA definition, and would enable a certifying agent to determine whether the applicant's management methods meet the requirements of the Act and the regulations of this part. We also believe that the establishment of an organic plan, as proposed here, would be a means by which organic producers and handlers could evaluate their operations and develop strategies to help them maintain compliance with the relevant organic production or handling requirements.

Section 205.205 of this proposal would require a certification applicant to submit an organic plan to the certifying agent. In a State with an approved State program, as proposed and discussed in section 205.402 of subpart F, the applicant also would have to submit the organic plan to the applicable governing State official. The organic plan would have to identify, as applicable to the operation for which certification is requested, a description of the practices and activities previously implemented, and intended to be implemented and maintained, to establish a system of organic farming and handling that complies with the applicable crop, livestock, wild crop harvesting, and handling requirements proposed in Subpart B. Details of any multi-year planning necessary in order to comply with all applicable requirements would have to be included in the organic plan. For example, a rotation plan or a description of other methods for ensuring adequate pest management, such as introduction of diverse species into areas planted with perennial crops, would have to be

provided for each field or farm parcel, as provided for in section 205.6 of subpart B. The organic plan also would have to describe practices implemented and intended to be implemented to comply with proposed section 205.3(b) of subpart B, which proposes that any practices used not result in measurable degradation of soil and water quality and that non-synthetic substances be chosen in preference to synthetic substances, to the extent possible. For example, a farmer might describe practices implemented to ensure that soil quality is not measurably degraded by tillage practices or that contamination of water by nitrates does not occur when manure is applied. The organic plan also would have to describe activities to evaluate the effects of practices for which more specific restrictions are proposed. For example, a farmer who is using a composted waste material that contains a non-active residue of a substance, as proposed in section 205.7(b)(4), would include information in the organic plan to demonstrate that the level of non-active residues that may be present in the composted waste material was not increasing in the soil to which it is applied.

The information delineated in sections 205.205(b) through 205.205(e) would have to be submitted as it was applicable to the operation for which certification is sought. These proposed paragraphs would require sufficient information about the farm, wild crop harvesting or handling operation for which certification is sought to evaluate whether an applicant is complying with or is able to comply with the Act and our proposed organic production and handling requirements in sections 205.3 through 205.28 of subpart B. It also is needed to aid the certifying agent in determining which areas of the operation should be observed in the course of the on-site inspection.

Section 205.205(b) proposes the information that would have to be submitted with respect to a farm operation. This information includes a description of the farm's crops, livestock, and on-farm processing activities, total acreage, and a map or maps showing all fields or farm parcels for which certification is requested. The map(s) are required to show field and farm parcel boundaries, sizes, locations, and any significant identifying features. They must also show any adjoining land, that is not part of the operation to be certified, to which a prohibited substance may be applied, and the location of any facility used for livestock housing, storage, or post-harvest handling. Information also would be required that provides a history of the crops grown and fertilizers or other production inputs applied to each field or farm to be certified for the three year period immediately preceding the date of the request for certification. The information would have to include the crops intended to be planted or managed on each field in the coming crop year, and a list of agricultural products to be sold as organic or as made with certain organic ingredients.

A farm operation also would have to submit information about the intended use of certain categories of production inputs. First, information would have to be submitted that listed all substances intended to be used as production inputs in the crop year. This list would have to indicate each substance intended to be applied to land or crops, its source, the anticipated quantity of it to be used, and where it would be applied. We also propose to request a list of all the seeds or planting stock intended to be purchased that would indicate for each of these its source (e.g. nursery or seed company), the approximate quantity to be used, and whether it was organically produced, treated, or untreated.

We propose that a livestock producer submit a list of all animals or livestock management units (such as flocks of poultry or colonies of bees) to be maintained on the operation and to be purchased in the following year for use as organic livestock or for the production of organic livestock products. The list also would have to indicate the source of the livestock (e.g., born on the farm, or name of the hatchery), estimated number of each type of livestock to be used and purchased in the certification year, the intended use of the livestock (such as slaughter stock, milk, wool, or breeding), and whether the livestock were purchased from a certified operation. Other information required to be submitted would indicate the livestock feed and feed supplements intended to be purchased in the certification year, and their source (e.g., local feed mill, or neighboring farm) and estimated quantity. Additionally, information as to what portion, if any, of the purchased feed was not organically produced would need to be provided. The livestock operation also would have to submit the name of the veterinarian from whom the producer obtains animal drugs or prescriptions for animal drugs, and a list of any animal drug expected to be used in the certification year, including its source, estimated amount to be used, and the types of livestock to which it might be administered. Finally, a farm operation would have to describe the post-harvest handling or processing methods and facilities to be used. Examples of post-harvest handling facilities would include fresh produce washing and packing facilities, grain cleaners, milk bottling, herb drying, and slaughtering facilities, whether the facilities are part of the farm operation to be certified or located elsewhere.

It should be noted that, in cases where the regulation provides for the use of a particular substance or production input only when other applicable proposed methods or production inputs are not effective or are not commercially available, such as botanical pesticides (section 205.9), treated seeds (section 205.8), or non-organically produced livestock feed (section 205.13), a description of the reasons for using a restricted substance or production input would have to be included in the organic plan. For example, a farmer might describe why botanical pesticides, rather than measures that did not involve the use of a substance, were used to control particular pests on particular crops. Similarly, a livestock producer would describe the reasons for feeding non-organic feed, such as an unanticipated expansion of a dairy herd. Annual updates to the plan also would describe the conditions that necessitated any allowed emergency or unanticipated use of a particular production input. For example, if treated seed were used to replant a corn crop lost to flooding, the farmer would provide this information as part of the next annual update to the organic plan.

Paragraph (c) of this section would require that an applicant requesting certification of a split operation (a farm or facility using both organic and non-organic practices in different field units or aspects of the operation) submit certain additional information. This information would include: anticipated quantities and locations of any crop, livestock or livestock product intended to be grown or raised both organically and non-organically in the coming crop year; each prohibited substance that was applied on the farm in the three years prior to the request for certification; each prohibited substance or practice that may be used in the certification year on a non-organic portion of the farm; and a description of the measures that will be used to prevent commingling of organic and non-organic products, and contact of organic field units or products with prohibited substances. This information is needed to determine whether there is any potential for organically managed portions of the operation to come into

contact with synthetic pesticides or other substances that are prohibited for use in organic farming and handling under the Act.

In paragraph (d) of this section we propose that a certification applicant be required to submit the following information regarding a wild crop harvesting operation: a map showing each area from which wild crops will be harvested in the certification year; the ownership of the area and evidence of permission to harvest in this area; a history of this area that demonstrates that no prohibited substance has been applied within three years prior to the initial harvest of a wild crop to be sold or represented as organic; each species of plant to be harvested, as well as its botanical name, the part of the plant to be taken (such as leaves, roots, flowers, fruits, or the whole plant), and the quantities of the plant expected to be harvested in the coming crop year; the dates of the harvest season; other information that the certifying agent might need to assess the impacts of the harvest operation on the environment and sustained growth and production of the wild crop; each type of wild product expected to be sold or represented as organic or made with certain organic ingredients, and the quantity of each type of product to be sold or represented (such as dried flowers in bulk, fresh roots and potpourri mixes); and a list of all post-harvest handling or processing methods and facilities to be used by the applicant.

As proposed in paragraph (e) of this section for handling operations, a handling operation applying for certification must submit: a brief, general description of the type of handling operation and the processing, manufacturing or other handling procedures it will use (such as grain cleaning and milling, meat or produce packing, dairy processing, or frozen food manufacturing); a description of the structural pest management methods used and intended to be used in each facility; and a list of each product intended to be handled and sold or represented in the certification year as organic or made with certain organic ingredients. A handling operation that produces both organic and non-organic products also would have to provide a list of each non-organically produced product or type of product to be sold in the certification year, and a description of the measures to be used to prevent the commingling of organic and non-organic products and ingredients, and the contact of organic products, and packaging and storage areas used for organic products, with prohibited substances. Finally, the handling operation would have to submit a list of each ingredient, incidental additive, and type of packaging material to be used for organic products in the certification year, and specify for each, as applicable, whether it is an organic agricultural product, a non-organic agricultural product, or a non-agricultural ingredient; the estimated quantity to be used; its source or manufacturer (e.g., name of the farm(s), flavor company, or packaging manufacturer from which it is purchased); and the country of origin for each imported organic agricultural product to be used. The source of any water to be used as an ingredient in an organic product would have to be identified in order to determine that the water meets the Safe Drinking Water Act (42 U.S.C. 300(f) *et seq.*) requirements. This determination needs to be made because section 2111(a)(7) of the OFPA (7 U.S.C. 6510(a)(7)) prohibits handling operations from using water that does not meet all the Safe Drinking Water Act requirements.

We would like to point out that we believe that the information we are requiring be submitted to certifying agents when an application for certification is made could result in many positive benefits for the organic program. We believe that the submitted information will significantly decrease the amount of time it will take to conduct inspections of operations seeking certification. If this occurs, then the costs incurred by operations applying for certification will be reduced.

We also believe that the information submitted at the time an application for certification is made will also lessen the burdens that could be incurred by certifying agents in making their own certification decisions, and in responding to requests for information from other certifying agents. This could occur because certifying agents will not have to continually re-contact certification applicants or certified operations when carrying out their responsibilities.

Additionally, we believe that information that is immediately available will help ensure that timely decisions are made. For example, the marketing of multi-ingredient products that may require multiple certifications should be able to occur in a timely and efficient manner because accredited certifying agents will be able to readily exchange the information needed to assure that these multiple certifications occur. Additionally, the easy accessibility to information that documents what is to occur in a certified operation will provide both certifying agents and the Administrator with the ability to help ensure that violations of the organic program that occur can promptly be substantiated, thus helping to ensure the integrity of representations made about the organic nature of a product.

However, an alternative scheme for having the necessary records available for certification decisions might be a scheme in which information needed for certification decisions would be required to be created by an applicant and made available for review and copying at an applicant's sites of operation, but would not be required to be submitted to certifying agents at the time an application for certification is made. In this scheme, these records would be reviewed by inspectors acting on behalf of certifying agents when an inspection is carried out as part of the process of determining whether an applicant should be certified. If records are needed at any other time, they could either be submitted to the certifying agent or made available for review at a farm or handling operation.

We would like comments from the public in regard to our proposed scheme, and the possible alternative to it discussed above. In particular, we would like information regarding the following:

(1) Whether the suggested alternative scheme which would require the creation and availability, but not the submission, of needed records would provide certifying agents with the records they need to make certification decisions in a timely and efficient manner;

(2) Whether the suggested alternative scheme would be less, or alternatively, more burdensome economically, or in any other manner, than the proposed scheme for submission of records for anyone participating in the organic certification program, including certifying agents, inspectors, farming operations, and handling operations, and if so, how and why it would be less or more burdensome; and

(3) Whether any records we are proposing to be submitted as part of the certification application, which in our alternative scheme would be maintained at the sites of operation, are not needed to make appropriate certification decisions or to ensure the integrity of the organic program. For example, we would like comments as to whether certifying agents need to know the anticipated quantities of non-organic agricultural products intended to be grown or harvested in order to make certification decisions for split operations. We also would like comments in this area regarding our requirement that split operations submit

information that indicates the expected quantity and location of each substance prohibited for use under the OFPA that may be used on a non-certified portion of the split operation.

*Statement of Compliance—Section 205.206*

We propose in this section, in accordance with section 2107(a)(4) of the OFPA (7 U.S.C. 6506(a)(4)), that an applicant for certification also submit a statement agreeing to comply with the Act and the regulations in this part, including the requirements for receiving and maintaining certification proposed in section 205.203, to the Secretary and the certifying agent. This statement of compliance would be submitted along with the certification application, and annually thereafter.

*Preliminary Evaluation of an Application for Certification—Section 205.207*

Section 205.207 would require a certifying agent to make a preliminary evaluation to determine whether the applicant may be in compliance with the applicable production and handling requirements before conducting an inspection. This preliminary evaluation, which would be based on an examination of the application materials received, would avoid the necessity of conducting an inspection of an applicant who clearly could not be in compliance with the applicable organic requirements, thus preventing unnecessary burdens on both the certifying agent and the applicant.

This section also would require that the certifying agent verify that an applicant who had previously applied to another certifying agent and received a notification of non-compliance, as proposed in section 205.215(a), had submitted documentation to support the correction of any deficiencies identified in the notification of non-compliance. This provision would assist a certifying agent to identify corrections made in response to deficiencies in compliance that previously had been noted by another certifier. Once the preliminary evaluation was completed and the information indicated that the operation may be in compliance with the Act and the regulations, the certifying agent would then arrange to conduct an on-site inspection of the operation.

*Arranging for Inspections—Section 205.208*

Section 2107(a)(5) of the OFPA (7 U.S.C. 6506(a)(5)) requires that an annual on-site inspection be performed by the certifying agent of each farm and handling operation that has applied for certification or that is certified. In section 205.208(a), we propose that a certifying agent arrange to conduct an initial on-site inspection of each farm, facility, and site that is included in an operation for which certification is requested, for the purpose of determining whether to approve the request for certification. Another on-site inspection would be conducted each year thereafter, to determine if the certification should be continued. Paragraph (b) of this section would require that such initial inspection be conducted within a reasonable time following a favorable preliminary evaluation of an application for certification, as proposed in section 205.207. While the Act does not specify that on-site inspections be performed prior to granting certification, performing at least one inspection prior to certification is the customary and required procedure for all existing certification programs of which we are aware, and we believe that it should be required in our proposal in order to verify that the information provided in an application for certification accurately reflects the practices used by the operation requesting certification. We have not specified a time period within which an inspection must be conducted because this will vary depending on when an application is submitted and the type of operation to be inspected.

In paragraph (c) of this section, we propose that an inspection be scheduled at a time when the inspector can observe land, facilities, and activities that demonstrate the operation's compliance with, or capacity to comply with, the organic production and handling requirements proposed in subpart B. Inspections also would have to be arranged so that the applicant or an authorized representative of the applicant who is knowledgeable about the operation will be present during the inspection. This requirement is necessary so that information pertinent to whether an applicant is complying or can comply with the Act and the regulations, can be obtained or clarified through discussion with personnel knowledgeable about the operation being certified.

*Verification of Information—Section 205.210*

Section 2105(3) of the OFPA (7 U.S.C. 6504(3)) requires that an agricultural product to be sold or labeled as an organically produced agricultural product must be produced and handled in compliance with an organic plan agreed to by the producer and handler of the product and the certifying agent. In section 205.210 we propose the means by which a certifying agent, through the use of an inspector, would verify that the information provided in the application for certification and in the organic plan, as proposed in sections 205.204 and 205.205, or in any annual update to this information, as provided in section 205.217, accurately represents that the applicant is complying or has the ability to comply with the Act and the regulations. When an inspection is conducted to evaluate continuation of certification, its purposes also would include verification that the provisions of the organic plan are being implemented.

The inspector should be able to determine from his or her observations whether the facilities and equipment used by an applicant for certification would enable the operation to be in full compliance with all the applicable requirements. For example, the inspector might verify that a produce operation that was preparing to plant annual vegetable seedlings had already obtained or produced seedlings that comply with section 205.8. If non-organically produced seedlings were being used, the inspector also would examine the operation's records that demonstrate that comparable organically produced seedlings were not commercially available.

In order to verify that the information submitted to the certifying agent is accurate and that practices used by the applicant are in compliance with the applicable provisions of the Act and the regulations, an inspection might include an examination of the applicant's fields, buildings, storage areas, production inputs, equipment, and other facilities, including any off-site facilities used by the operation for organic production or handling. In addition, all supplies and inventories of products that are, or that are intended to be, sold, labeled or represented as organic or as made with certain organic ingredients might be examined to observe whether they are stored and handled in a manner that creates any possibility of their being commingled with non-organic products. Labels, labeling, and other market information might also be examined to determine if such material was in compliance with the requirements of Subpart C. The inspector also might observe boundaries, buffer zones, and other critical control points where prohibited substances could contact organic crops, livestock, or other agricultural products, equipment or production areas used in organic production or handling, and places where commingling with nonorganic products might occur, especially in split

operations. Observations of the overall general health and condition of the soil, livestock, crops and other biological elements, such as hedgerows and waterways, as appropriate, also might be made. Additionally, the inspector might examine the operation's records and recordkeeping system, as needed to determine the applicant's compliance, or ability to comply with, the recordkeeping requirements proposed in section 205.216. Additionally, the inspector might need to collect samples of materials or substances for laboratory analysis that may serve as evidence of compliance, as proposed in sections 205.430 and 205.431 of subpart F, when instructed to do so by the certifying agent, or when the inspector observed a situation, such as herbicide damage to plants, which could indicate that any crop, field, livestock, product or facility within the operation has come into contact with a prohibited substance.

*Post-inspection Conference—Section 205.211*

In section 205.211 we propose to require that the inspector conduct a post-inspection conference with the certification applicant or an authorized representative of the inspected operation. During this conference, the inspector would discuss specific observations made concerning the applicant's compliance, or ability to comply, with the Act and the regulations, such as the adequacy of buffer areas observed to prevent contact with organically managed fields by prohibited substances, or the adequacy of the segregation of organic products from non-organic products in storage areas. We have proposed this requirement because such discussions are routinely included in procedures currently used by most existing certification programs, and we believe that permitting an applicant to clarify any information that is to be reported by the inspector to the certifying agent would help ensure the accuracy of the information. For example, if a crop being grown in a particular field is different from the crop indicated in the applicant information, the applicant could explain why the alternative crop had been substituted. This discussion also would assist the applicant in preparing future revisions to the organic plan and in making other changes to the operation, such as implementing practices that reduce the need to use pest control substances or animal drugs.

*Reporting to the Certifying Agent—Section 205.212*

In section 205.212, we propose that the certifying agent would require that the inspector prepare and submit to the certifying agent, within thirty days of completing an inspection, a written report that describes the inspector's observations and assessments of the inspected operation's compliance, or ability to comply, with the Act and the regulations. The inspection report is a key document that will be used by the certifying agent to verify an applicant's compliance, or ability to comply, with the regulations of the National Organic Program.

In accordance with section 2105(3) of the OFPA (7 U.S.C. 6504(3)) which requires that organic products be produced and handled in compliance with an organic plan agreed to by both the producer or handler and the certifying agent, we believe that sufficiently detailed information must be contained in an inspection report in order for the certifying agent to determine whether to approve the organic plan or require that it be revised, and also to determine whether a certified operation is complying with the organic plan as previously approved. Therefore, it is critical that the report include a complete, detailed description of the observations and assessments made by the inspector pursuant to section 205.210.

*Additional Inspections—Section 205.213*

In paragraph (a) of this section, we propose that, in addition to the annual on-site inspection required in section 205.208(a), a certifying agent could conduct an inspection of any farm, facility, or site used by a certified operation or an applicant for certification when necessary to determine compliance with the Act and the regulations in this part. In paragraph (b) of this section, we propose that the Secretary also may require that additional inspections be performed for the purpose of determining compliance with the Act and the regulations in this part. In a State in which there was an approved State program, the governing State official also would be able to require additional inspections. A certifying agent thus could decide to conduct additional inspections of certification applicants or certified operations as necessary to obtain information that was needed by the certifying agent to determine or verify the certification of the operation.

We believe that the requirements and procedures proposed in sections 205.208 through 205.213 to be followed by a certifying agent in conducting an inspection of an applicant for organic certification or a certified operation represent a key provision of our proposed certification program. The inspection process is critical for maintaining the integrity of the national organic certification program and must be undertaken in a reliable, thorough and consistent manner. Clear, consistent criteria for performing inspections are essential because of the diversity of private and State certifying agents who will be conducting inspections and evaluating inspection reports under this program.

*Approval of Certification—Section 205.214*

In this section we propose the basis for a certifying agent to approve an application for certification, and the procedure to be used by the certifying agent in notifying the applicant of the approval. Paragraph (a) of this section would require that the certifying agent review the information submitted by the applicant, including the organic plan, and the report submitted by the inspector, and request that the certification applicant submit any additional information and documentation that may be needed to determine if the certification applicant is complying, or is able to comply, with the Act and the regulations. For example, this might include information about changes in crops actually planted in certain fields, additional livestock added to the operation, or new sources for ingredients in a processed product, that occurred since the inspection took place.

Based on a review of all the information submitted by the certification applicant and the inspector, including any additional information the applicant has provided pursuant to paragraph (a) of this section, paragraph (b) of this section would require the certifying agent to approve an application for certification after determining that the applicant's operation satisfies four criteria. First, the certifying agent would need to determine that the practices and substances used, or intended to be used, by the operation are consistent with a system of organic farming and handling, as defined in section 205.2, and comply with the applicable production and handling requirements in this proposal. The second criterion that must be met is that the applicant satisfies the general requirements for certification, as proposed in section 205.203. Third, the certifying agent would have to determine that the applicant's organic plan satisfies the applicable requirements of the Act and the production and handling regulations in subpart B, including the provisions for the use of substances proposed in the

National List. The fourth criterion that must be met is that the applicant's records and recordkeeping system satisfy the applicable requirements proposed in section 205.216.

After the certifying agent determines that an application for certification should be approved, paragraph (c) of this section would require that the certifying agent send the applicant a written notification, and to state in the notice any restrictions or requirements that are being imposed as a condition of certification. For example, if the inspector noted that information about persons who had applied substances to certain farm parcels was missing from the applicant's records, the notice would require that such information be submitted by a certain time.

Along with the notification of approval, the certifying agent would provide a certificate which the operation could use as proof of certification. In paragraph (d) of this section, we propose that the certificate include the name of the certified operation, the effective date of the certification, and the category(ies) and type(s) of products and crop year, if applicable, covered by the certification.

*Denial of Certification—Section 205.215*

In this section we propose the procedure to be followed if the certifying agent has reason to believe, based on a review of the information specified in section 205.214(a), that an applicant for certification is not able to comply, or is not in compliance, with the requirements of the Act and the regulations in this part. When this occurs, the certifying agent would be required to provide a written notification of non-compliance to the applicant, as proposed in section 205.218(a). This notification would be sent by certified mail to the certification applicant, and would contain a description of each deficiency in the applicant's ability to comply with the Act and the regulations in this part that the certifying agent has reason to believe has occurred, the evidence on which the notification is based, and the date by which the operation must correct each deficiency in compliance identified in the notification.

Following the correction of deficiencies identified in the notification of non-compliance, section 205.215(b) would permit the applicant to submit a new application for certification to any accredited certifying agent. A new application would include documentation of actions taken by the applicant to correct the deficiencies in compliance identified in the notification of non-compliance sent pursuant to paragraph (a) of this section. If a new application is submitted to a different certifying agent, the certification applicant would be required to simultaneously inform the certifying agent who issued the notification of non-compliance that a new application has been submitted and the name of the certifying agent to whom it was submitted. It should be noted that an applicant for certification must provide information to a certifying agent about previous applications for certification and their outcome, as proposed in section 205.204(d) (applicant information). A certifying agent thus would be able to determine whether a new applicant previously had received a notification of non-compliance from a different accredited certifying agent and would be required to include with the application for certification documentation that deficiencies in compliance identified in the previous notification had been corrected.

Finally, in paragraph (c) of this section, we propose that if a certification applicant who receives a notification of non-compliance does not correct the deficiencies or does not notify the certifying agent that it has submitted a new application within the time specified in the notice of non-compliance, the certifying agent would submit to the Administrator a notice of its recommendation to deny certification to the applicant. The Administrator then could institute proceedings to deny certification pursuant to the Rules of Practice, 7 CFR 1.130, *et seq.* The Rules of Practice provide for the formal filing of a complaint by the Secretary, an opportunity for the certification applicant to answer the complaint, a procedure for holding a hearing, and a procedure for further appealing an adverse decision following any hearing that is held. A final determination to deny certification would not be made until the applicant had received notice and an opportunity to be heard.

*Recordkeeping—Section 205.216*

Section 2112(d) of the OFPA (7 U.S.C. 6511(d)) requires that producers who operate a certified organic farm or handling operation maintain certain records for five years concerning the production or handling of agricultural products that are sold or labeled as organically produced. We accordingly propose in section 205.216 that a certified operation maintain records concerning the production, harvesting, and handling of agricultural products that are, or that are intended to be, sold, labeled or represented as organic or made with certain organic ingredients sufficient to demonstrate compliance with the Act and the regulations, for a period of five years. These records would have to be made available to authorized representatives of the Secretary, the applicable governing State official in a State with an approved State program, as proposed and discussed in section 205.402 of subpart F, and the certifying agent, for the purpose of verifying the operation's compliance with the Act and the regulations in this part and the provisions of the applicable State program. Records maintained in accordance with this provision could include written, electronic, or graphic documentation, such as maps or plant diagrams, that serve to support and substantiate any information provided to the certifying agent concerning the operation's production and handling methods.

In paragraph (b) of this section we propose that certain specific records would have to be maintained by a certified operation. Other records, in addition to those indicated, also may be maintained as considered appropriate by the operation to support information provided to the certifying agent. In paragraphs (b)(1) and (b)(2) of this section it is proposed, in accordance with sections 2105(2) and 2112(d) of the OFPA (7 U.S.C. 6504(2) and 6511(d)), that the operation would have to maintain a list of all substances applied to fields or land that are part of the certified operation for a period of no less than three years preceding the intended or actual time of harvest of an organic crop from such fields or land, along with the name and address of any person who applies or has applied any substance to any part of the farm, the name of the substance, and the date(s), location(s), rate(s) and method(s) of application. Section 2110(f)(2) of the OFPA (7 U.S.C. 6509(f)(2)) requires that certain records be kept with respect to livestock maintained under organic management. Accordingly, we propose in section 205.216(b)(3) that, for each animal (or livestock management unit, such as a poultry flock or bee colony) that is, or whose products are, intended to be sold or represented as organic in accordance with the livestock production requirements proposed in sections 205.12 through 205.15 of subpart B, the producer would have to keep records of: the source of the animal or livestock management unit and the date it entered the certified operation; the amounts and sources of all animal drugs administered to it; all feeds and feed supplements fed to it; and the location of the field, farm unit, or

facility where it is maintained, as applicable. These records all are necessary in order to maintain a detailed, verifiable audit trail so that each animal (or livestock unit) can be traced back to the farm, as required by section 2110(f)(1) of the OFPA (7 U.S.C. 6509(f)(1)).

A fourth category of records we propose would have to be maintained includes any information submitted to a certifying agent as part of an application for certification or as part of continuation of certification, as proposed in sections 204.204 and 205.217.

We are also proposing that the records would have to be adequate to establish an audit trail. An audit trail is defined as the ability to follow, through documentation, the transfer of ownership and the transportation of any agricultural product labeled as organic or made with certain organic ingredients. This information would include, as applicable, the source, production and handling methods, transfer of ownership, and transportation of any agricultural product labeled as organic or made with certain organic ingredients that is received by or shipped from the certified operation. Although section 2110(f)(1) of the OFPA (7 U.S.C. 6509(f)(1)) imposes a verifiable audit trail requirement only on livestock operations, our proposal to establish a verifiable audit trail for all organically produced products is needed in order to adequately enforce the provisions of the Act. It also is consistent with the recordkeeping requirements of most existing certification programs we have reviewed, and consistent with the recommendations provided by the NOSB.

Paragraph (c) of this section reiterates that any operation that is exempt or excluded from certification under section 205.202 (a) or (b) must maintain records in accordance with proposed section 205.202(c).

*Continuation of Certification—Section 205.217*

Section 2107(a)(4) of the OFPA (7 U.S.C. 6506(a)(4)) requires that a certified operation certify on an annual basis that it is producing agricultural products that are sold, labeled, or represented as organic in compliance with the Act and the regulations. Additionally, section 2107(a)(5) of the OFPA (7 U.S.C. 6506(a)(5)) requires an annual on-site inspection of each certified operation. The annual submission of updated information proposed in paragraph (a) of this section would provide a certifying agent with information about changes that may have been made in an operation during the preceding year which is needed by the certifying agent to properly prepare for the annual inspection. Although nearly all the existing certification programs we reviewed require an annual renewal of certification, we are proposing in section 205.217 that a certified operation needs to submit only updated information to the certifying agent on an annual basis. As proposed here, an approved certification status would continue in effect until the operation voluntarily ceased to be certified or was terminated, as proposed in section 205.219.

As proposed in paragraph (a) of this section, a certified operation would submit to the certifying agent any additions or changes to each item of information contained in the previous year's application and any amendments to the organic plan, including a description of activities undertaken in the previous year, and intended to be undertaken in the coming year, to implement the provisions of the organic plan, as proposed in sections 205.204 and 205.205. For example, if a farm had expanded its acreage in organic production or the number of livestock included in its operation had decreased, this information would have to be included in the update. The certifying agent would have the previous application information on file, or would be able to obtain it from the certifying agent who had previously certified the operation, so that the applicable information specified in section 205.204 and 205.205 would be available when preparing for the on-site inspection.

The application materials also would have to include a statement that the certified operation will remain in compliance with the Act and the regulations in this part, as well as any other information that may be requested by the certifying agent. In section 205.217 (b) and (c) we propose that after receiving the updated information as specified in paragraph (a) of this section, the certifying agent would arrange to conduct an on-site inspection of the certified operation pursuant to sections 205.208 through 205.211. After conducting an on-site inspection of the certified operation pursuant to section 205.212, if a certifying agent has reason to believe that a certified operation is not complying with the requirements of the Act and the regulations, the certifying agent would provide a written notification of non-compliance to the operation, as proposed in section 205.218(a).

*Notification of Non-compliance With Certification Requirements—Section 205.218*

Section 2107(a)(7) of the OFPA (7 U.S.C. 6506(a)(7)) requires that a certification program established under the Act provide for appropriate and adequate enforcement measures. In section 205.218 we propose the procedure by which a certifying agent would identify any problems that may occur in the compliance with, or possible violations of, the Act or the regulations in this part by a certified operation, or a certification applicant, and then provide an opportunity for the operation to correct any defects in its compliance.

In paragraph (a) of this section we propose that a certifying agent would send a written notification of non-compliance by certified mail sent to the place of business of the certification applicant or the certified operation. The notification would have to contain the following information: a description of each deficiency in compliance and each possible violation of the Act and the regulations that the certifying agent has reason to believe has occurred; the evidence on which the notification is based; and the date by which the operation must correct each deficiency in compliance and each possible violation delineated in the notification, and submit documentation to the certifying agent to support such corrections.

In paragraph (b) of this section we propose the procedure to be followed after a certifying agent sends a notification of non-compliance to an operation it has certified. If the documentation to support corrections received by the certifying agent from an operation it has certified is not adequate to demonstrate that each deficiency in compliance and each possible violation has been corrected, we propose that the certifying agent would conduct an additional inspection, if one is necessary, to determine whether the operation is complying with, or has violated, the Act or the regulations. After conducting an additional inspection, if one is necessary, or without conducting an additional inspection, if one is not necessary, the certifying agent would review the status of the certified operation to determine whether the operation or any portion of the operation has ceased to comply with, or has violated, the Act and the regulations.

Paragraph (b)(3) of this section proposes the procedure to be followed after the certifying agent has reviewed the certified operation's status, pursuant

to paragraph (b)(2) of this section. Following a review of a certified operations's status, if a certifying agent determines that the operation is in compliance with the Act and the regulations, the certifying agent would be required to notify the certified operation in writing of its determination of compliance. If the outcome of the review gives the certifying agent reason to believe that the certified operation or any portion of the operation is not in compliance with the Act and the regulations, the certifying agent would submit to the Administrator a notice of its recommendation to terminate the certification of the certified operation or any portion of the certified operation that the certifying agent believes to have ceased to comply with the Act and the regulations. It should be noted that a recommendation could be made to terminate the certification of only a portion of an operation: for example, when a prohibited substance is applied to only one field that is part of a certified farm operation, but all other fields remain in compliance with the Act and the regulations.

*Termination of Certification—Section 205.219*

In section 205.219 we propose the procedure to be followed to terminate the certification of an operation or a portion of an operation that a certifying agent believes has ceased to comply with the Act and the regulations. In paragraph (a) of this section we propose that a certifying agent would send the certified operation a notification of non-compliance and follow the other procedures proposed in section 205.218 if the certifying agent has reason to believe that a certified operation or a person responsibly connected with a farm, wild crop harvesting, or handling operation it has certified has: violated the purposes of the national organic certification program; made a false statement; or attempted to have a label indicating that an agricultural product is organically produced affixed to such product when such product was not organically produced in accordance with the Act and the regulations.

In section 205.219(b) we propose that if a certifying agent has reason to believe that a certified operation or a person responsibly connected with an operation certified by the certifying agent has wilfully violated the Act and the regulations, the certifying agent would not send a notification of non-compliance pursuant to section 205.218. Instead, the certifying agent would submit to the Administrator a notice of its recommendation to terminate the certification of the certified operation or any portion of the certified operation that the certifying agent believes to have ceased to comply with the Act and the regulations. The names of any persons the certifying agent believes to have willfully violated the Act and the regulations would have to be listed in the recommendation to terminate certification submitted to the Administrator.

In section 205.219(c) we propose that the Administrator could institute the proceedings to terminate certification (pursuant to the Rules of Practice 7 CFR 1.130, *et seq.*) following the Administrator's receipt from a certifying agent of a notification of a recommendation to terminate the certification of an operation or any portion of an operation. The Rules of Practice provide for the formal filing of a complaint by the Secretary, an opportunity for the person(s) named in the complaint to answer the complaint, a procedure for holding a hearing, and a procedure for further appealing an adverse decision following any hearing that is held. A final determination to terminate the certification would not be made, therefore, until the person(s) believed to have violated the Act and the regulations had received notice and an opportunity to be heard. A notification of a certifying agent's recommendation to terminate certification could be submitted either in accordance with paragraph (b) of this section, or in accordance with section 205.218(b)(3)(ii) following a review of the status of a certified operation.

Section 2120(c) of the OFPA (7 U.S.C. 6519(c)) requires that, after notice and an opportunity to be heard, a person who is determined to have violated the Act and the regulations; made a false statement; or attempted to have a label indicating that an agricultural product is organically produced affixed to such product that such person knows, or should have reason to know, was not organically produced, shall not be eligible to receive certification for five years from the occurrence of such violation. Section 205.219(d)(1) is proposed in accordance with the Act's requirement, with the period of ineligibility to begin when a determination is made subsequent to the proceedings to terminate certification as proposed in paragraph (c) of this section. This section of the Act also permits the Secretary to waive or reduce the period of ineligibility if it is in the best interests of the certification program established under the Act, and we accordingly propose in paragraph (d)(2) of this section that the Secretary may waive ineligibility for certification if it is in the best interests of the certification program established under subpart D.

*Notification of Certification Status—Section 205.220*

In section 205.220 we propose that a certifying agent would be required to submit to the Administrator a copy of any notification of non-compliance, sent pursuant to section 205.218, simultaneously with its issuance to the certification applicant or the certified operation, and also to submit to the Administrator on a quarterly calendar basis the name of each operation whose application for certification has been approved. This information is needed in order for the Administrator to maintain current information concerning the status of certified farm, wild crop harvesting and handling operations, and therefore provide adequate enforcement measures. Information about any operation that has received a notification of non-compliance, pursuant to section 205.218(a), is needed in order to ensure that information about possible violations of the Act and the regulations is provided to the Administrator in a timely manner. This provision also would enable a certifying agent to determine whether a new certification applicant had previously received a notification of non-compliance from a different certifying agent, and was therefore required to document that any defects in compliance had been corrected.

SUBPART D—WHAT HAS TO BE CERTIFIED

| Entity | Needs to be certified | Records required for organic ingredients and organic products |
|---|---|---|
| ORGANIC OPERATION SELLING or HANDLING NO MORE THAN $5,000 annually in agricultural products § 205.202(a)(1). | NO ..... | *SALES RECORDS § 205.202(c)(1).<br>*Sales records for all agricultural products. |

SUBPART D—WHAT HAS TO BE CERTIFIED—Continued

| Entity | Needs to be certified | Records required for organic ingredients and organic products |
|---|---|---|
| ORGANIC OPERATION SELLING or HANDLING MORE THAN $5,000 in agricultural products or a HANDLING OPERATION (i.e., co-packer, etc.) that provides handling services to THREE (3) OR MORE operations that produce or handle agricultural products sold, labeled, or represented as organic or as made with certain organic ingredients § 205.201(a). | YES | ALL RECORDS § 205.216. |
| HANDLER of made with certain organic ingredients product §§ 205.201(a) and (b) | YES | ALL RECORDS § 205.216. |
| HANDLER of products that contain less than 50% organic ingredients § 205.202(a)(3). | NO | SOURCE/QUANTITY RECEIVED—§ 205.202(c)(3)(i). COMMINGLING/CONTACT—§ 205.202(c)(3)(i). DESTINATION/QUANTITY SHIPPED—§ 205.202(c)(3)(ii)). |
| HANDLER (distributor, warehouser, etc.) of packaged or otherwise enclosed products that remain in the same packages § 205.202(b)(1). | NO | SOURCE/QUANTITY RECEIVED—§ 205.202(c)(3)(i). COMMINGLING/CONTACT—§ 205.202(c)(3)(i). DESTINATION/QUANTITY SHIPPED—§ 205.202(c)(3)(ii)). |
| RETAIL OPERATION that does not process organic products § 205.202(a)(2) | NO | |
| RETAIL OPERATION that processes in the course of normal retail activity solely for the purpose of offering the product to the consumer § 205.202(b)(3). | NO | |
| RETAIL OPERATION that processes other than in the course of normal retail activity, i.e., combines into a single product products previously labeled organic and represents for sale under a new label § 205.201(a). | YES | ALL RECORDS—§ 205.216. |
| RESTAURANTS and FOOD SERVICE ESTABLISHMENTS that process ready-to-eat food but do not package and label the food § 205.202(b)(2). | NO | |

## Subpart E—Accreditation of Certifying Agents

Section 2115(a) of the OFPA (7 U.S.C. 6514(a)) requires that the Secretary establish and implement a program to accredit a governing State official, and any private person, who meets the requirements of the Act, as a certifying agent for the purpose of certifying a farm or handling operation as a certified organic farm or certified organic handling operation. Section 2104 of the OFPA (7 U.S.C. 6503) provides for the establishment of an organic certification program, which we have proposed in subpart D of this proposal, and section 2104(d) of the OFPA (7 U.S.C. 6503(d)) requires that the Secretary implement the certification program through certifying agents. We accordingly have proposed the provisions contained in this subpart to establish a program to accredit certifying agents to implement the certification program that is proposed in subpart D. We have developed this subpart following an extensive review of information about, and consultation with representatives of, existing organic certification programs and existing accreditation programs. We also have reviewed recommendations provided by the NOSB and public input submitted to the NOSB and the USDA.

This subpart delineates the procedure which a governing State official or a private person must follow in order to apply for and maintain accreditation as a certifying agent. A governing State official is defined by the Act as 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 agricultural operations of the State, such official, who administers an organic certification program under the Act. A person is defined as an individual, group of individuals, corporation, association, organization, cooperative, or other entity. Over 33 private certification organizations currently exist, including some that are organized for profit and others that are non-profit membership organizations. Some of these organizations cover a broad geographic scope and certify a wide range of operations producing diverse agricultural products. Others are small and cover limited geographical areas or types of operations. This proposal has been developed to provide enough flexibility to allow for diversity of organizational types, while ensuring that the requirements of the Act are met. We anticipate that new private certifying agents will be organized when certification becomes mandatory for the marketing of agricultural products that are represented as organically produced. Eleven States currently certify organic producers in accordance with State laws, and additional States have expressed interest in establishing organic certification programs in their States.

Additionally, a governing State official may establish an approved State program, as proposed and discussed in section 205.402 of subpart F, in accordance with section 2108 of the OFPA (7 U.S.C. 6507). A State could elect to operate the certification component of an approved State program by utilizing accredited certifying agents who are private persons; the State would not need to apply for and receive accreditation as a certifying agent as a condition of its State program being approved by the Secretary. Conversely, a governing State official could apply for and receive accreditation as a State certifying agent without having to establish an approved State program.

*Synopsis of Proposed Accreditation Program*

This subpart delineates the requirements that must be met for a private person or a governing State official to receive and maintain accreditation as a certifying agent. These requirements include those that are provided under sections 2115 and 2116 of the OFPA (7 U.S.C. 6514 and 6515) which include having sufficient expertise in organic farming and handling techniques. They also include other requirements that we believe are necessary in order to perform the certification functions we have

proposed in subpart D, such as having an annual internal review conducted of the accredited certifying agent's operations.

Subpart E also provides a procedure for applying for accreditation, including the information that an applicant must submit. The application material includes basic information about the applicant's operation, information that provides evidence of its expertise in organic farming and handling techniques, evidence of the applicant's ability to implement the organic certification program required under the Act, and an agreement to comply with the Act and the regulations, as well as certain other terms and conditions. A private person would have to agree to certain additional terms, including agreeing to hold the Secretary harmless for any failure on its part, and to furnish reasonable security to protect the rights of participants in the certification program in the event the applicant ceases its operations.

This subpart then delineates the procedures by which the Administrator either would approve or deny an application for accreditation. The procedure for denial of accreditation would not be initiated until the applicant had been notified of defects in its ability to comply with the requirements and given an opportunity to correct them. This proposal would require an initial on-site evaluation of an accredited certifying agent's operations within a reasonable time after approving an application for accreditation, and a subsequent review by a peer review panel, as provided under section 2117 of the OFPA (7 U.S.C. 6516). The Administrator then would review the site evaluation report and the recommendations provided by each peer reviewer to determine whether to confirm or deny confirmation of the agent's accredited status. Following confirmation of accreditation, this proposal would require a certifying agent to submit fees and reports annually, and to request renewal of accreditation every 5 years. Each USDA review of a certifier's request for renewal of accreditation would include an on-site evaluation of a certifying agent's operations and a subsequent review by a peer review panel. This proposal also would permit the Administrator to conduct site evaluations whenever needed, including prior to approving accreditation, in order to verify the accuracy of information submitted and ensure compliance with the Act and the regulations.

This proposal further provides for certain enforcement actions to be taken if a certifying agent is not complying with or has violated the Act or the regulations in this part. A notification would be sent to a certifying agent if the Administrator has reason to believe that the certifying agent is not complying with the Act and the regulations. The basis for initiating the procedure for suspending or terminating an accreditation, which would be initiated after the certifying agent had an opportunity to correct deficiencies in compliance, is then proposed. A private person or a governing State official whose accreditation was suspended could reapply for accreditation after taking corrective actions to bring its activities into compliance with the Act and the regulations. A private person whose accreditation was terminated would be ineligible to receive accreditation for no less than three years, as provided by section 2120(e)(2) of the OFPA (7 U.S.C. 6519(e)(2)).

*Distinctions Between Certifying Agents*

The OFPA provides that a governing State official and any private person can become an accredited certifying agent if it successfully can demonstrate that it meets the requirements for accreditation established by the Secretary. All organic certifying agents, whether new or existing, or a private person or a governing State official, generally will have to meet the same qualifications, demonstrate the same capabilities, and undergo the same accreditation process. There are, however, certain requirements stated in the OFPA that pertain only to private certifying agents. Section 2116(e) of the OFPA (7 U.S.C. 6515(e)) requires only private certifying agents to furnish reasonable security, in an amount determined by the Secretary, to protect the rights of participants in the organic certification program. This section of the Act also requires only a private certifying agent to agree to hold the Secretary harmless for any failure on its part to carry out the Act's provisions.

Another difference between private and State certifying agents concerns the termination of accreditation. Section 2120(e) of the OFPA (7 U.S.C. 6519(e)) provides for the loss of accreditation only for a private certifying agent who violates the provisions of the Act and the regulations or who negligently certifies an operation, and also requires that the private certifying agent be ineligible for accreditation for a period of at least three years. Section 2116(j)(1) of the OFPA (7 U.S.C. 6515(j)(1)) provides for the suspension of accreditation for any certifying agent who is not properly adhering to the provisions of the OFPA and does not require a minimum period of ineligibility. These provisions of the Act are reflected in our proposed section 205.316 (termination of accreditation).

*Areas of Accreditation—Section 205.300*

As provided by section 2115(a) of the OFPA (7 U.S.C. 6514(a)), this section proposes that the Secretary shall accredit a qualified accreditation applicant in the areas of crops, livestock, wild crops, or handling, or any combination thereof, to certify a farm, wild crop harvesting operation, or handling operation as a certified organic farm, a certified organic wild crop harvesting operation, or a certified organic handling operation. This proposal would allow certifying agents who may have limited areas of expertise to become accredited to conduct certifications only of those types of operations for which they have expertise. Thus, certifying agents would not be required to have expertise in areas for which they are not requesting accreditation, in order to obtain accreditation in the areas for which they request it. For example, a certifying agent that only wanted to be accredited to certify mushroom farming operations would not have to have expertise in the raising of organic livestock in order to become accredited to certify mushroom operations. Additionally, a number of the existing non-profit certification programs we have reviewed certify only farms, since their personnel are not knowledgeable enough about manufacturing and processing procedures to certify those types of operations. Under this proposal, these organizations would not have to acquire the capability to certify other types of operations in order to be accredited to certify only farms.

*General Requirements for Accreditation—Section 205.301*

Sections 2115 and 2116 of the OFPA (7 U.S.C. 6514 and 6515) delineate certain requirements that accredited certifying agents must meet in carrying out the organic certification program mandated by the Act. This section of our proposal delineates those general requirements that are provided in these sections of the Act, as well as certain additional requirements that we have determined to be necessary to ensure the integrity of the program. These additional requirements are authorized by section 2107(a)(11) of the OFPA (7 U.S.C. 6506(a)(11)) which permits a program established under the Act to require other necessary terms and conditions, as determined by the Secretary.

All of the requirements proposed in paragraph (a) of this section would apply equally to both State and private certifying agents. The first two require that an accredited certifying agent have sufficient expertise in organic farming and handling techniques, and demonstrate the ability to fully comply with the requirements for accreditation to implement the certification program under the Act and the regulations, as provided respectively in sections 2115(b)(2) and 2116(a) of the OFPA (7 U.S.C. 6514(b)(2) and 6515(a)).

The third requirement we propose in section 205.301(a) is that a certifying agent carry out the provisions of the Act and the regulations in this part, which would include sections 205.207 through 205.214 of subpart D that describe certifying agent responsibilities and section 205.430 of subpart F, concerning compliance testing. The fourth requirement proposed in paragraph (a) of this section is consistent with section 2116(b) of the OFPA (7 U.S.C. 6515(b)), which requires a certifying agent to use a sufficient number of inspectors to implement the applicable organic certification program. Our proposal also would include in this requirement personnel other than inspectors, such as those who review applicants for certification. After reviewing information from existing certification programs, we have concluded that sufficient qualified personnel in addition to inspectors are essential for a certifying agent to have the expertise necessary to implement the certification program as proposed in subpart D of this part. Paragraph (a)(4) of this section additionally would require that the personnel be adequately trained to implement the organic certification program established under the Act and the regulations.

In section 205.301(a)(5) we propose that a certifying agent be required to conduct an annual performance review for each inspector used and to implement measures to correct any possible defects in compliance with the Act and the regulations identified in each such review. The quality and consistency of the performance of inspections is critical to the integrity of the certification program we have developed and proposed in subpart D. In order to ensure that all inspections are conducted in a manner that adequately scrutinizes certified operations, we believe that a certifying agent must annually evaluate the performance of each inspector it uses during the year. Paragraph (a)(6) of this section similarly would require that an annual internal evaluation review be conducted of the certifying agent's own certification activities, and that measures to correct any possible defects in compliance with the Act and the regulations be implemented, as identified in each such review. We propose this requirement in order to safeguard further the integrity of the certification process, and also to provide an additional means of evaluating the adequacy of a certifying agent's performance and compliance with the Act and the regulations. Such a procedure is consistent with accepted quality management methods and would assist the certifying agent in helping to ensure that its operations continue to comply with the requirements of the Act and the regulations. The requirements proposed in paragraphs (a)(5) and (a)(6) of this section would help ensure that a certifying agent possesses the requisite expertise to conduct certification activities, as required by section 2115(b)(2) of the OFPA (7 U.S.C. 6514(b)(2)), and maintains the administrative capability to fully implement the proposed program, as required by section 2116(a) of the OFPA (7 U.S.C. 6515(a)).

In section 205.301(a)(7) we propose the requirement that a certifying agent provide sufficient information to persons seeking certification to enable an applicant for certification to comply with the applicable requirements of the Act and the regulations. This would require that a certifying agent provide applicable information, such as information about the National Organic Program's requirements for: the production and handling of agricultural products; wild crop harvesting; certification; labeling; inspection; appeals of adverse actions; fees and expenses; approved State program requirements; and any other information that is needed for a person to be able to apply for certification and comply with all the relevant requirements.

Section 2116(c) of the OFPA (7 U.S.C. 6515(c)) requires that a certifying agent maintain records of its activities under the Act for not less than 10 years, and that it allow only representatives of the Secretary and the governing State official access to these records. Paragraph (a)(8) of this section reflects those requirements. Section 2116(g) of the OFPA (7 U.S.C. 6515(g)) requires that a certifying agent maintain strict confidentiality with respect to its clients under the applicable organic certification program and not disclose any business related information of its clients to third parties, with the exception of the Secretary or the applicable governing State official. Paragraph (a)(9) of this section reflects this provision, and also allows for certain exceptions, as proposed and discussed in section 205.304(b)(5) of this subpart.

The requirements provided in section 2116(h) of the OFPA (7 U.S.C. 6515(h)) address the prevention of conflicts of interest by certifying agents, and paragraph (a)(10) of this section is proposed to be consistent with those provisions. We have found it necessary in some cases to add certain clarifications to the language contained in the Act in order to establish requirements that are both feasible for the diverse range of certifying agents and adequate to prevent conflicts of interest. The first provision proposed in paragraph (a)(10) of this section is that a certifying agent could not certify an operation in which the agent, or a responsibly connected party of the agent, has held a commercial interest, including the provision of consultancy services, within 12 months prior to the application for certification. This provision also would require that a certifying agent not certify an operation through the use of any employee that has or has held a commercial interest in the operation, including the provision of consultancy services, within the 12 month period prior to the application for certification. This proposal therefore would permit a certifying agent to certify the operation of an employee provided that the employee was not used in certifying that operation. This clarification is consistent with the intent of the Act, and would permit the use by certifying agents of peer reviewers, as is the practice in many of the current organic certification programs we have examined. While the Act does not mention responsibly connected parties, which we have defined as any person who is a partner, officer, director, holder, manager, or owner of 10 per centum or more of the voting stock of an applicant or a recipient of certification or accreditation, we believe that any such person should be limited in the same way as the agent itself. Section 2116(h)(1) of the OFPA (7 U.S.C. 6515(h)(1)) also does not specify a time limit for previous commercial relationships in its conflict of interest provisions; however, we are proposing here that the prohibition of commercial relationships extend only to the previous 12 months. We believe that extending this period indefinitely into the past would prevent certifying agents from hiring qualified personnel who at some time had a financial interest in an operation certified by the agent. An indefinite extension would have the effect of severely curtailing most

certifying agents' ability to comply with the Act's requirement of employing people with sufficient expertise to implement the applicable certification program. We believe that 12 months is a sufficient period to ensure that any previous commercial interest would not create a conflict of interest situation, since this time period is consistent with similar provisions governing conflict of interest for government employees.

The second provision proposed in paragraph (a)(10) of this section would similarly prohibit a certifying agent from assigning an inspector to perform an inspection of an operation in which the inspector has or has held a commercial relationship within the 12 months prior to conducting the inspection. We propose this because of the fact that many existing organic certification programs use inspectors who are neither employees nor responsibly connected parties, but who instead are independent contractors who work for multiple certifying agents. As proposed here, such inspectors would be appropriately prevented from performing inspections in which they had any conflict of interest.

In accordance with section 2116(h)(2) of the OFPA (7 U.S.C. 6515(h)(2)), the third provision proposed in paragraph (a)(10) of this section would prohibit a certifying agent and any employee, inspector, or other personnel involved in certification activities to accept payment, gifts, or favors of any kind, other than prescribed fees, from any business inspected. We would not consider a volunteer who performs services for a not-for-profit certifying agent as providing favors to any particular individual in that agency and, therefore, would not consider the certifying agent as being in a conflict of interest situation by accepting such services from volunteers. The final provision of paragraph (a)(10) of this section, proposed in accordance with section 2116(h)(3) of the OFPA (7 U.S.C. 6515(h)(3)), would prohibit a certifying agent from providing advice concerning organic practices or techniques to any certification applicant for a fee other than as part of the fees established for its accredited certification program.

Section 205.301(a)(11) would require that a certifying agent accept the certification decisions made by another USDA accredited certifying agent as equivalent to its own. We believe this provision is necessary so as to prevent certifying agents from requiring handlers to purchase only organic products originating from operations certified by the particular certifying agent, under the premise that products originating from operations certified by other certifying agents are not equivalent. Such a situation would conflict with the purposes of the Act to establish national standards for organically produced products and to facilitate interstate commerce for organically produced agricultural products.

Section 205.301(12) would require a certifying agent 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. For example, a certifying agent could describe its procedure for certifying organic production methods, but it could not claim that its certification procedure offers a guarantee of product quality. We believe that this provision is needed to prevent the dissemination of inaccurate or misleading information to consumers about organically produced products, which is consistent with the purpose of the Act to assure consumers that organically produced products meet a consistent standard.

Section 205.301(a)(13) would require that a certifying agent charge only such fees to applicants for certification and operations it certifies that the Secretary determines are reasonable. This provision is consistent with section 2107(a)(10) of the OFPA (7 U.S.C. 6506(a)(10)), which requires the certification program established under the Act to provide for the collection of reasonable fees from producers and handlers who participate in such program. AMS will review the fees charged by the certifying agents when they apply for accreditation and when they submit annual reports to ensure that the fees are reasonable and that small businesses are not unduly burdened. Section 205.301(a)(14) would require a certifying agent to pay and submit fees to AMS in accordance with sections 205.421 and 205.422(b) of subpart F, in which we propose that certifying agents would be required to pay certain fees to become accredited and to maintain accreditation, and also would be required to collect National Organic Program fees from farmers and handlers to be submitted to AMS.

In section 205.301(a)(15) we propose that a certifying agent would have to comply with and implement such other terms and conditions deemed necessary by the Secretary. This provision is made in accordance with section 2116(d) of the OFPA (7 U.S.C. 6515(d)).

Paragraph (b) of this section would permit a certifying agent to establish a seal, logo or other identifying mark that could be used by farm, wild crop harvesting, and handling operations that it certifies for the purpose of denoting affiliation with that certifying agent. This provision, authorized by section 2107(a)(11) of the OFPA (7 U.S.C. 6506(a)(11)), is proposed in consideration of public input provided by many organic producers and handlers expressing their desire to identify their operations with a particular certification program. Some existing certification programs also stated that they have made a considerable investment in developing consumer recognition for their names or logos. Although we also received comments stating that the use of certifying agent seals or logos should be prohibited, we have determined that a prohibition of seals and logos is not necessary. We believe that the use of certifying agent identification to indicate affiliation with a certifying agent would provide information of value to some consumers and would not be in conflict with the purpose stated in section 2102(2) of the OFPA (7 U.S.C. 6501(2)) of assuring consumers that organically produced products meet a consistent national standard.

This proposal would require that the use of any such seal or logo not be required as a condition for receiving certification, and, thereby, its use would be optional on the part of the farmer or handler. In order to ensure that any use of a certifying agent's logo does not conflict with the purposes of the Act, proposed section 205.301(b)(2) also specifies that the agent could not require, as a condition for use of its identification mark, compliance with any farming or handling requirements in addition to those provided for in the Act and the regulations in this part. Some public input has been received suggesting that certifying agents be allowed to use their logo or seal to recognize ''additional achievements'' on the part of farmers and handlers that exceed the requirements proposed in the national organic standards. This position was not recommended by the NOSB, which instead adopted a recommendation as a policy matter that was consistent with the provisions of this section of our proposal. Our proposal would not prohibit a certifying agent from verifying that a producer or handler it certifies is meeting contractual specifications that include requirements in addition to those of the Act and the regulations. It would prohibit the use of the certifying agent's logo or seal on a label, labeling material or other market information to represent compliance with farming or handling requirements in addition to those

provided under the Act and the regulations in this part.

In accordance with section 2116(e) of the OFPA (7 U.S.C. 6515(e)), section 205.301(c) proposes three additional requirements for a certifying agent who is a private person. These requirements are that a private certifying agent must: 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; furnish reasonable security, in an amount and according to terms as may be prescribed by regulation by the Secretary, for the purpose of protecting the rights of farms and handling operations certified by certifying agents under the Act and the regulations in this part; and transfer to the Secretary and make available to the applicable 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. The amount and the type of reasonable security that must be furnished by a private certifying agent for the purpose of protecting the rights of operations certified by the agent will be the subject of future rule making by the Department.

*Applying for Accreditation—Section 205.302*

As provided under section 2115(b)(1) of the OFPA (7 U.S.C. 6514(b)(1)), this section instructs a private person or a governing State official who wishes to become accredited under this proposal to submit applicable documents and information, as delineated in proposed sections 205.303 through 205.305, and the fees required in section 205.421(a) of subpart F to the Program Manager of the National Organic Program. The Administrator then would determine whether the applicant demonstrates sufficient expertise and ability to fully implement the organic certification program proposed in subpart D of this part.

*Information to be Submitted by an Accreditation Applicant—Section 205.303*

In order to evaluate an applicant for accreditation, it is necessary to identify who the applicant is, how it may be contacted, who is responsible for conducting its operations, if it is a private person, and the extent of the certification activities it intends to conduct under the Act and the regulations. Accordingly, in this section we propose that a person seeking accreditation as a certifying agent provide certain descriptive information about its organization and intended certification activities. This includes the name of the applicant, location of its offices, and its contact numbers (telephone, fax number, and Internet address). A private person also would have to identify the individual responsible for its day-to-day operations, as required by section 2116(i) of the OFPA (7 U.S.C. 6515(i)), and its taxpayer identification number. Paragraph (b) of this section requires the applicant to submit a list of any organization units, such as chapters or subsidiary offices, including the names of contact persons, office addresses and other contact information. This information is needed in order to determine whether multiple sites are used to conduct certification activities and, if so, to evaluate whether these activities are conducted in compliance with the Act and the regulations.

In paragraph (c) of this section, we propose that the accreditation applicant specify the intended scope of its certification activities, and estimate the numbers of producers or handlers in each type of operation, such as crops, wild crops, livestock, or handling, that it expects to certify each year. This information is needed so that the Administrator may determine the types of certifications a certifying agent is qualified to conduct. This proposed provision would require an applicant that was limited in scope, such as one that intends to certify producers of only one commodity, to demonstrate only that it had sufficient capability and expertise to conduct the types and numbers of certifications that fell within its requested scope of accreditation.

Paragraph (d) of this section requests an accreditation applicant to indicate the type of entity it is (i.e., for profit private, non-profit private, or State), and to provide documentation pertaining to its legal status and organizational structure. An applicant who is a governing State official would have to submit a copy of the official's statutory or regulatory authority to conduct certification activities in that State, and a private person would have to submit information about its status and organizational purpose, such as articles of incorporation, by-laws, ownership or membership provisions, and the date of establishment. This type of documentation is generally maintained on file by an organization, and would be required to assist the Administrator in verifying that the purposes of the organization are consistent with its intended activities under the Act and the regulations in this part.

Paragraph (e) of this section would require an applicant to submit a list of all the States where it currently conducts and intends to conduct certification activities. This information would be required so that the Administrator could determine whether a certifying agent who conducts or intends to conduct certifications in more than one State is knowledgeable of any additional requirements of an approved State program, if applicable, as provided under section 2108(b) of the OFPA (7 U.S.C. 6507(b)).

*Evidence of Expertise and Ability to be Submitted by an Accreditation Applicant—Section 205.304*

Sections 2115(b)(2) and 2116(a) of the OFPA (7 U.S.C. 6514(b)(2) and 6515(a)) require that a private person or a governing State official seeking accreditation as a certifying agent have sufficient expertise in organic farming and handling techniques and be able to fully implement the applicable organic certification program established under the Act. This section accordingly requests that an applicant for accreditation submit information and documents that demonstrate such expertise and ability. Paragraph (a) of this section requests information concerning personnel used by the applicant to conduct certification activities. The first item requested in this proposed paragraph is a description of the applicant's policies and procedures for training, supervising, and evaluating personnel. This information is needed for the Administrator to determine whether the applicant is providing sufficient oversight over personnel involved in certification activities to ensure compliance with the Act and the regulations in this part. The second item requested in this paragraph is the names and functions of all personnel intended to be used in the certification operation, including all parties responsibly connected to the applicant, administrative staff, certification inspectors, and members of certification review and internal evaluation committees. This information may include the job title or position of each person and a description of the organic certification functions they will perform. This information would enable the Administrator to determine that the applicant has sufficient personnel to perform the certification activities for which it seeks accreditation, and whether it has a sufficient number of inspectors to implement the certification program, as required under section 2116(b) of the OFPA (7 U.S.C. 6515(b)).

The third item in proposed paragraph (a) of this section requests the submission of more descriptive

information about the qualifications, such as past experience, training, and education in organic farming and handling, of each of the applicant's inspectors and persons designated to review or evaluate certification applicants. This proposal would provide the Administrator with the information needed to evaluate the qualifications of inspectors and review personnel when determining whether the applicant possesses the requisite expertise in organic farming and handling techniques.

Although inspector qualifications would receive careful scrutiny by the Secretary, we have not proposed the specific types of training and experience a certification inspector must possess. We have determined through consultation with experienced organic inspectors that such provisions would not be feasible because of the variability of expertise needed for the types of operations to be inspected. Furthermore, current organic inspectors differ widely in terms of their background, training and experience, as well as in their relationship to existing certification programs. For example, current organic inspectors may be seasonal employees of a private certifying agent, full-time State employees who conduct inspections for several State regulatory agencies, or independent contractors used by several certifying agents, and the expertise required in each case would differ significantly. We also are aware of at least one existing association that accredits independent professional organic inspectors according to criteria consistent with the requirements of our proposed certification program; we would consider an inspector's receipt of such accreditation when we evaluate the inspector's qualifications.

The final item in paragraph (a) of this section would request a description of any training measures the accreditation applicant has provided or intends to provide to its personnel in organic farming and handling and in the skills needed to ensure compliance with the Act and the regulations in this part. This information would enable us to determine whether the applicant would take measures to ensure that its personnel maintain adequate levels of expertise and are able to fully implement the certification program.

Paragraph (b) of proposed section 205.304 delineates the information that we propose an applicant for accreditation must submit concerning its administrative policies and procedures. We have determined that this information is needed to evaluate whether the applicant is able to fully implement the proposed certification program and to meet the general responsibilities and requirements proposed in section 205.301. The first item in this paragraph would request a description of the procedure to be used by the applicant to evaluate certification applicants and issue certificates. This information might, for example, include copies of any forms to be used to record inspection visit results and other information about certification applicants. This information would be used by the Administrator to determine that an accreditation applicant has adequate procedures in place to properly evaluate the eligibility of a farmer or handler to receive certification for their operations.

The second item in this paragraph requests information about the applicant's procedures for reviewing whether operations that it will certify are in compliance with the Act and the regulations in this part and for reporting violations to the Secretary and the applicable governing State official. Sections 2112(a) through (c) of the OFPA (7 U.S.C. 6511(a) through (c)) require certain testing to be done to assist in enforcement of the Act. We have addressed and discussed these provisions in sections 205.430 through 205.432 of subpart F. The information requested in paragraph (b)(2) of this section would help the Administrator determine whether an applicant would be able to comply with these requirements. This information also would assist in determining whether the applicant would be able to comply with the requirement in section 2120(d) of the OFPA (7 U.S.C. 6519(d)) that a certifying agent immediately report any violations of the Act to the Secretary or the governing State official, if applicable.

The third and fourth items proposed in paragraph 205.304(b) request a description of procedures the applicant would use to comply with the recordkeeping and confidentiality provisions proposed in sections 205.301(a)(8) and (9), in accordance with sections 2116(c) and (g) of the OFPA (7 U.S.C. 6515(c) and (g)). This information would be used to evaluate an applicant's ability to maintain records of its activities under the Act for 10 years, maintain strict confidentiality of its records with respect to its clients' business information, and allow representatives of the Secretary and the governing State official access to these records, as required under the Act.

Section 2107(a)(9) of the OFPA (7 U.S.C. 6506(a)(9)) requires that a certification program provide for public access to certification documents and laboratory analyses that pertain to certification. The fifth item proposed in section 205.304(b) accordingly requests that an accreditation applicant submit a description of its procedures for making certain information available to the public upon request. This information includes a list of all the operations it has certified, effective dates of certification, organic products produced by each certified operation, and the results of laboratory analyses for residues of pesticides and other prohibited substances. This information would have to be made available for certifications conducted up to ten years prior to receipt of the request. As proposed here, the policies and procedures described also would provide for public access to other non-confidential business information as permitted by the producer or handler and approved by the Secretary. This provision would permit a certifying agent to disclose to the public other non-confidential information about its clients' production practices if permitted to do so by the client and approved by the Secretary.

Paragraph (c) of proposed section 205.304 requests a description of the applicant's policies and procedures for the collection and disbursement of funds, and documents that identify anticipated sources of income, including all fees to be collected from producers and handlers in accordance with the requirements proposed in section 205.301(a)(15) of this subpart and section 205.422(a) of subpart F. This information is needed to determine whether the applicant is charging reasonable fees to its clients, and whether it has sufficient income to submit the required fees proposed in section 205.421. This information also would help the Administrator determine that certification decisions were not influenced by the concern for their financial impact on the certifying agent and to review an applicant's anticipated revenue sources for other potential conflicts of interest, such as fees charged on the basis of the sale of organic products by certified operations.

Paragraph (d) of section 205.304 requests information about policies and procedures to be implemented by the applicant to prevent conflicts of interest. Conflict of interest requirements are proposed in section 205.301(a)(10) in accordance with section 2116(h) of the OFPA (7 U.S.C. 6515(h)). This proposal would request information concerning any food and agriculture-related business interests of the applicant's personnel, as well as the business interests of immediate family members, so that the Administrator may

determine whether conflicts of interest may exist.

Some accreditation applicants currently may be conducting organic certification activities under State laws or private programs. Paragraph (e) of this section accordingly provides for the optional submission of information about certification activities currently conducted by these applicants. This information could include a list of all farms and handling operations currently certified by the applicant, and copies of inspection reports and certification documents for representative farms or handling operations certified by the applicant during the previous year. An accreditation applicant who previously has undergone a process of accreditation or evaluation of its organic certification activities, such as might be performed by a private accreditation body, also could submit any information concerning such a process conducted within the previous year. We believe that documentation of a previously conducted independent evaluation of the applicant's expertise and organizational capability would be helpful in determining whether the certifying agent is qualified and prepared to comply with the Act and the regulations. Although we would not expect an applicant for accreditation to have been complying with the requirements of the Act and the regulations in this part prior to becoming accredited, these documents would be valuable as an indication of the applicant's prior experience in evaluating organic farming and handling operations and of its ability to implement the proposed certification program. Finally, because we recognize that an applicant may possess other information that is relevant to the Secretary's decision whether to approve an accreditation, we propose in paragraph (f) of this section that an applicant for accreditation could submit any other information the applicant believes may support the Secretary's evaluation of its request for accreditation.

As previously discussed, an applicant for accreditation may be a newly formed organization that intends to begin conducting certifications after it is accredited, or it may be a certification organization that currently exists. Based on a review of currently existing certification programs, we believe that all the information requested in sections 205.303 and 205.304 should be readily available to any person or governing State official who is eligible for accreditation under the Act and the regulations in this part and is applicable to both existing and newly formed organizations preparing to perform certification activities under the National Organic Program or an approved State program. We also believe that all of the information we are proposing to require in sections 205.303 and 205.304 is essential to enable the Administrator to make a determination concerning approval of an application for accreditation.

*Statement of Agreement To Be Submitted by an Accreditation Applicant—Section 205.305*

In this section we propose that an applicant for accreditation would have to submit a statement of agreement along with the information and documents delineated in sections 205.303 and 205.304. Paragraph (a) of this section delineates seven provisions to which a private person or governing State official seeking accreditation must agree. Two provisions of this agreement would be to carry out the provisions of the Act and the regulations in this part and to implement and carry out any other terms and conditions that the Secretary determines appropriate, both of which are required by section 2116(d) of the OFPA (7 U.S.C. 6515(d)). It should be noted that this agreement would encompass all the general requirements proposed under section 205.301, including the provision repeated here that a certifying agent accept a certification decision made by another USDA accredited certifying agent as equivalent to its own.

The remaining four provisions to which an accreditation applicant would have to agree would state the requirements proposed in sections 205.301(a)(5), (a)(6), (a)(12), and (a)(13). These provisions are that the applicant agrees to: 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; conduct an annual performance review for each inspector to be used and implement measures to correct any possible defects in compliance with the Act and the regulations in this part identified in each review conducted; have an annual internal evaluation review conducted of its certification activities and implement measures to correct any possible defects in compliance with the Act and the regulations in this part identified in each review conducted; and pay and submit fees to AMS in accordance with sections 205.421 and 205.422(b) of subpart F of this part.

Paragraph (b) of this section provides for certain agreements that would apply only to certifying agents who are private persons, as provided for in section 2116(e) of the OFPA (7 U.S.C. 6515(e)), and as proposed in section 205.301(c) as general requirements for accreditation. These provisions are that a private certifying agent must agree to hold the Secretary harmless for any failure on the part of the certifying agent to carry out the provisions of the Act, and also must furnish reasonable security for the purpose of protecting the rights of participants in the applicable organic certification program. We also have proposed, in accordance with section 2116(c)(3) of the OFPA (7 U.S.C. 6515(c)(3)), that a private certifying agent agree to transfer to the Secretary and make available to the applicable 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.

*Approval of Accreditation—Section 205.306*

In this section we propose that if the Administrator determines that an applicant has submitted all of the information and the statement of agreement proposed in sections 205.303 through 205.305, has paid the required fee as proposed in section 205.421(c) of Subpart F, and meets or is capable of meeting the general requirements for accreditation as proposed in section 205.301, the Administrator would notify the applicant in writing that its request for accreditation has been approved. We also provide for the Administrator to consider information obtained from a site evaluation visit, as proposed in section 205.309, in making this determination. The written notice of approval of accreditation would state the area(s) for which accreditation was given and the effective date of the accreditation. A private person also would be notified of the amount and type of security determined by the Administrator that would be needed to protect the rights of farming and handling operations certified by such certifying agent, in accordance with section 2116(e)(2) of the OFPA (7 U.S.C. 6515(e)(2)).

We have received public input expressing concerns about granting accreditation to applicants prior to conducting a site evaluation and a peer review process. However, we believe that the procedure proposed here is appropriate for several reasons. First, we believe that the document review process proposed here is sufficiently rigorous to permit a well-founded assessment of the applicant's capabilities and qualifications. In cases

where the application documentation reveals possible concerns about the applicant's expertise and ability to implement the proposed certification program, our proposed section 205.309 would authorize us to conduct a preliminary site evaluation visit. Our proposal would allow all eligible certifying agents, both existing and newly formed, to receive accreditation in a timely manner and would avoid conferring an advantage on those certifying agents for whom we complete the initial site evaluation and peer review process before those of competing certifying agents. We further believe that conducting a site evaluation of a newly established certifying agent before it had begun any certification activities might not contribute information that would be useful for our evaluation. Previously existing certifying agents also would need time to make adjustments in their operations to comply with the National Organic Program regulations.

Finally, section 2107(a)(1)(A) of the OFPA (7 U.S.C. 6506(a)(1)(A)) requires that any product sold as organic be produced and handled by a certified operation; this provision of the Act cannot be implemented until certifying agents have been accredited by AMS. We have received considerable public input that the OFPA should be implemented as quickly as possible. A proposal that would require full site evaluations and peer reviews to be conducted prior to granting accreditation would further delay implementation of the Act.

*Denial of Accreditation—Section 205.307*

In section 205.307 we propose the procedure for denying an application for accreditation. Paragraph (a) provides that, if there was reason to believe, based on a review of the information specified in sections 205.303 through 205.305, 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 Part 205, including the general requirements proposed in section 205.301, the Administrator would provide a written notification of non-compliance to the applicant, as proposed in section 205.315(a). The notification would be sent by certified mail to the accreditation applicant, and would state any deficiencies in the ability of the applicant to comply with the Act and the regulations that the Administrator believes exist, the evidence on which the notification is based, and a date by which the deficiencies must be corrected.

In section 205.307(b) we propose that, following the correction of deficiencies identified in the notification issued in accordance with paragraph (a) of this section, the applicant could submit a new application for accreditation to the Administrator. The new application would have to include documentation of actions taken by the applicant to correct the deficiencies delineated in the notification of non-compliance.

If an accreditation applicant who receives a notification pursuant to paragraph (a) of this section does not correct the deficiencies identified within the time specified in the notice of non-compliance, paragraph (c) of this section would require that the Administrator institute proceedings to deny accreditation.

*Maintaining Accreditation—Section 205.308*

This section proposes that, in order to maintain its accreditation, a certifying agent must continue to satisfy the general requirements of section 205.301 of this subpart throughout the duration of its accredited status, and must pay the required fees in accordance with the provisions proposed in sections 205.421 and 205.422(b) of subpart F.

*Site Evaluations—Section 205.309*

This section of our proposal would require AMS to conduct a site evaluation of each certifying agent's operation initially, and at least once every 5 years thereafter, to examine its operations in order to evaluate the agent's compliance with the Act and the regulations. A site evaluation to determine compliance may include an examination of the certifying agent's facilities, records, procedures and activities conducted under the Act and the regulations set forth in Part 205. Although the Act does not specifically require that site evaluations be conducted, we concur with the recommendations made by the NOSB that such a process is necessary for the Secretary to maintain adequate oversight of the activities of accredited certifying agents under the Act and the regulations in this part. This procedure is integral to other accreditation programs that we reviewed, and is analogous to the annual on-site inspection that is required of all operations that are certified under the Act, as provided for in section 2107(a)(5) of the OFPA (7 U.S.C. 6506(a)(5)).

This proposal provides that the Administrator would arrange and conduct the site evaluations to verify compliance with the Act and the regulations in this part. In order to verify the certifying agents's compliance, the Administrator might conduct visits to selected farm, wild crop harvesting, and handling operations that have been certified by the agent. We anticipate that the operations to be visited might be chosen in consultation with the agent and as might be determined necessary by the Administrator to verify the agent's compliance with the regulations. A site evaluation report would be prepared which described the observations made about the certifying agent's compliance with the Act and the regulations in this part, including its performance of certification activities.

We have received some public input suggesting that we use peer reviewers, as provided for in section 2117 of the OFPA (7 U.S.C. 6516), in the site evaluation process. We have not provided for peer reviewers to participate in site evaluations. We believe that the use of peer reviewers to conduct site evaluations is unnecessary and could pose an excessive burden on the certifying agents, because the use of persons other than a single AMS evaluator would increase the costs of conducting site evaluations, due to additional travel and per diem expenses, and could delay site evaluations due to the need to accommodate the peer reviewers' scheduling constraints. Furthermore, AMS personnel will be sufficiently qualified and prepared to perform the site evaluations.

Paragraph (a) of this section also provides for a site evaluation of a newly accredited certifying agent to be conducted within a reasonable time after the date on which the certifying agent's notice of approval of accreditation is issued, provided that the agent has conducted sufficient certification activities under the Act and the regulations upon which the Administrator may base an evaluation. We expect to confer closely with newly established certifying agents prior to scheduling an initial site evaluation to determine that they have performed enough certifications on which to base the evaluation.

We proposed in paragraph (b) of this section that a site evaluation of an accreditation applicant or a certifying agent's operation and performance may be conducted by the Administrator at any time to determine compliance under the Act and the regulations in this part. For instance, site evaluations of the operations of a certifying agent requesting renewal of accreditation would be conducted under this proposal as part of the renewal process, which we propose in section 205.314(b) to occur

every five years. However, as proposed in section 205.309(b), site evaluations could be conducted whenever the Administrator determined that one was necessary to evaluate whether the certifying agent's operations and performance are in compliance with the Act and the regulations. Thus, although accreditation would have to be renewed every five years, a site evaluation could occur more often than every five years. We believe that the frequency of site evaluations needed to properly oversee the activities of certifying agents would likely be higher than once every five years in the initial few years after implementation, but that a five year period may be a reasonable interval of time for conducting site evaluations of established accredited certifying agents. This proposal would give us the flexibility to conduct site evaluations based on an assessment of the previous performance of the certifying agent and the need to oversee the agent's certification activities. Comments as to the impacts of this proposed provision on certifying agent operations are invited.

Additionally, this section would give the Administrator the authority to conduct an additional site evaluation prior to the approval of accreditation, as needed to verify whether an accreditation applicant can comply with the general requirements of section 205.301. We also believe it is essential to be able to conduct a site evaluation at any time that circumstances warrant a site visit to ensure the integrity of the organic certification program. For example, a site visit may be necessary if we receive a significant number of substantiated complaints from clients or the public about the performance of a certifying agent.

*Peer Review Panel—Section 205.311*

Section 2117 of the OFPA (7 U.S.C. 6516) provides for the establishment of a peer review panel to assist the Secretary in evaluating applicants for accreditation. This section of our proposal accordingly delineates the function, composition, duties, and the meeting and reporting procedures for the peer review panel. In section 205.311(a) we are proposing that a peer review panel be required to review the accreditation status of a certifying agent after AMS has conducted a site evaluation for confirmation or renewal of accreditation, as proposed in sections 205.309(a) and 205.314(b) of subpart E, respectively. This section would require the Administrator to consider the reports received from each individual member of a peer review panel when making a determination whether to confirm the accreditation of a certifying agent, pursuant to section 205.312, or when making a determination whether to renew the accreditation of a certifying agent, pursuant to section 205.314(b). We are also proposing that the Administrator could choose to convene a peer review panel at any time for the purpose of evaluating a certifying agent's activities under the Act and the regulations. This provision would provide flexibility for the Administrator to seek recommendations from peer reviewers at other times when it may be necessary to evaluate a certifying agent's compliance with the Act and the regulations.

In paragraph (b) of this section we propose that the Administrator establish a pool of peer review panel members to perform a review of any certifying agent for which an initial or renewal site evaluation has been conducted, pursuant to proposed section 205.309. We anticipate that a notice calling for candidates for the peer review panel pool would be published in the **Federal Register** shortly after publication of the final rule. Candidates would be requested to submit a letter to the Program Manager of the National Organic Program requesting appointment to the peer review panel pool, stating in the letter their name and address, qualifications, and a disclosure of any association with any person who is or who may become an accredited certifying agent, which may constitute a conflict of interest, such as being a responsibly connected party of a certified operation. Candidates accepted for this pool would be notified by the Administrator and could continue to serve until otherwise notified. As the need arose for additional members of the pool, the Administrator would publish an announcement to that effect in the **Federal Register**.

Section 2117(b) of the OFPA (7 U.S.C. 6516(b)) provides for the peer review panel to consist of no less than three persons who have expertise in organic farming and handling methods, and for at least two of the panelists to be other than USDA or approved State program personnel. This proposal is consistent with these requirements. Section 205.311(b) of this proposal calls for the Administrator to convene a three to five member panel from the pool of peer reviewers. Each panel would include one member from AMS as a permanent member, who would be responsible for presiding over any proceedings to ensure that they are conducted in accordance with AMS policy. Under the scheme proposed here, personnel from an approved State program could be included as an additional panel member on a panel that consisted of at least four members. Our proposal would keep the panel to a minimum size so as to minimize costs, but would permit sufficient numbers of persons with organic production and certification expertise to participate in the accreditation process.

In paragraph (b)(2) of this section we propose that each convened peer review panel include no less than one member who possesses sufficient expertise, as determined by the Administrator, in the areas of accreditation delineated in the notice of approval of accreditation, as proposed in section 205.306(a), for each certifying agent whose operations and performance are to be reviewed. This approach would allow for the selection of panelists whose expertise matches the characteristics of the particular certifying agents under review. For example, a panelist with a background in organic processing and manufacturing practices, but who was unfamiliar with organic mushroom production, would not be used to review a certifying agent whose scope of certification included only mushroom producers.

We propose in paragraph (b)(3) of this section to prohibit the selection of a peer reviewer who was associated with a certifying agent being reviewed in a manner that would constitute a known or perceived conflict of interest, as determined by the Administrator. We believe that to ensure the integrity of our proposed program we must take measures to ensure that any recommendations provided by peer reviewers are not influenced by the possibility of a financial interest in the outcome of the Administrator's determination.

Some public input we received suggested that we include representatives of consumer, environmental and other public interest groups as members of the peer review panel as a means of having broader public involvement in the oversight of certifying agents. The Act requires that persons who possess the necessary technical expertise in organic production and handling practices evaluate the performance of certifying agents. Persons representing consumer, environmental, or other similar groups who possess the necessary expertise could be eligible to participate in the peer review panel if they file a letter with the Administrator, and are determined to meet the criteria established to become a peer review panel member.

We propose in section 205.311(c) that each peer review panel member would individually review the site evaluation

report prepared by the Administrator and any other information that may be provided by the Administrator relevant to confirming or renewing the accreditation status of a certifying agent. Each peer review panel member would provide an individual report to the Administrator regarding the certifying agent's ability to conduct and perform certification activities under the regulations. We also propose in this section that each peer reviewer would have to agree to treat the information received for review as confidential, and could not release, copy, quote, or otherwise use material from the information received, other than in the report required to be submitted. This provision is needed in order to protect the confidentiality of business information received by USDA concerning the operations of certifying agents, as well as any information about operations certified by those agents.

In section 205.311(d) we propose that the Administrator could decide to convene a meeting or conference call of a peer review panel, if necessary, for evaluating the accreditation status of a certifying agent, or if it is requested by at least one peer review panel member. This section also would permit the Administrator to include in this meeting or conference call the certifying agent being evaluated, or a representative of the agent, for the purpose of providing additional information. This provision is proposed so that members of the peer review panel may have the opportunity to request clarification of any aspect of the agent's activities described in the site evaluation report. However, any meeting or conference call would have to be conducted in a manner that will ensure that the actions of panel members are carried out on an individual basis with any opinions and recommendations by a member being individually made.

Section 205.311(d) would additionally permit copies of peer review panel reports to be provided to the certifying agent, who could then submit a written response for consideration by the Administrator. This provision would permit a certifying agent to submit clarifications or additional information bearing on its activities under the Act and the regulations, whether or not a meeting or conference call of the peer review panel was conducted.

In the final paragraph of this section we propose that each peer review panelist would individually provide a written report to the Administrator. This report would contain the panelist's recommendations concerning confirmation or renewal of accreditation for each certifying agent reviewed, and a description of the basis for each recommendation. These recommendations might, for example, include conditions that the reviewer believes should be included in the notice of confirmation of accreditation, as proposed in section 205.312, or the notice of renewal of accreditation, as proposed in section 205.314(c).

We are soliciting comments on our proposed accreditation provisions, including whether alternative provisions should be promulgated. In particular, we would like comments on whether the peer review process for accreditation should occur when the initial application for accreditation is made, as opposed to when accreditation is confirmed after a site visit.

*Confirmation of Accreditation—Section 205.312*

In this section we propose that the Administrator would make a determination whether or not to confirm the accreditation of a certifying agent. This determination would occur following review of a site evaluation report and the reports from the peer reviewers. If the Administrator determined that the certifying agent was in compliance with the Act and the regulations, including the general requirements proposed in section 205.301, the Administrator would issue the agent a written notice of confirmation of accreditation status. Confirmation notices, therefore, would not be issued to any certifying agent who was not complying with the Act and the regulations, which would include payment to AMS of all fees owed by the certifying agent and the furnishing of reasonable security by a private certifying agent. The confirmation notice would include any terms or conditions that must be addressed by the certifying agent before the certifying agent submits a request for renewal of its accreditation. After confirmation, a certifying agent's accreditation would be effective until such time that the certifying agent fails to renew accreditation in accordance with section 205.314, or the accreditation was suspended or terminated pursuant to section 205.316, or the certifying agent voluntarily ceased its certification operations.

*Denial of Confirmation—Section 205.313*

In section 205.313 we propose the procedure to be followed to deny confirmation of accreditation to a certifying agent. Paragraph (a) of this section provides that, if the Administrator has reason to believe, based on a review of the information specified in sections 205.303 through 205.305, and the results of a site evaluation and reports submitted by the peer review panel, pursuant to sections 205.309 and 205.311(e), respectively, that the certifying agent is not complying with the requirements of the Act and the regulations in this part, including the general requirements for accreditation proposed in section 205.301, the Administrator would provide a written notification of non-compliance to the applicant in accordance with section 205.315(a) of this subpart.

In paragraph (b) of this section we propose that if a certifying agent who receives a notification pursuant to paragraph (a) of this section corrects the deficiencies identified within the time specified in the notice of non-compliance, and submits documentation supporting actions taken by the certifying agent to correct the deficiencies, as proposed in section 205.315(a)(3), the Administrator would issue a notice of confirmation of accreditation to the certifying agent, pursuant to section 205.312(a). Paragraph (c) of this section would permit the Administrator to institute proceedings to deny confirmation of accreditation if the certifying agent does not correct the deficiencies identified in the notice of non-compliance.

*Continued Accreditation—Section 205.314*

We propose in paragraph (a) that an accredited certifying agent shall submit certain information annually to the Administrator on or before the anniversary date of the issuance of the notice of confirmation of accreditation. This information would be reviewed by the Administrator to determine whether the certifying agent was maintaining its accreditation status in accordance with proposed section 205.308 of subpart E and to assess the need to conduct a site evaluation visit. We believe that an annual process of reviewing information submitted by certifying agents is necessary so that the Administrator can be informed of any changes in the procedures and personnel used by certifying agents, who also must annually review the certification of producers and handlers, in accordance with section 2107(a)(4) of the OFPA (7 U.S.C. 6506(a)(4)).

We propose that the accredited certifying agent annually submit four kinds of information in addition to the proposed fees required in section 205.421(a) of subpart F. First, the agent would have to update the general information and evidence of expertise

and ability submitted in the previous year, pursuant to sections 205.303 and 205.304 of subpart E. Second, if an agent is requesting any changes in its areas of accreditation, as delineated in section 205.300, the additional information needed to support the request for a change in the certifying agent's scope of certification activities would be submitted. Third, we propose that the certifying agent submit a report that describes the measures the agent has implemented in the previous year, and any measures it plans to implement in the coming year, to address the conditions delineated by the Administrator in the most recent notice of confirmation of accreditation or renewal of accreditation. The certifying agent also would be required to describe the corrective actions implemented and intended to be implemented by the certifying agent in response to the most recent inspector performance reviews and the required internal evaluation review of the agent's operations.

Section 2115(c) of the OFPA (7 U.S.C. 6514(c)) provides for accreditation to be granted for a period not to exceed five years. Section 205.314(b) would accordingly require that an accredited certifying agent request renewal of accreditation on or before the fifth anniversary of the issuance of the notice of confirmation of accreditation, and of each subsequent renewal of accreditation. The Administrator would then review the information contained in the annual reports submitted in accordance with paragraph (a) of this section, along with the results of the site evaluation(s) performed in accordance with section 205.309 and peer review panel reports submitted in accordance with section 205.311(e), in order to determine whether the certifying agent was still in compliance with the Act and the regulations.

Because section 2115(c) of the OFPA (7 U.S.C. 6514(c)) stipulates that accreditation may be granted for a period of time ''not to exceed'' 5 years, we considered proposing a period of time less than 5 years before a certifying agent would be required to renew its accreditation. Our intent in considering a lesser period of time for renewal of accreditation would be to establish an adequate level of oversight activity to ensure that the certifying agent is in compliance with the Act and the regulations. However, we believe that an adequate level of oversight necessary to ensure compliance with the Act and the regulations would be provided by the requirement proposed in section 205.314(a) that certifying agents submit annual updates to the Administrator. Additionally, as proposed in sections 205.309(b) and 205.311(a)(2) of this subpart, the Administrator could decide to conduct an additional site evaluation and peer review of a certifying agent's activities at any time. We also believe that a requirement that accreditation be formally renewed more frequently than every five years might pose an undue burden on certifying agents. Comment concerning the length of time for which accreditation should be granted is invited.

We propose in section 205.314(c) that the Administrator would issue a notice of renewal of accreditation after having made the determination that the certifying agent continues to comply with the Act and the regulations in this part. The notice of renewal, as in the case of the notice of confirmation of accreditation, would specify any terms and conditions that would have to be addressed by the certifying agent, and the time within which the terms and conditions must be satisfied. In paragraph (d) of this section, we propose that if the Administrator determines that there is reason to believe that the certifying agent is not in compliance with the Act and the regulations, the Administrator would issue a notification of non-compliance to the certifying agent, as proposed in section 205.315.

*Notification of Non-Compliance With Accreditation Requirements—Section 205.315*

In section 205.315 we propose the procedure for the Administrator to notify an accredited certifying agent, or an applicant for accreditation, of deficiencies in its compliance, or ability to comply, with the Act and the regulations, including the general requirements proposed in section 205.301, and provide an opportunity to correct any deficiencies identified. In paragraph (a) of this section we propose that a written notification of non-compliance would be sent by certified mail to the place of business of the accreditation applicant or the certifying agent, as applicable. The notification would contain the following information: a description of each deficiency in compliance and each violation of the Act and the regulations in this part that the Administrator has reason to believe has occurred; the evidence on which the notification is based; and the date by which the accreditation applicant or the certifying agent, as applicable, must correct each deficiency and each violation delineated in the notification, and submit documentation to the Administrator to support such corrections.

In paragraph (b) of this section we propose the procedure to be followed if an accredited certifying agent does not provide documentation to the Administrator, pursuant to paragraph (a)(3) of this section, that is adequate to demonstrate that each deficiency in compliance and each violation has been corrected by the date indicated in the written notification. This paragraph would permit the Administrator to conduct an additional site evaluation, as provided for in section 205.309, to determine whether the certifying agent is complying with, or has violated, the Act or the regulations, including the general requirements proposed in section 205.301.

In section 205.315(c)(1) we propose that the Administrator would notify the certifying agent in writing of a determination that the agent was complying with the Act and the regulations, if, following receipt of a notification of non-compliance as proposed in paragraph (a) of this section, the certifying agent submitted the requisite documentation of corrective actions taken, and if, following any additional site evaluation conducted pursuant to paragraph (b) of this section, the Administrator determined that the certifying agent was fully complying with the Act and the regulations. This paragraph further provides in paragraph (c)(2) of this section that, if the Administrator has reason to believe that the certifying agent is not in compliance with the Act and the regulations in this part, the Administrator may institute a proceeding to suspend or terminate the certifying agent's accreditation.

*Termination of Accreditation—Section 205.316*

Section 2116(j)(1) of the OFPA (7 U.S.C. 6515(j)(1)) provides for the suspension of a certifying agent's accreditation if the Secretary determines that the certifying agent is not properly adhering to the provisions of the Act and the regulations. This provision of the OFPA would permit the Secretary to suspend the accreditation of either a governing State official or a private certifying agent. Section 2120(e) of the OFPA (7 U.S.C. 6519(e)) provides for the loss of accreditation by a private certifying agent if the certifying agent violates the provisions of the Act and the regulations, or if the agent falsely or negligently certifies any farming or handling operation that does not meet the requirements for a certified operation under the certification program established by the Act. In section 205.316 we accordingly propose that the accreditation of any certifying

agent could be suspended, but that only a private certifying agent could have its accreditation terminated.

In section 205.316(a) we propose that if the Administrator has reason to believe that an accredited certifying agent or a person responsibly connected with an accredited certifying agent has ceased to comply with or has violated the Act or the regulations, including the general requirements proposed in section 205.301, then the Administrator would initiate the process proposed in section 205.315 by issuing a notification of non-compliance. However, as proposed in paragraph (b) of this section, if the Administrator has reason to believe that an accredited certifying agent or a person responsibly connected with an accredited certifying agent has wilfully violated the Act and the regulations in this part, including the general requirements proposed in section 205.301, the Administrator may institute a proceeding to suspend or terminate the accreditation of the certifying agent pursuant to the Rules of Practice 7 CFR 1.130, *et seq.* The Rules of Practice provide for the formal filing of a complaint by the Secretary, an opportunity for the certifying agent to answer the complaint, a procedure for holding a hearing, and a procedure for further appealing an adverse decision following any hearing that is held. A final determination to suspend the accreditation would not be made, therefore, until the certifying agent had received notice and an opportunity to be heard.

In section 205.316(c) we propose that a private person or a governing State official whose accreditation as a certifying agent is suspended or terminated would have to cease any certification activity in each area of accreditation and in each State for which its accreditation is suspended, or in the case of a private person whose accreditation is terminated, cease all certification activities conducted under the Act and the regulations. The person or governing State official whose accreditation was either suspended or terminated would have to transfer to the Secretary, and make available to the applicable governing State official, all records concerning its certification activities that were suspended or terminated. This would enable the Secretary to promptly determine whether farms or handling operations certified by such certifying agent may retain their organic certification. This provision is consistent with section 2116(j)(2) of the OFPA (7 U.S.C. 6515(j)(2)), which requires the Secretary to promptly determine whether farms or handling operations certified by a certifying agent who has lost accreditation may retain their organic certification.

As proposed, a certifying agent who was determined to be in compliance with all the requirements for certifying certain types of operations, such as farms, but no longer had the requisite expertise to certify other types of operations, such as handling operations, could have its accreditation suspended only in the area of handling operations. Additionally, if a certifying agent was determined not to be complying with the additional requirements of an approved State program, but was otherwise complying with the Act and the regulations, this proposal would permit its accreditation to be suspended only in that state.

The Act provides for the Secretary or a governing State official to suspend the accreditation of a private certifying agent. However, we have not included a provision for the governing State official to suspend accreditation in this proposal because the Act only provides for the Secretary, not the governing State official, to grant (or reinstate) accreditation. Therefore, we believe that the authority to remove an accredited status must remain with the Secretary. In the event that a private certifying agent was to cease complying with, or to violate, the provisions of an approved State program, we would expect the applicable governing State official to present this information to the Secretary for appropriate action.

In section 205.316(d) we propose that a private person or a governing State official whose accreditation as a certifying agent is suspended by the Secretary under this section could at any time submit a new request for accreditation, pursuant to section 205.302. The new request for accreditation would have to be accompanied by documentation that demonstrates that appropriate corrective actions to comply with and remain in compliance with the Act and the regulations, including the general requirements proposed in section 205.301, have been taken. This might, for example, entail payment of outstanding accreditation fees or evidence that sufficient funds have been provided for the required reasonable security to protect the rights of certified farms and handling operations.

In accordance with section 2120(e)(2) of the OFPA (7 U.S.C. 6519(e)(2)), we propose in section 205.316(e) that a private person whose accreditation as a certifying agent is terminated would be ineligible to be accredited as a certifying agent under the Act and the regulations for a period of not less than three years following the date of such determination.

## Subpart F—Additional Regulatory Functions

### State Programs

Section 2104(a) of the OFPA (7 U.S.C. 6503(a)) requires the Secretary to establish an organic certification program for producers and handlers of agricultural products. Section 2104(b) of the OFPA (7 U.S.C. 6503(b)) requires that the Secretary permit each State to implement a State organic certification program for producers and handlers of organic products that have been produced using organic practices as provided for in the OFPA. Section 2108(b) of the OFPA (7 U.S.C. 6507(b)) provides for State programs under certain circumstances to contain more restrictive requirements, than in the program established by the Secretary, for the production or handling of agricultural products sold or labeled as organically produced in such State and for the certification of farms and handling operations. Section 2103(20) of the OFPA (7 U.S.C. 6502(20)) defines a State organic certification program as one that meets the general requirements for an organic program set forth in section 2107 of the OFPA (7 U.S.C. 6506), is approved by the Secretary, and is designed to ensure that a product that is sold or labeled as organically produced is produced and handled using organic methods. Under a State program, an accredited State official and/or private certifying agent would perform certification activities for producers and handlers according to the procedures and requirements established in subpart D; such agents are discussed in subpart E (Accreditation) of this proposal. As discussed in subpart E, it is not necessary for a State to have a State program to be accredited as a certifying agent, and vice versa.

In order for a State program to be approved as meeting the general requirements set forth in section 2107 of the OFPA (7 U.S.C. 6506), the program must have regulatory provisions that meet the following requirements: (1) provide that an agricultural product to be sold or labeled as organically produced must be produced only on certified organic farms and handled only through certified organic handling operations in accordance with the requirements of the Act; and be produced and handled in accordance with such program; (2) require that producers and handlers desiring to participate under such program establish an organic plan as provided for in section 2114 of the OFPA (7 U.S.C.

6513); (3) provide for procedures that allow producers and handlers to appeal an adverse administrative determination under the Act; (4) require each certified organic farm, certified organic wild crop harvesting operation, and each certified organic handling operation to certify to the governing State official, on an annual basis, that such farmer or handler has not produced or handled any agricultural product sold or labeled as organically produced except in accordance with this title; (5) provide for annual on-site inspection by the certifying agent of each farm, wild crop harvesting, and handling operation that has been certified under this title; (6) require periodic residue testing by certifying agents of agricultural products that have been produced on certified organic farm and handled through certified organic handling operations to determine whether such products contain any pesticide or other nonorganic residue or natural toxicants and to require certifying agents, to the extent that such agents are aware of a violation of applicable laws relating to food safety, to report such violation to the appropriate health agencies; (7) provide for appropriate and adequate enforcement procedures; (8) protect against conflict-of-interest as specified under section 2116(h) of the OFPA (7 U.S.C. 6515(h)); (9) provide for public access to certification documents and laboratory analyses that pertain to certification; (10) provide for the collection of reasonable fees from producers, certifying agents and handlers who participate in the program; and (11) require such other terms and conditions as may be determined by the Secretary to be necessary.

Once a State program is approved, farm, wild crop harvesting, and handling operations in that State that wish to sell, label, or represent their product as organically produced would have to be approved as a certified operation under the State program. The determination as to whether or not a farm, wild crop harvesting, or handling operation meets a State's certification requirements would be made by a certifying agent accredited by the USDA under the National Organic Program. The accredited certifying agent who would make this determination either would be a private person who has been accredited by the USDA, or a governing State official who has been accredited by the USDA.

In order to be certified under the State program, an operation would have to meet all of the State certification requirements. However, these certification requirements, as discussed previously, must reflect the requirements of the National Organic Program. Certified operations in States that have their own program would be producing products that are represented as organically produced in accordance with the requirements of the National Organic Program, which will have been included in the State program in accordance with section 2107 of the OFPA (7 U.S.C. 6506). Therefore, the provisions set forth in our proposal in part 205 would be applicable to operations that are located in States that have their own programs since these provisions would be included in programs that are approved by the Secretary. It is important that all interested persons provide comments on the provisions of our proposed rule since these are the provisions that would be required to be included in a State program in accordance with section 2108 of the OFPA ( 7 U.S.C. 6507). If an operation is located in a State that does not have an approved State program, that operation would carry out its operations only under the requirements of the National Organic Program.

States may have requirements that are in addition to those of the National Organic Program if they are approved by the Secretary and meet the statutory criteria for approval. This means that if a State has received approval from the Secretary for requirements in its program that are in addition to those of the National Organic Program, all certified farm, wild crop harvesting, and handling operations that operate in that State would have to comply with these additional requirements that have been approved. However, one State would not be allowed to require farm, wild crop harvesting, and handling operations in another State to comply with any additional requirements that have been approved by the Secretary for the former State.

*Requirements of State Programs—Section 205.401*

As required in section 2104(b) of the OFPA (7 U.S.C. 6503(b)), we propose in section 205.401(a) to permit a State to establish a State program for producers and handlers of agricultural products within the State that have been produced and handled using organic methods as provided by the OFPA and its implementing regulations.

The accreditation of a governing State official to conduct certification activities of farms and handling operations is specifically authorized in section 2115(a) of the OFPA (7 U.S.C. 6514(a)) and is set forth in subpart E of our proposal. As reflected in our proposal, the approval by the Secretary of a State organic program would be a separate decision from the determination of whether a governing State official who applies to be a certifying agent should be accredited. Although the Act provides for the accreditation of a governing State official as a certifying agent, it does not require that the certification of producers and handlers operating in a State that has an approved program be performed solely by the State certifying agent. Rather, the required certification of producers and handlers operating under an approved State program can be conducted by either the State certifying agent or a private certifying agent. Producers and handlers of organic products operating in a State that chooses to implement a State program, but which does not obtain accreditation for a governing State official, would be certified by private certifying agents.

In accordance with section 2108(a) of the OFPA (7 U.S.C. 6507(a)), we would require in section 205.401(b) that a State program meet the requirements of the regulations in part 205 and the Act, including the general requirements for an organic program listed in section 2107(a) of the OFPA (7 U.S.C. 6506 (a)). These requirements would require: that an agricultural product that is to be sold or labeled as organically produced be produced and handled only on certified operations in accordance with the Act and the regulations in part 205; that participating producers and handlers establish an organic plan; that an annual on-site inspection by the certifying agent of each certified farm and handling operation be done; that reasonable fees be collected from producers, certifying agents and handlers who participate in such program; that public access to certification documents and laboratory analyses that pertain to certification be established; that procedures that allow producers and handlers to appeal an adverse administrative determination be established; that appropriate and adequate enforcement procedures and conflict-of-interest provisions be established; and that periodic residue testing by certifying agents of agricultural products that have been produced on certified organic farms and handled through certified organic handling operations be done.

As provided for in section 2108(b)(1) of the OFPA (7 U.S.C. 6507(b)(1)), we propose in section 205.401(c) that a State program that meets the requirements of regulations in part 205 and the Act also could contain more restrictive requirements governing the certification of organic farming and

handling operations and the production and handling of organic agricultural products than those in USDA's National Organic Program. However, in accordance with section 2108(b)(2) of the OFPA (7 U.S.C. 6507(b)(2)), we propose that any additional requirements must further the purposes of the Act and the regulations in part 205; not be inconsistent with the Act and the regulations in part 205; not be discriminatory towards agricultural commodities organically produced in other States in accordance with the Act and the regulations in part 205; and not become effective until approved by the Secretary.

One concern expressed by private certification organizations in response to the NOSB draft recommendations was that a State that had its own program also might implement its own accreditation program for certifying agents, and require that a certifying agent be accredited by the State, as well as by the USDA. In this regard, section 2115(a) of the OFPA (7 U.S.C. 6514(a)) requires that both a governing State official and a private person be accredited solely by the Secretary and, thus, provides for the Secretary alone to establish and implement an accreditation program for existing and new certifying agents. Accordingly, a State cannot implement an accreditation program for certifying agents.

Another concern expressed by private certification organizations was that a State might attempt to prevent them from certifying farm and handling operations in that State by charging a high, unreasonable fee to them for registering with the State as a certifying agent or for purchasing a business operating license. As part of the approval process for a State organic certification program, we would review any fees established by States with respect to the requirements in section 2107(a)(10) of the OFPA (7 U.S.C. 6506(a)(10)) for the collection of reasonable fees from certifying agents and in section 2108(b)(2)(A) of the OFPA (7 U.S.C. 6507(b)(2)(A)) that additional State program requirements further the purposes of the Act. In order for the State program to be approved, the fees established would have to be determined to be reasonable.

We know that some current requirements in existing State organic programs vary from our proposed regulations. We also expect State program proposals to include requirements we have not considered. Therefore, in section 205.401(c) of the proposed regulation we do not include a list of additional requirements which might be determined to be in compliance with the Act's criteria for approval of additional requirements. Rather, each State program's proposal would be reviewed to ensure that it complies with the provisions of section 205.401(c) (1) through (4) which are the Act's criteria for approval of additional requirements.

*Approval of State Programs and Program Amendments—Section 205.402*

In section 205.402(a), we propose that a governing State official must submit to the Secretary any proposed State program, or proposed substantive amendments to a State program, and must obtain the Secretary's approval prior to implementation of the program and any amendments to it. In section 205.402(b), we propose that the Secretary would notify the governing State official within six months after receipt of the program or any proposed change to the program as to whether the program or substantive amendment is approved or disapproved. This is consistent with the provisions of section 2108(c) of the OFPA (7 U.S.C. 6507(c)). After receipt of the notice disapproving a State program, the governing State official may reapply at any time.

*Review of Approved Programs—Section 205.403*

In section 205.403, we propose that the Secretary would review a State program not less than once every five years from the date of initial approval of the State program. This is consistent with section 2108(c)(1) of the OFPA (7 U.S.C. 6507(c)(1)), which requires this be done. The State program would be notified within six months after initiation of the review, whether the program is approved or disapproved, and if disapproved, the reasons for the disapproval.

*Fees*

Section 2107(a)(10) of the OFPA (7 U.S.C. 6506(a)(10)) authorizes the collection of reasonable fees from farmers, handlers, and certifying agents who participate in the national organic certification program. In sections 205.421 through 205.424 we propose the fees we intend to charge to reflect the cost of the services provided by the USDA. The statute provides that the fees collected be deposited into the general fund of the U.S. Treasury. Accordingly, the agency must obtain appropriated funds to operate this program.

In our efforts to assemble the economic and demographic information needed to develop the details for assessing and collecting reasonable fees, we consulted extensively with both State and private certifying agencies. We received assistance from the USDA Economic Research Service, as well as from other programs within AMS, in identifying various options for the assessment of fees in this program. Additionally, we determined the number of certifying agents and their chapters that are currently operating in the United States and conducted an analysis to determine the number of organic farms and handling operations that were operated in the United States for 1994 (Dunn, Julie Anton. 1995. ''Organic Food and Fiber: An Analysis of 1994 Certified Production in the United States.'' U.S. Department of Agriculture, Agricultural). We also examined an analysis of data collected by the California Department of Food and Agriculture concerning registered organic farms and handling operations in that state (California Department of Health Services. 1995. ''Report on the Registration of California Organic Processed Food Firms.'' Sacramento: State of California Marketing Service). Based on these analyses, we estimate that 44 certifying agents may apply for accreditation and that 30 chapters or subsidiary offices would be included in their applications. We further estimate that 4,000 farmers and 600 handlers would be eligible for certification.

We estimate that it will cost approximately $1,000,000 in the first full year of operation to operate our program when it is implemented. These costs include approximately $644,000 for the salaries and benefits of 12 staff members, which would be comprised of a program manager, 8 marketing specialists, and 3 support staff personnel, and approximately $356,000 for general administrative overhead and operating costs, such as printing, training, travel, NOSB meetings, equipment, supplies, rent, heat, and communications. A description of the services that would be provided to program participants by the NOP staff is presented in the applicable supplementary information sections on fees that follow.

Based on 1994 workload data, we estimate that $500,000 of this $1,000,000 will be collected from farms, handling operations, and wild crop harvesting operations, $389,000 from applicants for accreditation and accredited certifying agents, and $112,000 from private foreign certification programs, for a total of $1 million. Note, actual billing may be somewhat greater due to inflation since 1994. We have included a chart at the end of the fee discussion that illustrates the fees that will be charged. The fees in this rule are based upon estimates of the cost to AMS of providing each of the

services described, and may be adjusted in future years based upon program experience and projected or actual changes in the cost of operations (e.g. inflation).

We again would like to point out that, in addition to the fees that certified operations would be required to submit to USDA, farm, wild crop harvesting, and handling operations that want to be certified under the Act, and those that have been so certified, also would need to pay certifying agents, whether State or private, for the certification services provided by them. These certification services would include review of an initial application for certification, annual review of updated information, review of an organic plan and updates to the organic plan, and conducting annual inspections both before and after certification is granted. As part of the accreditation process for certifying agents that we propose in subpart E, USDA would require certifying agents to submit for approval the fees they intend to charge to operations for which they are going to conduct certification activities. If the intended fees submitted are deemed reasonable, as required in section 2107(a)(10) of the OFPA (7 U.S.C. 6506(a)(10), USDA will approve the fees schedule submitted.

The AMS, as set forth in section 205.423 of this proposal, also would be charging fees to foreign organic certification programs, other than those operated by a foreign country itself. These fees would cover the costs AMS will incur in determining whether these programs have requirements equivalent to those of the AMS program. These fees are authorized under the Independent Offices Appropriations Act (31 U.S.C. 9701 *et seq.*).

*Fees for Accreditation Applicants and Accredited Certifying Agents—Section 205.421*

Section 2107(a)(10) of the OFPA (7 U.S.C. 6506(a)(10)) provides for the collection of reasonable fees from certifying agents who participate in the program. This section discusses the fees proposed to be paid by applicants who are initially applying for accreditation and fees to be paid by accredited certifying agents.

In section 205.421(a)(1) we propose that each applicant for accreditation, and each accredited certifying agent submitting an annual report, would be required to submit to the Administrator a non-refundable fee of $640. This fee would cover the AMS cost to review and evaluate the material required to be submitted to become accredited or to continue accreditation. We believe it is appropriate to establish a fee structure to recover the cost of this service.

We estimate that it will take an average of 16 hours to review each application for accreditation, or each annual report, for certifying agencies that do not have chapters or subsidiary offices. Our estimation is based upon knowledge gained from examining current accreditation programs as well as our general experience and knowledge gained from other AMS programs that involve the submission and review of applications. We estimate that the hourly cost for AMS personnel to handle and review the applications and annual reports will be $40 per hour. This is the average hourly cost for AMS to conduct a program of this nature. Based on an hourly fee of $40 per hour and an estimated time of 16 hours for handling and review, we estimate the cost to evaluate accreditation applications and annual reports to be $640 per applicant or accredited certifying agent, as applicable. Therefore, we are proposing that each applicant of this type (i.e., single, non-multi-unit organization) seeking accreditation or submitting an annual report pay a $640 non-refundable fee at the time of submission of application for accreditation or an annual report.

Assessing a uniform fee for accreditation application and submission of an annual report is based on our knowledge gained from other AMS programs and current accreditation programs being operated. We are not proposing a fee for this activity based on the size and complexity of the certifying agent because we believe that differences in the size and complexity of the certifiers would result in an insignificant difference in the amount of time needed to review applications and annual reports.

We further propose in section 205.421(a)(2) that an additional application or annual report review fee of $160 be charged for each chapter or subsidiary office of an accreditation entity. This additional fee of $160 is the cost we estimate AMS will incur for the additional 4 hours we estimate will be necessary to review the additional information required to be submitted for each part of a multi-unit organization. We estimate the hourly cost will be $40, the same average hourly cost we propose for reviewing application information and annual reports submitted by applicants and accredited certifying agents. Based on our estimate that 44 certifying agents with 30 chapters or subsidiary offices may apply for accreditation, we estimate that we may collect $32,960 annually from fees associated with reviewing accreditation applications and annual reports.

In paragraph (b) of section 205.421, we are proposing the fees that certifiers would be assessed for a site evaluation visit conducted by AMS. The fees that would be assessed for a site evaluation visit would be any travel and per diem expenses incurred as a result of the conduct of site evaluations, as well as the hourly costs to conduct the site evaluation. Site evaluations are proposed in section 205.309(a) of subpart E to be performed by AMS within a reasonable time after issuance of a notice of approval of accreditation to verify compliance of the certifying agent with the Act and the regulations. In section 205.309(b), we propose that a site evaluation also may be conducted at any time to determine an applicant's or certifying agent's compliance with, or quality of performance under, the Act and the regulations. Additionally, we propose in section 205.314(b) that a site evaluation would occur every 5 years as part of the process of renewal of accreditation for an accredited certifying agent.

We estimate that the hourly cost of performing site evaluations will be $40, calculated to the nearest fifteen minute period, for each AMS evaluator conducting the site evaluation visit, including travel time to and from the evaluator's duty station. This is the average cost for AMS to conduct evaluations of this nature. We anticipate that the time necessary for AMS to conduct a site evaluation, and therefore the total cost to be assessed a certifying agent for a site evaluation, will vary between certifying agents due to differences in their size, complexity, and other similar factors. The fee we propose in paragraph (b) of this section would be a direct assessment on applicants and accredited certifying agents for the hourly costs and travel and per diem expenses associated with conducting our site evaluations. As proposed, an applicant or accredited certifying agent would be required to pay these fees within 30 days following the date the bill is issued. As proposed in section 205.424 of this subpart, the fees submitted as payment for the costs of the site evaluation would be required to be submitted by certified check or money order made payable to AMS and sent to the address specified on the bill.

AMS estimates that an average site evaluation would require 5 days and would cost a certifying agent $3,500. The $3,500 expense would result from the hourly costs for staff time necessary to prepare for and conduct the site evaluation, and the related travel and per diem expenses, such as air fare, car

rental, lodging, meals, and incidental expenses. We estimate that of the $3,500 cost, approximately $1,100 would result from related travel and per diem expenses and approximately $2,400 would result from the time (hourly costs) necessary to prepare for and conduct the site evaluation. We anticipate that of this $2,400 hourly cost, $1,600 would result from the time spent by one AMS evaluator being on site for 5 days (40 hours) at $40 per hour, and $800 would result from the 20 hours we estimate will be needed to prepare for the evaluation, write an evaluation report, and communicate the results of the evaluation process to the certifying agent. As previously noted, the actual cost for each site evaluation will vary based on the length of the evaluation, due to such factors as the certifying agent's location, size and complexity.

Based on our estimate that 44 certifying agents with 30 subsidiary offices or chapters may be accredited, we expect to receive $259,000 annually from fees associated with site evaluations. We note that under our scheme for site evaluations proposed in section 205.309 of subpart E, a site evaluation visit may not be performed each year for every certifying agent and every subsidiary office or chapter. However, also under our scheme, a site evaluation may be performed more than once each year for a certifying agent or its subsidiary office or chapter, when determined necessary by the Administrator to determine the certifier's compliance or evaluate its performance. For the purpose of estimating fees to be collected annually from certifying agents, we assumed that for the intital year that site visits are performed, a site visit would be performed for each certifying agent and each subsidiary office or chapter. Thereafter, a site visit of a certifying agent, subsidiary office, or chapter may be performed more or less often than annually. The previously discussed number of 12 NOP staff members estimated to be needed to conduct program activities would be adjusted accordingly with an increase or decrease in workload.

A different model which we considered for the site evaluation fee, but which we are not proposing, was based on categorizing certifiers according to their size and assessing them a fee for a site evaluation based solely on this factor. In such a scenario, for example, a certifying agent who certified less than 50 clients might be assessed a fee equivalent to 3 days of work while a certifying agent that certified more than 500 clients would be assessed a fee equivalent to 30 days of work. We decided not to propose this model after determining that site evaluation costs would depend on factors other than the size of the certifying agent's operation, such as the complexity of the certification activities conducted by the certifier, the location of the certifier's facilities, and the certifier's organizational structure.

In paragraph (c) of this section, we propose that an administrative fee of $2,000 be paid by a certifying agent upon the initial granting of accreditation, upon the granting of confirmation of accreditation, and upon the submission of each subsequent annual report. Under the regulatory scheme we are proposing, a person who wants to be an accredited certifying agent first would have to apply for and be granted accreditation, then would have to have this accreditation confirmed, and then would have to submit annual reports to provide current information.

Our $2,000 fee is based upon the yearly cost we estimate we would incur for providing various administrative services to accredited agents which would cover the administrative costs discussed below. Since we expect that confirmation of accreditation would occur approximately 12 months after the granting of initial accreditation, and that submission of an annual report would occur subsequently one year later, we propose to assess a $2,000 fee for each of these yearly periods so that the fees charged will reflect the cost of the services provided. We also are proposing that, upon the granting of initial accreditation, upon the granting of confirmation of accreditation, and upon the submission of an annual report, a certifying agent would pay an additional fee of $300 for each chapter or subsidiary of the agent's organization. Our fees here are based on knowledge gained from the review of currently existing accreditation programs such as the International Organization for Standardization program and the International Federation of Organic Agricultural Movements program.

Our administrative fees would cover costs for the operation of our accreditation program that are not covered by paragraphs (a) and (b) of section 205.421. The $2,000 fee would cover day-to-day program activities and operational and overhead costs for single-site accreditation entities. Examples of operational and overhead costs are utilities, rent, supplies, printing, equipment purchases, and communication. Program activities include: develop and provide guidance on the NOP production, handling and certification requirements; compile, copy, and mail site evaluation reports; conduct peer review panel meetings or conference calls; and enforce the program. The $300 fee for each additional chapter or subsidiary would cover the additional time for program activities, and additional overhead and operating expenses, we believe can be attributed to, and which are necessary for, our providing the previously identified services to chapters and subsidiary offices. Based on our estimate that 44 certifying agents with 30 subsidiary offices or chapters may be accredited, we expect to receive $97,000 annually from administrative fees.

Payment of the non-refundable fees would be required 30 days from the date of issuance of a notification of approval of accreditation and notification of confirmation of accreditation, and with the submission of each annual report.

An alternative model for the administrative fee that we considered would be to base the administrative fee on the types of certifications performed by certifiers. For example, certifying agents who certify farmers and handlers trading in international markets, or who certify processors producing multi-ingredient products, would pay a higher administrative fee. The underlying assumption is that certifying agents who provide more complex services to farmers and handlers utilize more program resources and derive greater benefit from the National Organic Program than other certifiers. In evaluating this alternative, we considered that the AMS costs to administer this model would be considerably higher than the costs associated with the uniform administrative fee model we are proposing.

*Fees for Certified Operations—Section 205.422*

In order for AMS to carry out the OFPA, and in turn fulfill the mission of AMS, certain program activities must be undertaken. We used the time required to accomplish these program activities as the basis for determining the amount of fees charged to each certified farm or handling operation. Program activities that would have to be carried out include: financial and staff support for the NOSB; compliance and enforcement; provision to the public of information about the program; attendance at meetings, conferences and trade fairs conducted both inside and outside the United States to convey information about the program; and other general and administrative functions. To accomplish these activities, we would need to pay various

fixed costs, including costs for overhead (utilities, rent and communications), equipment costs for computers and copying machines, and staff expenses, which would include salaries, benefits and travel costs.

In this section, we propose the fees to be collected from certified farmers, wild crop harvesters, and handlers. The total cost for the program activities which we estimate that AMS will provide for farm, wild crop harvesting, and handling operations certified under the National Organic Program is $500,000, one half of the annual projected program cost of $1,000,000. We estimate that approximately 40 percent of the $500,000, or $200,000, would be needed to carry out program activities concerned with the issues of certified farms and wild crop harvesting operations, and that approximately 60 percent of the $500,000, or $300,000, would be needed to carry out activities concerned with the issues of certified handling operations.

The fee we propose is based upon dividing our estimated cost for program activities for farmers and harvesters, and handlers, respectively, among the estimated 4,000 farmers and 600 handlers we believe will participate in our program. Accordingly, we propose that each farmer and wild crop harvester would pay $50 annually, or $200,000 divided by 4,000 farmers. We propose that each handler would pay $500 annually, or $300,000 divided by 600 handlers. We used this manner to determine the fee that will be charged each farmer, each wild crop harvester, and each handler because almost all of the activities that would be carried out for each group, i.e., for the certified farmers and wild crop harvesters, and for the certifier handlers, will be equally applicable to each farmer and harvester, and each handler. It would not be practical to apply any of the possible small portion of activities that remain to individual farmers, wild crop harvesters, and handlers separate and apart from the overall costs to each group. We request any additional information that would improve the estimates of farmer, wild crop harvesting, and handler participation, so that a more accurate estimate of these fees can be developed.

In our consideration of farmer, harvester, and handler fees, we determined that the allocation of a higher percentage of costs to handlers' issues (60 percent), as opposed to farmer/harvester issues (40 percent), would be appropriate. We anticipate that handling issues, especially such issues as enforcement; record keeping and auditing; labeling, including use of the USDA seal and State seals on different product lines; equivalency of imported organically produced ingredients; and maintenance of the National List of non-agricultural ingredients, will require greater program staff time and operating expenses than farming and harvesting issues.

In developing our proposed fee structure, we considered proposing a fee structure that did not include a fee collected directly from producers and handlers, but that instead assessed fees on certifying agents to cover the total $1,000,000 cost of the National Organic Program. We considered this alternative because we recognize that any fee charged to a certifying agent ultimately will be incorporated into the fee that the certifying agent charges the producer and handler for certification services. However, we did not propose this alternative because we consider our proposal that would directly assess producers, handlers and certifying agents for services we provide to them to better represent an appropriate and practical method of providing transparency and distributing overall program costs among the universe of potential participants and beneficiaries.

We also considered developing a sliding scale of fees to be charged to producers and handlers, based on the size and complexity of their operations. For example, a farmer or handler who sells $5,000 annually of agricultural products would be charged proportionately less than a farmer or handler whose sales exceed $5,000. However, we are proposing fees that are related directly to the costs of services provided by AMS, rather than to such factors as a participant's sales volume or income from the sale of organically produced products, because we estimate that a scheme for charging fees based on factors such as sales volume or income is a more complex scheme and would require additional recordkeeping burden and administrative costs for producers and certifiers.

As discussed previously, we have made a distinction between services provided to farmers/harvesters as a group and handlers as a group. However, we have not made a distinction within each group for assessing fees to farms and harvesting operations, and handling operations, based on their size, complexity, or other similar factor. Because we are concerned about the impact of our proposed uniform fee structure on smaller farms and smaller handling operations, we are requesting public comment on the impact of our proposed structure on smaller operations. Additionally, we are request public comment on alternative methods for calculating fees, including, but not limited to (1) the actual cost of providing services to each individual or operation, and (2) the size of the operation or value of the product(s) for which service is being provided.

*Fees for Import Programs—Section 205.423*

We are proposing in section 205.423(a) that foreign organic certification programs, other than those operated by a foreign country itself, pay a fee of $40 per hour plus any travel and per diem costs that might be incurred to establish the equivalency of the program. This is the average hourly cost for AMS to conduct a program of this nature. Before equivalency is final and effective for foreign certification programs for which payment for determination of equivalency is required, payment must be made to AMS.

In section 205.423(c) we are proposing that the fees must be submitted by certified funds made payable to AMS and paid within 30 days following the date of notification of AMS of its intent to approve the program subject to receipt of the fees. Fees should be submitted according to the instructions provided by AMS. As indicated in the proposal, no program would be approved until all required fees are paid.

*Payment of Fees and Other Charges—Section 205.424*

In section 205.424(a) we propose that all fees be submitted in the form of a certified check or money order made payable to AMS and sent to the address identified in the bill issued for these fees. We also propose, in accordance with section 3717 of the Debt Collection Act of 1982 as amended (31 U.S.C. 3717), that all fees required to be submitted would incur interest, penalties, and other costs in the case of late payment of the fees due. In addition, failure to submit payment, or a late payment, of a bill owed to AMS may result in the loss of, or failure to obtain, certification, accreditation, or equivalency status.

Fees for application for accreditation or for the review of an annual report must be included with the application or with the annual report. Without payment of the fee, AMS will not act on the application. Fees for site evaluations and administrative fees that are not paid or that are received late may cause AMS to refrain from issuing, confirming, or continuing accreditation. Certification of farm, wild crop harvesting and handling operations is dependent upon

the payment of the fees. Import programs, other than those operated by a foreign country itself, would not be acknowledged as being equivalent until payment is made to cover the AMS cost for the establishment of equivalency.

ESTIMATED NATIONAL ORGANIC PROGRAM FEES

[Based on 1994 data]

| Description | Certification agents (est. 44) | Subsidiary offices or chapters (est. 30) | Handlers (est. 600) | Farmers (est. 4,000) | Private foreign certification programs (est. 16) |
|---|---|---|---|---|---|
| Application or Annual Report Fee | $640/Annually | $160/Annually | $0 | $0 | $0 |
| Administrative Fee | 2,000/Annually | 300/Annually | 500/Annually | 50/Annually | 0 |
| Site Evaluations | 3,500* | 3,500* | 0 | 0 | 0 |
| Equivalency Review | 0 | 0 | 0 | 0 | 7,000 |
| Total Estimated Fees** | 270,160 | 118,800 | 300,000 | 200,000 | 112,000 |

* The $3,500 estimated cost is based on a 5 day site evaluation computed at $40 per hour plus travel and per diem costs. The actual cost will vary based on the length of the evaluation. Initial site evaluations would be performed approximately 12 months after initial granting of accreditation, after which site evaluations will be conducted at least once every 5 years and as necessary to determine compliance. The $40 per hour rate, which is used in many of the National Organic Program fees, is based upon the average hourly cost for AMS to conduct a program of the nature.

** The estimated numbers of farmers, handlers and certifiers are based on data collected in 1994; therefore, the total estimated fees may not represent the number of farmers, handlers and certifiers who might participate in the National Organic Program after implementation. We also estimated the number of equivalency reviews conducted for private foreign certification programs to be approximately 16 per year. An equivalency review may cost more than accreditation of a certification agent because it would include an analysis of the following: production standards, criteria for allowing certain substances to be used, certification requirements, enforcement measures and accreditation process, and may include a site visit to the foreign program headquarters. We request information that would improve the estimates of farmer, handler, certifier and private foreign program participation so a more accurate estimate of these fees can be developed.

**Compliance Review and Other Testing**

Sections 205.430 through 205.433 contain our proposed provisions for compliance review, preharvest tissue testing, application of a prohibited substance due to emergency pest or disease treatment, and the reporting of the application of a prohibited substance. Section 2107(a)(6) of the OFPA (7 U.S.C. 6506(a)(6)) requires the establishment of a program under which certifying agents would conduct periodic residue testing of agricultural products from certified farms and handling operations and report any violations of food safety laws which they are aware of to the appropriate health agencies. Section 2112 of the OFPA (7 U.S.C. 6511)) requirements in regard to preharvest tissue testing and testing of products sold or labeled as organically produced also are addressed in the proposal. Additionally, the proposal addresses the provisions of section 2107(b)(2) of the OFPA (7 U.S.C. 6506(b)(2)) regarding the application of prohibited substances on certified organic farms that occur as the result of a Federal or State emergency pest or disease treatment program.

*Compliance Review—Section 205.430*

This proposed section would implement the residue testing requirements of sections 2107(a)(6) of the OFPA (7 U.S.C. 6506(a)(6)) and 2112(a) and (b) of the OFPA (7 U.S.C. 6511(a) and (b)). Section 2107(a)(6) of the OFPA (7 U.S.C. 6506(a)(6)) requires a certifying agent to undertake periodic residue testing of products from certified farms and handling operations to determine if such products contain a detectable residue level of a pesticide or other prohibited substance and to report violations of food safety laws, if found, to the appropriate health agencies. Section 2112(a) of the OFPA (7 U.S.C. 6511(a)) requires the Secretary, the applicable governing State official or the certifying agent to utilize a system of residue testing to test products sold or labeled as organically produced to assist in enforcement of this title. Section 2112(c) of the OFPA (7 U.S.C. 6511(c)) further requires the Secretary, applicable governing State official and the certifying agent to conduct an investigation of a certified farm or handling operation when the residue test of a product from the certified farm or operation shows a detectable residue level of a pesticide or other prohibited substance, to determine if the organic certification program has been violated, and may require the producer or handler of such product to prove that any prohibited substance was not applied to such product.

In paragraph (a) of this section we propose that a certifying agent would arrange with inspectors to conduct periodic sampling for the purpose of testing organically produced agricultural products from farm, wild crop harvesting, and handling operations certified by that agent to enforce the Act and the regulations set forth in this part. Certifying agents would instruct inspectors when to sample organically produced products on certified farm, wild crop harvesting, and handling operations. We do not propose that this sampling would be performed at each annual inspection. We believe that the frequency of sampling should be adequate to monitor compliance with the section 2105(2) of the OFPA (7 U.S.C. 6504(2)) provision that prohibits the sale or labeling of agricultural products as organic that are produced on land to which any prohibited substances, including synthetic chemicals, have been applied during the 3 years immediately preceding the harvest of the agricultural products, but yet not so frequent as to be unnecessary or burdensome to the certified operations. We have proposed testing not less frequently than every 5 years. However, we specifically request comment on whether this period of time is appropriate. As required by the Act, we also propose to require certifying agents, to the extent that such agents are aware of a violation of applicable laws relating to food safety, to report such violation to the appropriate health agencies (Federal, State, and local).

In paragraph (b) of this section, which addresses the compliance provisions of section 2112(a) of the OFPA (7 U.S.C. 6511(a)), we propose that the Secretary or governing State official would arrange for sampling and residue testing of organically produced products at any point of production or distribution, and may require the certifying agent to conduct sampling and residue testing of organically produced products originating from operations certified by that agent. These product samples could be taken from any point in the

distribution chain, from the farm to the retail store. We believe that taking samples from any point in the distribution chain would assist in maintaining the integrity of organically produced agricultural products after they leave the certified operation and would provide consumers with added assurance that no pesticide or other prohibited substance was used in producing or handling the products.

The results from all sampling and testing would be used to determine if an agricultural product contains any detectable residue level of a pesticide or other prohibited substance. We define the detectable residue level in proposed section 205.2 of subpart A as being the level that is 5 percent or greater of the established EPA tolerance level for the product that was tested, provided that if there is no tolerance level established, but an action level has been established, the detectable residue level will be the action level established by FDA for the product tested. The EPA tolerance levels, expressed in terms of parts of a pesticide residue per million parts of the food (ppm), refer to the amount of a pesticide residue that may legally be present in or on a raw agricultural commodity, as set forth in section 408(a) of the Federal Food, Drug and Cosmetic Act (FFDCA) (21 U.S.C. 346(a)), or present in processed food or feed under the terms of the food additive regulation as set forth in section 409 of the FFDCA (21 U.S.C. 348). Tolerance levels for raw agricultural commodities are published in 40 CFR Part 180; for processed foods, in 40 CFR Part 185; and for processed feed, in 40 CFR Part 186. The FDA action levels, which are based on recommendations received from the EPA, also are expressed in terms of parts of a pesticide residue per million parts of the food and are used to regulate the occurrence of very low levels of pesticide residues that result from pesticides that are persistent in the environment and for which EPA does not establish a tolerance level. The FDA action levels are published in FDA's Compliance Policy Guide (CPG), Chapter 5 (Foods), subchapter 575, section 575.100. We have based our compliance testing proposals on the EPA tolerances and the FDA action levels because they represent the best data available on what are appropriate and safe residue levels.

In our proposal, we have determined that the detectable residue level for a prohibited substance would be at 5 percent of the EPA tolerance for the product tested, or at the actual FDA action level for the product tested, as applicable, so as to establish a practical benchmark for determining when to conduct an investigation pursuant to section 2112(c)(1) of the OFPA (7 U.S.C. 6511(c)(1)). A practical benchmark must be low enough to provide adequate protection against the use of pesticides or other prohibited substances and yet high enough not to burden a producer or handler, and the national or applicable State program, with an investigation unless a reasonable question of non-compliance exists. Our proposed levels of 5 percent of the EPA tolerance, or at the actual FDA action level, as indicators of a detectable residue level are based upon the historical use of 5 or 10 percent of the EPA tolerance, or the actual FDA action level, by States and other certifying agents in the organic industry.

The NOSB recommended that the USDA enter into an arrangement with the Department of Health and Human Services to conduct sampling and testing of raw organic agricultural products as a part of the FDA's regulatory monitoring program of all agricultural products for pesticide residues. The NOSB suggested a similar arrangement with States that conduct their own pesticide residue monitoring programs. After implementation, we will consider these possibilities and similar arrangements with other existing pesticide residue testing programs to fulfill the proposed sampling provision set forth in paragraph (b) of this section.

In paragraph (c) in this section, we propose to require each product sample collected by an inspector representing the Secretary, a certifying agent, or applicable governing State official, as part of the compliance review, to be submitted to a laboratory facility accredited to test the commodity sampled. (Laboratory accreditation is not a part of the USDA accreditation program and is currently administered through private and independent third parties.) Each product sampled would be collected in accordance with instructions provided in subchapter 400 of the FDA Investigations Operations Manual (IOM). We have chosen the IOM because it serves as the FDA's primary guide to field investigators and inspectors on investigational policies and procedures, and thus provides for consistency in periodic and random sample collection. The analytical methods used to test each product sample to determine if an agricultural product contains a detectable residue level of a pesticide or other prohibited substance would be selected as appropriate from the FDA's Pesticide Analytical Manual (PAM) Volumes I and II, the Official Methods of Analysis of the Association of Official Analytical Chemists, or the Food Safety Inspection Service (FSIS) Residue Chemical Guidebook. We have adopted the analytical methods contained or referenced in these publications because they serve as the standard analytical methods used by the FDA, FSIS, and other laboratories to examine food and animal feed for pesticide residues for regulatory purposes. The results of such tests would be reported to the certifying agent or governing State official, as applicable, and to the Secretary.

Our proposed paragraph (c)(3) of this section would require that the Secretary, the governing State official, or the certifying agent, as applicable, inform the appropriate regulatory agency in the event a residue test level exceeded either the EPA tolerance level or the FDA action level, as applicable, for that substance. This proposal is consistent with section 2107(a)(6) of the OFPA (7 U.S.C. 6506(a)(6)), which requires reporting of violations related to food safety to the appropriate health agencies.

Paragraphs (d)(1) and (2) of this section propose the actions that would be undertaken by the Secretary after the receipt of a residue test result that indicated a detectable residue level of a prohibited substance. Our proposed paragraph (d)(1) of this section would require the Secretary, applicable governing State official, or certifying agent to conduct an investigation to determine the cause of a detectable residue level of a prohibited substance in the sample, as provided for under section 2112(c)(1) of the OFPA (7 U.S.C. 6511(c)(1)). The investigation may include a visit to the certified operation to determine whether the detectable residue level exceeds the unavoidable residual environmental contamination level for the prohibited substance at the specific certified operation.

Proposed paragraph (d)(2) of this section would implement the provision of section 2112(c)(2) of the OFPA (7 U.S.C. 6511(c)(2)) which prohibits organically produced agricultural products from being sold or labeled as organically produced if the investigation into the cause of a detectable residue level in a sample determines that the residue was the result of an intentional application of a prohibited substance or was at a level greater than the unavoidable residual environmental contamination level for the prohibited substance. The NOSB recommended that the unavoidable residual environmental contamination level be at the actual FDA action level, or not to exceed 5 percent of the EPA tolerance, as applicable. We propose instead that the unavoidable residual environmental contamination be established for each

specific site only after a product produced on that site is found to contain a detectable residue level of 5 percent of the EPA tolerance, or at the actual FDA action level, as applicable. We believe that unavoidable residual levels of contaminants in the environment vary so greatly by region, State, and site so as to render impractical the use of a uniform level. The certification eligibility of certified operations also would be better evaluated by our proposal to establish a site-specific unavoidable residual level during the investigation, rather than applying a pre-determined level. Proposed paragraph (d)(2) of this section would authorize the Administrator to institute proceedings to terminate the certification of an operation, or portion of an operation, after an investigation determined that the residue resulted from an intentional application of a prohibited substance or that the residue level exceeded the unavoidable residual environmental contamination level. The termination procedure is more fully described in section 205.219 of subpart D.

*Preharvest Tissue Testing—Section 205.431*

Section 2112(b) of the OFPA (7 U.S.C. 6511(b)) authorizes the Secretary, the governing State official, or the certifying agent to conduct preharvest tissue testing of any crop grown on soil suspected of harboring contaminants. We accordingly propose in paragraph (a) of this section that such a test may be conducted when the soil is suspected by the Secretary, the governing State official or the certifying agent of containing contaminants. We have defined contaminant in section 205.2 of subpart A to be a residue of a prohibited substance that persists in the environment. This pre-harvest tissue test would be conducted to determine whether the crop to be harvested contained levels of any contaminant greater than either the actual FDA action level, or EPA tolerance, as applicable, for that contaminant.

We also believe a pre-harvest tissue test could assist producers of organically grown crops raised on soil to which certain highly persistent prohibited substances were applied more than three years prior to the harvest of an organic crop to be knowledgeable of the residue levels contained in their crops. For example, any soil could potentially harbor sufficient amounts of prohibited substances, such as chlorinated hydrocarbons, that are known to causes certain types of crops, such as squash or cucumbers, to absorb enough of these contaminants to exceed established FDA action levels or EPA tolerances.

In paragraph (b) of this section, we propose that preharvest tissue samples be collected by an inspector representing the certifying agent or applicable governing State official and submitted in accordance with subchapter 400 of the FDA Investigations Operations Manual (IOM). The analytical methods used for determining if preharvest tissue samples contain a detectable residue of a pesticide or prohibited substance are identified among the methods contained or referenced in the FDA's Pesticide Analytical Manual Volume I and II or the Official Methods of Analysis of the Association of Official Analytical Chemists. This parallels the procedure for compliance testing and sampling as proposed in section 205.430(c).

Paragraph (c) of this section would require the certifying agent or the governing State official to report the results of each preharvest tissue test to the Secretary and to the appropriate health agencies if a pre-harvest tissue test result indicated that the residue level of a contaminant exceeds the EPA tolerance or the FDA action level, as applicable, for that contaminant.

The NOSB submitted recommendations addressing instances of drift of prohibited substances upon organically produced crops. The NOSB defined drift as the physical movement of prohibited pesticides or fertilizers from the intended target site onto a certified organic field or farm, or portion thereof, caused by a person who is not the certified organic producer or a person working under the direction of the certified organic producer. They recommended that agricultural products exposed to drift should not be sold or labeled as organically produced or fed to livestock on certified operations and that pre-harvest tissue tests be required to verify which crops were not drifted upon.

We have not provided in our proposal for instances of drift, or for the use of pre-harvest testing to verify portions of fields that receive drift. Although drift may be commonplace, especially in those agricultural regions where pesticide use on non-organic lands is routine and heavy, exposure to drift does not constitute use of a prohibited substance and does not affect the integrity of organically produced crops because the amount of prohibited substance to which the crops are exposed is negligible. We believe our provisions proposed in sections 205.430 and 205.431 for the testing of organically produced agricultural products, both before and subsequent to harvest, to determine residue levels and, if necessary, to conduct an investigation as to the cause of a detectable residue level, are adequate to protect the integrity of agricultural products sold or labeled as organically produced.

*Emergency Pest or Disease Treatment—Section 205.432*

This proposed section would address situations where certified organic farms are subject to Federal or State emergency pest or disease programs. It would, pursuant to the discretionary requirements of 2107(b)(2) of the OFPA (7 U.S.C. 6506(b)(2)), provide that a farm subject to such treatment program would not have its certification status affected, so long as certain prohibitions in the proposed regulations are complied with.

The NOSB recommended, and we agree, that land that is subject to an emergency treatment program with a prohibited substance should not be required to be withheld from production of organically produced products for a period of three years. Therefore, we are proposing that a certified farm that is otherwise in compliance with the regulations would not have its certification status affected as a result of a Federal or State emergency pest or disease treatment program, provided that the conditions stated in paragraphs (a) and (b) of this section, as applicable, are satisfied.

Paragraph (a) of this section would prohibit the sale or labeling of any crop harvested from a treated farm as organically produced if the harvested crop, or plant part to be harvested, had come in contact with a prohibited substance applied as part of the emergency program. Field observations by the producer, combined with the reporting requirements of proposed section 205.433 and the testing and sampling provisions of sections 205.430 and 205.431 would be used to determine which crops had come in contact with the prohibited substance and to monitor that they were not being sold or labeled as organically produced.

We propose in paragraph (b) of this section that any livestock that were treated with a prohibited substance as part of a Federal or State emergency pest or disease treatment program, or product derived from such livestock, could not be sold as organically produced. However, exceptions to the prohibition on the sale of treated livestock and their products as organically produced are proposed in paragraphs (b)(1) and (b)(2) of this section. In accordance with section 2110(e)(2) of the OFPA (7 U.S.C. 6509(e)(2)), we propose in paragraph

(b)(1) of this section that milk and milk products from a treated dairy animal could be sold as organically produced beginning no less than twelve months following the last treatment with the prohibited substance. Additionally, in accordance with section 2110(b) of the OFPA (7 U.S.C. 6509(b), we propose in (b)(2) of this section that offspring from breeder stock that was not in the last third of its gestation at the time of the last application of a prohibited substance could be considered as organic at the time of birth.

*Reporting the Application of a Prohibited Substance—Section 205.433*

Section 205.433 provides a general requirement that producers or handlers immediately notify the certifying agent of any instance of an application of a prohibited substance on their certified operations. This requirement would ensure that the certifying agent was made aware of any incident of this type, that occurs on an operation certified by them, which might affect the integrity and status of an agricultural product sold as organically produced by the operation or the status of the operation from which an agricultural product is harvested. Failure to notify the certifying agent may result in termination of certification, as provided for in section 205.219 of subpart D.

**Appeals**

*General—Section 205.452*

Section 2121(a) of the OFPA (7 U.S.C. 6520(a)) requires the Secretary to establish an administrative appeals procedure under which persons may appeal an action of the Secretary or a certifying agent that adversely affects such person or that is inconsistent with the applicable organic certification program. We accordingly propose in this section that any person subject to the OFPA who believes that he or she is adversely affected by a decision of a member of the National Organic Program staff or by a certifying official may appeal such decision to the Administrator of the Agricultural Marketing Service.

**Equivalency of Imported Organic Products**

Section 2106(b) of the OFPA (7 U.S.C. 6505(b)) provides that agricultural products imported into the United States may be sold or labeled as organically produced only if the Secretary determines that the products have been produced and handled under an organic certification program that provides safeguards and guidelines that are at least equivalent to the requirements of the Act. We are proposing provisions concerning equivalency and the process for establishing equivalency in accordance with this requirement.

*Eligibility of Agricultural Products for Importation Into the United States—Section 205.480*

Section 205.480 requires that imported agricultural products, or ingredients in products, that are to be sold or labeled as organic must have been produced and handled under an organic certification program that the Secretary has determined has safeguards and guidelines equivalent to those in the Act and our proposed regulations.

*Determination of the Equivalency of Foreign Programs—Section 205.481*

To provide for the importation of organic agricultural products, we propose in section 205.481 that an evaluation of a foreign organic certification program would include a review of its: standards for production and handling of agricultural products; lists of substances allowed and prohibited for use and the criteria used to establish the lists; inspection and certification requirements for farm and handling operations and oversight of certification provisions; enforcement provisions; the accreditation process and requirements for an accredited status; and any additional information deemed necessary by the Secretary to use to determine equivalency. Examples of other information that may be required to be submitted are a list of products certified by the program and copies of inspection reports used in determining certification status.

It is necessary to evaluate these elements in order to satisfy the provisions of the OFPA that foreign programs provide safeguards and guidelines at least equivalent to the requirements of the OFPA and its implementing regulations. These equivalent safeguards and guidelines should include: standards for organic farming and handling, including substances allowed and prohibited for use in the production and handling of organic products; provisions for certification of farming and handling operations; and oversight of persons and organizations who will be responsible for the certification of farm and handling operations. In addition, there should be equivalent measures provided for enforcement of any program requirements.

One example of an element that may be examined in determining equivalency is whether the program's standards for farm and handling operations incorporate, as does the Act and our proposed regulations, the principle of prevention, i.e., prevention of disease in animals, pest infestation in crops, and commingling of non-organic products with organic products in a food handling operation.

We note that farms and handling operations certified by agents operating under a foreign organic certification program that is determined to be equivalent with the USDA National Organic Program would be able to import products into the United States without the certified farm or handling operation itself having to apply for approval for importation from the USDA.

We recognize that not all organic products produced in foreign countries are produced in countries that would have established their own equivalent foreign organic certification programs. We intend that the determination of equivalency of any other type of foreign organic certification program, such as one conducted by a certifying agent that operates in a country that has not been determined to have an equivalent program, also be based on an evaluation and determination of the components set forth in section 205.481. We also are aware that the accreditation of some foreign organic certification programs may be conducted by an agency other than an agency of the government.

*Process for Establishing Equivalency of Foreign Programs—Section 205.482.*

In this section, we propose the process by which a foreign organic certification program may apply for a determination of the equivalency of its program with the National Organic Program, and in turn, the procedure for notification of a determination of equivalency or nonequivalency. In paragraph (a) of this section, a foreign organic certification program that wants to establish the equivalency of its organic program with the National Organic Program would submit to the Secretary a complete and accurate description of its program, including any of the laws and applicable requirements upon which the program is based and any other information requested by the Secretary.

In paragraph (b) of this section, we propose that the Secretary would make a determination of equivalency or nonequivalency and notify the foreign organic certification program of the decision. If the Secretary determines that a foreign organic certification program is equivalent to the USDA National Organic Program, we propose that the Secretary provide the foreign organic certification program written

notification of the date upon which organically produced agricultural products produced and handled under the program may be imported into the United States and labeled or sold as organic. If a foreign organic certification program has been determined by the Secretary not to be equivalent, we propose that the Secretary provide the foreign organic certification program written notification and state the basis for such determination. After receipt of such notice, the foreign organic certification program may reapply at any time.

We propose in paragraph (c) of this section that, if at any time the Secretary determines that a foreign program is not equivalent, the Secretary may withdraw the equivalency status. Termination of the equivalency status will be effective upon receipt by the foreign organic program of the notice.

*Maintenance of Eligibility for Importation—Section 205.483*

In order to determine if a foreign organic certification program continues to be eligible to import agricultural products into the United States that are to be sold or labeled as organic, we propose in section 205.483 that reviews of the foreign organic certification program be conducted periodically to reevaluate whether the program continues to be equivalent. The Secretary will review, as a part of the reevaluation, documents and other information related to the conduct of the foreign organic certification program, including any amendments made to the program requirements since its last evaluation. Continuance of the eligibility for importation of products produced and handled under a program would depend on the results of these reviews and the timely submissions of all documents and other information needed for the review.

## List of Subjects in 7 CFR Part 205

Administrative practice and procedure, Agriculture, Animals, Archives and records, Foods, Imports, Labeling, Organically produced products, Plants, Reporting and recordkeeping requirements, Seals and insignia, Soil conservation.

For the reasons set forth in the preamble, it is proposed that Title 7, Chapter I of the Code of Federal Regulations be amended as follows:

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—Organic Crop and Livestock Production and Handling Requirements

205.3 Applicability.
205.4 [Reserved]

**Organic Crop Production Requirements**

205.5 Land requirements.
205.6 Crop rotation.
205.7 Soil fertility and crop nutrient management.
205.8 Selection and use of seeds, seedlings and planting stock.
205.9 Prevention and control of crop pests, weeds, and diseases.
205.10 [Reserved]
205.11 Wild crop harvesting.

**Organic Livestock Production Requirements**

205.12 Origin of livestock.
205.13 Livestock feed.
205.14 Livestock health care.
205.15 Livestock living conditions and manure management.

**Organic Handling Requirements**

205.16 Product composition.
205.17 Processing practices.
205.18 Prevention and control of facility pests.
205.19 Prevention of commingling and contact with prohibited substances.

**The Use of Active Synthetic Substances, Non-synthetic Substances, Non-Agricultural (Non-organic) Substances and Non-organically Produced Ingredients in Organic Farming and Handling Operations, Including the National List of Allowed and Prohibited Substances**

205.20 General rules for categories of substances and ingredients permitted for use in organic farming and handling.
205.21 General rules for categories of substances and ingredients prohibited for use in organic farming and handling.

**The National List of Allowed and Prohibited Substances**

205.22 Active synthetic substances allowed for use in organic crop production.
205.23 Non-synthetic substances prohibited for use in organic crop production.
205.24 Active synthetic substances allowed for use in organic livestock production.
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**Authority:** 7 U.S.C. 6501–6522.

## PART 205—NATIONAL ORGANIC PROGRAM

## 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 governing State official or private person 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.*).

*Active ingredient in any input other than pesticide formulations.* Any substance, that when used in a system of organic farming or handling, becomes a chemically functional part of that system; is a labeled ingredient or food additive; or is a substance that is otherwise of significant consequence to the production, handling and integrity of an organically produced agricultural product.

*Active ingredient in pesticide formulations.* Any substance (or group of structurally similar substances) as specified by the EPA in 40 CFR 152.3(b), that will prevent, destroy, repel or mitigate any pest, or that functions as a plant regulator, desiccant, or defoliant, within the meaning of section 2(a) of the Federal Insecticide, Fungicide, and Rodenticide Act, as amended (7 U.S.C. 136(a)).

*Administrator.* The Administrator for the Agricultural Marketing Service (AMS), United States Departure of Agriculture, or the representative to whom authority has been delegated to act in the stead of the Administrator.

*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.

*Agroecosystem.* A system consisting of the functions, interactions, and balances of biological, hydrological, geological, and other environmental elements that are found within a given farm operation.

*Allowed synthetic.* A substance that is included on the National List of synthetic substances allowed for use in organic farming.

*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 operations.* The types of operations: crops, livestock, wild crop harvesting, 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 organic or made with certain organic ingredients, or of any agricultural product 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.

*Botanical pesticides.* Natural (non-synthetic) pesticides derived from plants.

*Breeding.* Selection of plants or animals to reproduce desired characteristics in succeeding generations.

*Buffer area.* An area located between a certified farm or portion of a farm, and an adjacent land area that is not maintained under organic management. A buffer area 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.

*Cation balancing agent.* A mineral substance applied to the soil to adjust the ratio among positively charged (cation) nutrients on soil colloids. The major cation nutrients are calcium (Ca), magnesium (Mg), and potassium (K), and the cation micronutrients include iron (Fe), zinc (Zn), copper (Cu) and manganese (Mn).

*Certification or certified.* A determination made by a certifying agent that a farm, wild crop harvesting, or handling operation is in compliance with the Act and the regulations in this part, which is documented by a certificate that identifies the entity certified, the effective date of certification, and the types of agricultural products for which certification is granted.

*Certification activities.* Activities conducted by a certifying agent in regard to certification applicants or certified farms, handling operations and wild crop harvesting operations.

*Certification applicant.* A producer or handler of agricultural products who applies to a certifying agent for certification.

*Certified facility.* A processing, manufacturing, livestock housing or other site or structure maintained or operated to grow, raise or handle organically produced agricultural products that is part of a certified organic farm, a certified organic wild crop harvesting operation, or a certified organic handling operation.

*Certified organic farm.* A farm, or portion of a farm, or site, where agricultural products or livestock are

produced, that is certified by the certifying agent under the Act as utilizing a system of organic farming as described by the Act and regulations in this part.

*Certified organic handling operation.* An operation, or portion of a handling operation, that is certified by a certifying agent as utilizing a system of organic handling as described under the Act and the regulations in this part.

*Certified organic wild crop harvesting operation.* An operation, or portion of an operation, that is certified by a certifying agent as harvesting wild crops in compliance with the Act and the regulations in this part.

*Certifying agent.* 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 the 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, wild crop harvesting operation, or handling operation as a certified organic farm, wild crop harvesting, 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.

*Chapter.* A subsidiary organizational unit of a certifying agent that conducts certification activities in a manner consistent with relevant policies and procedures developed by the certifying agent in accordance with the Act and the regulations of this part.

*Commercially available.* The ability to obtain a production input in an appropriate form, quality, and quantity to be feasibly and economically used to fulfill an essential function in a system of organic farming and handling.

*Commingling.* Physical contact between unpackaged organically produced and non-organically produced agricultural products during production, transportation, storage or handling, other than during the manufacture of a multi-ingredient product containing both types of ingredients.

*Compost.* A process that creates conditions that facilitate the controlled decomposition of organic matter into a more stable and easily handled soil amendment or fertilizer, usually by piling, aerating and moistening; or the product of such a process.

*Confirmation of accreditation.* A determination made by the Secretary following the receipt of an AMS site evaluation report and peer review panel reports that a certifying agent is operating in compliance with the Act and regulations in this part.

*Contaminant.* A residue of a prohibited substance that persists in the environment.

*Control.* Any method that reduces or limits damage by, or populations of, pests, weeds or diseases to levels that do not significantly reduce productivity.

*Critical control point.* Any point, step or procedure in a certified production or handling operation where loss of control may result in a loss of an organic product's integrity, such as the commingling of organic products with non-organic products or contact of organic products with prohibited substances.

*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 during two or more crop years.

*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 used to enhance crop and livestock health and prevent weed, pest or disease problems without the use of substances; examples include the selection of appropriate varieties and planting sites; selection of appropriate breeds of livestock; providing livestock facilities designed to meet requirements of species or type of livestock; proper timing and density of plantings; irrigation; and extending a growing season by manipulating the microclimate with green houses, cold frames, or wind breaks.

*Cytotoxic mode of action.* Having a toxic effect by means of interference with normal cell functions.

*Degradation.* Measurable evidence of damage or adverse effects over the course of two or more crop years, as determined by monitoring one or more indicators of soil or water quality.

*Detectable residue level.* The level of a pesticide or other prohibited substance that is 5 percent or greater of the established EPA tolerance level, as set forth in 40 CFR Parts 180, 185, and 186, for the product that was tested, provided that if there is no tolerance level established, but an action level has been established, the detectable residue level will be the action level established by FDA for the product tested.

*Disease vectors.* Plants or animals that harbor and carry disease organisms which may attack crops or livestock.

*Emergency pest or disease treatment program.* A mandatory program authorized by a State, federal or local agency for the purpose of controlling or eradicating a pest or disease.

*Employee.* Any person who will be involved in certification decisions.

*Extract.* The action of producing a substance by a process of dissolving the soluble fractions of a plant, animal or mineral in water or another solvent; or the product thereof.

*Farm.* An agricultural operation maintained for the purpose of producing agricultural products.

*Fertilizer.* A single or blended substance applied to the soil to supply any of the three primary plant nutrients, nitrogen (N), phosphorus (P) and potassium (K), needed for the growth of plants.

*Field.* An area of land identified as a discrete unit within a farm operation.

*Foliar nutrient.* Any liquid substance applied directly to the foliage of a growing plant for the purpose of delivering essential nutrient(s) in an immediately available form.

*Formulated product.* A commercial product composed of more than one substance.

*Fungicide.* Any substance that kills fungi or molds.

*Generic name.* The general or scientific name of a substance that is not a trade name.

*Genetic engineering.* Genetic modification of organisms by recombinant DNA techniques.

*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 an organic certification program under the Act.

*Handle.* To sell, process, or package agricultural products.

*Handler.* Any person engaged in the business of handling agricultural products, 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.

*Incidental additive.* An additive present in agricultural products at an insignificant level that does not have any technical or functional effect in the product and is therefore not an active ingredient.

*Inert ingredient in any input other than pesticide formulations.* Any substance other than an active ingredient intentionally included in any product used in organic crop production.

*Inert ingredient in pesticide formulations.* Any substance (or group of structurally similar substances if designated by the EPA) other than an active ingredient which is intentionally included in a pesticide product (40 CFR 152.3(m)).

*Information panel.* That part of the label of a packaged product that is immediately contiguous 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 limitations.

*Ingredients statement.* The listing of the ingredients contained in a product listed by their common and usual names in the descending order of predominance.

*Inspector.* Any person retained or used by a certifying agent who is qualified to conduct inspections of certification applicants or certified farms, handling operations or wild crop harvesting operations.

*Intentionally applied.* The deliberate use of a substance on a certified organic farm or handling operation.

*Label.* Any 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 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 for the product.

*Livestock.* Any cattle, sheep, goats, swine, poultry, equine animals used for food or in the production of food, fish used for food, wild or domesticated game, or other nonplant life.

*Made with certain organic ingredients.* An agricultural product wherein organic agricultural products used as ingredients comprise at least 50 percent, but less than 95 percent, of the total weight of the finished product, excluding water and salt; additionally, the percentage of the total weight of the finished product, excluding water and salt, that is not comprised of organic agricultural products is some combination of non-agricultural ingredients and/or non-organically produced agricultural products included on the National List.

*Market information.* Any written, printed, audio-visual or graphic information, including advertising, pamphlets, flyers, catalogues, posters and signs, that are used to assist in the sale or promotion of a product.

*Mating disrupter.* A biochemical substance that serves to prevent pest insects from reproducing by interfering with their ability to locate a suitable mate.

*Micronutrient.* A soil or crop mineral nutrient required in very small quantities.

*Mulch.* Any material, such as wood chips, leaves, straw, paper or plastic that serves to suppress weed growth, moderate soil temperature or conserve soil moisture.

*National list.* A list of allowed and prohibited substances as provided for in section 2118 of the OFPA (7 U.S.C. 6517).

*National organic program.* The program authorized by the Act for the purpose of implementing its provisions.

*National Organic Standards Board.* 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.

*Non-active residues.* Any synthetic substance that does not appear on the National List of synthetic substances allowed for use, any non-synthetic substance that appears on the National List of non-synthetic substances prohibited for use, or any non-synthetic (natural) poison (such as arsenic or lead salts) that has long-term effects and persists in the environment, and which occurs in a very small quantity as a non-active substance in a production input or water.

*Non-agricultural ingredient.* 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 non-agricultural ingredient also includes any substance, such as gums, citric acid or pectin, that is extracted, isolated from, or is a fraction of an agricultural product, so that the identity of the agricultural product is unrecognizable in the extract, isolate or fraction.

*Non-organic agricultural ingredient or product.* An agricultural ingredient or product that has not been produced or handled in accordance with the Act and the regulations in this part.

*Non-synthetic (natural).* A substance that is derived from mineral, plant or animal matter and does not undergo a synthetic process as defined in section 2103(21) of the OFPA (7 U.S.C. 6502(21)). For the purposes of this part, non-synthetic is used as a synonym for natural as the term is used in the Act.

*Non-toxic.* Not known to cause any adverse physiological effects in animals, plants, humans or the environment.

*Organic.* A term that refers to a raw agricultural product produced in accordance with the Act and the regulations in this part; or, to an agricultural product wherein organic agricultural products used as ingredients comprise between 95 percent and 100 percent of the total weight of the finished product, excluding water and salt; additionally, the percentage of the total weight of the finished product, excluding water and salt, that is not comprised of organic agricultural products is some combination of non-agricultural ingredients and/or non-organically produced agricultural products included on the National List.

*Organic matter.* The remains, residues or waste products of any living organism.

*Organic plan.* A plan of management of an organic farming 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 B of this part, including crop rotation and other practices as required under the Act.

*Package.* A container or wrapping that bears a label and which encloses an agricultural product, except for agricultural products in bulk containers, shipping containers, or shipping cartons.

*Packaging.* Material used to wrap, cover, or contain an agricultural product, including wax applied directly to an edible surface of an agricultural product.

*Peer review panel.* A panel of individuals who have expertise in organic farming and handling methods and certification procedures, and who are appointed by the Administrator to assist in evaluating the performance of a certifying agent.

*Person.* An individual, group of individuals, corporation, association, organization, 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, including rhizomes, shoots, leaf or stem cuttings, roots or tubers used in plant production or propagation.

*Preliminary evaluation.* A determination made by a certifying agent, prior to an initial inspection of the operation to be certified, as to whether a person seeking certification of an operation may be in compliance with the regulations in this part.

*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.

*Processing.* Cooking, baking, heating, drying, mixing, grinding, churning, separating, extracting, cutting, fermenting, eviscerating, preserving, dehydrating, freezing, or otherwise manufacturing, and includes the packaging, canning, jarring, or otherwise enclosing food in a container.

*Processing methods.* Mechanical, biological and chemical procedures used in the preparation of an agricultural product for market.

*Producer.* A person who engages in the business of growing or producing food or feed.

*Production aid.* A substance, material, structure, or device, but not an organism, which may or may not be an active ingredient and may or may not be a synthetic substance, used to significantly aid a producer or handler to produce, handle, or maintain the integrity of, an agricultural product during, production, handling and marketing.

*Production input.* A substance or agricultural product that is used to produce or handle an agricultural product.

*Prohibited substance.* A substance whose use in any aspect of organic production or handling is prohibited or not provided for in the Act or the regulations in subpart B of this part.

*Proper manuring.* Any use or application of plant or animal materials, including green manure crops, so as to improve soil fertility, especially its organic content, including the use of compost and other recycled organic wastes whether or not they contain livestock manure.

*Putrefaction.* Partial anaerobic decomposition of organic matter so that it releases noxious oxidation products and gases, attracts vermin, or harbors pathogens.

*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. Records include questionnaires, affidavits, inspection reports, field or production logs, maps or facility diagrams, receipts, invoices, billing statements, bills of lading, inventory control documents, laboratory analysis reports, minutes of meetings, personnel files, correspondence, photographs and other materials.

*Responsibly connected.* Any person who is a partner, officer, director, holder, manager, or owner of 10 per centum or more of the voting stock of an applicant or a recipient of certification or accreditation.

*Routine use of parasiticide.* Administering a parasiticide to an animal without cause.

*Secretary.* The Secretary of Agriculture or a representative to whom authority has been delegated to act in the Secretary's stead.

*Site evaluation.* An examination of a certifying agent's operations and records at its places of business for the purpose of determining, reviewing or evaluating accreditation status under these regulations.

*Slaughter stock.* Any animal that is intended to be slaughtered for human consumption.

*Soil amendment.* Substance or material applied to the soil as a production input to improve its physical qualities or biological activity, complement or increase soil organic matter content, or complement or adjust a soil nutrient level.

*Soil quality.* Observable indicators of the physical, chemical or biological condition of soil.

*Split operation.* An organic farming operation that also produces crops or livestock that are not organically produced in accordance with the Act and the regulations of this part.

*State.* Any State, Territory, the District of Columbia, or the Commonwealth of Puerto Rico.

*State organic certification program.* A program that meets the requirements of section 2107 of the OFPA (7 U.S.C. 6506), is approved by the Secretary, and is designed to ensure that an agricultural product that is sold or labeled as organically produced under the Act is produced and handled using organic methods.

*Subtherapeutic.* Administration of an animal drug, at levels that are below the levels used to treat clinically sick animals, for the purpose of increasing weight gain or improving feed efficiency.

*Suspension of accreditation.* An action taken by the Secretary that results in a certifying agent losing its authority to carry out certification activities.

*Synergist.* A substance that is an active ingredient which enhances the activity or efficiency of another substance, thereby reducing the amount of other active ingredients needed to achieve the desired function or result.

*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.

*Synthetic volatile solvent.* A synthetic substance used as a solvent, which evaporates readily, such as hexane or isopropyl alcohol.

*System of organic farming and handling.* A system that is designed to produce agricultural products by the use of methods and substances that maintain the integrity of organic agricultural products until they reach the consumer. This is accomplished by using, where possible, cultural, biological and mechanical methods, as opposed to using substances, to fulfill any specific function within the system so as to: maintain long-term soil fertility; increase soil biological activity; ensure effective pest management; recycle wastes to return nutrients to the land; provide attentive care for farm animals; and handle the agricultural products without the use of extraneous synthetic additives or processing in accordance with the Act and regulations in this part.

*Transplant.* An annual seedling grown on a certified organic farm and transplanted to a field on the same farm operation to raise an organically produced crop.

*Treated.* A seed, plant propagation material or other material purchased for use as a production input in an organic farming or handling operation that has been treated or combined with a synthetic pesticidal substance (that does not appear on the National List) prior to having been purchased.

*Unavoidable residual environmental contamination.* The residue level of a prohibited substance, as determined by the Secretary in consultation with the

applicable governing State official and the appropriate environmental regulatory agencies, that could be expected to exist in the soil at, or in a product originating from, a specific production site to which the prohibited substance had not been applied for a minimum of three years.

*Untreated seeds.* Seeds that have not been treated with a prohibited substance.

*USDA Seal.* The logo described in § 205.107 of subpart C of this part.

*Weed.* Any plant that directly competes or interferes with the growth or harvest of a crop.

*Wild crop.* Any plant or portion of a plant that is collected or harvested from an area of land that is not maintained under cultivation or other agricultural management.

## Subpart B—Organic Crop and Livestock Production and Handling Requirements

### § 205.3 Applicability.

(a) Any agricultural product that is sold, labeled, or represented as organic shall be:

(1) Produced in accordance with the requirements specified in § 205.3 and §§ 205.5 through 205.9, or §§ 205.12 through 205.15, and all other applicable requirements of part 205 on a certified organic farm; or

(2) Harvested, if a wild crop, in accordance with the requirements specified in § 205.11 and all other applicable requirements of part 205; and

(3) Handled in accordance with the requirements specified in § 205.3 and §§ 205.16 through 205.19 and all other applicable requirements of part 205 in a certified organic handling operation.

(b) A method or substance that is used in accordance with this subpart shall be used in accordance with all applicable requirements of part 205 and shall be selected and used such that:

(1) Use or application of the practice or substance does not result in measurable degradation of soil or water quality; and

(2) A commercially available non-synthetic (natural) substance is selected in preference to an allowed synthetic substance if the two substances are equally suitable for the intended purpose and there is no discernable difference between the two substances in terms of their effects on soil or water quality.

### § 205.4 [Reserved]

## Organic Crop Production Requirements

### § 205.5 Land requirements.

(a) Any field or farm parcel from which organically produced crops are intended to be harvested shall:

(1) Have had no prohibited substances, as delineated in the categories of substances prohibited for use in organic farming and handling set forth in § 205.21, applied to it for a period of three years immediately preceding harvest of the crop; and

(2) Have clearly defined and identifiable boundaries.

(b) If organically managed land adjoins any area that is not under organic management, a producer shall implement, or include in the organic plan a proposal to implement, physical barriers, diversion of runoff, buffer areas or other means to prevent the possibility of unintended application of a prohibited substance to the land or contact of a prohibited substance with the land on which organically produced crops are grown.

### § 205.6 Crop rotation.

A crop rotation or other means of ensuring soil fertility and effective pest management in any field or farm parcel shall be established.

### § 205.7 Soil fertility and crop nutrient management.

(a) *Tillage and cultivation.* Tillage and cultivation implements and practices shall be selected and used in a manner that does not result in measurable degradation of soil quality.

(b) *Proper manuring.* Composted or uncomposted plant or animal materials used to replenish soil organic matter content and essential crop nutrients shall be selected according to the following order of preference, and used in a manner that does not significantly contribute to water contamination by nitrates and bacteria, including human pathogens, or result in other measurable degradation of soil or water quality:

(1) Any composted materials, except those materials provided for in paragraphs (b)(4) and (5) of this section;

(2) Any uncomposted materials of plant or animal origin, including aged, fully decomposed animal manure, that are not known to have a high soluble nutrient content or that are not prone to putrefaction.

(3) Any materials of plant or animal origin that are known to have a high soluble nutrient content or that are prone to putrefaction.

(4) Plant or animal waste materials that contain non-active residues of substances may be applied, *Provided, That* the plant or animal material is composted prior to application, and *Provided, Further That* levels of any non-active residues detected in the raw plant or animal waste materials do not increase in the soil.

(5) Chemically altered plant and animal waste materials may be applied, *Provided, That* such material appears on the National list of active synthetic substances allowed for use in organic crop production provided for in § 205.22, and *Provided, Further That* levels of any non-active synthetic residues or heavy metals detected in the plant or animal waste materials do not increase in the soil.

(c) *Providing mineral nutrients.* A substance used as a source of major nutrients or micronutrients shall be selected from the following:

(1) A non-synthetic substance of low solubility may be added to soil, including:

(i) A non-synthetic mineral having a low solubility and salt index;

(ii) A substance extracted from a plant or animal substance or from a mined mineral; and

(iii) Ash obtained from the burning of a plant or animal material, except as prohibited in paragraphs (d) (2) or (3) 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 non-synthetic substances prohibited for use in organic crop production.

(2) A highly soluble or synthetic substance may be added to soil to correct a known nutrient deficiency, *Provided, That* its use does not result in measurable degradation of soil or water quality. Highly soluble or synthetic substances include:

(i) A synthetic substance included on the National List of active synthetic substances allowed for use in organic crop production applied as a source of micronutrients, *Provided, That* the substance is not applied in a manner intended to be herbicidal;

(ii) A non-synthetic mineral that is highly soluble and has a high salt index; or

(iii) A cation balancing agent, *Provided, That* the specific cation balancing agent appears on the National List of active synthetic substances allowed for use in organic crop production if it is synthetic or of unknown origin.

(d) *Prohibited.* The following methods or substances are prohibited for use in soil fertility and crop nutrient management:

(1) The use of any fertilizer or commercially blended fertilizer that

contains an active synthetic substance not allowed for use in crop production as provided for in § 205.22, or that contains an active prohibited substance;

(2) The use of ash obtained from the disposal of manure by burning; and

(3) The burning of manure or crop residues produced on the farm as a means of disposal.

**§ 205.8 Selection and use of seeds, seedlings and planting stock.**

(a) Organically produced seeds and planting stock, including annual seedlings and transplants, shall be used, except that non-organically produced seeds and planting stock may be used to produce an organic crop when an equivalent organically produced variety is not commercially available, and *Provided, That:*

(1) Treated seeds are used only when untreated seeds of the same variety are not commercially available or unanticipated or emergency circumstances make it infeasible to obtain untreated seeds; and

(2) Untreated planting stock is selected in preference to treated planting stock whenever there is a choice.

(b) Non-organically produced planting stock to be used as planting stock 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 on a certified organic farm for a period of no less than one crop year.

(c) Prohibited. Transplants that have been treated with a prohibited substance are prohibited for use as planting stock.

**§ 205.9 Prevention and control of crop pests, weeds, and diseases.**

(a) Pests, weeds, and diseases in crops shall be prevented by practices including, but not limited to:

(1) Crop rotation or other means provided for in § 205.6;

(2) Replenishment and maintenance of soil fertility in accordance with § 205.7;

(3) Sanitation measures to remove disease vectors, weed seeds and habitat for pest organisms; and

(4) 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) If pest prevention measures provided for in paragraph (a) of this section are not effective, pest problems shall be controlled through:

(1) Augmentation or introduction of predators or parasites of the pest species;

(2) Mechanical or physical controls; or

(3) Non-synthetic, non-toxic controls such as lures and repellents.

(c) If weed prevention measures provided for in paragraph (a) of this section are not effective, weeds shall be controlled through:

(1) Mulching with fully biodegradable materials;

(2) Livestock grazing;

(3) Mechanical, heat or electrical means; or

(4) Plastic or other synthetic mulches, *Provided, That* they are removed from the field at the end of the growing or harvest season.

(d) If disease prevention measures provided for in paragraph (a) of this section are not effective, plant diseases shall be controlled through practices that suppress the spread of disease organisms, including, but not limited to, steam sterilization of growing media.

(e) If the practices provided for in paragraphs (a) through (d) of this section are not effective to prevent or control crop pests, weeds and diseases, the following substances may be used *Provided, That* its use does not result in measurable degradation of soil or water quality:

(1) Any non-synthetic biological or botanical substance, or synthetic substance that is included on the National List of active synthetic substances allowed for use in crop production, may be applied to prevent, suppress or control pests, weeds or diseases.

(2) A synthetic substance that is included on the National List of active synthetic substances allowed for use in crop production may be used to defoliate cotton.

(f) Prohibited. A synthetic carbon-based substance that functions through a cytotoxic mode of action shall not be applied for any prevention or control purpose.

**§ 205.10 [Reserved]**

**§ 205.11 Wild crop harvesting.**

(a) Any land from which a wild crop intended to be sold, labeled or represented as organic is harvested shall have had no prohibited substance, as delineated in the categories of substances prohibited for use in organic farming and handling set forth in § 205.21, applied to it for a period of three years immediately preceding the harvest of the wild crop and at any time thereafter.

(b) A wild crop shall be harvested in a manner that assures that such harvesting or gathering will not be destructive to the environment and will sustain the growth and production of the wild crop.

## Organic Livestock Production Requirements

**§ 205.12 Origin of livestock.**

(a) *Origin of livestock.* Livestock on a certified organic farm that themselves or their products are to be sold, labeled, or represented as organically produced shall have been under organic management from birth or hatching, or shall be the offspring of parents who have been under organic management, except that:

(1) *Breeder stock.* Livestock may be designated as breeder stock for offspring that are to be raised as organic livestock upon entry onto a certified facility, *Provided, That,* if such livestock is a gestating mammal, she must be brought onto the certified facility prior to the last third of pregnancy;

(2) *Dairy livestock.* Livestock may be designated as organic dairy livestock from which milk or milk products obtained therefrom can be sold, labeled or represented as organically produced, *Provided, That* she is brought onto a certified facility beginning no later than 12 months prior to the production of the milk or milk products that are to be sold, labeled or represented as organic;

(3) *Poultry.* Poultry may be designated as organic poultry from which meat or eggs obtained therefrom can be sold, labeled or represented as organically produced, *Provided, That* they are brought onto a certified facility beginning no later than the second day of life;

(4) *Livestock used for the production of non-edible livestock products.* Livestock may be designated as livestock from which skin, fur, feathers, fibers and all non-edible products obtained therefrom can be sold, labeled or represented as organically produced, *Provided, That* such livestock are brought onto a certified facility in accordance with one of the subparagraphs of paragraph (a) of this section and, *Provided, Further That* any livestock not raised under organic management from birth or hatching shall have been under organic management no less than 90 days prior to harvest of the non-edible product intended to be sold, labeled, or represented as organic; and

(5) *Other livestock.* Livestock, other than those described in paragraphs (a)(1) through (4) of this section, may be designated as organic livestock from which edible products obtained therefrom, can be sold, labeled, or represented as organically produced, if brought onto a certified facility:

(i) At any stage of life for bees;

(ii) If necessary, no later than the 15th day of life for mammalian livestock of non-organic origin to be designated as organic slaughter stock for the production of meat; or

(iii) No later than the earliest commercially available stage of life for livestock types other than bees, or mammalian livestock designated as slaughter stock.

(b) *Prohibited*. The following practices are prohibited:

(1) The switching of livestock or facilities between organic and non-organic management methods for the purpose of circumventing any provision of this part; and

(2) The use of hormones for breeding purposes.

**§ 205.13 Livestock feed.**

(a) *Feeding of livestock*. (1) Agricultural products, including pasture and forage, that are organically produced and, if applicable, organically handled in accordance with the Act and the regulations in subpart B of this part shall comprise the total feed ration of livestock under organic management, *Provided, However, That* if necessary:

(i) Livestock, other than as provided for in paragraphs (a)(1)(ii) through (iv) of this section, may receive a maximum of 20 percent of the total feed ration in a given year that is not organically produced;

(ii) The Administrator may authorize the use of non-organic feed in addition to the amount provided for in paragraph (a)(1)(i) of this section in an emergency situation determined by the Administrator to affect the commercial availability of organic feed;

(iii) An entire distinct herd of dairy livestock that is converted to organic management for the first time may be provided with non-organic feed until 90 days prior to the production of milk or milk products to be sold, labeled, or represented as organic; and

(iv) Bees from which organic honey and other products are harvested shall have access to forage organically produced in accordance with the requirements specified in §§ 205.3 through 205.11 so as to comprise the predominant portion of their forage needs.

(2) Non-agricultural products provided as vitamin or mineral supplements may be used to satisfy the health requirements of livestock under organic management, *Provided, That* a synthetic supplement is included on the list of synthetic substances permitted for use in livestock production provided for in § 205.24.

(3) Synthetic amino acid additives that appear on the list of synthetic substances permitted for use in livestock production as set forth in § 205.24 may be fed to livestock under organic management only as necessary for the purpose of fulfilling the nutritional requirements of the livestock.

(b) *Prohibited*. The following substances or methods for the feeding of livestock are prohibited:

(1) The use of hormones or growth promoters whether implanted, injected, or administered orally;

(2) The use of the following for the purpose of stimulating the growth or production of the livestock:

(i) Antibiotics or other animal drugs;

(ii) Synthetic amino acid additives or synthetic trace elements fed above levels needed for adequate nutrition; and

(3) The feeding of plastic pellets for roughage, feed formulas containing urea, or the refeeding of manure.

**§ 205.14 Livestock health care.**

(a) The health of livestock under organic management shall be maintained by the implementation of preventive measures, including, but not limited to:

(1) Providing diverse feedstuffs;

(2) Establishing appropriate housing, pasture conditions and sanitation practices so as to minimize the occurrence and spread of diseases and parasites;

(3) Administering veterinary biologics, vitamins and minerals; and

(4) Selecting species and types of livestock with regard to suitability for site-specific conditions and resistance to prevalent diseases and parasites.

(b) If the preventive measures provided for in paragraph (a) of this section are not effective in maintaining livestock health, an animal drug may be administered to any animal at any time of life, except as prohibited by paragraph (d) of this section, and *Provided, That*:

(1) Animal drugs, other than animal drugs administered topically or parasiticides, may be administered to mammals intended as organic slaughter stock only within the first 21 days of life; and

(2) Animal drugs, other than animal drugs administered topically or parasiticides, may be administered to livestock intended as organic slaughter stock, other than mammals, only within the first 7 days after arrival onto a certified facility.

(c) A product from organic livestock to which an animal drug has been administered shall be obtained and thereafter sold, labeled, or represented as organic only after the producer has determined that the animal has fully recovered from the condition(s) being treated, but in no case shall that time be less than the withdrawal period specified on the label or labeling of the animal drug or as required by the veterinarian.

(d) Prohibited. The following livestock health care methods are prohibited:

(1) Administering any animal drug, other than vaccinations, in the absence of illness;

(2) The routine use of synthetic internal parasiticides; and

(3) The subtherapeutic use of antibiotics.

**§ 205.15 Livestock living conditions and manure management.**

(a) The following living conditions shall be adequately provided, as appropriate to the species, to promote livestock health:

(1) Protection from the elements;

(2) Space for movement;

(3) Clean and dry living conditions;

(4) Access to outside; and

(5) Access to food and clean water.

(b) If necessary, livestock may be maintained under conditions that restrict the available space for movement or their access to the outside, *Provided, That* the other living conditions specified in paragraph (a) of this section are adequate to maintain their health without the use of animal drugs, except as provided in § 205.14(b).

(c) Manure management practices used to maintain any area in which livestock are housed, pastured or penned shall be implemented in a manner that:

(1) Does not result in measurable degradation of soil quality;

(2) Does not significantly contribute to contamination of water by nitrates and bacteria, including human pathogens;

(3) Optimizes recycling of nutrients; and

(4) Does not include burning or any practice inconsistent with the provisions of § 205.14(a)(2).

## Organic Handling Requirements

**§ 205.16 Product composition.**

(a) For an agricultural product, including a raw agricultural product, sold, labeled, or represented as organic:

(1) Organically produced agricultural products shall comprise 100 percent of the total weight of the finished product, excluding water and salt, except that not more than five percent of the total weight of the finished product, excluding water and salt, may consist of one or more of the following ingredients that are included on the National List:

(i) Non-agricultural substances allowed as ingredients in or on processed products sold, labeled, or represented as organic or made with certain organic ingredients, provided for in § 205.26; and

(ii) Non-organically produced agricultural products allowed as ingredients in or on processed products sold, labeled, or represented as organic or made with certain organic ingredients, provided for in § 205.27.

(2) An ingredient intended to be used in a processed product sold, labeled, or represented as organic shall be selected according to the following order of preference:

(i) An organically produced agricultural product, if commercially available, shall be selected for use as an ingredient in preference to a non-organically produced agricultural product or a non-agricultural ingredient included on the National List;

(ii) A non-organically produced agricultural product, if commercially available, shall be selected for use as an ingredient in preference to a non-agricultural ingredient allowed on the National List; and

(iii) A non-organically produced agricultural product or a non-agricultural ingredient included on the National List that is extracted without the use of a synthetic volatile solvent or which does not contain propylene glycol as a carrier, if commercially available, shall be selected in preference to a product or ingredient that is extracted with a synthetic volatile solvent or which contains propylene glycol as a carrier.

(b) For an agricultural product sold, labeled, or represented as made with certain organic ingredients on the principal display panel:

(1) Organically produced agricultural products shall comprise at least 50 percent, but less than 95 percent, of the total weight of the finished product, excluding water and salt;

(2) The percentage of the total weight of the finished product, excluding water and salt, that is not comprised of organically produced agricultural products shall consist of one or more of the following ingredients:

(i) Non-agricultural substances allowed as ingredients in or on processed products sold, labeled, or represented as organic or made with certain organic ingredients, provided for in § 205.26; and

(ii) Non-organically produced agricultural products allowed as ingredients in or on processed products sold, labeled, or represented as organic or made with certain organic ingredients, provided for in § 205.27; and

(3) The finished product shall have been produced in compliance with §§ 205.16 through 205.19 of this subpart, except that the provisions set forth in §§ 205.16 (a) and (c) shall not apply.

(c) Multi-ingredient agricultural products that only represent the organic nature of such ingredients in the ingredients statement and which themselves are not sold, labeled or represented as organic or made with certain organic ingredients shall not be subject to the provisions of this subpart, except for the provisions for prevention of commingling and contact of organic products by prohibited substances, as set forth in § 205.19, with respect to any organically produced ingredients.

(d) Organic and non-organic forms of the same agricultural ingredient shall not be combined in a product sold, labeled, or represented as organic or made with certain organic ingredients if the ingredient is represented as organic in the ingredient statement.

(e) The addition of the following substances to any agricultural product intended to be sold, labeled, or represented as organic or made with certain organic ingredients is prohibited:

(1) Any sulfites, nitrates, or nitrites; or

(2) Water that does not meet the requirements of the Safe Drinking Water Act. (42 U.S.C. 300(f) *et seq.*).

**§ 205.17 Processing practices.**

(a) Mechanical or biological methods, including cooking, baking, heating, drying, mixing, grinding, churning, separating, extracting, cutting, fermenting, eviscerating, preserving, dehydrating, freezing or chilling shall be used to process an agricultural product intended to be sold, labeled, or represented as organic or made with certain organic ingredients for the purpose of retarding spoilage or otherwise preparing the agricultural product for market; *Provided, However, That* if necessary an incidental additive, except for volatile synthetic solvents prohibited in paragraph (b)(3) of this section, may be used to process such agricultural product.

(b) Prohibited. The following methods and substances are prohibited for use in the processing and preparation of a raw agricultural product, and on a finished agricultural product, intended to be sold, labeled, or represented as organic or made with certain organic ingredients:

(1) Storing, coating or packaging in a storage container or bin, including packages or packaging materials, that contain a synthetic fungicide, preservative, or fumigant;

(2) The use or reuse of any bag or container that had previously been in contact with any substance in such a manner as to compromise the organic integrity of any products; and

(3) The use of a volatile synthetic solvent.

**§ 205.18 Prevention and control of facility pests.**

(a) Pest occurrence in a certified organic handling facility shall be prevented by methods including, but not limited to:

(1) Measures to remove potential habitat of, or access to handling facilities by, pest organisms; and

(2) Management of environmental factors, such as temperature, light, humidity, atmosphere and air circulation to prevent pest reproduction.

(b) If pest prevention measures provided in paragraph (a) of this section are not effective, facility pest problems shall be controlled through:

(1) Augmentation or introduction of predators or parasites for the pest species;

(2) Mechanical or physical controls including, but not limited to, traps, light or sound; or

(3) Non-toxic, non-synthetic controls, such as lures and repellants.

(c) If pest prevention or control measures provided for in paragraphs (a) and (b) of this section are not effective, any substance may be used to control pests, *Provided, That:*

(1) The substance is approved for its intended use by the appropriate regulatory authority; and

(2) The substance is applied in a manner that prevents such substance from contacting any ingredient or finished product intended to be sold, labeled, or represented as organic or made with certain organic ingredients.

**§ 205.19 Prevention of commingling and contact with prohibited substances.**

A certified handling operation, and a handling operation that is exempt or excluded from certification in accordance with § 205.202(a)(3) or § 205.202(b) of subpart D, shall establish, as appropriate, adequate safeguards during the handling, storage and transportation of organically produced products in order to:

(a) Prevent the commingling of organic and non-organic products; and

(b) Assure that organic products and certified facilities are protected from contact with prohibited substances.

## The Use of Active Synthetic Substances, Non-Synthetic Substances, Non-Agricultural (Non-Organic) Substances and Non-Organically Produced Ingredients in Organic Farming and Handling Operations, Including the National List of Allowed and Prohibited Substances

### § 205.20 General rules for categories of substances and ingredients permitted for use in organic farming and handling.

(a) Any active synthetic substance or ingredient on the National List, as set forth in §§ 205.22, 205.24, 205.26 and 205.27, is permitted for use in a certified organic farming or handling operation in accordance with the Act and the regulations in part 205.

(b) Any other non-prohibited substance or ingredient may be used in a certified organic farming or handling operation if used in accordance with the Act and all other applicable provisions of part 205. These substances or ingredients are:

(1) A non-synthetic substance that is not included on the National List as a prohibited non-synthetic substance in either § 205.23 or § 205.25;

(2) A synthetic substance or device that does not function as an active ingredient or substance in a system of organic farming and handling, or as an active ingredient in a processed product; and

(3) A formulated product containing inert ingredients (substances) that is used in a certified organic farming operation, *Provided, That* the formulated product does not contain:

(i) Any active ingredient prohibited under § 205.21; and

(ii) Any synthetic inert ingredient classified by EPA as an inert of toxicological concern.

### § 205.21 General rules for categories of substances and ingredients prohibited for use in organic farming and handling.

The following synthetic and non-synthetic substances and ingredients are prohibited for use in a certified organic farming or handling operation:

(a) An active synthetic substance that is not included on the National List as an allowed synthetic substance in either § 205.22 or § 205.24, including any synthetic carbon-based substance that functions through a cytotoxic mode of action;

(b) A non-agricultural substance, used as an ingredient in or on a processed product labeled as organic or made with certain organic ingredients, that is not included on the National List as a non-agricultural substance in § 205.26;

(c) A non-synthetic substance that is included on the National List as a prohibited non-synthetic substance, in either § 205.23 or § 205.25;

(d) A formulated product that contains any synthetic inert ingredient classified by EPA as an inert of toxicological concern; and

(e) A fertilizer or commercially blended fertilizer that contains an active synthetic substance not allowed for use in crop production as provided for in § 205.22, or that contains an active prohibited substance.

## The National List of Allowed and Prohibited Substances

## Crop Production Substances

### § 205.22 Active synthetic substances allowed for use in organic crop production.

The following may be used in accordance with any restrictions specified in this section and §§ 205.3 through 205.10 of subpart B:

(a) Horticultural oils may be used as insect pest smothering or suffocating agents. Horticultural oils include:

(1) Dormant oils;

(2) Suffocating oils; and

(3) Summer oils.

(b) Soaps may be used as insecticides, algicides, de-mossers, large animal repellants, and herbicides.

(c) Production aids may be used as follows:

(1) Acetic acid may be used as a pesticide;

(2) Pheromones may be used as insect mating disruptors;

(3) Vitamins may be used as growth promoters and rooting facilitators;

(4) Vitamin D3 may be used as a rodenticide;

(5) Amino acids may be used as growth promoters;

(6) Antibiotics may be used as pesticides;

(7) Magnesium sulfate may be used as a cation balancing agent;

(8) Newspaper and other recycled paper products may be used as mulch and compost feedstocks;

(9) Piperonyl butoxide may be used as a synergist;

(10) Potassium sulfate may be used as a cation balancing agent; and

(11) Boric Acid may be used as a pesticide.

(d) Toxins, derived from genetically engineered bacteria (or other microorganisms) that are not released live into the agroecosystem, may be used as pesticides.

(e) Copper and sulfur compounds as follows may be used as pesticides:

(1) Bordeaux mixes;

(2) Copper, including fixed coppers exempt from tolerance by EPA: hydroxides, basic sulfates, oxychlorides, and oxides;

(3) Lime sulfur, including calcium polysulphide, and

(4) Sulfur dioxide.

(f) Micronutrient minerals as follows may be used:

(1) Chelated micronutrients;

(2) Soluble boron products; and

(3) Sulfates, carbonates, oxides, or silicates of zinc, iron, manganese, molybdenum, selenium, cobalt or copper.

(g) Minerals as follows may be used as defoliants in organic fiber production:

(1) Calcium chloride;

(2) Magnesium chloride;

(3) Sodium chlorate; and

(4) Sodium chloride.

### § 205.23 Non-synthetic substances prohibited for use in organic crop production.

None.

## Livestock Production Substances

### § 205.24 Active synthetic substances allowed for use in organic livestock production.

Any substance in the following categories may be used in organic livestock production in accordance with any restrictions specified in this section and §§ 205.3, and 205.12 through 205.15 of subpart B:

(a) Trace minerals;

(b) Nutrients and dietary supplements;

(c) Feed additives, *Provided, That* they are also included in § 205.26;

(d) Animal drugs and other animal health care substances;

(e) Vaccines and biologics; and

(f) Pest control substances, *Provided, That* they are also included in § 205.22.

### § 205.25 Non-synthetic substances prohibited for use in organic livestock production.

None.

## Processed Product Substances

### § 205.26 Non-agricultural (non-organic) substances allowed as ingredients in or on processed products labeled as organic or made with certain organic ingredients.

The following non-agricultural ingredients may be used only in accordance with any restrictions specified in §§ 205.3, and 205.16 through 205.19 of subpart B:

**Non-agricultural Substances Allowed as Ingredients in or on Processed Products Labeled as Organic or Made With Certain Organic Ingredients**

Agar-agar
Alginates
Alginic Acid
Aluminum-free baking powder
Ammonium bicarbonate

Ammonium carbonate
Ascorbic acid
Beeswax
Calcium carbonate
Calcium chloride
Calcium citrate
Calcium sulfate
Calcium hydroxide
Calcium phosphates (mono, di and tribasic)
Candelilla wax
Carbon dioxide
Carnauba wax
Carrageenan
Chymosin
Citric acid
Colors, non-synthetic
Cultures, dairy, non-synthetic
Dipotassium phosphate
Enzymes, non-synthetic
Glycerin
Gums
Lactic acid
Lecithin, unbleached or bleached
Magnesium chloride
Magnesium carbonate
Magnesium stearate
Magnesium sulfate
Mono and diglycerides
Natural flavoring agents, non-synthetic
Nutrient supplements
Pectin, low-methoxy and native (high-methoxy)
Potassium acid tartrate
Potassium carbonate
Potassium chloride
Potassium citrate
Potassium phosphate
Silicon dioxide
Sodium bicarbonate
Sodium carbonate
Sodium citrate
Sodium phosphates (mono, di and tribasic)
Sulfur dioxide (not to exceed 100 ppm when used in wine)
Tartaric acid
Tocopherols
Whey and its fractions
Wood rosin
Xanthan gum
Yeast autolysate, non-synthetic
Yeast, bakers, non-synthetic
Yeast, brewers, non-synthetic
Yeast, nutritional, non-synthetic
Yeast, smoked, non-synthetic

**§ 205.27 Non-organically produced agricultural products allowed as ingredients in or on processed products labeled as organic or made with certain organic ingredients.**

Any non-organically produced agricultural product may be used in accordance with any restrictions specified in § 205.16.

**§ 205.28 Amending the National List.**

(a) Purpose of petition process. Any person may petition the NOSB for the purpose of having a substance evaluated for recommendation to the Secretary for inclusion on the National List.

(b) A petition may be submitted to: Program Manager, USDA/AMS/TM/NOP, Room 2945 South Building, P.O. Box 96456, Washington, D.C. 20090–6456.

(c) Categories of substances. A substance may be added to the National List only in the following categories:

(1) Active synthetic substances allowed for use in organic crop or livestock production;

(2) Non-synthetic substances prohibited for use in organic crop or livestock production; or

(3) Non-agricultural substances allowed for use as ingredients in or on processed products labeled as organic or made with certain organic ingredients.

(d) Content of the petition. A person should include in the petition as much of the following information as is available to the person for each specific substance:

(1) Background information about the following:

(i) Substance name (generic or common name);

(ii) Manufacturer's name, address, and telephone number, if different from the petitioner's;

(iii) Area of intended or current use (crops, livestock, or handling);

(iv) Current or intended use of the substance;

(v) Sources from which the substance is derived;

(vi) Description of the manufacturing or processing procedures for the substance; and

(vii) Summary of previous reviews of the substance by State or private organic certification programs or other organizations that review materials.

(2) Regulatory Information (as applicable) including, but not limited to:

(i) EPA registration (include the registration number);

(ii) Food and Drug Administration registration;

(iii) State regulatory authority registration (include State registration number);

(iv) Chemical Abstract Service (CAS) number or other product number; and

(v) Labels of products that contain the petitioned substance.

(3) Research, characteristics, and safety information:

(i) Detailed findings relevant to the following characteristics of the substance:

(A) Detrimental chemical interactions with other materials used in organic production;

(B) Toxicity and persistence in the environment;

(C) Environmental contamination resulting from its use and manufacture;

(D) Effects on human health; and

(E) Effects on soil organisms, crops and livestock;

(ii) Bibliographies of pertinent research on the substance;

(iii) Material Safety Data Sheet (MSDS);

(iv) Information on the substance obtained from the National Institute of Environmental Health Studies; and

(v) Information on whether all or part of any submission is believed to be confidential commercial information, and if so, what parts, and the basis for the belief that it is confidential commercial information and should not be released to the public.

(4) Statements of justification for placement on the National List, as follows:

(i) If petitioning for approval of an active synthetic substance or non-agricultural ingredient, state the reasons why the substance is necessary to the production or handling of the organic product;

(ii) If petitioning for prohibition of a non-synthetic substance, state the reasons why the use of the non-synthetic substance should not be permitted in organic farming or handling; or

(iii) Describe alternative substances or alternative cultural methods that could be utilized in place of the substance, summarize effects on the environment, human health, and the agroecosystem, and describe its compatibility with a system of sustainable agriculture.

(e) The Secretary or the NOSB may request additional information from the petitioner following receipt of the initial petition if necessary to evaluate the substance.

**§§ 205.29 through 205.99 [Reserved]**

## Subpart C—Labels, Labeling, and Market Information

**§ 205.100 Agricultural products in packages sold, labeled, or represented as organic.**

(a) Agricultural products in packages described in § 205.16(a) of subpart B that are sold, labeled, or represented as organic may use the terms as described below:

(1) The term organic on the principal display panel to modify the name of the product;

(2) The term organic in the ingredients statement to modify the name of an ingredient organically produced and handled in accordance with the Act and the regulations in this part;

(3) On the principal display panel, the following terms or marks:

(i) The USDA seal described in § 205.107; and

(ii) A seal representing a State organic program approved by the Secretary, as

provided for in § 205.402 of subpart F; and

(4) On the information panel, the following terms or marks:

(i) The term organic used to modify the name of the product;

(ii) The USDA seal described in § 205.107;

(iii) A seal representing a State organic program approved by the Secretary, as provided for in § 205.402 of subpart F; and

(iv) A certifying agent's name, seal, logo, or other identification which represents that the farm, wild crop harvesting, or handling operation that produced or handled the finished product is a certified operation.

(5) On other panels of the label, labeling and market information: Any term or mark identified in paragraph (a)(4) of this section may be used on package panels of labels not covered by paragraph (a)(3) of this section as well as on any labeling or market information.

(b) [Reserved]

**§ 205.101 Agricultural products in packages sold, labeled, or represented as made with certain organic ingredients.**

(a) Agricultural products in packages described in § 205.16(b) of subpart B that are sold, labeled, or represented as made with certain organic ingredients shall use the terms and marks as described below:

(1) The statement made with certain organic ingredients on the principal display panel; and

(2) The term organic in an ingredients statement to modify the name of an ingredient organically produced and handled in accordance with the Act and the regulations in this part.

(b) Agricultural products in packages described in § 205.16(b) of subpart B that are sold, labeled or represented as made with certain organic ingredients may use the terms and marks as described below:

(1) On the information panel, the following terms or marks:

(i) The statement made with certain organic ingredients; and

(ii) A certifying agent's name, seal, logo, or other identification which represents that the farm, wild crop harvesting, or handling operation that produced or handled the finished product is a certified operation.

(2) On other panels of the label, labeling and market information: Any term or mark identified in paragraph (b)(1) of this section may be used on package panels of labels not covered by paragraphs (a) or (b)(1) of this section, as well as on labeling or market information.

**§ 205.102 Multi-ingredient agricultural products that only represent the organic nature of such ingredients in the ingredients statement.**

Any agricultural product composed of more than one ingredient, no matter the percentage organic ingredients it contains, that only represents in an ingredients statement the organic nature of its ingredients, may use the term organic in the ingredients statement of a label, labeling, or market information, to modify the name of an ingredient that is organically produced and handled in accordance with the Act and the regulations in this part, without the finished product having to comply with the certification requirements set forth in subpart D of this part, *Provided, That* the record keeping requirements of § 205.202(c) of subpart D are satisfied, and *Provided, Further That* the product itself is not sold, labeled, or represented as organic or made with certain organic ingredients.

**§ 205.103 Use of terms or statements that directly or indirectly imply that a product is organically produced and handled.**

Any label, labeling or market information that implies directly or indirectly that a product, including an ingredient, is organically produced and handled may be used only for an agricultural product, including an ingredient, that has been produced and handled in accordance with the Act and the regulations in this part.

**§ 205.104 Informational statements prohibited.**

The use of the following informational statements on the principal display panel and the ingredients statement of products sold, labeled, or represented as organic or made with certain organic ingredients, or products described in § 205.102 that contain organic ingredients, is prohibited:

(a) The phrase one hundred percent, stated in letters, numbers or symbols, used as part of any phrase or sentence that includes the term organic;

(b) A statement of the percentage of organic ingredients contained in a product; and

(c) The phrase organic when available or a term of similar meaning or intent.

**§ 205.105 Agricultural products in a form other than packages that are sold, labeled or represented as organic or made with certain organic ingredients.**

(a) Agricultural products described in § 205.16(a) of subpart B, in a form other than packages, that are sold or represented as organic at the time of retail sale may use the terms and marks as described below:

(1) The term organic on the retail display label, labeling or display container to modify the name of the product;

(2) The term organic in the ingredients statement to modify the name of an ingredient organically produced and handled in accordance with the Act and the regulations in this part; and

(3) A clearly recognizable organic identification mark(s) or term(s), selected from the following, located in plain view on the shipping container:

(i) The term organic used to modify the name of the product;

(ii) The USDA seal as described in § 205.107;

(iii) A seal representing a State organic program approved by the Secretary as provided for in § 205.402 of subpart F; or

(iv) The certifying agent's name, seal, logo, or other identification which represents that the farm, wild crop harvesting, or handling operation that produced or handled the finished product is a certified operation.

(b) Agricultural products described in § 205.16(b) of subpart B, in a form other than packages, that are sold, labeled, or represented as made with certain organic ingredients shall use the terms and marks as described below:

(1) The statement made with certain organic ingredients on the retail display label, labeling or display container;

(2) The term organic in the ingredients statement to modify the name of an ingredient organically produced and handled in accordance with the Act and the regulations in this part; and

(3) The statement made with certain organic ingredients, which may be accompanied by the certifying agent's name, seal, logo, or other identification, located in plain view on the shipping container.

**§ 205.106 Agricultural products produced on an exempt farm or handling operation.**

An agricultural product produced or processed on a farm, wild crop harvesting, or handling operation that annually sells no more than $5,000 in value of agricultural products and which has not been certified, shall not:

(a) Display the USDA seal, or any certifying agent's name, seal, logo, or other identification which represents that the farm, wild crop harvesting, or handling operation that produced or handled the product is a certified operation; or

(b) Be identified as an organic ingredient in a product produced or processed on a farm or handling operation that annually sells more than $5,000 in value of agricultural products.

**§ 205.107 USDA seal.**

(a) The USDA seal described in paragraphs (b) and (c) of this section shall be used in accordance with the provisions of this subpart and shall be used only on agricultural products (raw or processed) described in § 205.16(a) of subpart B that are sold, labeled, or represented as organic and which are produced and handled on certified operations.

(b) The USDA seal used on a label, labeling, or market information of an agricultural product shall replicate the form and design of the example in figure 1.

**Figure 1**

(c) Except as otherwise authorized by the Secretary, the USDA seal shall be:

(1) Printed on a light background with the wording and design in a dark color or on a dark background with the wording in a light color, *Provided, That* such design is legible and conspicuous on the material upon which it is printed; or

(2) Printed in a standard four color label as follows: concentric circles with arrows and diagonal on a light background with black letters; interior globe cyan blue with green continents; interior triangular sections green; exterior triangle (border) yellow; and both interior and exterior of triangular border edged with black.

**§§ 205.108 through 205.200 [Reserved]**

## Subpart D—Certification

**§ 205.201 What has to be certified.**

(a) Each farm, wild crop harvesting operation, or handling operation that produces or handles crops, livestock, livestock products, or other agricultural products that are, or that are intended to be, sold, labeled or represented as organic or made with certain organic ingredients must be certified according to the provisions of subpart D of this part, and must meet all other applicable requirements of this part, *Provided, That* any handling operation that provides handling services to fewer than three certified entities that produce or handle agricultural products that are, or that are intended to be, sold, labeled or represented as organic or made with certain organic ingredients, would not be required to be separately certified apart from the operations for which it provides such services, and *Provided, Further That* none of the operations set forth in paragraph (a) of this section must be certified if exempt or excluded in § 205.202 of this subpart.

(b) A handling operation, or portion of a handling operation, that handles only agricultural products that are, or that are intended to be, sold, labeled or represented as made with certain organic ingredients is exempt from the requirement to select a commercially available non-synthetic substance in preference to an allowed synthetic substance, as set forth in § 205.3(b)(2) of subpart B.

**§ 205.202 Exemptions and exclusions from certification.**

(a) *Exemptions.* (1) A farm, wild crop harvesting, or handling operation that sells agricultural products as organic or made with certain organic ingredients, but which annually sells no more than $5,000 in value of agricultural products, is exempt from complying with the requirements in this part, except for the applicable recordkeeping provisions delineated in paragraph (c)(1) of this section and the applicable labeling provisions set forth in subpart C of this part.

(2) A retail operation, or portion of a retail operation, that only 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 handles only agricultural products that contain less than 50 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 commingling and contact of organic products by prohibited substances set forth in § 205.19 of subpart B with respect to any organically produced ingredients used in an agricultural product; and

(ii) The applicable provisions for labeling set forth in subpart C of this part.

(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 § 205.19 of subpart B with respect to any organically produced products, if such operation, or portion of the operation, sells only agricultural products labeled as organic or made with certain organic ingredients 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 restaurant or other similar food-service type establishment that processes ready-to-eat food from organic agricultural products and which does not enclose the food in a package or container labeled or represented to the consumer as organic or as made with certain organic ingredients is excluded from the requirements of this part.

(3) A retail operation, or portion of a retail operation, that processes only agricultural products that are previously labeled as organic or made with certain organic ingredients before receipt or acquisition by the retail operation, is excluded from the requirements in this part, *Provided, That* the operation meets both of the following requirements:

(i) The agricultural product is processed by the retail operation, or portion of the retail operation, in the course of normal retail business practice solely for the purpose of offering the product to a consumer; and

(ii) The agricultural product offered to the consumer:

(A) Has not been created by the retail operation by combining two or more ingredients into a single product that is then labeled or represented by the retail operation as organic or as made with certain organic ingredients; and

(B) Has not been repackaged by the retail operation so as to provide a new label or labeling for the repackaged product which represents it as organic or made with certain organic ingredients.

(c) *Records to be maintained by exempt or excluded operations.* Any operation that is exempt or excluded from certification, as specified in paragraphs (a) or (b) of this section, shall maintain records as follows and shall allow representatives of the Secretary and the applicable governing State official access to these records to determine compliance with the applicable regulations set forth in this part:

(1) *Small farm or handling operations.* An operation that is exempt from certification pursuant to paragraph (a)(1) of this section shall maintain records for no less than one calendar year to substantiate that the operation did not

sell agricultural products in excess of $5,000 in value during the previous calendar year;

(2) *Handling operations exempt or excluded from certification.* A handling operation that is exempt from certification pursuant to (a)(3) of this section, or excluded from certification pursuant to (b)(1) of this section, shall maintain records as follows:

(i) Documentation as sufficient to verify the source and quantity of organic products received and that all organic products and ingredients have been handled in accordance with § 205.19 to prevent commingling and contact with prohibited substances shall be maintained for no less than one year from the date of receipt by the operation of a product, including ingredients, labeled as organic or made with certain organic ingredients; and

(ii) Documentation as sufficient to verify the destination and quantity of a product shipped from the operation shall be maintained for no less than one year from the date of shipping a product labeled as organic or as made with certain organic ingredients, or which contains any organic ingredients.

**§ 205.203 General requirements for certification.**

In order to receive and maintain organic certification under the Act and the regulations in this part, a farm, wild crop harvesting or handling operation shall:

(a) Comply with the applicable organic production and handling requirements of the Act and the regulations in this part;

(b) Establish, implement, and update annually an organic plan that is submitted to an accredited certifying agent as provided for in § 205.205;

(c) Permit an annual on-site inspection by the certifying agent, as provided for in § 205.208 through 205.211;

(d) Maintain all records applicable to the organic operation for a period of not less than five years from the date of creation of the record, and allow authorized representatives of the Secretary, the applicable governing State official, and the certifying agent access to such records to determine compliance with the Act and the regulations in this part, as provided for in § 205.216;

(e) Submit the applicable fees to the certifying agent, as provided for in § 205.422 of subpart F; and

(f) Immediately notify the certifying agent concerning:

(1) Any application of a prohibited substance to any field, farm unit, site, facility, livestock, or product that is part of a certified operation; and

(2) Any 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

**§ 205.204 Applying for certification.**

A person seeking certification of a farm, wild crop harvesting, or handling operation under this subpart shall submit a request for certification to the certifying agent. The request shall include the following information:

(a) An organic plan, as required in § 205.205;

(b) A statement of compliance, as required in § 205.206;

(c) The applicant's business name, address, phone and fax numbers, and, in addition, the names of personnel responsible for maintaining compliance with the Act and the regulations in this part; and

(d) 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.

**§ 205.205 Organic plan.**

A certification applicant shall submit to the certifying agent an organic plan that identifies, as applicable to its operation:

(a) *General.* Practices previously implemented, and intended to be implemented and maintained, to establish a system of organic farming and handling that complies with the applicable crop, livestock, wild crop harvesting, and handling requirements, provided in §§ 205.3, 205.5 through 205.9, and 205.11 through 205.28 of subpart B.

(b) *Farm operations.* The following information shall be submitted concerning a farm operation:

(1) The total acreage of the operation, the types of crops grown and livestock raised, and any on-farm processing activities;

(2) Map(s) of each field and farm parcel for which certification is requested, showing, for each parcel: A list of crops intended to be planted and/or managed; identification name or number; size; location; boundaries; any significant features that may assist the certifying agent to identify the field or parcel; identification of any adjoining land to which a prohibited substance may be applied; and the location of any facility used for livestock housing, storage, or post-harvest handling;

(3) A history of the crops grown and production inputs used for each field or farm parcel for which certification is requested, which covers the three year period immediately preceding the date of the request for certification;

(4) A list of each type of agricultural product produced on the farm that is intended to be sold, labeled or represented as organic or made with certain organic ingredients;

(5) A list of each substance intended to be used as a production input, indicating: its source, anticipated quantity to be used, and location(s) where it will be used;

(6) A list of any seeds or planting stock intended to be purchased, indicating: its source, approximate quantity to be used and whether it is treated, untreated, or organically produced;

(7) A list of all livestock to be maintained by the operation and to be purchased in the certification year for the production of agricultural products to be sold, labeled or represented as organic, or as made with certain organic ingredients, indicating: their source, the estimated number to be maintained and purchased, their intended use (e.g. slaughter stock, egg production), and whether the livestock originate from a certified organic livestock operation;

(8) A list of all livestock feed and feed supplements intended to be purchased, indicating: its source, estimated amount to be purchased, and what, if any, portion of the feed to be purchased will not be organically produced;

(9) The name of a veterinarian from whom animal drugs or a prescription for animal drugs are obtained, if applicable, and a list of any animal drugs that may be used, including their sources, estimated amount of each animal drug to be used, and the types of livestock (such as hogs, fish, or chickens) to which such drugs are to be administered; and

(10) A list of all post-harvest handling or processing methods and facilities to be used by the applicant.

(c) *Split operations.* The following information shall be submitted, as applicable, concerning a farm or wild crop harvesting operation that produces both organic and non-organic products:

(1) A list and anticipated quantities of livestock and any other agricultural product intended to be grown, raised or harvested both organically and non-organically;

(2) A list, indicating expected quantity and location, of each substance or practice prohibited for organic production under the Act and the regulations in this part that may be used on a non-certified portion of the farm; and

(3) A list of the measures used and that will be used to prevent

commingling of organic and non-organic products, and contact of organic field units, storage areas and packaging to be used for organic products, and organic products, including livestock, with prohibited substances.

(d) *Wild crop harvesting operations.* The following information shall be submitted concerning a wild crop harvesting operation:

(1) A map(s) of each area from which wild crops are designated to be harvested in the certification year;

(2) Information about the ownership of, and evidence of permission to harvest from, the area from which wild crops are designated to be harvested;

(3) A history of each designated area so as to demonstrate that no prohibited substance has been applied within three years prior to the initial harvest of a wild crop to be sold, labeled or represented as organically produced;

(4) A list of each species of plant(s) to be harvested, including: its botanical name(s); the part of the plant to be harvested (e.g., roots, flowers, fruits); the quantity expected to be harvested in the certification year; dates of the harvest season; and any available information on the impact of the intended harvest on the environment and on the growth and production of the wild crop;

(5) A list of each type of wild product to be sold or represented as an organic product, indicating the anticipated quantity of each type; and

(6) A list of all post-harvest handling or processing methods and facilities to be used by the applicant.

(e) *Handling operations.* The following information shall be submitted concerning a handling operation:

(1) A brief, general description of the type of handling operation and the processing, manufacturing, or other handling procedures used and intended to be used;

(2) A list of the structural pest management methods used or intended to be used;

(3) A list, including the quantity, of each product intended to be handled and sold or represented as organic, and as made with certain organic ingredients;

(4) A list of each non-organically produced product or type of product, if any, intended to be handled or sold;

(5) The measures that will be used to prevent the commingling of organic and non-organic products and ingredients and the contact of storage areas and packaging to be used for organic products, and organic products, with prohibited substances; and

(6) A list of each ingredient, incidental additive, and type of packaging material intended to be used as a production input in the handling of organic products specifying for each item listed, as applicable:

(i) Whether it is an organic agricultural product, a non-organic agricultural product, or a non-agricultural ingredient;

(ii) The estimated quantity to be used;

(iii) The source or manufacturer;

(iv) The country of origin for each imported organic agricultural product or ingredient; and

(v) The source of water used as an ingredient in any organic product, specifying whether it meets the Safe Drinking Water Act requirements (42 U.S.C. 300(f) *et seq.*).

**§ 205.206 Statement of compliance.**

A person seeking certification of a farm, wild crop harvesting or handling operation shall submit to the certifying agent a statement agreeing to comply with the Act and the regulations of this part, including the requirements for receiving and maintaining certification delineated in § 205.203 of this subpart.

**§ 205.207 Preliminary evaluation of an application for certification.**

A certifying agent shall, with respect to any applicant for certification:

(a) Make a preliminary evaluation of the operation's compliance and ability to comply with the applicable requirements of subpart B of this part;

(b) Verify that an applicant who previously applied to another certifying agent and received a notification of non-compliance, pursuant to § 205.215(a) of this subpart, has submitted documentation to support the correction of any deficiencies identified in such notification, as required in § 205.215(b) of this subpart; and

(c) Arrange to conduct an on-site inspection of the operation if the preliminary evaluation reveals that the farm, wild crop harvesting or handling operation may be in compliance with the applicable requirements of subpart B of this part.

**§ 205.208 Arranging for inspections.**

(a) A certifying agent shall arrange to conduct an initial on-site inspection of each farm, facility, and site that is included in an operation for which certification is requested, and an on-site inspection of each certified operation annually thereafter, for the purpose of determining whether to approve the request for certification or determining whether the certification of the operation should continue.

(b) The initial on-site inspection shall be conducted within a reasonable time following a favorable preliminary evaluation of an application for certification in accordance with § 205.207.

(c) The on-site inspection shall be scheduled at such time that:

(1) Land, facilities, and activities that demonstrate the operation's compliance with or capability to comply with the applicable provisions of subpart B of this part may be observed; and

(2) The applicant or an authorized representative of the applicant who is knowledgeable about the operation will be present during the inspection.

**§ 205.209 [Reserved].**

**§ 205.210 Verification of information.**

The inspection of an operation shall be sufficient to verify the operation's compliance, or ability to comply, with the Act and the regulations in this part, including verification that the information, including the organic plan, provided in accordance with §§ 205.204 or 205.217, and § 205.205, accurately reflects the practices used or to be used by the applicant for certification or by the certified operation and, in the case of an on-site inspection to evaluate continuation of certification, that the provisions of the organic plan are being implemented.

**§ 205.211 Post-inspection conference.**

The inspector shall conduct a post-inspection conference with an authorized representative of the inspected operation, and discuss observations made by the inspector regarding the compliance, or ability of the operation to comply, with the Act and the regulations in this part.

**§ 205.212 Reporting to the certifying agent.**

The certifying agent shall require that the inspector prepare and submit to the certifying agent, within thirty days of completing an inspection, a written report that describes the inspector's observations and assessments of the inspected operation's compliance, or ability to comply, with the Act and the regulations in this part.

**§ 205.213 Additional inspections.**

(a) In addition to the annual on-site inspection, required in § 205.208(a), a certifying agent may conduct an inspection of any farm, facility, or site used by a certified operation or an applicant for certification when necessary to determine compliance with the Act and the regulations in this part.

(b) The Secretary may require that additional inspections be performed for the purpose of determining compliance

with the Act and the regulations in this part.

**§ 205.214 Approval of certification.**

(a) Within a reasonable time after completion of the initial on-site inspection, a certifying agent shall review the inspection report, together with the application materials submitted pursuant to §§ 205.204 through 205.206 or § 205.217, as applicable, and shall request the applicant for certification to submit any additional information and documentation needed to determine if the certification applicant is complying, or is able to comply, with the Act and the regulations in this part.

(b) Following the receipt of any additional information and documentation submitted in accordance with paragraph (a) of this section, the certifying agent shall approve the application for certification upon a determination that:

(1) The practices and substances used or intended to be used by the applicant for certification are consistent with a system of organic farming and handling, as set forth in § 205.2 of subpart A, and comply with the applicable organic production and handling requirements, as set forth in §§ 205.3, 205.5 through 205.9, and §§ 205.11 through 205.28 of subpart B;

(2) The applicant has satisfied the general requirements for certification set forth in § 205.203;

(3) The organic plan satisfies the applicable requirements of the Act and the regulations in subpart B of this part; and

(4) The records and recordkeeping system maintained by the applicant satisfy the applicable requirements of § 205.216.

(c) Upon determining, pursuant to paragraph (b) of this section, to approve an application for certification, a certifying agent shall provide a written notification to the certification applicant's place of business, indicating in such notification restrictions or requirements, if any, imposed as a condition of certification.

(d) A notice of approval of certification sent to a certification applicant pursuant to paragraph (c) of this section shall include a certificate that states:

(1) The name of the certified operation;

(2) The effective date of the certification; and

(3) The category(ies), type(s) of products, and crop years, if applicable, covered by the certification.

**§ 205.215 Denial of certification.**

(a) If the certifying agent has reason to believe, based on a review of the information specified in § 205.214(a), that an applicant for certification is not able to comply, or is not in compliance, with the requirements of the Act and the regulations in this part, the certifying agent shall provide a written notification of non-compliance to the applicant in accordance with § 205.218(a) of this part.

(b) Following the correction of deficiencies identified in the notification issued in accordance with paragraph (a) of this section, the applicant may submit a new application for certification to any accredited certifying agent. If a new application is submitted to a certifying agent other than the agent who issued the notification of non-compliance, the certification applicant shall simultaneously inform the certifying agent who issued the notification of non-compliance that a new application has been submitted and shall identify the new certifying agent to whom it was submitted. The new application shall include documentation of actions taken by the applicant to correct the deficiencies delineated in the notification of non-compliance.

(c) If a certification applicant who receives a notification pursuant to paragraph (a) of this section does not correct the deficiencies or does not notify the certifying agent that it has submitted a new application, as provided for in paragraph (b) of this section, within the time specified in the notice of non-compliance, the certifying agent shall submit to the Administrator a notice of its recommendation to deny certification to the applicant. Upon receipt of a notice of a recommendation to deny certification, the Administrator may institute proceedings to deny certification.

**§ 205.216 Recordkeeping.**

(a) A certified operation shall maintain records concerning the production, harvesting, and handling of agricultural products that are or that are intended to be, sold, labeled or represented as organic or made with certain organic ingredients for a period of five years sufficient to demonstrate compliance with the Act and regulations in the part, and shall make such records available to authorized representatives of the Secretary, the applicable governing State official, and the certifying agent.

(b) The records that shall be maintained by the certified operation in accordance with paragraph (a) of this section shall include, but are not limited to:

(1) A list of all substances applied to fields and land that are part of the certified operation for a period of no less than three years preceding the intended or actual time of harvest of an organic crop from such fields or land;

(2) The name and address of any person, including the operator of the certified operation and employees of the certified operation, who applies and who has applied any substance to any part of the farm and any livestock or other agricultural product, including the name of the substance, and the date(s), location(s), rate(s) and method(s) of application;

(3) For each animal (or livestock management unit, such as a poultry flock or bee colony) that is, or whose products are, intended to be sold, labeled or represented as organic livestock or organic livestock products in accordance with the livestock production standards set forth in §§ 205.12 through 205.15 of subpart B:

(i) The source of the animal or livestock management unit and the date it entered the certified operation;

(ii) The amounts and sources of all animal drugs administered;

(iii) All feeds and feed supplements fed; and

(iv) The location of the field, farm unit, or facility where it is maintained, as applicable.

(4) Any information submitted to the certifying agent as part of the application for certification or as part of continuation of certification in accordance with § 205.204 or § 205.217 of this subpart, respectively; and

(5) Records sufficient to show the quantities, source of, production and handling methods used for, transfer of ownership of, and transportation of, any agricultural product, including livestock, sold, labeled or represented as organic or as made with certain organic ingredients, that is received by or shipped from the certified operation, sufficient to establish an audit trail.

(c) A farm, wild crop harvesting, handling, or other operation that is exempt or excluded from certification under §§ 205.202(a) or (b) shall maintain records as provided for in § 205.202(c).

**§ 205.217 Continuation of certification.**

(a) A certified operation shall annually submit the following information, as applicable, to the certifying agent:

(1) Any additions and changes to the information about the operation submitted in the previous year;

(2) Any amendments to the organic plan, including a description of any

activities undertaken in the previous year, and intended to be undertaken in the coming year, to implement the provisions of the organic plan;

(3) A statement that the certified operation will remain in compliance with the Act and the regulations in this part; and

(4) Any other information requested by the certifying agent, in accordance with § 205.214(a) of this subpart.

(b) Following the receipt of the information specified in paragraph (a), the certifying agent shall arrange and conduct an on-site inspection of the certified operation, pursuant to §§ 205.208 through 205.211.

(c) If the certifying agent has reason to believe, based on the on-site inspection and a review of the information specified in § 205.214(a), 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 non-compliance to the operation in accordance with § 205.218(a) of this subpart.

**§ 205.218 Notification of non-compliance with certification requirements.**

(a) A written notification of non-compliance shall be sent by certified mail to the place of business of the certification applicant or the certified operation and shall contain the following information:

(1) A description of each deficiency in compliance and each possible violation of the Act and the regulations in this part that the certifying agent has reason to believe has occurred;

(2) The evidence on which the notification is based; and

(3) The date by which the operation must correct each deficiency in compliance and each possible violation delineated in the notification, and submit documentation to the certifying agent to support such corrections.

(b) If the documentation received by the certifying agent from an operation it has certified, pursuant to paragraph (a)(3) of this section, is not adequate to demonstrate that each deficiency in compliance and each possible violation has been corrected, the certifying agent shall:

(1) Conduct an additional inspection of the certified operation, as provided for in § 205.213, if the certifying agent determines that an additional inspection is necessary to determine whether the operation is complying with, or has violated, the Act or the regulations in this part;

(2) Review the status of the certified operation to determine whether the operation or any portion of the operation has ceased to comply with, or has violated, the Act or the regulations in this part; and

(3) *Notification of determination or recommendation.* (i) If, following the review specified in paragraph (b)(2) of this section, the certifying agent determines that the operation is in compliance with the Act and the regulations in this part, the certifying agent shall notify the certified operation in writing of its determination.

(ii) If, following the review specified in paragraph (b)(2) of this section, the certifying agent has reason to believe that the certified operation or any portion of the operation is not in compliance with the Act and the regulations in this part, the certifying agent shall submit to the Administrator a notice of its recommendation to terminate the certification of the certified operation or any portion of the certified operation that the certifying agent believes to have ceased to comply with the Act and the regulations in this part.

**§ 205.219 Termination of certification.**

(a) A certifying agent shall follow the procedures in accordance with § 205.218 of this subpart if the certifying agent has reason to believe that a certified operation or a person responsibly connected with a farm, wild crop harvesting, or handling operation it has certified has:

(1) Made a false statement;

(2) Attempted to have a label indicating that an agricultural product is organically produced affixed to such product when such product was produced or handled in a manner that is not in accordance with the Act and the regulations in this part; or

(3) Otherwise violated the purposes of the certification program established in Subpart D of this part.

(b) Notwithstanding paragraph (a) of this section, if a certifying agent has reason to believe that a certified operation or a person responsibly connected with an operation that has been certified by the certifying agent has wilfully violated the Act and the regulations in this part, the certifying agent shall submit to the Administrator a notice of its recommendation to terminate the certification of the certified operation or any portion of the certified operation that the certifying agent believes to have ceased to comply with the Act and the regulations in this part. A notice of recommendation to terminate certification shall list the names of any persons the certifying agent believes to have violated the Act and the regulations in this part.

(c) Upon receipt by the Administrator of a notification of a recommendation to terminate the certification of an operation or any portion of an operation, submitted pursuant to paragraph (b) of this section or § 205.218(b)(3)(ii) of this subpart, as applicable, the Administrator may institute the proceedings to terminate certification.

(d) *Ineligibility and waiver.* (1) A certified farm, wild crop harvesting, or handling operation, or a person responsibly connected with such an operation, that violates the Act and the regulations in this part, as determined following the proceedings instituted pursuant to paragraph (c) of this section, shall not be eligible to receive certification for any farm, wild crop harvesting, or handling operation in which such operation or person has an interest for a period of 5 years from the occurrence of such violation.

(2) Notwithstanding paragraph (d)(1) of this section, the Secretary may waive ineligibility for certification if it is in the best interests of the certification program established under subpart D of this part.

**§ 205.220 Notification of certification status.**

A certifying agent shall submit to the Administrator:

(a) A copy of any notification of non-compliance, sent pursuant to § 205.218, simultaneously with its issuance to the certification applicant or the certified operation; and

(b) On a quarterly calendar basis, the name of each operation whose application for certification has been approved.

**§§ 205.221 through 205.299 [Reserved]**

## Subpart E—Accreditation of Certifying Agents

**§ 205.300 Areas of accreditation.**

The Secretary shall accredit a qualified applicant in the areas of crops, livestock, wild crops, or handling, or any combination thereof, to certify a farm, wild crop harvesting operation, or handling operation as a certified organic farm, certified organic wild crop harvesting operation, or certified organic handling operation.

**§ 205.301 General requirements for accreditation.**

(a) A private person or governing State official accredited as a certifying agent under this subpart shall:

(1) Have sufficient expertise in organic farming and 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 §§ 205.207 through 205.214 of subpart D, and § 205.430 of subpart F.

(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 D of this part;

(5) Conduct an annual performance review for each inspector used by the certifying agent, and implement measures to correct any possible defects in compliance with the Act and the regulations in this part identified in each review conducted;

(6) Have an annual internal evaluation review conducted of its certification activities, and implement measures to correct any possible defects in compliance with the Act and the regulations in this part identified in each review conducted;

(7) Provide sufficient information to persons seeking certification to enable an applicant for certification to comply with the applicable requirements of the Act and the regulations in this part;

(8) Maintain records and permit access to records as follows:

(i) Maintain all records concerning its activities under the Act and the regulations in this part for a period of not less than 10 years from the date of creation of the record; and

(ii) Allow representatives of the Secretary and the applicable governing State official access to any and all records concerning the certifying agent's activities under the Act and the regulations in this part;

(9) 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 governing State official) any business related information concerning any client obtained while implementing the regulations in this part, except as provided for in § 205.304(b)(5);

(10) Prevent conflict of interest by not:

(i) Certifying an operation if the certifying agent or a responsibly connected party of such certifying agent has or has held a commercial interest in the operation, including the provision of consultancy services, within the 12 month period prior to the application for certification, and by not certifying an operation through the use of any employee that has or has held a commercial interest in the operation, including the provision of consultancy services, within the 12 month period prior to the application for certification;

(ii) Assigning an inspector to perform an inspection of an operation if the inspector has or has held a commercial interest in the operation, including the provision of consultancy services, within the 12 months prior to conducting the inspection;

(iii) Permitting any employee, inspector, or other personnel to accept payment, gifts, or favors of any kind, other than prescribed fees, from any business inspected; and

(iv) Providing advice concerning organic practices or techniques to any certification applicant or certified organic farm or handling operation for a fee, other than as part of the fees established under the applicable certification program established under the Act;

(11) Accept the certification decisions made by another USDA accredited certifying agent as equivalent to its own;

(12) 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;

(13) Charge only such fees to applicants for certification and operations it certifies that the Secretary determines are reasonable;

(14) Pay and submit fees to AMS in accordance with §§ 205.421 and 205.422(b) of subpart F of this part; and

(15) Comply with and implement such other terms and conditions deemed necessary by the Secretary.

(b) A private person or governing State official accredited as a certifying agent under this subpart may establish a seal, logo or other identifying mark to be used by farms, wild crop harvesting operations, and handling operations certified by the certifying agent to denote affiliation with the certifying agent, *Provided,* That the certifying agent:

(1) Does not require as a condition of certification by it the display of its identifying mark on any product sold, labeled or represented as organically produced; and

(2) Does not require as a condition of use of its identifying mark compliance with any farming or handling requirements other than those provided for in the Act and the regulations in this part.

(c) A private person accredited as a certifying agent shall:

(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 Secretary may by regulation prescribe, for the purpose of protecting the rights of farms, wild crop harvesting operations, and handling operations certified by such certifying agent under the Act and the regulations in this part; and

(3) Transfer to the Secretary, and make available to any applicable 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.

**§ 205.302 Applying for accreditation.**

(a) A private person or governing State official seeking accreditation as a certifying agent under this subpart shall submit an application for accreditation which contains the applicable information and documents set forth in §§ 205.303 through 205.305 and the fees required in § 205.421(a) of subpart F to: Program Manager, USDA–AMS–TM–NOP, Room 2945–S, P.O. Box 96456, Washington, D.C. 20090–6456.

(b) Following the receipt of the information and documents, the Administrator will determine according to the provisions set forth in § 205.306 whether the applicant for accreditation should be accredited as a certifying agent.

**§ 205.303 Information to be submitted by an accreditation applicant.**

A private person or governing State official seeking accreditation as a certifying agent shall submit the following information:

(a) The name, primary office location, mailing address, and contact numbers (telephone, fax, and Internet address) of the applicant; additionally, for an applicant who is a private person, the name of the person designated to control its day-to-day operations, and its taxpayer identification number;

(b) The name, office location, mailing address, and contact numbers (telephone, fax, 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 numbers of each type of operation anticipated to be certified annually by the applicant;

(d) The type of entity the applicant is (e.g. State government agricultural

office, for-profit business, not-for-profit membership association); and, in addition, for:

(1) A governing State official, a copy of the official's authority to conduct certification activities under the Act and the regulations in this part; and

(2) A private person, documentation of its entity's status and organizational purpose, such as articles of incorporation and by-laws, ownership or membership provisions, and its date of establishment; and

(e) A list of each State in which the applicant currently certifies farms and handling operations, and, in addition, a list of each State in which the applicant intends to certify farms or handling operations.

**§ 205.304 Evidence of expertise and ability to be submitted by an accreditation applicant.**

A private person or governing State official seeking accreditation as a certifying agent shall submit the following documents and information to demonstrate its expertise in organic farming and handling techniques, its ability to fully comply with and implement the organic certification program established in §§ 205.201 through 205.220 of subpart D of this part, and its ability to comply with the requirements for accreditation set forth in § 205.301 of this subpart:

(a) *Personnel.* (1) A description of the applicant's policies and procedures for training, evaluating and supervising personnel;

(2) The name and functions of all personnel intended to be used in the certification operation, including administrative staff, certification inspectors, members of any certification review and internal evaluation committees, and all parties responsibly connected to the certification operation;

(3) A description of the qualifications, including past experience, training, and education in agriculture, including organic farming and handling, for:

(i) Each inspector intended to be used by the applicant; and

(ii) Each person designated or 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 can comply with and implement the requirements of the Act and the regulations in this part.

(b) *Administrative policies and procedures.* (1) A description of the procedure to be used to evaluate certification applicants, make certification decisions and issue certification certificates;

(2) A description of the procedures to be used for reviewing compliance of certified farm, wild crop harvesting, and handling operations 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 description of the procedures to be used for complying with the recordkeeping requirements set forth in § 205.301(a)(8);

(4) A description of the procedures to be used for maintaining the confidentiality of any business related information, as set forth in § 205.301(a)(9) of this subpart;

(5) A description of the procedures to be used for making the following information available to any member of the public upon request:

(i) A list of producers and handlers whose operations it has certified, and the effective dates of the certifications, during the ten year period preceding the receipt of the request from the public;

(ii) The organic agricultural products produced by each certified operation;

(iii) The results of laboratory analyses for residues of pesticides and other prohibited substances conducted during the ten year period preceding the request from the public; and

(iv) Other non-confidential business information as permitted by the producer or handler and approved by the Secretary.

(c) *Financial policies and procedures.* A description of the applicant's policies and procedures for the collection and disbursement of funds, and documents that identify anticipated sources of income, including all fees to be collected from producers and handlers in accordance with § 205.301(a)(13) of this subpart and § 205.422(a) of subpart F.

(d) *Conflict of interest.* (1) A description of procedures intended to be implemented to prevent the occurrence of conflicts of interest, as delineated in § 205.301(a)(10); and

(2) For each person identified in § 205.304(a)(2), the identification of any food and agriculture-related business interests, including business interests of immediate family members, that may cause a conflict of interest.

(e) *Current certification activities.* An applicant who currently certifies farms, wild crop harvesting, or handling operations may additionally submit:

(1) A list of all farms, wild crop harvesting, and handling operations currently certified by the applicant;

(2) Copies of the inspection reports and certification evaluation documents for farms, wild crop harvesting, or handling operations certified by the applicant during the previous year; and

(3) The results of an accreditation process, if any, conducted of the applicant's operation by an accrediting body during the previous year for the purpose of evaluating its certification activities; and

(f) *Other information.* Any other information the applicant believes may support the Secretary's evaluation of the applicant's expertise and ability.

**§ 205.305 Statement of agreement to be submitted by an accreditation applicant.**

(a) A private person or a governing State official seeking accreditation under this subpart shall submit a statement which affirms that, if granted accreditation as a certifying agent under this subpart, the applicant will:

(1) Carry out the provisions of the Act and the regulations in this part;

(2) Accept the certification decisions made by another USDA accredited certifying agent as equivalent to its own;

(3) 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;

(4) Conduct an annual performance review for each inspector to be used and implement measures to correct any possible defects in compliance with the Act and the regulations in this part identified in each review conducted;

(5) Have an annual internal evaluation review conducted of its certification activities and implement measures to correct any possible defects in compliance with the Act and the regulations in this part identified in each review conducted;

(6) Pay and submit fees to AMS in accordance with §§ 205.421 and 205.422(b) of subpart F of this part; and

(7) Implement and carry out any other terms and conditions determined by the Secretary to be necessary.

(b) A private person who seeks accreditation as a certifying agent under this subpart shall 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 Secretary may by regulation prescribe, for the purpose of protecting the rights of the farming and handling operations certified by such certifying agent under the Act and the regulations in this part; and

(3) Transfer to the Secretary and make available to the applicable 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.

**§ 205.306 Approval of accreditation.**

(a) Accreditation will be approved if:

(1) The accreditation applicant has submitted the information required by §§ 205.303 through 205.305 of this subpart;

(2) The accreditation applicant pays the required fee in accordance with § 205.421(c) of subpart F of this part; and

(3) The Administrator determines that the applicant for accreditation meets or is capable of meeting the general requirements for accreditation as stated in § 205.301 of this subpart, as applicable, as determined by a review of the information submitted in accordance with §§ 205.303 through 205.305 and, if necessary, a review of the information obtained from a site visit as provided for in § 205.309.

(b) On making a determination to approve an application for accreditation, the Administrator shall notify the applicant of approval of accreditation in writing, stating:

(1) The area(s) for which accreditation is given;

(2) The effective date of the accreditation; and

(3) For a certifying agent who is a private person, the amount and type of security that must be established to protect the rights of farm, wild crop harvesting, and handling operations certified by such certifying agent.

**§ 205.307 Denial of accreditation.**

(a) If the Administrator has reason to believe, based on a review of the information specified in §§ 205.303 through 205.305 of this subpart, 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, including § 205.301 of this subpart, the Administrator shall provide a written notification of non-compliance to the applicant in accordance with § 205.315(a) of this subpart.

(b) Following the correction of deficiencies identified in the notification issued in accordance with paragraph (a) of this section, the applicant may submit a new application for accreditation to the Administrator. The new application shall include documentation of actions taken by the applicant to correct the deficiencies delineated in the notification of non-compliance.

(c) If an accreditation applicant who receives a notification pursuant to paragraph (a) of this section does not correct the deficiencies identified within the time specified in the notice of non-compliance, the Administrator may institute proceedings to deny accreditation.

**§ 205.308 Maintaining accreditation.**

To maintain accreditation, an accredited certifying agent must continue to satisfy the requirements of the Act and the regulations in this part throughout the duration of its accreditation, and pay and submit fees in accordance with §§ 205.421 and 205.422(b) of Subpart F of this part.

**§ 205.309 Site evaluations.**

(a) An initial site evaluation of the operation of each certifying agent shall be performed for the purpose of verifying its compliance with the Act and the regulations in this part within a reasonable period of time after the date on which the agent's notice of approval of accreditation is issued, as set forth in § 205.306 of this subpart, and after the agent has conducted sufficient certification activities for the Administrator to examine its operations and evaluate its compliance with § 205.301 of this subpart.

(b) A site evaluation of an accreditation applicant or certifying agent's operation and performance may be conducted at any time to determine whether an accreditation applicant can comply with the general requirements set forth in § 205.301 of this subpart or to evaluate the certifying agent's operation and performance under the Act and the regulations in this part.

**§ 205.310 [Reserved].**

**§ 205.311 Peer review panel.**

(a) *Peer review panel(s).* (1) A peer review panel shall review the accreditation status of a certifying agent after any site evaluation performed pursuant to §§ 205.309(a) and 205.314(b) of this subpart.

(2) The Administrator may convene a peer review panel at any time for the purpose of evaluating a certifying agent's activities under the Act and the regulations in this part.

(3) The Administrator shall consider the reports received from each individual member of a peer review panel when making a determination whether to confirm the accreditation of a certifying agent, or when making a determination whether to renew the accreditation of a certifying agent.

(b) *Composition of peer review panels.* (1) The Administrator shall convene a peer review panel, which shall consist of between three and five persons selected from the established peer review panel pool, with the following membership requirements:

(i) One member shall be personnel of AMS who shall be responsible for presiding over the convened panel; and

(ii) At least two members shall not be personnel of AMS or an approved State program.

(2) Each convened peer review panel shall include no less than one member who possesses sufficient expertise, as determined by the Administrator, in the areas of accreditation delineated in the notice of approval of accreditation, pursuant to § 205.306(a) of this subpart, for each certifying agent whose operations and performance are to be reviewed.

(3) No person participating on a convened peer review panel shall be, or shall have been, associated with a certifying agent being reviewed by the panel in a manner that would constitute a known or perceived conflict of interest, as determined by the Administrator.

(c) *Duties and responsibilities of panel members.* (1) Each person on a convened peer review panel shall individually review the site evaluation report prepared by the Administrator and any other information that may be provided by the Administrator relevant to confirming or renewing the accreditation status of a certifying agent;

(2) Information about the certifying agent received as part of the review process is confidential information, and peer reviewers shall not release, copy, quote, or otherwise use material from the information received, other than in the report required to be submitted;

(3) Each peer reviewer must agree, specifically, to treat the information received for review as confidential; and

(4) Each person on a convened peer review panel shall provide an individual written report to the Administrator regarding a certifying agent's ability to conduct and perform certification activities.

(d) *Optional meeting or conference call procedure for a convened peer review panel.* (1) The Administrator may convene a peer review panel meeting or conference call if necessary for evaluating the accreditation status of a certifying agent or at the request of at least one peer review panel member. The Administrator may include the certifying agent being evaluated, or a representative of the agent, for the purpose of providing additional information. Any meeting or conference call shall be conducted in a manner that will ensure that the actions of panel members are carried out on an individual basis with any opinions and

recommendations by a member being individually made.

(2) Copies of the peer review panel reports may be provided to the certifying agent and written responses from the certifying agent may be submitted for consideration by the Administrator.

(e) *Peer review panel reports.* Each person who participates in a peer review panel shall provide a written report to the Administrator which shall contain the person's recommendations concerning confirmation or renewal of the accreditation for each agent reviewed and the basis for each recommendation.

**§ 205.312 Confirmation of accreditation.**

(a) *Notice of confirmation.* The Administrator shall issue a written notice of confirmation of accreditation to a certifying agent if the Administrator determines the agent is in compliance with the requirements of the Act and the regulations in this part. The notice of confirmation will set forth any terms and conditions that must be addressed by the certifying agent before submitting a request for renewal of accreditation.

(b) *Duration of accreditation.* The accreditation of a certifying agent shall continue in effect until such time as the certifying agent fails to renew accreditation as delineated in § 205.314, voluntarily ceases its certification activities, or accreditation is suspended or terminated pursuant to § 205.316.

**§ 205.313 Denial of confirmation.**

(a) If the Administrator has reason to believe, based on a review of the information specified in §§ 205.303 through 205.305 and the results of a site evaluation and the reports submitted by the peer review panel, pursuant to §§ 205.309 and 205.311(e) of this subpart, that the certifying agent is not complying with the requirements of the Act and the regulations in this part, the Administrator shall provide a written notification of non-compliance to the certifying agent in accordance with § 205.315(a) of this subpart.

(b) If a certifying agent who receives a notification pursuant to paragraph (a) of this section corrects the deficiencies identified within the time specified in the notice of non-compliance, in accordance with § 205.315(a)(3) of this subpart, the Administrator shall issue a notice of confirmation of accreditation to the certifying agent, pursuant to § 205.312(a).

(c) If a certifying agent who receives a notification pursuant to paragraph (a) of this section does not correct the deficiencies identified within the time specified in the notice of non-compliance, the Administrator may institute proceedings to deny confirmation of accreditation.

**§ 205.314 Continued accreditation.**

(a) *Annual report and fees.* An accredited certifying agent shall submit annually to the Administrator on or before the anniversary date of the issuance of the notice of confirmation of accreditation, pursuant to § 205.312(a) of this subpart, the following reports and fees:

(1) A complete and accurate update of information submitted pursuant to §§ 205.303 and 205.304;

(2) Information supporting any changes being requested in the areas of accreditation delineated in § 205.300;

(3) The measures that were 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 notice of confirmation of accreditation, in accordance with § 205.312(a) of this subpart, or notice of renewal of accreditation, in accordance with paragraph (c) of this section;

(4) The results of the most recent inspector performance reviews and internal evaluation review, and adjustments to the certifying agent's operation and procedures implemented, and intended to be implemented, in response to the reviews; and

(5) The fees required in § 205.421(a) of subpart F.

(b) *Renewal of accreditation.* An accredited certifying agent shall request renewal of accreditation on or before the fifth anniversary of issuance of the notice of confirmation of accreditation and each subsequent renewal of accreditation. 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 and the reports submitted by the peer review panel, pursuant to §§ 205.309 and 205.311(e) of this subpart, the Administrator shall determine whether the certifying agent remains in compliance with the Act and the regulations of this part.

(c) *Notice of renewal of accreditation.* Upon a determination that the certifying agent continues to comply with the Act and the regulations of this part, the Administrator shall issue a notice of renewal of accreditation. The notice of renewal shall 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.

(d) *Non-compliance.* Upon a determination that there is reason to believe that the certifying agent is not in compliance with the Act and the regulations of this part, the Administrator shall initiate the procedure delineated in § 205.315 of this subpart.

**§ 205.315 Notification of non-compliance with accreditation requirements.**

(a) A written notification of non-compliance shall be sent by certified mail to the place of business of the accreditation applicant or the certifying agent, as applicable, and shall contain the following information:

(1) A description of each deficiency in compliance and each violation of the Act and the regulations in this part that the Administrator has reason to believe has occurred;

(2) The evidence on which the notification is based; and

(3) The date by which the accreditation applicant or the certifying agent, as applicable, must correct each deficiency and each violation delineated in the notification, and submit documentation to the Administrator to support such corrections.

(b) If the documentation received by the Administrator, pursuant to paragraph (a)(3) of this section, is not adequate to demonstrate that each deficiency in compliance and each violation has been corrected by the date indicated in the written notification, the Administrator may conduct a site evaluation, as provided for in § 205.309, to determine whether the certifying agent is complying with, or has violated, the Act or the regulations in this part.

(c) *Notification of determination or recommendation.* (1) If, following the procedure pursuant to paragraphs (a) and (b) of this section, the Administrator determines that the certifying agent is in compliance with the Act and the regulations in this part, the Administrator shall notify the certifying agent in writing of this determination.

(2) If, following the procedure pursuant to paragraphs (a) and (b) of this section, the Administrator has reason to believe that the certifying agent is not in compliance with the Act and the regulations in this part, the Administrator may institute a proceeding to suspend or terminate the accreditation of the certifying agent.

**§ 205.316 Termination of accreditation.**

(a) The Administrator shall follow the procedures prescribed in § 205.315 of this subpart if the Administrator has reason to believe that an accredited certifying agent or a person responsibly

connected with an accredited certifying agent has ceased to comply with or has violated the Act or the regulations in this part.

(b) Notwithstanding paragraph (a) of this section, if the Administrator has reason to believe that an accredited certifying agent or a person responsibly connected with an accredited certifying agent has wilfully violated the Act and the regulations in this part, the Administrator may institute a proceeding to suspend or terminate the accreditation of the certifying agent.

(c) A private person or a governing State official whose accreditation as a certifying agent is suspended or terminated shall:

(1) Cease any certification activity in each area of accreditation and in each State for which its accreditation is suspended; or

(2) In the case of a private person whose accreditation is terminated, cease all certification activities; and

(3) Transfer to the Secretary and make available to any applicable governing State official all records concerning its certification activities that were suspended or terminated, so that the Secretary may promptly determine whether farms or handling operations certified by such certifying agent may retain their organic certification.

(d) A private person or a governing State official whose accreditation as a certifying agent is suspended by the Secretary under this section may at any time submit a new request for accreditation, pursuant to § 205.302 of this subpart. The request shall be accompanied by documentation that demonstrates that appropriate corrective actions have been taken to comply with and remain in compliance with the Act and the regulations in this part.

(e) A private person whose accreditation as a certifying agent is terminated 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 three years following the date of such determination.

**§§ 205.317 through 205.400 [Reserved].**

## Subpart F—Additional Regulatory Functions

### State Programs

**§ 205.401 Requirements of State programs.**

(a) A State may establish a State organic certification program for producers and handlers of agricultural products that have been produced within the State using organic methods as provided for in the Act and the regulations in part 205.

(b) The State program shall meet the requirements of the Act and the regulations in part 205.

(c) A State program may contain more restrictive requirements governing the certification of organic farms and handling operations and the production and handling of agricultural products that are to be sold or labeled as organically produced than are contained in the National Organic Program established by the Secretary, *Provided, That* such additional requirements:

(1) Further the purposes of the Act and the regulations in part 205;

(2) Are consistent with the provisions of the Act and the regulations in part 205;

(3) Do not discriminate towards agricultural commodities organically produced in other States in accordance with the Act and the regulations in part 205; and

(4) Are approved by the Secretary prior to being implemented.

**§ 205.402 Approval of State programs and program amendments.**

(a) A governing State official shall submit to the Secretary a proposed State program, and proposed substantive amendment(s) to a State program, and shall obtain the Secretary's approval prior to implementation of the proposed program and any proposed substantive amendments thereto.

(b) The Secretary will notify the governing State official within six months after the receipt of the proposed State program and proposed substantive amendment to the State program, as to whether the program or substantive amendment is approved or disapproved, and if disapproved, the reasons for the disapproval. After receipt of a notice of disapproval, the State may reapply at any time.

**§ 205.403 Review of approved programs.**

The Secretary will review a State organic certification program not less than once during each five-year period following the date of the initial approval of such program. The Secretary will notify the governing State official within six months after the initiation of the review, whether the program is approved or disapproved, and if disapproved, the reasons for the disapproval.

**§§ 205.404 through 205.420 [Reserved].**

### Fees

**§ 205.421 Fees for accreditation applicants and accredited certifying agents.**

(a) *Application fees.* (1) Each applicant for accreditation and each accredited certifying agent shall submit a non-refundable fee of $640 simultaneous with the submission of each application for accreditation or annual report, as applicable. Payment shall be made by certified check or money order made payable to Agricultural Marketing Service and sent with the application or annual report to: Program Manager, USDA/AMS/TM/NOP, Room 2945–S, P.O. Box 96456, Washington, D.C., 20090–6456.

(2) An applicant or an accredited certifying agent whose organizational structure consists of chapters or subsidiary offices also shall include a non-refundable fee of $160 for each chapter or subsidiary office, simultaneous with the submission of each application for accreditation or annual report, as applicable.

(b) *Site evaluation fees and related travel and per diem expenses.* Each applicant or accredited certifying agent for whom a site visit is conducted shall submit a non-refundable payment for the following fees and expenses related to a site evaluation visit conducted, pursuant to § 205.309 of subpart E, within 30 days following issuance of a bill from AMS for the cost of the site evaluation visit which shall include payment of:

(1) An hourly fee of $40 per hour, calculated to the nearest fifteen minute period, for each AMS evaluator to conduct the site evaluation visit, including travel time to and from the evaluator's duty station; and

(2) Travel expenses and per diem allowances for each AMS evaluator.

(c) *Administrative fee.* Each accredited certifying agent shall submit a non-refundable administrative fee of $2,000, and an additional non-refundable administrative fee of $300 for each chapter or subsidiary office belonging to the certifying agent, within 30 days following issuance of a notification of approval of accreditation pursuant to § 205.306(b) of subpart E; within 30 days following the issuance of a subsequent notification of confirmation of accreditation, pursuant to § 205.312(a) of subpart E; or with the submission of each annual report, pursuant to § 205.314(a) of subpart E.

**§ 205.422 Fees for certified operations.**

(a) Each farm or wild crop harvesting operation shall submit to the certifying agent a non-refundable fee of $50 and each handling operation shall submit to the certifying agent a non-refundable fee of $500 by money order or certified check made payable to the Agricultural Marketing Service within 15 days of the date of the issuance by a certifying agent

of a notice of approval of certification pursuant to § 205.214(c) of subpart D.

(b) Each certifying agent shall submit to AMS, according to the instructions provided by the Administrator, all fees collected pursuant to paragraph (a) of this section within 15 days following the date of receipt by the certifying agent.

**§ 205.423 Fees for import programs.**

(a) Each foreign certification program, other than those operated by a foreign country itself, that wants AMS to determine whether its program is equivalent to the AMS organic certification program shall submit, as authorized by the Independent Offices Appropriations Act (31 U.S.C. 9701 *et seq.*), a non-refundable payment in the amount stated in the AMS notice of intent to acknowledge equivalency sent to them by AMS. The payment required will be based on an hourly charge of $40 per hour for review time plus any travel and per diem expenses incurred.

(b) No determination of equivalency of such a program shall be final and effective until such payment is made.

(c) The payment required shall be submitted by certified funds to AMS within 30 days following issuance of a bill from AMS according to the instructions provided with the notice of intent to acknowledge equivalency sent by AMS.

**§ 205.424 Payment of fees and other charges.**

(a) All fees shall be submitted in the form of a certified check or money order made payable to the Agricultural Marketing Service and sent according to the billing instructions.

(b) All fees submitted later than the time indicated in the applicable section shall be subject to interest, penalties and administrative costs, as provided in the Debt Collection Act of 1982 (31 U.S.C 3717), and may result in the loss of or failure to obtain certification, accreditation, or equivalency status.

**§§ 205.425 through 205.429 [Reserved].**

## Compliance Review and Other Testing

**§ 205.430 Compliance review.**

(a) A certifying agent shall arrange for periodic sampling and residue testing, not less frequently than every five years, of agricultural products produced on certified organic farms or wild crop harvesting operations and handled through certified handling operations certified by that agent to determine if an agricultural product contains a detectable residue level of a pesticide or other prohibited substance. To the extent that certifying agents are aware of a violation of applicable laws relating to food safety, they are required to report such violation to the appropriate health agencies (Federal, State, and local).

(b) The Secretary or the applicable governing State official shall arrange for sampling and residue testing of agricultural products sold, labeled, or represented as organic, at any point of production or distribution, and may require the certifying agent to conduct sampling and residue testing of such products originating from operations certified by that agent in order to determine if such products contain a detectable residue level of a pesticide or other prohibited substance.

(c) *Sample collection.* (1) Each product sample collected pursuant to paragraphs (a) and (b) of this section shall be collected by an inspector representing the Secretary, certifying agent, or applicable governing State official and submitted for analysis to a laboratory accredited for the product test, in accordance with Subchapter 400 of the Food and Drug Administration ''Investigations Operations Manual,'' available from the FDA, Division of Emergency and Investigation Operations, 5600 Fishers Lane, Rockville MD 20857.

(2) The analytical methods used to test each product sample shall be selected as appropriate from:

(i) The FDA ''Pesticide Analytical Manual,'' Volumes I and II, available from the FDA, Department of Health, Education and Welfare, 200 C Street S.W., Washington, DC 20204;

(ii) The ''FSIS Residue Chemistry Guidebook'', available by request from: FSIS Quality Systems Branch, Room 516–A, Annex Building, 300 12th Street S.W., Washington, DC 20250–3700, or

(iii) The ''Official Methods of Analysis'' of the Association of Official Analytical Chemists International (AOACI), available by request from: AOACI, 481 North Frederick Ave., Suite 500, Gaithersburg, MD 20877.

(3) The results of all sampling and testing performed pursuant to paragraphs (a) and (b) of this section for each product sample shall be reported to the certifying agent or applicable governing State official, and to the Secretary, *Provided, That* if any test result indicates that the product sample contains a residue level of a pesticide or other prohibited substance that exceeds the EPA tolerance level [1] or the FDA action level,[2] as applicable, for that substance, the certifying agent, governing State official, or the Secretary also shall inform the appropriate health agencies of the results of the residue test.

(d) *Residue test investigations.* (1) If the results of the testing and sampling performed pursuant to paragraphs (a) and (b) of this section indicate that the product sample contains a detectable residue level of a pesticide or other prohibited substance, the certifying agent, the applicable governing State official, or the Secretary shall conduct an investigation of the certified operation that produced or harvested the product represented by the sample to determine the cause of the detectable residue level, and may require the producer or handler of such product to prove that any prohibited substance was not applied to such product.

(2) If the certifying agent, applicable governing State official, or the Secretary, determines as a result of the investigation that the detectable residue level of the pesticide or other prohibited substance exceeds the unavoidable residual environmental contamination level for the detected pesticide or other prohibited substance, or that the detected pesticide or other prohibited substance was the result of an intentional application, then the agricultural products represented by the sample shall not be sold or labeled as organically produced, and the Administrator may institute proceedings to terminate certification of the operation, or portion of an operation, from which the agricultural products represented by the sample originated, as provided for in § 205.219 of subpart D.

**§ 205.431 Preharvest tissue testing.**

(a) *General.* The Secretary, the applicable governing State official, or the certifying agent may require a preharvest tissue test of any crop to be sold or labeled as organically produced that is grown on soil suspected by the Secretary, the applicable governing State official, or the certifying agent of harboring a contaminant.

(b) *Preharvest tissue test sample collection.* (1) The preharvest tissue test sample collection conducted pursuant to paragraph (a) of this section shall be performed by an inspector representing the Secretary, certifying agent, or applicable governing State official and shall be collected and submitted for testing in accordance with Subchapter 400 of the ''FDA Investigations

[1] 40 CFR parts 180, 185, and 186.

[2] The FDA action levels are published in the FDA publication entitled ''Action Levels for Poisonous or Deleterious Substances in Human Food and Animal Feed.'' Single copies of this booklet are available fron: Industry Activities Section (HHF–326), CFSN/FDA, 200 C Street S.W., Washington, DC 20204.

Operations Manual'' to a laboratory accredited for the product test.

(2) The analytical methods used to determine whether a preharvest tissue test sample contains a residue of a contaminant shall be selected as appropriate from the FDA ''Pesticide Analytical Manual,'' Volumes I and II, or the ''Official Methods of Analysis'' of the Association of Official Analytical Chemists.

(c) *Reporting of preharvest tissue test results.* The results of each preharvest tissue test shall be reported to the Secretary and, *Provided, That* if the test result indicates that the residue level of a contaminant in the organically produced crop exceeds the EPA tolerance or FDA action level, the certifying agent or applicable official also shall report the results to the appropriate regulatory agency.

### § 205.432 Emergency pest or disease treatment.

If a pesticide or other prohibited substance is applied to a certified organic farm, wild crop harvesting, or handling operation due to a Federal or State emergency pest eradication 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 pesticide or other 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 eradication or disease treatment program is not sold or labeled 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, shall not thereafter be labeled or sold as organically produced, except that:

(1) 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; 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 last date that the breeder stock was treated with the prohibited substance.

### § 205.433 Reporting the application of a prohibited substance.

A producer or handler shall immediately report any instance of application of a prohibited substance on their certified operation to their certifying agent and shall inform the agent of the reason for, or the cause of, the application.

### §§ 205.434 through 205.451 [Reserved].

## Appeals

### § 205.452 General.

Any person subject to the Act who believes that he or she is adversely affected by a decision of a member of the National Organic Program staff or by a certifying official may appeal such decision to the Administrator.

### §§ 205.453 through 205.479 [Reserved].

## Equivalency of Imported Organic Products

### § 205.480 Eligibility of agricultural products for importation into the United States.

Any agricultural product imported into the United States that is labeled or sold as organic or that contains an ingredient represented as organic shall have been produced and handled under an organic certification program that the Secretary has determined provides safeguards and guidelines governing the production and handling of such products that are at least equivalent to the requirements of the Act and the regulations set forth in part 205.

### § 205.481 Determination of the equivalency of foreign programs.

The determination of the equivalency to the Act and regulations in part 205 of a foreign organic certification program will be based on an evaluation of the following components of the program's provisions for organically produced and handled agricultural products:

(a) The standards of production and handling for agricultural products;

(b) The list of substances allowed and prohibited for use in the production and handling of agricultural products and the criteria for establishing the allowance or prohibition of substances used in organic production and handling;

(c) The requirements for, and process by which, farms and handling operations are inspected and certified as operating under a system of organic farming and handling, including the requirements for documentation of the practices and substances used;

(d) The measures identified to provide adequate enforcement for, and protection against, violations of the program requirements;

(e) The requirements for and process by which agents are evaluated and accredited by an agency of the government as being qualified to certify organic farm, wild crop harvesting, or handling operations; and

(f) Any other information relevant to the production and certification of organically produced products including the administration of the foreign organic certification program.

### § 205.482 Process for establishing equivalency of foreign programs.

(a) A foreign organic certification program that wants a determination of the equivalency of its program, as provided for in § 205.481, shall submit to the Secretary a complete and accurate description of its program, including any of the laws and applicable requirements upon which the program is based and any information requested by the Secretary.

(b) The foreign organic certification program shall be notified of the determination as follows:

(1) A foreign organic certification program that the Secretary determines to have safeguards and guidelines equivalent to the Act and regulations in part 205, the program's representative shall be notified in writing of the date upon which agricultural products produced and handled under that program may begin to be imported into the United States and sold or labeled as organically produced; and

(2) A foreign organic certification program that the Secretary determines does not have guidelines and safeguards equivalent to the Act and the regulations in part 205, the program's representative shall be notified in writing of the basis for such determination. After receipt of the notice, the program representative may reapply at any time.

(c) If at any time the Secretary determines that a foreign program is not equivalent, the Secretary may withdraw the equivalency status. Termination of the equivalency status will be effective upon receipt of the notice.

### § 205.483 Maintenance of eligibility for importation.

(a) Maintenance of eligibility for importation of agricultural products into the United States that are to be sold or labeled as organic will depend on the results of periodic reviews by the Secretary of the foreign organic certification program under which the products are produced and handled, and the timely submission of documents and other information necessary to reevaluate the equivalency status of the foreign organic certification program, as requested by the Secretary, including any amendments made to the foreign

organic certification program's requirements.

(b) For agricultural products imported into the United States to continue to be eligible to be sold or labeled as organic, the program representative of the program under which they were produced and handled must notify the Secretary of any amendments made to the program requirements prior to their implementation.

**§§ 205.484—205.999 [Reserved]**

## PARTS 206—209 [RESERVED]

Dated: December 5, 1997.

**Michael V. Dunn,**

*Assistant Secretary, Marketing and Regulatory Programs.*

**Note:** The following Attachment will not appear in the Code of Federal Regulations.

**Attachment—Regulatory Impact Assessment for Proposed Rules Implementing the Organic Foods Production Act of 1990**

*The Need for the Proposed Action*

The Organic Foods Production Act (OFPA) of 1990, Title XXI of the Food, Agriculture, Conservation and Trade Act of 1990 (Farm Bill), U.S.C. Title 7, mandates that the Secretary of Agriculture develop a national organic program. The OFPA states that the Secretary shall 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. In addition, section 6514 of the OFPA requires the Secretary to establish and implement a program to accredit a governing State 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 mandated by the OFPA in section 6501, the regulations are proposed 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. The purposes of the OFPA are similar to those of the quality grading programs currently provided by USDA for many agricultural products.

The following regulatory assessment is provided to fulfill the requirements of Executive Order 12866. This assessment consists of a statement of the need for the proposed action, an examination of alternative approaches, and an analysis of the benefits and costs. The analysis is necessarily descriptive of the anticipated impacts of the proposed rule. In the absence of basic market data on the prices and quantities of organic goods and services and the costs of organic production, it is not possible to provide quantitative estimates of the benefits and costs of the proposed rule, except for the cost of fees and recordkeeping proposed by the USDA. Consequently, the analysis does not contain an estimate of net benefits. Rather, it describes the developments leading up to the passage of the OFPA, outlines current market conditions and recent trends, and identifies the types of benefits and costs suggested by the changes in market conditions that the rule is expected to produce.

The OFPA was introduced at the request of the organic community after it experienced a number of problems in the marketing of organic products. Because many consumers are willing to pay price premiums for organic food, producers (farmers and wild crop harvesters) and handlers have an economic incentive to label their products organic. But one problem is that organic products cannot be distinguished from conventionally produced products by sight inspection; hence, consumers rely on verification methods, such as certification by private entities or verification by retailers. To the extent that consumers cannot verify organic product claims and are therefore vulnerable to fraud from the mislabeling of organic products, implementation of uniform organic standards and mandatory certification can be presumed to be beneficial.

A second problem is the lack of uniformity in various aspects of standards defining organic production. As organic production became established in the 1980's, certifying agencies were formed and some States passed laws establishing standards for organic production. However, many standards for production, processing and labeling of organic products were different to some degree, causing disagreements between certifiers over whose standards would apply to ingredients used in multi-ingredient organic processed products. Disagreements about standards also created sourcing problems for handlers of these multi-ingredient products, which at times resulted in losses for producers of organic ingredients.

Producers, handlers and certifiers appear to pay the costs resulting from the lack of uniformity in standards, which interferes with efficient resource allocation. However, whether these costs are significant is an empirical question. The data needed to estimate the effect of disagreements between certifiers on producer and handler costs would have to be collected. The costs of negotiating and maintaining reciprocity agreements among certifiers would provide one cost measure. These reciprocity agreements, which specify the conditions under which certifiers recognize each others' standards, would be unnecessary within a uniform national standards program. The costs of private accreditation or shipment-by-shipment certification, required to gain access to some foreign markets such as the European Union (EU), offer another indirect measure of the burden of the current system of variable standards. Certifiers would need to be surveyed to estimate these costs.

The lack of uniformity in various aspects of organic standards potentially reduces consumer welfare by creating confusion over the meaning of organic. However, the existence of different standards for organic production may provide consumers with a choice of products which they may not have under a program with a uniform standard. Our review of the literature did not find results of surveys of consumers' perceptions of the characteristics of organic foods. Consumer surveys focusing specifically on the meaning of organic and consumer preferences for organic standards would need to be conducted to determine more precisely the nature and extent of consumer confusion with, and level of confidence in, the status quo.

A third problem is the constraint on market growth resulting from the prohibition on labeling meat and poultry products as organic. The USDA Food Safety and Inspection Service (FSIS) has withheld approval for the use of organic labels on these products pending the outcome of this rulemaking. Industry data indicate the existence of a small market for ''natural'' meat, measured as sales of meat from natural foods stores, but no data are available on what proportion of these sales might be represented by organic meat. The data also are lacking with which to estimate the demand for organic meat and processed products containing organic meat. Consumer surveys indicating the degree of interest in these products would provide a measure of demand.

**Alternatives to the Proposed Rule**

*Status Quo: The Organic Market in the Absence of Regulation*

Sales of organic food products produced under a wide variety of protocols have grown at approximately 20 percent per year since 1990, the year the OFPA was passed (Table 1). Annual sales data are not available prior to 1990, but sales growth was approximately 10 percent from 1980 to 1989. Although the growth in the organic industry since 1989 has occurred without direct involvement of the Federal government, the establishment of national standards and accreditation could have been anticipated by the industry since 1990, when Congress passed the OFPA. Economic theory suggests the hypothesis that investments in production, new product development, and marketing during this period may have incorporated expectations for OFPA implementation. It has not been possible to test this hypothesis or to separate out the effect of these expectations from other forces on industry growth.

The EU is the largest market for organic food outside the United States. Valued at approximately $1.7 billion in 1990, the European market has been projected to grow at a rate of 25 percent per year, reaching approximately $14 billion by the year 2000 (Tate, p. 72). 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) (Byng, p. 21). These rules are being implemented by EU Member Countries, many of whom already have been operating under their own nationally recognized and mandated standards of production and inspection. The EU regulations allow for imports from non-EU countries whose national standards have been recognized as equivalent to the EU standards (Commission Regulation 94/92).

International access to domestic organic products may be very influential on development of the organic industry in the United States. In the absence of national standards, U.S. organic producers have been able to access European markets only by obtaining specific product permissions granted to individual importers by organic regulatory authorities in an EU Member State (Byng, p. 27–28). This process requires the importer to satisfy the authorities, through documentation and possible site inspection, that the product in question has been certified to have been produced under equivalent standards of production and inspection. It was intended as a temporary arrangement to accommodate non-EU countries that had not yet established government systems regulating organic production and certification. Growth in the trade of organic products, particularly exports, may be affected if equivalency between the EU and the United States is not established.

In the absence of a national program, the use of the term organic may be affected by the policies and regulations of other regulatory bodies. For example, FSIS currently does not approve the use of an organic label on meat and poultry, and without national standards they may continue their current restrictions, thus limiting growth in the sales of organic meat and poultry. The Food and Drug Administration (FDA) has allowed organic labeling for all other food products with the expectation that standards will be forthcoming. In the absence of a national standard, FDA's future position on organic labeling is uncertain. Additionally, in the absence of a national program, certifying agents would not be required to recognize another certifier's standards as equivalent. A lack of reciprocity between certifiers also may stifle the growth in trade of organic products for reasons previously discussed in the section of this assessment which discusses the need for this proposed action.

*A Pure Food Model*

Some consumers expect organic food to be pure food: that is, food which is completely free of synthetic chemicals (Burros, p. C–1). A pure food standard could be defined either as one which would not allow any exceptions to the prohibition on the use of synthetic substances, including the proposed use of some substances in emergency situations, or as one which would require that food test completely free of chemical residues. Such a standard could be posed as an alternative to the proposed rule; however, it would be more restrictive than the standard outlined in the OFPA, and would require an amendment to the OFPA.

Residue free food may be more restrictive than the standards of production and handling currently adopted by the organic industry itself. Standards based on residue testing have been rejected by the industry because: (1) residue testing focuses on the end product rather than the production process; (2) not all synthetic chemicals used in production are detectable as residues; and (3) some residues may appear in a product that has been produced organically because of unavoidable contamination in the soil, drift, or for other reasons which are beyond the farmer's control.

Establishing organic standards to meet a pure food definition could be expected to increase marginal costs, causing the supply curve to shift in and prices to increase, ceteris paribus. Some consumers, such as chemically sensitive persons or those who advocate pure food, likely would be willing to pay for a more restrictive definition for organic food. Other consumers would find the higher prices likely to result from a pure food standard beyond their willingness to pay for organic products and, therefore, may choose not to purchase organic products.

The niche market for pure food could be supplied by organic producers and handlers within the context of the regulations and restrictions contained in the final rule. Individual farmers and handlers would continue to have the option of putting additional information about their production methods on labeling materials of organic products, or otherwise meeting the product specifications of a pure food model, as long as these were not inconsistent with the national standards. Such additional information is subject to the same truth in labeling requirements as applied to all products. A certifier would be able to supply verification of additional product claims as a service to its clients, without requiring that all of its certified clients meet such product specifications.

*Exemption of Small Certifiers From Accreditation*

As explained below in the section entitled ''Costs of the Proposed Rule'' and as demonstrated in Table 5, the smallest certifiers (those with annual revenues of $25,000 or less) may not have the resources to meet all of the requirements of the rule, such as accreditation fees, administrative and personnel requirements, and conflict of interest restrictions, based on their current structure and revenues. Therefore, exempting the smallest certifiers from the accreditation requirement, similar to small producers being exempt from certification requirements, could mitigate the adverse impact of the rule on this group. This option, however, would require a legislative amendment to the OFPA.

The exemption of the smaller certifiers from accreditation would carry with it many of the limitations resulting from the absence of Federal oversight. International trade would likely be limited to products certified by accredited certifiers. Protecting domestic consumers from inappropriate organic claims on the labels of products certified by exempt certifiers would likely lead to greater confusion over labels in the marketplace. Federal enforcement agencies such as FDA, the Bureau of Alcohol, Tobacco and Firearms (ATF), and FSIS might wish to distinguish accredited certifiers from those certifiers who are exempt, perhaps by requiring accredited certifiers' clients to include the USDA seal on their product labels.

One of the purposes of the OFPA described in the statute is to assure consumers that organically produced products meet a consistent standard. Without Federal oversight of certifiers, it would be difficult to ensure that one national standard of production and handling for agricultural products would be employed. The result could be the continuation of reciprocity agreements between small, exempt certifiers and large accredited ones. This could result in a cost for small entities, while providing less benefit to certified producers and handlers than would be provided them by accreditation of all certifiers.

**Benefits of the Proposed Rule**

There are three points to note regarding the following discussion of benefits. First, while the costs of the rule may initially fall on certifiers, the benefits should be more widely distributed. The expected growth in the demand for organic products should create benefits for consumers, producers, handlers and certifiers. Second, not all benefits that may arise from the rule are primarily economic or quantifiable. Potential benefits which are neither quantifiable, such as increased protection for consumers producers and handlers, nor economic, such as greater communication among program participants and the NOP staff, are discussed here along with the economic benefits. Third, where economic data are available, they are generally not adequate to quantify economic benefits.

*Consumer Benefits*

Two potential benefits may accrue to consumers as a result of the proposed rule: protection from false and misleading organic food labels and a choice of a wider variety of organic foods.

Without a national standard, consumers can be mislead by labels on processed products claiming to contain organic ingredients, when in fact some of the ingredients may not be organically produced or individual ingredients may be certified under different standards of organic production. The proposed organic standards and USDA accreditation of certifiers might benefit consumers by providing assurance of the authenticity of organic claims. However, without additional data, it is not possible to quantify this benefit.

Establishing a national standard for the organic label is expected to increase the supply and variety of organic products, especially organic meat and poultry, available to consumers in the market. The organic label on meat and poultry products, including processed foods such as soups and entrees containing meat and poultry, would likely account for the bulk of new items that would enter the market following implementation.

*Producer and Handler Benefits*

As previously discussed, the proposed rule addresses the problem of existing certifying agents using different standards and not granting reciprocity to other certifying agents. By accrediting certifiers, the rule would establish the requirements and enforcement mechanism that would protect producers and handlers from inconsistent certification services, lack of reciprocity between certifiers, and competition from fraudulent products, all of which can increase costs or reduce revenues. In the absence of a system of accreditation, the certifier of a final

product is not required to recognize the certification of an intermediate product. Thus, both primary farmers and food handlers face a risk of being unable to sell certified organic product when more than one certifier is involved. The monitoring activities of accreditation should reduce the risk of restricted market access, and ensure that certifiers are using consistent criteria for certification and that certification personnel are knowledgeable and free from conflicts of interest.

The lack of a national standard for the organic label may present a barrier to marketing organic food products in the United States and abroad. Current data show organic sales growing at the rate of about 20 percent per year. It is unclear whether the growth rate will continue, increase, or decrease as a result of regulating the organic industry. In the absence of technical barriers to increasing production, implementation of the rule is expected to result in an increase in the rate of growth for organic exports and organic meat and poultry.

It is expected that national standards would create the conditions necessary for increased access to international markets. 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 Union, and the organic market share has been projected to reach 2.5 percent of total food consumption expenditures by 1998. Austria expects its organic market share to equal one third of all food sales by the year 2000 (FAS, Austria). In 1994, France and Germany combined had total retail sales of organic foods equal to that of the United States (approximately $2 billion) (FAS, France and Germany). Japan's retail sales for that year were estimated to be $688 million (SRI International, p. 15). Other EU countries report growth rates equal to or greater than the current growth rate in the United States of about 20 percent per year. Upon recognition of equivalency by the EU and the removal of the trade restrictions expected to follow implementation of the final rule, larger growth in exports of organic food products might be anticipated.

Increased access to international markets also implies that imports of organic products to the U.S. may increase. Currently, there are no restrictions on importing organic products to the U.S. in addition to those regulations applying to conventional products. Data are needed on the current trade balance in organic products to establish a baseline from which to measure changes in trade following implementation. The U.S. Customs Agency does not collect trade data that distinguish organic from conventional goods.

The impact of national organic standards on domestic production depends on increasing demand and on whether producers and handlers can lower their unit costs through expansion of their economies of scale of operations. Increasing demand may also create an incentive for new producers to enter the organic market. Input costs also may decline if economies of scale are achieved in input industries producing for the organic market. These conclusions are necessarily speculative given the lack of information on costs and production relationships for organic goods. However, such expectations are consistent with economic theory and experiences in other industries. Gains to organic producers and handlers may be partially offset by a decrease in the demand for comparable non-organically produced agricultural products, causing conventional producers and handlers to lose market share.

With the introduction of national standards to regulate labeling of organic products, processed organic products would acquire commercial item descriptions which are currently used by the food industry to identify conventional products. Adopting bar codes and industry accounting practices which identify organic goods would make sales information more accessible for research and marketing purposes.

*Certifier Benefits*

Certifiers might experience benefits from the rule through reductions in their administrative costs, greater exchange of information, and an increase in demand for certification resulting from an increased demand for organic products and from an expansion of the organic market due to new products entering the market.

There are several ways in which certifiers' administrative costs may be reduced as a result of the rule. First, increased assurance through accreditation might reduce certifiers' costs of maintaining access to organic markets for their clients. Costs associated with establishing reciprocity between certifiers could be eliminated. Accreditation and national standards would remove the need to negotiate individual reciprocity agreements with other certifiers, and would simplify the process of certifying multiple ingredient products, thus reducing certification costs. The responsibility for meeting production and certification requirements of each ingredient would rest with the certified producers and accredited certifiers of the individual ingredients.

Second, certifiers would no longer would have to pay private organizations for the accreditation required to gain access to some international markets. This would be of particular benefit to the smaller certifiers who may have been unable to enter these markets because of the high cost of international accreditation. A portion of the administrative fees paid by each certifying agent would support USDA activities to negotiate equivalency of organic standards in world markets so that producer clients of all USDA accredited certifiers could have access to these markets.

Third, in the long run, uniform standard of production, certification and accreditation should reduce the cost of training certification staff. Industry-wide training costs may increase initially, but should decline as the pool of trained certifiers and certification personnel increases and the corresponding cost of training new certification personnel decreases, especially in those instances where personnel transfer from one certifier to another. Standardized materials, such as compliance guides and training manuals, also should contribute to a reduction in the cost of training certification staff. In addition, USDA accreditation of certifiers would present opportunities for sharing information about standards, practices and the general requirements of the program through the National Organic Program staff. This information is most frequently provided in Small Entity Compliance Guides and other printed material.

The contribution of national standards to increasing domestic demand and opening international markets to U.S. organic products provides opportunities for growth in certification services. Certifiers' average costs of operation may decline as fixed costs are spread over a growing number of producers.

**Costs of the Proposed Rule**

*Direct Program Costs*

The proposed rule would impose direct costs on certifiers in the form of a fee paid to the Federal government for USDA accreditation, which the OFPA requires of all certifiers of organic food products in the United States. Certifiers, in turn, generate revenue by charging producers and handlers a certification fee. Although the proposed rule does not regulate the amount of certification fees, the OFPA does require that food products labeled organic be certified, and that the fees which certifiers collect from producers and handlers for this service be reasonable.

The OFPA also provides for the collection of reasonable fees by USDA from producers and handlers who participate in the national program. The following analysis of costs thus considers both fees to be charged to certifiers and fees to be charged to producers and handlers to recover other program costs.

Certifiers' costs of accreditation are assumed to be passed on to producers and handlers through an increase in certification fees. 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. The majority of certifiers 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.

Direct national program costs would equal the cost of the accreditation program plus the costs of other functions carried out by the organic program staff (salaries, overhead, materials review, compliance costs, etc.). These costs are estimated at approximately $1 million for the first year that the program is in full operation (Table 2). In future years, direct national program costs would depend upon the number of accreditation applicants, annual reports received from certifiers, and the number of producers, handlers and certifiers who participate in the program. Data collected by AMS indicate that the number of organic farmers increased about 12 percent per year and the number of organic handlers increased at about 11 percent per year during the period 1990 to 1994. There

is no indication that the rate of growth has continued, or that the implementation of the organic program would cause an increase in the number of organic operations; however, 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 may increase.

At the current (1995) level of retail sales, the $1 million program costs imply an additional consumer cost from the regulation of approximately .04 cents per dollar. If the known current 44 certifiers were to be accredited and assume the total program cost of $1 million, annual average costs per certifier would be $22,727. Assuming these costs are passed on to the estimated number of 4,600 existing certified organic farmers and handlers, and assuming that these certified farmers and handlers continue in business, certification costs for these 4,600 farmers and handlers would increase by an average of $217 per year as a result of the organic program. This increase may be smaller if more than 4,600 farmers and handlers are certified. Although the current fees are based on the anticipated certification of 4,600 farmers and handlers, we considered for purposes of estimating the reporting and recordkeeping burdens of the proposed rule that the actual total number of certified farmers and handlers who may participate in the national program during the first three years of the program may approximate 12,000 total farmers and handlers combined. These distributions of direct program costs are shown in Table 3. The actual distribution of program costs will be a function of the elasticity of demand for organic goods. The more inelastic the demand, the greater the portion of costs paid by consumers. If demand is elastic, producers and handlers will share a larger portion of the cost, and supply will be affected.

Producers and handlers would be required to produce and handle products in accordance with the standards set forth in the rule, and supply the information necessary to certifiers to verify certification requirements. These requirements are not expected to impose additional costs on those currently certified. Certified farmers and handlers of organic products are currently complying with certification requirements which are not substantially different from those in the proposed rule. Organic producers and handlers who currently are not certified, and new entrants to organic production and handling, would face higher costs.

The type of government fee structure largely would determine how program costs are distributed among certifiers and, secondarily, among producers and handlers. The impact of program costs on certifiers also would depend on the basis for the fees certifiers charge their customers, and on their customers' characteristics.

The provisions for assessing fee for direct services presented in the proposed rule set fixed application and administrative fees of $640 and $2,000, respectively, to be paid by certifiers, with the bulk of accreditation costs billed to certifiers on a time rate for direct services to conduct site visits. The level of these fixed fees, plus the variable fee for direct services, sets a lower bound on the size at which a certifier could operate and be economically viable. A certifier would have to collect enough revenue from the clients it certifies to cover these fees plus operating costs. Due to the fixed components of the fees, larger certifiers would have the ability to spread their costs over a greater number of farmers/handlers. Additionally, as required by the OFPA, a private certifying agent would have to furnish reasonable security for the purpose of protecting the rights of farms and handling operations certified by the certifying agent. The amount and type of security would be established through future rulemaking.

Under the fee for direct services provisions, labor hours, travel and per diem costs for the site inspection required for accreditation would be included in the variable fee for direct services. This practice is used by other USDA agencies that conduct inspection programs. The AMS estimates the average cost to conduct each accreditation site visit to be $3,500 per visit. The frequency of site-evaluations for each certifying agent could be expected to decrease as the operator becomes more familiar with the program regulations. Pre-accreditation site valuations might be necessary to enable the certifier to become accredited, and an evaluation would be required for confirmation of accreditation and thereafter for renewal of accreditation, which occurs every 5 years.

The travel cost component of this figure would vary based on the certifier's distance from Washington, D.C., because site visits will be conducted by the organic program staff headquartered there. An alternative method of distributing travel costs would be to estimate an average annual cost per trip, given the expected number of trips and the geographic distribution of all certifiers, and charge that amount for all site visits, regardless of location.

A measure of size is incorporated into the fee structure, i.e., the time spent conducting each accreditation by organic program staff. The variable portion of the fee would distribute program costs among certifiers according to the resources actually consumed in providing the accreditation service. The more complex and larger the certifier, the more time required to conduct an evaluation and the larger their fee for accreditation. However, imposing an hourly rate for accreditation services introduces a subjective measure in the determination of fees. With several national program staff conducting accreditation evaluations, disputes over the time required to complete a specific accreditation process would be difficult to resolve on an objective basis.

If program costs were distributed uniformly among existing certifiers, the smallest certifiers, those with annual revenues of $25,000 or less, may not have the financial capacity to continue to operate within the requirements of the regulation, based on their current revenues. Distributing program costs based on a measure of size would permit more small certifiers to stay in business, provided that they met other qualifications for accreditation. Generally, a fee structure proportionate to size would result in certifiers contributing to the costs of the program in proportion to the gains they accrue from it, their revenues being based largely on the share of total organic output produced by the operations they certify.

An additional feature of the proposed fees for direct services is that it attempts to distribute program costs according to a simplified measure of size through a variable fee charged directly to farmers and handlers who are certified by an accredited certifying agent. Under the proposed rule, a farmer would pay USDA an annual fee of $50 and a handler would pay $500 per year. The difference between farmer and handler fees is designed to account for the difference in staff time AMS estimates will be devoted to handler and processed food issues relative to farmer and raw product issues. Half of the total program cost of $1 million is assumed to be covered by these fees.

*Administrative Requirements and Associated Costs*

The proposed rule also would impose administrative costs, such as submission of information, recordkeeeping, and access to records that may constitute an additional burden. The actual amount of the additional administrative costs that would be imposed by the final rule is expected to be different for those entities who would begin their activities only after the national program is implemented. Certifiers, farmers, wild crop harvesters 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. The following list describes several proposed administrative requirements or optional submissions and the probable resources required for compliance:

1. A list of farmers, wild crop harvesters and handlers currently certified. This information could be compiled from existing records. After implementation, certifiers would be required to submit on a quarterly basis a list of operations certified during that quarter.

2. A description of the certification decision process, compliance review procedures, a plan for allowing public access to records, and measures taken to prevent conflicts of interest. These policies may have to be created or modified to conform to the regulation.

3. Documentation of financial capacity and compliance with other administrative requirements (e.g., fee structure, recordkeeping capability, income sources, and business relationships showing absence of conflicts of interest). Some of this information would be compiled from existing records (e.g., income sources and fee schedules), and some may be generated from other sources.

4. Retention of certification documents for 10 years. This activity requires records and database management capabilities and resources (storage space, file cabinets, electronic storage, etc.). In an informal inquiry, AMS found that most existing certifiers currently retain records for at least 10 years, and use both electronic and paper storage. We believe that this requirement

would not pose an additional burden on existing certifiers.

The Act also requires producers and handlers to retain their records for a minimum of five years. According to the same informal AMS inquiry, the industry generally requires records to be kept for three years. Overall, producer and handler operation records required by the proposed regulation are extensions of, or modifications to, documents already maintained under normal industry practice, and therefore this requirement would have minimal impact on operations currently certified.

5. Public access would have to be provided 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 would have minimal impact given the requirements for retaining records.

6. Certifiers are required to supply program information to certification applicants. To comply with this requirement, certifiers may need to modify existing standards and practice.

The criteria for qualified personnel required in the proposed rule may likely result in an increase in labor costs for some existing certifiers and, initially, an increase in training costs. The amount of additional costs to these certifiers would depend on the level of expertise among current certification agency staff, the extent to which certifiers currently rely on volunteers, and the current costs of training certification staff.

Our proposed inspector training requirements conform closely to current established practice in the industry and are not expected to impose an additional burden on most existing certifiers. 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 certifiers (IOIA, p. 1).

Costs to existing certifiers 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 certifiers, producers and handlers by providing guide books and other printed material that would enable participants to better understand the regulations. In addition, AMS intends to continue open and frequent communication with certifiers and inspectors to provide as much information as possible to aid them in fulfilling the requirements of the regulations.

Table 5 estimates the total initial costs for an applicant to become accredited as a certifying agent under the NOP, and the estimated total initial costs for a producer or handler to become certified. The costs presented in Table 5 are the upper-bound estimates for participation in the National Organic Program for new organic certifiers, farmers and handlers.

*State Program Costs of the Proposed Rule*

The proposed rule is based on the OFPA, a review of State and private certification programs, National Organic Standards Board (NOSB) recommendations, EU regulations, and foreign organic program provisions. Table 4 compares many general provisions of the proposed rule to existing State and private certification programs and the NOSB recommendations. The proposed rule encompasses most of the principles of existing State programs, with specific requirements modified to be performance-based rather than design-based. For example, the proposed standards for housing poultry require that farmers provide adequate light and space, rather than requiring a particular method of housing. With a performance-based rule, certifiers are free to exercise their judgement regarding how farmers meet the standards. Thus, the proposed rule provides greater flexibility than is provided by many existing programs in determining how a particular standard can be met.

In many cases, the proposed rule provides standards where many existing State programs are silent. For example, according to AMS data, only two of the eleven State agencies and 16 of the 33 private agencies certified livestock in 1994. In the same year, only six of the eleven States and 15 of the 33 private agencies certified processors or handlers.

There are 27 States with some standards governing the production or handling of organic food, and comparing features of State standards to the provisions of the proposed rule provides a means of examining the potential impact of the rule on existing State programs. There are two situations in which implementation of a national program may impose additional costs on States by requiring changes in their existing programs. First, 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. Second, where State standards exceed the Federal standards and the differences are not approved by the USDA, 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. In States with existing organic standards but no certification program, such as California, the national standards would apply to private certifiers operating within the State and, therefore, they also are relevant to indicating the degree of impact a national program would have on existing State programs. An analysis of selected aspects of specific standards follows:

*Transition period.* The transition period, which would specify the time period during which prohibited materials cannot be applied before a field can be certified as organic, is included in most State organic standards. The OFPA specifies a required transition period of three years before certifying a field. Existing certifiers and farmers will have had several years prior to implementation to conform with this requirement and its impact is expected to be minimal. In fact, a required transition period of three years is currently in effect in 20 out of 23 States.

*Animal drug use.* Another common feature of organic standards is the restricted use of animal drugs for livestock. Where livestock standards have been adopted by existing State programs, most prohibit the use of animal drugs except for the treatment of a specific disease condition. Use of animal drugs is generally prohibited within 90 days prior to slaughter, or the sale of milk or eggs as organic. The standards in the proposed rule would impose a more restrictive time period for drug use in animals for slaughter, but do not differ from most existing State standards in prohibiting the use of drugs on healthy animals.

*Materials list.* Lists of approved synthetic materials, including soil amendments and pesticides, vary from one State program to another. A detailed analysis of specific differences in the various existing materials lists shows them to be overlapping in most cases, but mutually exclusive in others. The impact of the national program would not be determined by how the national standards differ from current certification standards, but rather by how the national standards differ from actual practice. Data on materials currently used in organic production are not available to make this comparison.

*Non-Quantifiable Costs*

Some certifiers have identified the loss of independence in setting certification standards within a uniform national standard program as imposing a cost. Certification to a national standard has been described as ''forced reciprocity,'' that is, compelling certifiers to recognize as equal in value a product certified by a competitor. A national accreditation program would preclude a certifier of an end product from refusing to accept a different certification of an ingredient used in the end product. A lack of reciprocity can, in fact, impose costs on manufacturers in the form of lost product (Natural Foods Merchandiser, April 1995). Other certifiers welcome the enforcement of uniform national standards and view mandatory accreditation as a benefit because it would eliminate the risk of potentially costly reciprocity disputes. What appears to be at stake is the determination of market shares among certifiers: losses to one certifier would constitute gains to others.

Another possible cost of the rule may result from the requirement that certifiers provide access to records. The Secretary and the applicable governing State official would have access to all records and certifiers would have to provide public access to laboratory analyses and certification documents other than confidential business information. While not quantifiable, this requirement may represent a substantial change in the way some certifiers currently operate and interact with producers, other certifiers, government agencies, and the public.

**Conclusion**

Ideally, the net benefits of the proposed rule would be estimated by employing a welfare analysis. In a welfare model, the quantitative assessment of benefits would be represented by net changes in consumer and producer surplus, i.e., the difference between

the willingness to pay (or firm cost structure in the case of producers) and the market price of organic food. These net changes would be estimated using information about the cost structure of the industry, the demand for organic food, and projected shifts in supply and demand resulting from the various factors discussed in the assessment. Although researchers have conducted numerous small-scale studies to determine consumers' willingness to pay for certain organic products (primarily fresh produce) and to identify reasons why conventional food buyers do not choose organic food products (Hammitt, 1990 and 1993; Jolly; Misra et al.; Park and Lohr; Weaver et al.), the available data are insufficient to support a quantitative assessment of this type.

USDA has identified the entities that may be affected by the proposed rule and has analyzed the anticipated impacts of the rule on them based on our knowledge of the industry and limited data. However, USDA lacks data to thoroughly and quantitatively describe the existing organic industry and quantitatively analyze the effects of the proposed rule. To assist in the assessment of comments on the rule and to better report to the public the effects of the rule, USDA welcomes responses in the following areas. USDA is particularly interested in data and analyses that are nationally representative.

1. To establish a baseline, USDA requests data on the number of farmers producing and marketing organic goods, the number of handlers of organic goods, and the number of organic farmers, wild crop harvesters and handlers who are operating with third party certification, and the number who operating without third party certification..

2. To establish a baseline, USDA requests data on the number of entities certifying organic farmers and handlers and the number of organic certifiers who currently are accredited.

3. To establish a baseline, USDA requests data to characterize the costs of organic production and revenues from organic farming.

4. To assess the impact of the proposed program, USDA requests data on fees currently paid by organic producers and handlers for certification services and on fees currently paid by organic certifiers for accreditation.

5. To assess the impacts of the proposed program and to better project the costs of operating the National Organic Program (which will be recovered by fees), USDA requests information to project the number of organic producers and handlers who would apply for certification under the National Organic Program. USDA also requests information to project the number of entities which would seek USDA accreditation as an organic certifying agent.

6. The regulatory impact assessment for the proposed rule considers that cost may be incurred by fraudulent labeling of organic products. To what extent does mislabeling of non-organically produced products as organic occur and what are the market impacts in terms of quantities of organic goods sold and the prices for organic goods?

7. This rule would permit the marketing of meat and poultry products as organic, which is not currently permitted. USDA requests data and analyses which would support projections of the demand for organic meat and poultry.

8. The regulatory impact assessment for this rule reports that sales of organic goods have been growing at an annual rate of 20 percent. Are there data to support a different rate?

9. We estimate that the organic industry may grow after program implementation due to the introduction of organic meat and poultry and increased exports of organic agricultural products. Are there data to estimate the impact that this rule is likely to have on overall industry growth?

10. The organic industry and consumers of organic goods may benefit if industry growth results in economies of scale, and production and marketing efficiencies. What has been the industry experience in this area and do industry participants anticipate such benefits from this rule?

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TABLE 1.—ORGANIC SALES, 1980–1995

| Year | Sales (in $ millions) |
|---|---|
| 1980 | 178 |
| 1989 | 631 |
| 1990 | 1,000 |
| 1991 | 1,250 |
| 1992 | 1,540 |

TABLE 1.—ORGANIC SALES, 1980–1995—Continued

| Year | Sales (in $ millions) |
|---|---|
| 1993 | 1,890 |
| 1994 | 2,310 |
| 1995 | 2,800 |

Source: Emerich, p. 23.

TABLE 2.—BREAKDOWN OF PROJECTED NATIONAL ORGANIC PROGRAM COSTS

[Total Program Costs]

| | |
|---|---|
| Salaries and Benefits | $644,000 |
| Operating Costs* | 180,617 |
| Agency Overhead** | 100,403 |
| Division Overhead** | 74,980 |
| Total | 1,000,000 |
| Total Staffing | 12 |

*Operating costs include travel, printing, training, equipment, supplies, rent and other services.

**Agency and Division overhead includes administrative support, contract and other fees for services, rent, heat, communications, and major equipment purchases.

Source: AMS.

TABLE 3.—DISTRIBUTION OF DIRECT ANNUAL PROGRAM COSTS FOR OFPA

[In dollars]

| | |
|---|---|
| Direct program costs | $1,000,000 |
| Costs per dollar sales ($2.8 billion) | 0.00036 (.036¢) |
| Costs per certifier (44 certifiers) | 22,727 |
| Costs per farmer/handler (4,600 farmers/handlers) | 217 |

Source: AMS data; Emerich, p. 23.

TABLE 4.—COMPARISON OF THE PROPOSED NATIONAL ORGANIC PROGRAM REGULATIONS WITH THE NOSB RECOMMENDATIONS AND REPRESENTATIVE STATE AND PRIVATE PROGRAMS

| USDA provision in the proposed rule | NOSB recommendation | State programs | Private programs |
|---|---|---|---|
| PRODUCTION AND HANDLING: | | | |
| Standards based on identified organic principles | Recommended principles which USDA used in the proposed rule. | Similar principles | Similar principles. |
| Management includes long-range planning, such as an organic plan | Similar | Similar | Similar. |
| Preventive measures and mechanical or biological methods, as opposed to substances, used to control pests, weeds, and disease in crops and livestock. | Similar | Similar; few States have livestock standards. | Similar; few programs have livestock standards. |
| Organic planting stock, livestock, and ingredients used in preference to non-organic. | Similar | Similar | Similar. |
| Livestock may be fed non-organic feed under certain circumstances | Similar | Similar | Similar. |
| Prevention of prohibited substances contacting organic products | Similar | Similar | Similar. |
| Allowed use of specific synthetic substances | Proposed National List reflects almost all of the NOSB recommendations. | Similar; lists vary among States. | Similar; lists vary among programs. |
| Criteria for list of allowed synthetic substances | Similar | General criteria are similar. | General criteria are similar. |
| Mechanical or biological methods, as opposed to substances, used in handling operations. | Similar | Similar; few States have handling standards. | Similar; few programs have handling standards. |
| Allowed use of non-organic agricultural ingredients in processed organic food. | Similar | Similar | Similar. |
| Allowed use of specific non-agricultural ingredients in processed organic food. | Proposed National List reflects almost all of the NOSB recommendations. | Similar, but few States have handling standards; lists differ. | Similar, but few programs have handling standards; lists differ. |
| CERTIFICATION: | | | |
| Products labeled organic must originate from certified operations | Similar | Few States do their own certification but generally producers and handlers are certified. | Private programs generally certify. |
| Certification performed by a third-party in a prescribed manner | Similar | Similar for States that require certification. | Similar. |
| Annual certification with verification by inspection of site and records | Similar | Similar for States that require certification. | Similar. |
| All certifications granted by accredited certifiers are to be considered equivalent. | Similar | Equivalency granted on a case-by-case basis. | Equivalency granted on a case-by-case basis. |
| ACCREDITATION: | | | |

TABLE 4.—COMPARISON OF THE PROPOSED NATIONAL ORGANIC PROGRAM REGULATIONS WITH THE NOSB RECOMMENDATIONS AND REPRESENTATIVE STATE AND PRIVATE PROGRAMS—Continued

| USDA provision in the proposed rule | NOSB recommendation | State programs | Private programs |
|---|---|---|---|
| All certifiers must be accredited by USDA | Similar | Very few States accredit or register certifiers. | Very few programs are accredited by private organizations. |
| Certifiers evaluate and train inspectors and certification personnel | Similar | Similar; differs among States. | Similar; differs among programs. |
| Recordkeeping requirements, public access requirements, and safeguard requirements for confidential information. | Similar | Similar | Similar. |
| Measures enforced to prevent conflict of interest by certifier | Similar | Similar, as part of State's general requirements. | Similar, but may not be monitored. |
| Certifier performance reviewed by peers | Similar | Similar in any State accrediting certifiers. | Similar for the purpose of establishing reciprocity. |
| OTHER ELEMENTS: | | | |
| Site-specific unavoidable residual environmental contamination level used to determine organic status. | Predetermined unavoidable residual environmental contamination level should be used to determine organic status. | Similar, but some States also use a predetermined specified residue level to determine organic status. | Similar, but some programs also use a predetermined specified residue level to determine organic status. |
| Enforcement by Federal government | Similar | Intra-State enforcement of existing State regulations. | Enforcement of individual program policies. |
| Access to international markets | Not applicable | Individually acquired agreements. | Individually acquired agreements. |
| Evaluation of foreign programs to determine equivalency | Similar | Not applicable | Not applicable. |

Source: AMS.

TABLE 5.—ESTIMATED UPPER-BOUND COSTS OF ACCREDITATION AND CERTIFICATION

| | |
|---|---|
| **ESTIMATED COST TO CERTIFIERS FOR INITIAL ACCREDITATION** | |
| Accreditation application fee | $640 |
| Site evaluation fee* | 3,500 |
| USDA Administrative fee | 2,000 |
| Total fees | 6,140 |
| Paperwork reporting burden | 23,931 (for new organic certifiers) |
| Paperwork recordkeeping burden | 60 |
| Total reporting and recordkeeping | 23,991 |
| ESTIMATED TOTAL COST FOR INITIAL ACCREDITATION | 30,131 |
| **ESTIMATED COST TO PRODUCERS FOR INITIAL CERTIFICATION** | |
| Certification fee** | $413 |
| USDA fee | 50 |
| Total fees | 463 |
| Paperwork reporting burden | 381 (for new organic producers) |
| Paperwork recordkeeping burden | 34 |
| Total reporting and recordkeeping | 415 |
| ESTIMATED TOTAL COST TO PRODUCERS FOR INITIAL CERTIFICATION | 878 |
| **ESTIMATED COST TO HANDLERS FOR INITIAL CERTIFICATION** | |
| Certification fee** | 943 |
| USDA fee | 500 |
| Total fees | 1,443 |
| Paperwork reporting burden | 433 (for new organic handlers) |
| Paperwork recordkeeping burden | 34 |
| Total reporting and recordkeeping | 467 |

TABLE 5.—ESTIMATED UPPER-BOUND COSTS OF ACCREDITATION AND CERTIFICATION—Continued

| | |
|---|---|
| ESTIMATED TOTAL COST TO HANDLERS FOR INITIAL CERTIFICATION | 1,910 |

*Each certifying agent would have a site-evaluation to confirm accreditation, and thereafter a subsequent renewal evaluation at least every 5 years following confirmation of accreditation. In some cases, a pre-confirmation site visit may be necessary. We anticipate that the frequency of site evaluation would be based on the performance of the certifying agent and would be higher during the initial years of the program.

**The estimated certification fee is based on the average of fees charged by a representative group of certifying agents: private non-profit, private for-profit and a State agency. Most certifying agents in our representative group include the cost of inspection and, if applicable, required laboratory testing in the certification fee.

Source: AMS.

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## Part III

# Department of Housing and Urban Development

**Funding Availability for: The HUD-Administered Small Cities Community Development Block Grant (CDBG) Program—Fiscal Year 1997 and Fiscal Year 1998; and the Section 108 Loan Guarantee Program for Small Communities in New York State; Notice**

## DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

**[Docket No. FR–4256–N–01]**

## Notice of Funding Availability for: The HUD-Administered Small Cities Community Development Block Grant (CDBG) Program—Fiscal Year 1997 and Fiscal Year 1998; and the Section 108 Loan Guarantee Program for Small Communities in New York State

**AGENCY:** Office of the Assistant Secretary for Community Planning and Development, HUD.

**ACTION:** Notice of Funding Availability for Fiscal Years 1997 and 1998.

**SUMMARY:** This Notice of Funding Availability (NOFA) announces: (1) the availability of approximately $49,456,000 in Fiscal Year (FY) 1997 funding and approximately $54,000,000 in Fiscal Year 1998 funding for the HUD-administered Small Cities Program in New York State under the Community Development Block Grant (CDBG) Program; and (2) the availability of a maximum of approximately $200,000,000—$250,000,000 in FY 1998 funding under the Section 108 Loan Guarantee program for small cities in New York State. Amounts available under the Section 108 Loan Guarantee program are not awarded competitively and are not rated under the criteria of this NOFA. Grants awarded under this NOFA for activities and projects for which Section 108 assistance will also be needed, however, will be conditioned upon approval of the requisite Section 108 application within a stated time.

The exact amount of funds that will be available from the approximately $49,456,000 of FY 1997 funds and the approximately $54,000,000 of FY 1998 funds that communities will be able to compete for under this NOFA is not known at this time. This amount will not be known until HUD receives applications and makes determinations for grants based on multiyear plans approved in FY 1995 and FY 1996. In addition, in FY 1997 HUD carried out the Canal Corridor Initiative (see the NOFA for this initiative in the **Federal Register** on December 3, 1996 (61 FR 64196) and the amendment published in the **Federal Register** on December 12, 1996 (61 FR 66692)). Pursuant to that NOFA, HUD approved Canal Corridor applications for approximately $6.5 million in Fiscal Year 1997 New York Small Cities funds. HUD must also be prepared, pursuant to 24 CFR 570.432, to use CDBG funds each year, as necessary, for the sole purpose of paying any amounts due on debt obligations, for up to 20 years, issued by units of general local government (or their designated public agencies) and guaranteed by the Secretary pursuant to section 108 of the Housing and Community Development Act of 1974, as amended, for projects approved under the Canal Corridor Initiative NOFA. At this time, the exact amount of CDBG funds that will be needed to meet required debt obligation payments during Fiscal Year 1998 is not known. However, in the December 3, 1996 NOFA, HUD estimated that the average amount of CDBG funds required to meet the debt obligation payments would not exceed an average of $3 million per year over a 20-year period.

The funds announced in this NOFA provide small communities and counties in New York State with an opportunity to propose programs that focus on creating or expanding job opportunities, addressing housing needs, or meeting local public facilities needs. HUD encourages communities to propose programs that are creative and innovative in addressing the needs of their community. A community may propose a program that is ''single purpose'' in nature addressing a specific area of need. In the final rule published in the **Federal Register** on November 25, 1997 (62 FR 62912), HUD decreased the maximum grant amount for a Single Purpose grant to $400,000, except for applications from a county. The maximum amount for a Single Purpose grant to a county is $600,000. However, because this NOFA covers funding for two fiscal years, applicants may submit and be funded for up to two applications. The $400,000 (or $600,000 in the case of a county) maximum grant award limit will apply to each application and grant awarded. Each application will be rated and ranked independently and must be for independent projects. HUD will not make any Single Purpose multiyear awards with FY 1997 or FY 1998 funds under this NOFA. HUD will honor previous multiyear plans approved in FY 1995 and FY 1996. Multiyear recipients should carefully review the limitations and requirements contained in section I.D. of this NOFA.

**DATES:** Applications (including applications from recipients approved for a multiyear plan for second or third component in FY 1997 or FY 1998) are due by March 2, 1998. Application kits may be obtained from and must be submitted to either HUD's New York or Buffalo Office. (The addresses for these offices are provided in Section II. of this NOFA.)

Applications, if mailed, must be postmarked no later than midnight on March 2, 1998. If an application is hand-delivered to the New York or the Buffalo Office, the application must be delivered to the appropriate office by no later than 4:00 p.m. (local time) on March 2, 1998.

Application kits will be made available by a date that affords applicants no fewer than 45 days to respond to this NOFA. For further information on obtaining and submitting applications, please see Section II. of this NOFA.

The above-stated application deadline is firm as to date and hour. In the interest of fairness to all competing applicants, HUD will treat as *ineligible for consideration* any application that is not received by 4:00 p.m. on, or postmarked by, March 2, 1998. Applicants should take this procedure into account and make early submission of their materials to avoid any risk of loss of eligibility brought about by unanticipated delays or other delivery-related problems.

**FOR FURTHER INFORMATION CONTACT:** Cornelia B. Robertson-Terry, State and Small Cities Division, Office of Community Planning and Development, Department of Housing and Urban Development, Room 7184, 451 Seventh Street SW, Washington, DC 20410; telephone (202) 708–1322 (this is not a toll-free number). Hearing or speech-impaired individuals may access this number via TTY by calling the toll-free Federal Information Relay Service at 1–800–877–8339.

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## I. Purpose and Substantive Description

### *A. Authority and Background*

#### 1. Authority

Title I, Housing and Community Development Act of 1974 (42 U.S.C. 5301–5320) (1974 HCD Act); 24 CFR part 570, subpart F, for the New York State Small Cities program, and subpart M for the Section 108 Loan Guarantee program.

#### 2. Background

Title I of the 1974 HCD Act authorizes the Community Development Block Grant (CDBG) Program. Section 106(d) of Title I permits States, in such manner and at such time as the Secretary shall prescribe, to elect to assume the administrative responsibility for the CDBG Program for nonentitled areas within their jurisdiction. Section 106 provides that HUD will administer the CDBG Program for nonentitled areas within any State that does not elect to assume the administrative responsibility for the program. HUD's regulations at 24 CFR part 570, subpart F describe the requirements for HUD's administration of the CDBG Program in nonentitled areas (Small Cities Program). This NOFA supplements subpart F of 24 CFR part 570.

In accordance with 24 CFR 570.421(b), and with the requirements of section 102 of the Housing and Urban Development Reform Act of 1989 (HUD Reform Act), HUD is issuing this NOFA for New York State's Small Cities Program for FY 1997 and FY 1998. This NOFA announces the allocation of funds for a Single Purpose grant competition, and establishes the deadline for filing grant applications. The NOFA explains how HUD will apply the regulatory threshold requirements for funding eligibility, and the selection criteria for rating and scoring applications for Single Purpose grants.

HUD has issued final regulations at 24 CFR 570.420—570.432 which govern the HUD-administered Small Cities program in New York. HUD will no longer approve new multiyear plans. HUD will honor previous multiyear plans approved in FY 1995 and FY 1996. HUD intends to fund future years of previously approved multiyear plans on a noncompetitive basis, based on satisfactory past performance and a continuing capacity for carrying out the proposed CDBG program activities and submission of an acceptable application and certifications.

Other information about the Small Cities Program will be provided in the application kit, which will be made available to applicants by HUD's New York Office and Buffalo Office (see Section II. of this NOFA).

#### 3. Other Program Requirements

a. *Abbreviated Consolidated Plan.* Each jurisdiction that applies for funds under this NOFA must have submitted a consolidated plan, as provided in 24 CFR part 91. An applicant under this NOFA for more than one grant need submit only one consolidated plan or abbreviated consolidated plan, as applicable, covering the activities proposed in both applications. A jurisdiction that does not expect to be a participating jurisdiction in the HOME program under 24 CFR part 92 may submit an abbreviated consolidated plan that is appropriate to the types and amounts of assistance sought from HUD (see 24 CFR 91.235). Any applicant that plans to undertake a housing activity with funds under this NOFA needs to prepare and submit, at a minimum, an abbreviated consolidated plan that is appropriate to the types and amounts of housing assistance sought under this NOFA.

Even if the community's Small Cities application is approved, HUD must also approve an abbreviated consolidated plan that covers activities proposed in such application(s) before the community may receive Small Cities funding. Further, that applicant must also include a certification that the housing activities in its CDBG Small Cities application are consistent with the consolidated plan. The applicant's consolidated plan must describe the jurisdiction's priority nonhousing community development needs eligible for assistance under the CDBG program by eligibility category, reflecting the needs of families for each type of activity, as appropriate, in terms of dollar amounts estimated to meet the priority need for the type of activity (see 24 CFR 91.235(c)(2)).

The abbreviated consolidated plan is subject to the same citizen participation requirements as is the jurisdiction's Small Cities CDBG application. Both must meet the citizen participation requirements before they may be submitted to HUD (see 24 CFR 570.431). A Section 108 Loan Guarantee application would also have to meet citizen participation requirements, as described in 24 CFR 570.704, if the jurisdiction submits one to HUD for consideration.

If possible, an applicant should submit the abbreviated consolidated plan in advance of the Small Cities application due date. The latest time at which the abbreviated consolidated plan will be accepted by HUD for the HUD-administered Small Cities Program in New York will be March 2, 1998 (the application due date for the Small Cities application). *Failure to submit the abbreviated consolidated plan by the due date is not a curable technical deficiency.* Questions regarding the abbreviated consolidated plan should be directed to the appropriate HUD field office.

Any application that is fundable but does not have an approved consolidated

plan will receive a conditional approval subject to HUD's approval of the abbreviated consolidated plan. If HUD is unable to approve the abbreviated consolidated plan within a reasonable period of time (but not more than 60 days from the date that the conditional approval is announced), HUD will rescind the award. In such event the funding will be awarded to the highest rated fundable applicant that did not receive funding under this competition.

b. *Section 3.* Assistance provided under this NOFA is subject to the requirements of section 3 of the Housing and Urban Development Act of 1968 (12 U.S.C. 1701u), and HUD's implementing regulations in 24 CFR part 135. One of the purposes of this NOFA, which is consistent with section 3, is to give, to the greatest extent feasible and consistent with Federal, State, and local laws and regulations, job training, employment and other contracting opportunities generated from certain HUD financial assistance to low- and very low-income persons. Public entities awarded funds under this NOFA that intend to use the funds for housing rehabilitation, housing construction, or other public construction must comply with the applicable requirements set forth in 24 CFR part 135.

4. Accountability in the Provision of HUD Assistance: Documentation and Public Access Requirements; Applicant/Recipient Disclosures

Section 102 of the Department of Housing and Urban Development Reform Act of 1989 (42 U.S.C. 3545) (HUD Reform Act) and the regulations codified in 24 CFR part 4, subpart A, contain a number of provisions that are designed to ensure greater accountability and integrity in the provision of certain types of assistance administered by HUD. On January 14, 1992 (57 FR 1942), HUD published a notice that also provides information on the implementation of section 102. The documentation, public access, and disclosure requirements of section 102 are applicable to assistance awarded under this NOFA as follows:

a. *HUD Responsibilities.* (1) *Documentation and Public Access.* HUD will ensure that documentation and other information regarding each application submitted pursuant to this NOFA are sufficient to indicate the basis upon which assistance was provided or denied. This material, including any letters of support, will be made available for public inspection for a 5-year period beginning not less than 30 days after the award of the assistance. Material will be made available in accordance with the Freedom of Information Act (5 U.S.C. 552) and HUD's implementing regulations at 24 CFR part 15. In addition, HUD will include the recipients of assistance pursuant to this NOFA in its **Federal Register** notice of all recipients of HUD assistance awarded on a competitive basis.

(2) *Disclosures.* HUD will make available to the public for 5 years all applicant disclosure reports (HUD Form 2880) submitted in connection with this NOFA. Update reports (also Form 2880) will be made available along with the applicant disclosure reports, but in no case for a period less than 3 years. All reports—both applicant disclosures and updates—will be made available in accordance with the Freedom of Information Act (5 U.S.C. 552) and HUD's implementing regulations at 24 CFR part 15.

b. *Units of General Local Government Responsibilities.* Units of general local government awarded assistance under this NOFA must ensure that documentation and other information regarding each application submitted to the recipient by a subsequent recipient applicant are adequate to indicate the basis upon which assistance was provided or denied. The unit of general local government must make this material, including any letters of support, available for public inspection for a 5-year period beginning not less than 30 days after the award of the assistance. Unit of general local government recipients must also notify the public of the subsequent recipients of the assistance. Each recipient will develop documentation, public access, and notification procedures for its programs.

*B. Allocation Amounts*

1. Total Available Funding

The nonentitlement CDBG funds for New York State for FY 1997 total approximately $56,022,000 and for FY 1998 total approximately $54,000,000. The exact amount of funds available for the Small Cities CDBG is not known at this time. The final amount available will not be known until HUD receives applications and makes grants based on multiyear plans approved in FY 1995 and FY 1996. This amount will not be known until the communities have submitted their applications to HUD and determinations have been made by HUD regarding each community's past performance and the community's continuing capacity to carry out additional CDBG activities; however, the total amount of previously approved multiyear plans, if submitted and approved by HUD, would be approximately $24.6 million in FY 1997 funds and approximately $12 million in FY 1998 funds. In addition, in FY 1997 HUD carried out the Canal Corridor Initiative (see the NOFA for this initiative in the **Federal Register** on December 3, 1996 (61 FR 64196) and as amended on December 18, 1996 (61 FR 66692)). HUD must be prepared, pursuant to 24 CFR 570.432, to use CDBG funds each year, as necessary, for the sole purpose of paying any amounts due on debt obligations, for up to 20 years, issued by units of general local government (or their designated public agencies) and guaranteed by the Secretary pursuant to section 108 of the Housing and Community Development Act of 1974, as amended, for projects approved under the Canal Corridor Initiative NOFA. HUD approved approximately $6.55 million in FY 1997 Small Cities funds for Canal Corridor grants. However, at this time, the exact amount of CDBG funds that will be needed to meet required debt obligation payments during Fiscal Year 1998 is not known. Of the approximately $103,456,000 available under this NOFA, approximately *$90,835,000* is allocated for distribution to eligible units of general local government within the jurisdiction of HUD's New York Buffalo Field Office. Approximately *$12,621,000* is allocated for distribution to eligible units of general local government within the jurisdiction of HUD's New York Office. Once HUD has determined the final amount of funds available for competitive distribution under this NOFA, HUD will allocate such funds in the same ratio as above to HUD's Buffalo and New York Offices. However, HUD has the option to revise these final allocations between offices by up to $400,000 in order to assure full distribution of funds. Finally, HUD reserves the right, in its sole discretion, not to award all of the funds available under this NOFA and to make any such funds available in a future NOFA, if an insufficient number of applications are determined fundable under this NOFA.

2. Imminent Threats

All imminent threat projects must meet the national objective of benefitting low-and moderate-income persons. HUD may elect to set aside up to 15 percent of the FY 1997 and/or the FY 1998 allocations for imminent threat projects. These funds will be available until the rating and ranking process for funds distributed under this NOFA is completed.

*C. Eligibility*

1. Eligible Applicants

Eligible applicants are units of general local government in New York State, excluding: (1) metropolitan cities; (2) urban counties; (3) units of government which are participating in urban counties or metropolitan cities even if only part of the participating unit of government is located in the urban county or metropolitan city; and (4) Indian tribes (as defined in section 102(a)(17) of the 1974 HCD Act). Applications may be submitted individually, or jointly, as described in 24 CFR 570.422. However, applicants that were approved for a 2- or 3-year comprehensive plan in FY 1995 or FY 1996 may submit the required application by the deadline date set above for applications under this NOFA in order to receive the second and/or third year increment as applicable (see sections I.D.2.b. and I.D.4.b. of this NOFA), but may not submit a separate application for single purpose grant under this NOFA unless they notify HUD no later than the deadline for receipt of applications under this NOFA that they are relinquishing their second or third year multiyear funds.

2. Previous Grantees

Eligible applicants that previously have been awarded Small Cities Program CDBG grants are also subject to an evaluation of capacity and performance (see generally, section I.E.2. of this NOFA). Numerical thresholds for drawdown of funds have been established to assist HUD in evaluating a grantee's progress in implementing its program activities. (These standards apply to all CDBG Program grants received by the community.) In FY 1996 an additional threshold was established which relates to the submission of annual Performance Assessment Reports (PARs). A PAR was due on October 31, 1997, for each grant which a local government received prior to April 1, 1996. *Failure to submit a PAR is not a curable technical deficiency.*

Applicants generally will be determined to have performed adequately in the area(s) where the thresholds are met. Where a threshold has not been met, HUD will evaluate the documentation of any mitigating factors, particularly with respect to actions taken by the applicant to accelerate the implementation of its program activities.

3. Eligible Activities and National Objectives

Eligible activities under the Small Cities CDBG Program are those identified in subpart C of 24 CFR part 570. With respect to the Section 108 Loan Guarantee program, eligible activities are identified in § 570.703. Note that § 570.703 does not include all CDBG-eligible activities. Each activity under both programs must meet one of the national objectives (i.e., benefit to low- and moderate-income persons, elimination of slums or blighting conditions, or meeting imminent threats to the health and safety of the community; see § 570.208), and each grant and use of Section 108 Loan Guarantee proceeds must meet the requirements for compliance with the primary objective of principally benefitting low- and moderate-income persons, as required under § 570.420(e). The principal benefit requirement under the CDBG program is 70 percent. The method of calculating the use of these funds for compliance with the 70 percent overall benefit requirement is set forth in § 570.420(e). In general, all applications must describe the projects and activities proposed in sufficient detail that compliance with these and other applicable statutory, regulatory, and NOFA provisions can be determined.

4. Environmental Review Requirement

The HUD environmental review procedures contained in 24 CFR part 58 apply to this program. Under part 58, grantees assume all of the responsibilities for environmental review, decisionmaking and action pursuant to the National Environmental Policy Act of 1969 (42 U.S.C. 4321 et seq.) and the other provisions of law specified by the Secretary in 24 CFR part 58 that would apply to the Secretary were he to undertake such projects as Federal projects.

*D. Types of Grants*

1. Comprehensive Grants

There will not be a competition for new comprehensive grant awards for FY 1997 or FY 1998. However, HUD will honor those existing multiyear commitments awarded in FY 1995 and FY 1996, provided the community submits to HUD an acceptable application and HUD's review of the community's past performance is satisfactory. HUD's review must also indicate that the community has sufficient continuing capacity to carry out the proposed CDBG activities.

2. Single Purpose Grants

a. *General.* Single Purpose grants are designed to address and resolve a specific community development need. A Single Purpose grant may consist of more than one project. A project may consist of one activity or a set of activities. Each project must address community development needs in one of the following problem areas:

- Housing.
- Public Facilities.
- Economic Development.

Each project will be rated against all other projects addressing the same problem area, according to the criteria outlined below. It should be noted that each project within an application will be given a separate impact rating, if each one is clearly designated by the applicant as a separate and distinct project (i.e., separate Needs Description, Community Development Activities, Impact Description and Program Schedule forms have been filled out, indicating project names). In some cases, it may be to the applicant's advantage to designate separate projects for activities that can ''stand on their own'' in terms of meeting the described need, especially where a particular project would tend to weaken the impact rating of the other activities, if they were rated as a whole, as has been the case with some economic development and housing projects. If, however, the projects tend to meet impact criteria to the same extent, or the weaker element is only a small portion of the overall project, there is no discernable benefit in designating separate projects.

b. *Grant Limits and Funding Requirements.* The maximum annual grant for a Single Purpose grant is $400,000, except that counties may apply for up to $600,000 in Single Purpose funds, if the project will be carried out in more than one community. If other sources of funds are to be used with respect to a project, the source of those funds must be identified and the level of commitment indicated. With respect to grant limits for joint applicants, the maximum amount that may be awarded pursuant to a joint application is the maximum single grant limit established above for communities and counties multiplied by the number of participants in the cooperation agreement, provided that for purposes of determining such a multiple grant limit, and in order to receive that amount, a participating joint applicant must receive a substantial direct benefit from the activities proposed in the application and must not be acting solely on behalf of or in conjunction

with another jurisdiction for the sole purpose of raising the maximum grant amount that may be awarded. In addition, the statistics of each participant counted for maximum grant limits purposes shall also be used for purposes of the selection factors under section I.E.3. of this NOFA.

Because this NOFA covers funding for two fiscal years, applicants may submit up to two applications and receive two grants. The $400,000 (or $600,000 in the case of a county) maximum grant award limit will apply to each application and grant awarded. Each application will be rated and ranked independently, and must be for independent projects.

c. *Special Limitations for Multiyear Plan Recipients.* With respect to a 3-year multiyear plan approved for FY 1995, FY 1996 and FY 1997, in which the applicant still wishes to apply for and receive its FY 1997 increment, the applicant may apply for and receive approval for one Single Purpose grant of $400,000 (or $600,000 in the case of a county) under this NOFA. Similarly, a grantee that received approval of a 2-year, multiyear plan for FY 1996 and FY 1997, and for which the applicant still wishes to apply for and receive its FY 1997 increment, that community may apply for and receive approval for one Single Purpose grant of $400,000 (or $600,000 in the case of a county) under this NOFA. However, an applicant that received approval of an FY 1996 multiyear plan for FY 1996, 1997, and 1998, and that still wishes to apply for and receive approval for its FY 1997 and FY 1998 increments, may not apply for a Single Purpose grant under this NOFA. Similarly, a multiyear applicant that wishes to forgo applying for its FY 1997 or FY 1998 multiyear grant increment(s) may do so and would thus be eligible to apply for and receive up to one or two Single Purpose grants, as applicable.

3. Applications With Multiple Projects

If an application contains more than one project, each project will be rated separately for program impact. Applicants should note that regardless of the number of projects, the total grant amount cannot exceed the limits identified in section I.D.2.b. of this NOFA.

4. Multiyear Plans

a. *General.* Multiyear plan grants will not be awarded for FY 1997 or FY 1998. However, multiyear plan grants awarded in FY 1995 and FY 1996 will be honored for the FY 1997 and FY 1998 funding increments, provided HUD's review indicates that the grantee has acceptable past performance, the grantee has continuing capacity to carry out the CDBG activities proposed in the application, and the grantee submits an acceptable application and certifications. HUD reserves the right to lower the amount of funds for succeeding years if grantees are not in compliance with performance requirements and applicable regulations. Note that a multiyear applicant that received a 3-year multiyear plan approval in FY 1996 for FY 1996, 1997, and 1998, should submit two separate applications: one application for the FY 1997 increment; and one application for the FY 1998 increment. See section I.D.2.b., above, regarding grant limits and funding requirements for guidance on when a previously approved multiyear applicant may submit an application for a Single Purpose Grant under this NOFA. All applications for funding of a second or third year increment of a previously approved multiyear plan must be submitted by the deadline date for applications established by this NOFA.

b. *Previously Funded Multiyear Plans.* The maximum annual grant available for a FY 1996 multiyear plan was $1,900,000. The maximum funding for implementing an entire multiyear plan was $3,100,000 for a 2-year multiyear plan, and $5,000,000 for a 3-year multiyear plan. The maximum grant awarded in FY 1996 was $1,200,000. Grant funds requested must have been sufficient, either by themselves or in combination with funds from other sources (including any Section 108 Loan Guarantee resources requested in conjunction with a Small Cities application under this NOFA), to complete the project within a reasonable amount of time. If other sources of funds were to have been used with respect to a project, the source of those funds should have been identified and the level of commitment indicated. The maximum grant for a multiyear plan that was originally funded in FY 1995 and which was not revised in FY 1996 was $900,000.

E. Selection Criteria/Ranking Factors and Final Selection

1. General

Complete applications received from eligible applicants by March 2, 1998 will be rated and scored by HUD. Applications are rated and scored against five factors. These five factors are discussed in more detail in section I.E.3. of this NOFA. Note that when an applicant proposes to use Section 108 Loan Guarantee assistance as a partial funding resource for a proposed project under this NOFA, HUD, when applying the rating factors to such projects, will consider the applicant's description of the Section 108 assisted project in arriving at the score for a particular factor. An applicant may either have an approved 108 Loan Guarantee application, submit a full Section 108 Loan Guarantee application or provide a description of the Section 108 Loan Guarantee application. (The description must be specific as to the amount of the Section 108 Loan Guarantee commitment that the applicant will request and the purpose for which the 108 Loan Guarantee proceeds will be used. See section II.C.1. of this NOFA for more information on this subject.) However, any such CDBG application under this NOFA that is fundable and relies upon Section 108 Loan Guarantee assistance to partially carry out the activities and does not have an approved Section 108 Loan Guarantee commitment will receive a conditional approval. If the applicant does not submit and HUD does not approve the required Section 108 Loan Guarantee application within a reasonable period of time (see section II.C.1.(f)(2) of this NOFA), HUD may rescind the award. In such event the funding will be awarded to the highest rated fundable applicant that did not receive funding under this competition.

2. Performance Evaluation

As noted in section I.C. of this NOFA, previous grantees of Small Cities Program CDBG grants are subject to an evaluation of performance and continuing capacity to undertake the proposed program. For purposes of making performance evaluations, HUD will use any information that becomes available before grant awards are announced. Performance also will be evaluated using information which may be available already to HUD, including previously submitted performance reports, site visit reports, audits, monitoring reports and annual community assessments. The HUD Office may request and consider additional information in cases where it is essential to make the required performance judgments (see 24 CFR 570.423(d), Thresholds). No grants will be made to an applicant that does not have the capacity to undertake the proposed program. A performance determination will be made by an evaluation of the following areas:

a. *Community Development Activities.* The following thresholds for performance in expending CDBG funds have been established for FY 1997 and FY 1998 and pertain to all Single Purpose and Comprehensive Grants,

including grants pursuant to approved multiyear plans:

FY 1992 and earlier—Grants must be closed out

FY 1993—Grant funds 100 percent expended

FY 1994—Grant funds 75 percent expended

FY 1995—Grant funds 30 percent expended

FY 1996—Recipients must be on target with respect to the latest Small Cities Program Schedule received by HUD.

**Note:** These standards will be used as benchmarks in judging program performance, but will not be the sole basis for determining whether the applicant is ineligible for a grant due to a lack of capacity to carry out the proposed project or program. Any applicant that fails to meet the percentages specified above may wish to provide updated data to HUD, either in conjunction with the application submission or under separate cover, but in no case will data received by HUD after March 2, 1998 be accepted, unless specifically requested by HUD.

b. *Compliance With Applicable Laws and Regulations.* An applicant will be considered to have performed inadequately if the applicant:

(1) Has not substantially complied with the laws, regulations, and Executive Orders applicable to the CDBG Program, including applicable civil rights laws as may be evidenced by: (1) an outstanding finding of civil rights noncompliance, unless the applicant demonstrates that it is operating in compliance with a HUD-approved compliance agreement designed to correct the area(s) of noncompliance; (2) an adjudication of a civil rights violation in a civil action brought against it by a private individual, unless the applicant demonstrates that it is operating in compliance with a court order designed to correct the area(s) of noncompliance; (3) a deferral of Federal funding based upon civil rights violations; (4) a pending civil rights suit brought against it by the Department of Justice; or (5) an unresolved charge of discrimination issued against it by the Secretary under section 810(g) of the Fair Housing Act, as implemented by 24 CFR 103.400;

(2) Has not resolved or attempted to resolve findings made as a result of HUD monitoring; or

(3) Has not resolved or attempted to resolve audit findings.

An applicant will be ineligible for a grant where the inadequate performance in compliance with applicable laws and regulations evidences a lack of capacity to carry out the proposed project or program. For example, an application will not be accepted from a unit of general local government which has an outstanding audit finding or monetary obligation for any HUD program. Additionally, applications will not be accepted from any entity which proposes an activity in a unit of general local government that has an outstanding audit finding or monetary obligation for any HUD program. The Director of the Community Planning and Development Division of the HUD field office may provide an exception to this prohibition if the unit of general local government has made a good faith effort to clear the audit finding. No exception will be provided if funds are due HUD, unless a satisfactory arrangement for repayment of the debt has been made.

c. *Performance Assessment Reports.* Under 24 CFR 570.507, Small Cities CDBG grantees are required to submit Performance Assessment Reports (PARs) on October 31st, for the period ended September 30th, for all open grants awarded before April 1st of the same year. For an application for FY 1997/1998 funds to be considered for funding, the applicant must be current in its submission of PARs. Failure to submit a PAR is not a curable technical deficiency under section V. of this NOFA.

3. Five Factor Rating

As noted in section I.E.1. of this NOFA, all applications are rated and scored against five factors. These five factors are:

- Need based on absolute number of persons in poverty;
- Need based on the percent of persons in poverty;
- Program Impact;
- Outstanding performance in fair housing and equal opportunity; and
- Welfare to Work Initiative.

A maximum of 605 points is possible under this system with the maximum points for each factor being:

| | Points |
|---|---|
| Need—absolute number of persons in poverty | 75 |
| Need—percent of persons in poverty | 75 |
| Program Impact | 400 |
| Outstanding performance—FHEO: | |
| a. Provision of fair housing choice | 20 |
| b. New Horizons Fair Housing Assistance Project | 20 |
| c. Equal opportunity employment | 10 |
| Welfare to Work Initiative | 5 |
| Total | 605 |

Each of the five factors is outlined below. All awarded points for each factor will be rounded to the nearest whole number.

a. *Need—Absolute number of persons in poverty.* HUD uses 1990 census data to determine the absolute number of persons in poverty residing within the applicant unit of general local government. Applicants which are county governments are rated separately from all other applicants. For applications from joint applicants, data from each participating unit of general local government (as described in 24 CFR 570.422) will be aggregated. Applicants in each group are compared in terms of the number of persons whose incomes are below the poverty level. Individual scores are obtained by dividing each applicant's absolute number of persons in poverty by the greatest number of persons in poverty of any applicant and multiplying by 75.

b. *Need—Percent of persons in poverty.* HUD uses 1990 census data to determine the percent of persons in poverty residing within the applicant unit of general local government. Applicants in each group are compared in terms of the percentage of their population below the poverty level. For applications from joint applicants, data from each participating unit of general local government will be aggregated. Individual scores are obtained by dividing each applicant's percentage of persons in poverty by the highest percentage of persons in poverty of any applicant and multiplying by 75.

c. *Program Impact—Single Purpose Grants.* In evaluating program impact, HUD will consider various factors. Within each activity type described below is a set of factors and scoring weights that will be used. Each proposal will be rated using the factors and scoring weights described in the selection criteria below.

Assessments are done on a comparative basis and, as a result, it is important that each applicant present information in a detailed and uniform manner.

For projects consisting of more than one activity, the activity that directly addresses the need must represent at least the majority of funds requested. Other activities must be incidental to and in support of the principal activity. For example, public improvements included in a rehabilitation project that addresses housing need must: (1) be a relatively small amount in terms of funds requested; (2) clearly be in support of the housing objective; and (3) demonstrate a positive and direct link to the national objective. For incidental activities claiming benefit to low- and moderate-income persons on an area basis, the application must document that at least 51 percent of the residents of the service area meet the low- and moderate-income requirement. Funds should not be requested for activities

that are not incidental to and in support of the principal activity.

In addressing Program Impact criteria, applicants should adhere to the following general guidelines for quantification. Where appropriate, absolute and percentage figures should be used to describe the extent of community development needs and the impact of the proposed program. This includes, but is not limited to, appropriate units of measure (e.g., number of housing units or structures, linear feet of pipe, pounds per square inch, etc.), and costs per unit of measure. These quantification guidelines apply to the description of need, the nature of proposed activities and the extent to which the proposed program will address the identified need.

Appropriate documentation should be provided to support the degree of need described in the application. Basically, the sources for all statements and conclusions relating to community needs should be included in the application or incorporated by reference. Examples of appropriate documentation include planning studies, letters from public agencies, newspaper articles, photographs and survey data.

Generally, the most effective documentation is that which specifically addresses the subject matter and has a high degree of credibility. Applicants which intend to conduct surveys to obtain data are advised to contact the appropriate HUD office prior to conducting the survey for a determination as to whether the survey methodology is statistically acceptable.

There are a number of program design factors related to feasibility which can alter significantly the award of impact points. Accordingly, it is imperative that applicants provide adequate documentation in addressing these factors. Common feasibility issues include site control, availability of other funding sources, validity of cost estimates, and status of financial commitments as well as evidence of the status of regulatory agency review and approval.

Past productivity and administrative performance of prior grantees will be taken into consideration when reviewing the overall feasibility of the program. Overall program design, administration and guidelines are other feasibility issues that should be articulated and presented in the application, since they are critical in assessing the effectiveness and impact of the proposed program.

Each project will be rated against other projects addressing the same problem area, so that, for example, housing projects only will be compared with other housing projects, according to the criteria outlined below. It should be noted that each project within an application will be given a separate impact rating, if each one is clearly designated by the applicant as a separate and distinct project (i.e., separate Needs Descriptions, Community Development Activities, and Impact Description and Program Schedule forms have been filled out, indicating separate project names).

In some cases, it may be to the applicant's advantage to designate separate projects for activities that can ''stand on their own'' in terms of meeting the described need, especially where a particular project would tend to weaken the impact rating of the other activities, if they were all related as a whole, as has been the case with some economic development projects. If, however, the projects tend to meet the impact criteria to the same extent, or the weaker element is only a small portion of the overall program, there is no discernable benefit in designating separate projects.

Applicants should bear in mind that the impact of the proposed project will be judged by persons who may not be familiar with the particular community. Accordingly, individual projects will be rated according to how well the application demonstrates in specific, measurable terms, the extent to which the impact criteria are met. General statements of need and impact alone will not be sufficient to obtain a favorable rating. HUD will not make a Small Cities grant when it determines that the grant will only have a minimal or insignificant impact on the grantee. For the purposes of this NOFA, any application not scoring above 100 points of the possible 400 points for the Program Impact factor will be deemed to have a minimal or insignificant impact on the grantee and will not be funded regardless of the number of points the applicant may otherwise receive or the ranking it attains as a result of its score due to points received on other rating factors.

For purposes of this NOFA, *Champion Community* means an urban or rural area that: (1) was designated by the Secretary of HUD as an urban Empowerment Zone or Enterprise Community, or designated by the Secretary of Agriculture as a rural Empowerment Zone or Enterprise Community; or (2) was nominated by one or more local governments and the State or States in which it is located for consideration of designation as an Empowerment Zone or Enterprise Community pursuant to 24 CFR part 597 or 7 CFR part 25, meets the eligibility requirements in 24 CFR part 597, subpart B, or 7 CFR part 25, subpart B, but was not so designated because of statutory limits on the number of such designations. The Champion Communities in New York State are: Kingston, Steuben County, Chenango County, Sullivan County and Chautauqua County.

(1) *Program Impact—Single Purpose—Housing.* There are three distinct types of Single Purpose Housing projects: Housing Rehabilitation, Creation of New Housing and Direct Homeownership Assistance. Separate rating criteria are provided for each type of project.

(a) *Housing Rehabilitation.* The following factors and weights will be used evaluate proposed housing rehabilitation projects:

(i) Severity of Need (proportion of units that are substandard and extent of disrepair) (up to 160 points of the total Program Impact score). Each application should provide information on the total number of units in the project area, the number that are substandard, and the number of substandard units occupied by low- and moderate-income households. The purpose of this information is to establish the relative severity of housing conditions within the designated project area compared to other housing rehabilitation applications. The application also should describe the date and methodology of any surveys used to obtain the information, including any explicit and detailed definition of ''substandard.''

*Surveys of Housing Conditions.* Surveys of housing conditions serve several purposes in evaluating applications for housing rehabilitation activities. These include establishing the seriousness of need for such assistance in the project area, providing a basis for estimating overall budgetary needs, and providing an indication of the marketability of the project.

(ii) Extent to which proposed program will resolve the identified problem (up to 40 points of the total Program Impact score). Note that programs that propose minimal rehabilitation may not necessarily be addressing the identified problem.

(iii) Feasibility (marketability, project design affecting timely completion of the project) (up to 40 points of the total Program Impact score). The application should describe the project in sufficient detail to allow the reviewer to assess its feasibility and its probable impact on the conditions described. It also should describe project requirements in such a

way that regulatory and policy concerns will be addressed.

HUD encourages communities to support a new Secretarial initiative, called Healthy Homes. Applicants applying for Small Cities CDBG funds to rehabilitate housing and/or construct new housing units may support these initiatives by including Healthy Homes features in their program design, such as window locks, deadbolt locks on doors, locks or safety latches on medicine cabinets, smoke detectors, carbon monoxide detectors, energy efficient windows, elimination of lead-based paint, and any other activities that contribute to Healthy Homes, especially regarding children.

(iv) Leveraging of other resources (up to 60 points of the total Program Impact score). HUD encourages communities to design projects supplementing Small Cities rehabilitation funds with private funds wherever feasible and appropriate, especially in the case of rental units and housing not occupied by lower-income persons. In such cases, the Small Cities grant subsidy should be as low as possible, while retaining sufficient incentive to attract local participants. On the other hand, projects designed for low-income homeowners should not require private contributions at a level that puts the project out of reach of potential participants.

(v) Cost per unit (up to 80 points of the Program Impact score). HUD will review the applicant's documentation to determine whether the applicant's cost-per-unit is lower than other applicants' costs-per-unit. All applications should provide documentation to justify the cost-per-unit estimates, particularly grantees where past performance does not support the estimates in the applications. In reviewing applications from grantees with prior housing rehabilitation projects, reasonableness of cost-per-unit, stated in the application, will be compared against the grantee's actual past performance.

(vi) Extent to which the project supports the strategic plan of a Champion Community (up to 20 points of the total Program Impact score).

(b) *Creation of New Housing.* CDBG funds may be used to support the construction of new housing units, the creation of new units proposed through conversion of existing structures (currently vacant structures or conversion of nonresidential structures for residential use) and, in certain circumstances, to finance the actual cost of constructing new units. New construction may be carried out by an eligible nonprofit entity pursuant to 24 CFR 570.204, or as last resort housing. Note that for purposes of specific uses of Section 108 Loan Guarantee proceeds, eligibility is limited to assistance for community economic development projects under § 570.204(a)(2). See also 24 CFR 570.703(i)(2). Support of new construction could include nonconstruction assistance such as the acquisition and/or clearance of land, the provision of infrastructure, or the payment of certain planning costs.

The following factors and weights will be used to evaluate proposed projects for the creation of new housing:

(i) Severity of need for new housing affordable to low- and moderate-income persons shown in the project area (up to 160 points of the total Program Impact score). Where the creation of new units is proposed, the application should document the need for additional units based on vacancy rates, waiting lists, and other pertinent information.

(ii) Extent to which the proposed program will create new housing units affordable to low- and moderate-income persons (up to 40 points of the total Program Impact score). The proposed project clearly must support, or result in, additional units for low- and moderate-income persons. The units may result from new construction projects for which the proposed project will provide nonconstruction assistance.

(iii) Feasibility (marketability, project design affecting timely completion of the project) (up to 40 points of the total Program Impact score). Applicants should address issues of site control and marketability, in addition to addressing feasibility from the standpoint of market financing.

(iv) Leveraging of other resources (up to 60 points of the total Program Impact score). Where the proposed project involves the use of Federally assisted housing, the applicant must identify and document the current commitment status of the Federal assistance. Lack of a firm financial commitment for assistance may adversely affect project impact.

(v) Cost per unit (up to 60 points of the total Program Impact score). HUD will review the applicant's documentation to determine whether the applicant's cost-per-unit is lower than other applicants' costs-per-unit. All applications should provide documentation to justify the cost-per-unit estimates, particularly grantees where past performance does not support the estimates in the applications. In reviewing applications from grantees with prior housing projects, reasonableness of cost-per-unit, stated in the application, will be compared against the grantee's actual past performance.

(vi) Extent to which the project would affirmatively further fair housing (either through spatial deconcentration of minorities throughout the community or through spatial deconcentration of low- and moderate-income households if there are no areas of minority concentration) (up to 20 points of the total Program Impact score).

(vii) Extent to which the project supports the strategic plan of a Champion Community (up to 20 points of the total Program Impact score).

(c) *Direct Homeownership Assistance.* Homeownership activities are defined as activities which would promote homeownership within the applicant jurisdiction, focusing particularly on aiding low- and moderate-income persons in becoming homeowners. This may include activities authorized under 24 CFR 570.201(n) for purposes of use of Small Cities grant funding. However, activities eligible solely under 24 CFR 570.201(n) are not permitted uses of Section 108 loan guarantee proceeds. While declining to identify any particular type of proposed project as superior, HUD is identifying several criteria which must be addressed within the project design, in order for the application to receive the maximum project impact.

Applications must include a well developed description of homeownership needs in the applicant jurisdiction, focusing particularly on the needs of low- and moderate-income persons. The description also should include, if applicable, any alternative approaches which have been considered in meeting homeownership needs. Project feasibility must be addressed as part of the application.

The application must demonstrate that the proposed project would make effective use of all available funds. This would include any local, State or other Federal funds which would be utilized by the proposed project. If other such funds are included as part of the proposed project, the applicant must demonstrate that such funds are committed and truly available for the project. Any efforts which would affirmatively further fair housing, by promoting homeownership among minorities as well as homeownership throughout the community, must be outlined in the application.

The application must explain how the project would benefit low- and moderate-income homebuyers, particularly focusing on first-time and minority homebuyers. The application also should address any homeownership counseling services, including counseling pertaining to Federal, State, and local fair housing

laws and requirements, which would be provided to persons selected to participate in the proposed project. Finally, the application should describe how the project would utilize public/private partnerships to promote homeownership, particularly in the sense that private sector financing would be accessible, as necessary, to project participants to complement available public sector funds, including CDBG money.

The following factors and weights will be used to evaluate proposed direct homeownership assistance projects:

(i) The extent to which the application demonstrates severity of homeownership needs in the community (up to 160 points of the total Program Impact score).

(ii) The extent to which: the project design is appropriate to meet demonstrated homeownership needs; the project would make effective us of available funds; alternative approaches to meeting the homeownership needs have been considered; and the proposed project would target first-time homebuyers (up to 60 points of the total Program Impact score).

(iii) The extent to which the project is feasible and likely to be implemented in accordance with a project schedule (up to 40 points of the total Program Impact score).

(iv) The extent to which the proposed project would: complement other Federal, State or local programs that promote homeownership; and utilize public/private partnerships in attempting to promote homeownership, particularly in regard to participation by local financial institutions considering the cost per unit (up to 80 points of the total Program Impact score).

(v) The extent to which the proposed project would provide homeownership counseling to project participants (up to 20 points of the total Program Impact score).

(vi) The extent to which the project would affirmatively further fair housing through proposed initiatives to reach out to potential minority homeowners and/or to promote homeownership opportunities throughout the community (up to 20 points of the total Program Impact score).

(vii) The extent to which the project supports the strategic plan of a Champion Community (up to 20 points of the total Program Impact score).

(2) *Program Impact—Single Purpose—Public Facilities Affecting Public Health and Safety.* In the case of public facility projects, documentation of the problem by outside, third-party sources is of primary importance. In the case of water and sewer projects, documentation from public agencies is particularly helpful, especially where such agencies have pinpointed the exact cause of the problem and have recommended courses of action which would eliminate the problem. Such supporting documentation should be as up-to-date as possible; the older the supporting material, the more doubt arises that the need is current and immediate. Applicants also should be sure to indicate how the project would address public health and safety needs and conditions. Quantification also is essential in describing needs. Documentation from those affected should be included.

The following factors and weights will be used to evaluate proposed public facilities projects affecting the public health and safety:

(a) Severity of Need (up to 160 points of the total Program Impact score). The applicant should describe, including appropriate documentation, as best as possible, the degree to which the need is serious, current and requires prompt attention.

(b) Extent to which the proposed program will resolve the identified problem and public health and safety concerns (up to 40 points of the total Program Impact score). The applicant should demonstrate that the project will completely solve the problem and, if applicable, the applicant should address whether the proposal would be satisfactory to other State/local agencies which have jurisdiction over the problem.

(c) Feasibility (up to 40 points of the total Program Impact score). The applicant should address whether the proposal is the most cost effective and efficient among the possible alternatives considered, and the funding requested will be sufficient to resolve the problem. Total project costs should be documented by qualified third-party estimates, and be as recent as possible.

(d) Extent of benefit to affected persons and the cost per household (up to 80 points of the total Program Impact score).

(e) Leveraging other resources to minimize project costs (up to 40 points of the total Program Impact score). To the extent that Small Cities grant funds will not cover all costs, the source of other funds should be identified and committed. If local funds are to be used, the applicant should show both the willingness and the ability to provide the funds.

(f) Extent to which the project addresses deficiencies in accessibility for disabled persons and/or provides a significant increase in the number of public facilities accessible to disabled persons (up to 20 points of the total Program Impact score).

(g) Extent to which the project supports the strategic plan of a Champion Community (up to 20 points of the total Program Impact score).

(3) *Program Impact—Single Purpose—Economic Development Projects.* As discussed earlier in this section of the NOFA, each individual Single Purpose project will receive a separate impact rating. Applicants whose proposed economic development program will include multiple proposals should determine the most appropriate form of submission. This determination will require a choice as to either the incorporation of all proposals into a single project or the submission of separate projects for each proposal (each transaction will be considered a separate project). The single project format presents an ''all or nothing'' situation. In determining the appropriate submission format, applicants should consider the ability of a transaction to rate well on its own, based on the magnitude of employment impact, size of the financial transaction and the other factors discussed in this section.

The submission of proposals as separate projects must be clearly designated by the applicant with individual Needs Descriptions, Community Development Activities, Impact Descriptions and Program Schedule forms, including an appropriate name for each project on HUD Form 4124.1.

Section 807(c)(3) of the Housing and Community Development Act of 1992 (42 U.S.C. 5305 note) provides that it is the sense of Congress that each grantee should devote one percent of its grant for the purpose of providing assistance under section 105(a)(23) of the 1974 HCD Act to facilitate economic development through commercial microenterprises. A ''microenterprise'' is defined as a commercial enterprise with five or fewer employees, one or more of whom owns the enterprise. While not a requirement, this intent should be considered in developing an economic development application.

It is noted that in accordance with section 105 of the 1974 HCD Act, HUD published on January 5, 1995 (60 FR 1922), a final rule relating to evaluation and selection of Economic Development activities by grantees, including evaluation of public benefit (generally codified at 24 CFR 570.209). Economic Development applications must be specific enough to permit a determination that such threshold public benefit standards are met.

(a) Scoring. The following factors and weights will be used to evaluate proposed economic development projects:

(i) The extent to which the project will have a direct and positive impact on employment opportunities for persons from low-and moderate-income households (up to 160 points of the total Program Impact score). Applicants are reminded that for an activity to be consistent with the statutory objective of low-and moderate-income benefit, as a result of the creation or retention of jobs, at least 51 percent of created or retained employment opportunities must be held by, or made available to, persons from low-and moderate-income families. Applicants must fully document and describe employment benefits. In addition, applicants should address the following issues:

*a.* All employment data must be expressed in terms of full-time equivalents (FTEs). Only permanent jobs may be counted, and applicants must take into account such factors as seasonal and part-time employment. A seasonal job may be considered permanent if the season is long enough to be considered the person's principal occupation; permanent part-time jobs must be converted to the full-time equivalent.

*b.* The amount of CDBG assistance required to produce each full-time equivalent job will affect the impact assessment by HUD. Lower CDBG costs per job are preferable to higher CDBG costs per job. Such assessments of impact will be done on a comparative basis among all projects submitted, rather than by comparison to a given standard.

*c.* The use of CDBG funds to assist a business with transferring to a different community will generally be considered as having *no* employment impact. Exceptions to this rule may include an expansion to the business as a result of, or concurrent with, the transfer; or if the business can demonstrate that it is infeasible to continue operations at the current site. An applicant that fails to document a basis for such an exception could receive a substantially lower score under this ranking factor. Applicants are encouraged to use CDBG funds for projects that provide as many jobs as possible for individuals that are currently receiving public assistance. Providing employment to recipients of public assistance will help break the cycle of dependency and empower low-income citizens to take control of their lives.

(ii) The extent to which market analysis and other risk data provides assurance that the proposed project will be successful (up to 40 points of the total Program Impact score).

(iii) The extent to which the proposed project addresses all appropriate feasibility issues (including extent of firm private financing commitments) and the extent to which there is reasonable assurance that the project will be completed in a timely manner (up to 40 points of the total Program Impact score). Projects that are likely to encounter feasibility issues which would hinder the timely completion of the project will receive a lower score under this criterion. Such issues include, but are not limited to: site control, zoning, public approvals and permits, infrastructure, environment, and relocation. Applicants should address these and any other applicable issues and provide documentation where appropriate.

Applicants also must demonstrate the reasonable likelihood of the project's success, from both a financial and employment standpoint. An analysis or market data, which indicates an inordinate risk in the undertaking of the project, will affect the overall rating of program impact. In order to receive a higher rating, the costs must be reasonable (i.e., not inflated).

(iv) Extent to which the project provides Public Benefits relative to other proposals' cost per job (up to 80 points of the total Program Impact score).

(v) The extent to which Small Cities grant funds will leverage the investment of private and other dollars and the extent to which Small Cities grant funds are NOT used to substitute for private financing (up to 60 points of the total Program Impact score). Leverage is defined as the amount of private debt and equity to be invested as a direct result of the CDBG-funded activity. Projects which provide the maximum feasible level of private investment will be considered as having appropriate leverage. The extent of firm commitments for private financing will be reviewed as well as the amount of equity investment. The project will be reviewed to determine whether CDBG funds are replacing private sources of funds. In order to receive maximum impact CDBG funds may not replace private financing, CDBG assistance must be limited to the amount necessary to fund the project without replacing CDBG funds for private funds, and equity funds should bear the greatest risk in the project.

(vi) The extent to which the project supports the strategic plan of a Champion Community (up to 20 points of the total Program Impact score).

In addition to the standard submission requirements, HUD will evaluate the following as part of its Eligibility Review prior to considering an application for funding in the FY 1997/1998 competition.

(b) *The Appropriate Determination.* HUD has developed guidelines for review of economic development activities undertaken with CDBG funds. These guidelines are composed of two components: guidelines for evaluating project costs and financial requirements; and standards for evaluating public benefit. The standards for evaluating public benefit are mandatory, but the guidelines for evaluating project costs and financial requirements are not. The guidelines for evaluating project costs are to ensure:

(i) *Reasonableness of Proposed Costs.* The applicant must review each project cost element and determine that the cost is reasonable and consistent with third-party, fair-market prices for that cost element. The general principle is that the level of CDBG assistance cannot be adequately determined if the project costs are understated or inflated.

(ii) *Commitment of Other Sources of Funds.* The applicant shall review all projected sources of funds necessary to complete the project and shall verify that all sources (in particular private debt and equity financing) have been firmly committed to the extent practicable, and are available to be invested in the project. Verification means ascertaining that: the source of funds is committed; that the terms and conditions of the committed funds are known; and the source has the capacity to deliver.

(iii) *No Substitution of CDBG Funds (including Section 108 Loan Guarantee proceeds) for Private Sources of Funds.* The applicant shall financially underwrite the project and ensure to the extent possible that CDBG funds are not being substituted for available private debt financing or equity capital. The analysis must be tailored to the type of project being assisted (e.g., real estate, user project, capital equipment, working capital, etc.). Real estate projects require different financial analysis than working capital or machinery and equipment projects. Applicants should ensure that both a significant equity commitment by the for-profit business exists and that the level of certainty of the end use of the property or project is sufficient to ensure the achievement of national objectives within a reasonable period of time.

(iv) *Establishment of Small Cities Grant Financing Terms.* The amount of Small Cities grant assistance provided to a for-profit business ideally should be

limited to the amount, with appropriate repayment terms, sufficient to go forward without substituting Small Cities grant funds for available private debt or cash equity. The applicant should structure its repayment terms so that the business is allowed a reasonable rate of return on invested equity, considering the level of risk of the project. Equity funds generally should bear the greatest risk of all funds invested in a project.

(v) *Public Benefit Determination.* The applicant's activities must meet the public benefit standards found in 24 CFR 570.209(b). Activities covered by these guidelines (subject to certain exceptions) must, in the aggregate, either:

- Create or retain at least one full-time equivalent, permanent job per $35,000 of CDBG funds used; or
- Provide goods or services to residents of an area, such as the number of low- and moderate-income persons residing in the areas served by the assisted businesses amounts to at least one low- and moderate-income person per $350 of CDBG funds used.

(c) *CDBG Assistance Must Minimize Business and Job Displacement.* Each applicant will evaluate the potential of each economic development project for causing displacement of existing businesses and lost jobs in the neighborhood where the project is proposed to be located. When the grantee concludes that the potential exists to cause displacement, given the size, scope or nature of the business, then the grantee must, to the extent practicable, take steps to minimize such displacement. The project file must document the grantee's review conclusions and, if applicable, the steps the grantee will take to minimize displacement.

(d) *Section 105(a)(17) Requirements.* Section 105(a)(17) of the 1974 HCD Act requires that an activity assisted under that section achieve one of the following criteria:

(i) Creates or retains jobs for low- and moderate-income persons (note that a project which meets the national objective of principally benefitting low- and moderate-income persons by creating or retaining jobs, 51 percent of which are for low- and moderate-income persons, will be deemed to have met this criterion without any additional documentation);

(ii) Prevents or eliminates slums or blight (note that a project which meets the national objective of aiding in the prevention or elimination of slums or blight on an area basis will be deemed to have met this criterion without any additional documentation);

(iii) Meets an urgent need (note that a project which meets the national objective of meeting community development needs having a particular urgency will be deemed to have met this criterion without any additional documentation);

(iv) Creates or retains businesses owned by community residents;

(v) Assists businesses that provide goods or services needed by and affordable to low- and moderate-income residents;

(vi) Provides technical assistance to promote any of the activities under (i) through (v) of this subsection.

(e) *National Objectives.* As previously stated in this NOFA, all CDBG-assisted activities must address one of the three broad national objectives. Since economic development projects usually result in new employment or the retention of existing jobs, these activities most likely would be categorized as principally benefitting low- and moderate-income persons in this manner. Such projects will be considered to benefit low- and moderate-income persons where the criteria of 24 CFR 570.208(a)(4) are met. HUD will consider an activity to qualify under this provision where the activity involves jobs at least 51 percent of which are taken by or made available to such persons, or retained by such persons. The extent to which the proposed project will directly address employment opportunities for low- and moderate-income persons in the applicant jurisdiction will be a primary factor in HUD's assessment of the proposed program.

The application must contain adequate documentation to explain fully, and to support, the process that will be used to ensure that project(s) comply with the low- and moderate-income employment requirements. The documentation must be sufficient to show that the process has been developed and that program participants have agreed to adhere to that process. In determining whether the person is a low- and moderate-income person for these activities, it is the person's family income at the time the CDBG assistance is provided that is determinative. When making judgments concerning whether an individual qualifies as a low- and moderate-income person, both family size and the income of the entire family must be considered. This consideration is necessary because a ''low- and moderate-income person'' is defined as a member of a low- and moderate-income family.

HUD will accept a written certification by a person of his or her family income and size to establish low- and moderate-income status. The certification may simply state that the person's family income is below that required to be low- and moderate-income in that area. The form for such certification must include a statement that the information is subject to verification.

In addition to person-by-person income certifications discussed above, under section 105(c)(4) of the 1974 HCD Act, an employee may be presumed to be a low- and moderate-income person if the employee resides in a census tract where not less than 70 percent of the residents are low- and moderate-income persons, and a presumption of low- and moderate-income may also be made if the business is located in and/or the employee resides in a census tract (or block numbering group) where 20 percent of the residents are in poverty. The key consideration in this presumption is the location of the business or employee. The documentation to support the presumption must contain the location. (See 24 CFR 570.209(b)(2)(v) for more information on this subject.)

In cases where an activity (e.g., a shopping center or a super market) provides goods and services to residents of an area, the low- and moderate-income objective may be met by the area benefit requirements at 24 CFR 570.208(a)(1). To document low and moderate income, 51 percent of the residents of the area or block numbering group must be low- and moderate-income persons.

(f) *Application Requirements.* To the extent feasible, the material listed below should be submitted for economic development projects. The material should be submitted for each proposed activity, whether the proposed activity is presented as a separate project or as part of a project involving multiple activities. Since economic development projects are rated against each other, the more completely these submission requirements are met, the greater the potential exists for enhancing the impact score of the project.

(i) A letter from each appropriate developmental entity which includes at least the following information:

*a.* A detailed physical description of the project with a schedule of events and maps or drawings as appropriate.

*b.* The estimated costs for the project, including any working capital requirements.

*c.* A discussion of all financing sources, including the need for CDBG, the terms of the CDBG assistance, and the proposed lien structure. The amount, source, and nature of any equity investment(s) must also be

provided as well as a commitment to invest the equity.

*d*. A discussion of employment impact which includes a schedule of newly created positions. The schedule should identify the number, salary and skill level of each permanent position to be created. If jobs are made available to low- and moderate-income persons, the applicant must also demonstrate and document how persons from low- and moderate-income households will be accorded first consideration for employment opportunities.

*e*. A discussion of all appropriate feasibility issues including, but not limited to: site control, zoning, public approvals and permits, impact fees, corporate authorizations, infrastructure, environment and relocation.

*f*. An analysis and summary of market and other data which supports the anticipated success of the project.

(ii) A development budget showing all costs for the project, including professional fees and working capital.

(iii) Documentation to support project costs. Documentation generally should be from a third-party source and be consistent with the following guidelines:

*a*. Acquisition costs should be supported by an appraisal.

*b*. Construction/renovation costs should be certified by an architect, engineer or contractor. Use of Federal Prevailing Wage Rates should be cited where applicable.

*c*. Machinery and equipment costs should be supported by vendor quotes.

*d*. Soft costs (e.g., legal, accounting, title insurance) need be substantiated only where such costs are anticipated to be abnormally high.

(iv) Letters from all financing sources discussing (at a minimum) the amount and terms of the proposed financing, and the current status of the application for funding.

(v) Historical financial data of the development entity, preferably for the last 3 years. This information may be submitted under separate cover with confidentiality requested. It is recognized that historical financial data may be unavailable or inappropriate for some projects (e.g., start-up companies and real estate transactions).

(vi) A 2- to 5-year cash flow pro forma with accompanying notes citing basic assumptions.

(vii) The applicant's assessment of the project's consistency with the CDBG program eligibility requirements and standards for evaluating project cost, financial requirements and public benefit.

d. *Fair Housing and Equal Opportunity Evaluation*. Documentation for the 50 points for these items is the responsibility of the applicant. Claims of outstanding performance must be based upon actual accomplishments. Clear, precise documentation will be required. Maps must have a census tract or block numbering area (BNA), and they must be in accordance with the 1990 Census data. Additionally, maps must identify the locations of areas with minorities by census tract or BNA. If there are no minority areas, state so on the map. Only population data from the 1990 Census will be acceptable for purposes of this section.

Please note that a ''minority'' is a person belonging to, or culturally identified as, a member of any one of the following racial/ethnic categories: Black, Hispanic, Asian or Pacific Islander, and American Indian or Alaskan Native. For the purposes of this section, the separate category of ''women'' is not considered a minority.

Counties claiming points under this criterion must use county-wide statistics (excluding entitlement communities). In the case of joint applications, points will be awarded based on the performance of the lead entity only.

The following factors will be used to judge outstanding performance in these areas. Please note that points for outstanding performance may be claimed under each criterion:

(1) *Housing Achievements* (40 points total).

(a) *Provision of Fair Housing Choice (20 points)*

(i) HUD will consider the extent to which the applicant demonstrates that it has provided housing assistance for low and moderate income families that results in housing choice in areas outside of minority or low- and moderate income concentration. Such actions may include the construction or rehabilitation of housing in areas outside of minority or low and moderate income concentration; the provision of Section 8 Existing Certificate or Voucher assistance in ways that lessen concentration of such assisted units within minority and low- and moderate income concentrated areas; or the provision of direct homeownership assistance such as homeownership counseling, downpayment assistance, or first-time homebuyer assistance. If applicable, the applicant may use a map to show the general location(s) of individual projects and/or housing occupied by Section 8 Existing Program participants.

(ii) Points also may be awarded for efforts which enable low- and moderate-income persons to remain in their neighborhood when such neighborhoods are experiencing revitalization and substantial displacement as a result of private reinvestment. Applicants requesting points under this criterion would not need to meet the requirements of paragraphs (a) and (b) in order to receive points. Points will be awarded where more than one-half of the families displaced were able to remain in their original neighborhood through the assistance of the applicant. Applicants must show that:

- The neighborhood experienced revitalization;
- The amount of displacement was substantial;
- Displacement was caused by private reinvestment;
- Low- and moderate-income persons were permitted to remain in the neighborhood as a result of action taken by the applicant.

If the community is inhabited predominantly by persons who are members of minority and/or low-income groups, points will be awarded where there is a balanced distribution of assisted housing throughout the community.

(b) *Implementation of a Fair Housing Strategy that Affirmatively Furthers Fair Housing (20 points).* The applicant must demonstrate that it is implementing or plans to implement a Fair Housing Strategy on its own or demonstrate that it does or plans to participate in a county/State or regional analysis of impediments to fair housing choice. A fair housing strategy must include the following elements:

- Local compliance activities;
- Educational programs to enhance the clarity and understanding of the community's fair housing policy. For communities with few or no minorities, this should include publication in the surrounding communities of the applicant's policy of fair housing for minorities and persons with disabilities;
- Assistance to minority families; and
- Special programs (e.g., utilization of Community Housing Resource Board (CHRB) Programs, efforts to encourage local realtors to enter into voluntary agreements to encourage equal access to financial institutions, etc.).
- Assistance to minority families through mobility counseling programs and other activities that encourage such families to pursue such housing opportunities outside of minority concentrated areas;
- Special programs targeted at lenders, builders, realtors, and other housing industry groups;
- Affirmative marketing strategies targeted at those groups in the eligible population considered least likely to apply without special outreach.

The fair housing strategy must include goals for each of the above elements. The date of adoption or development of the strategy should be indicated, as well as the date proposed activities will be or have been implemented.

(2) *Entrepreneurial Efforts and Local Equal Opportunity Performance.* HUD encourages the use of minority contracting, although it will not be used as an evaluation factor in this NOFA.

(3) *Equal Opportunity Employment.* (10 points) Under this factor, the applicant must document that its percentage of minority, permanent full-time employees is greater than the percentage of minorities within the county or the community, whichever is higher. Applicants with no full-time employees may claim points based on part-time employment provided that they document that the only permanent employment is on a part-time basis.

e. *Welfare to Work Initiative.* (5 points) Five bonus points will be added to proposals which support the Welfare to Work Initiative. These points will be added to those proposals that include activities which will provide assistance to persons moving from welfare to work. Examples of such activities are: jobs, day care slots, training or transportation assistance.

4. *Final Selection.* The total points received by a project for all of the selection factors are added, and the project is ranked against all other projects from all applications, regardless of the program areas in which the projects were rated. The highest ranked projects will be funded to the extent funds are available. If an applicant submits two applications under this NOFA, it may receive up to two single grants in the amounts of the project or projects applied for in those applications which were ranked high enough to be funded. In the case of ties at the funding line, HUD will use the following criteria in order to break ties:

- The project receiving the highest program impact rating will be funded;
- If tied projects have the same program impact rating, the project having the highest combined score on the needs factors will be funded;
- If tied projects have the same program impact ratings and equal needs factor scores, the project having the highest score on the percent of persons in poverty needs factor will be funded; and
- If tied projects have the same program impact ratings, equal needs factor scores, and an equal percent of persons in poverty needs factor score, the application having the most outstanding performance in fair housing and equal opportunity will be funded.

As soon as possible after the rating and ranking process has been completed, HUD will notify all applicants regarding their rating scores and funding status. Thereafter, applicants may contact HUD to discuss scores or any aspects of the selection process.

## II. Application and Funding Award Process

### *A. Obtaining Applications*

All nonentitled communities in New York State may obtain application kits through HUD's New York or Buffalo Offices. The addresses for HUD's Buffalo and New York offices are:

Department of Housing and Urban Development, Office of Community Planning and Development, Attention: Small Cities Coordinator, 26 Federal Plaza, New York, NY 10278–0068, Telephone (212) 264–2885

Department of Housing and Urban Development, Community Planning and Development Division, Attention: Small Cities Coordinator, 465 Main Street, Lafayette Court, Buffalo, NY 14203, Telephone (716) 551–5768

### *B. Submitting Applications*

A final application must be submitted to HUD no later than March 2, 1998. A final application includes an original and two photocopies. Final applications may be mailed, and if they are received after the deadline, must be postmarked no later than midnight, March 2, 1998. If an application is hand-delivered to the New York or Buffalo Offices, the application must be delivered by 4:00 p.m. on the application deadline date. Applicants in the counties of Sullivan, Ulster, Putnam, and in nonparticipating jurisdictions in the urban counties of Dutchess, Orange, Rockland, Westchester, Nassau, and Suffolk should submit applications to the New York Office. All other nonentitled communities in New York State should submit their applications to the Buffalo Office. Applications must be submitted to the HUD office at the addresses listed above in section II.A.

The above-stated application deadline is firm as to *date* and *hour*. In the interest of fairness to all competing applicants, HUD will treat as *ineligible for consideration* any application that is not received on, or postmarked by March 2, 1998. Applicants should take this practice into account and make early submission of their materials to avoid any risk of loss of eligibility brought about by unanticipated delays or other delivery-related problems.

### *C. The Application*

1. Application Requirements

An application for the Small Cities Program CDBG Grants is made by the submission of:

(a) A completed HUD Form 4124, including HUD Forms 4124.1 through 4124.6 and all appropriate supporting material;

(b) A completed Standard Form 424;

(c) A signed copy of certifications required under the CDBG Program, including, but not limited to the Drug-Free Workplace Certification, and the Certification Regarding Lobbying pursuant to section 319 of the Department of Interior Appropriations Act for Fiscal Year 1990 (31 U.S.C. 1352), generally prohibiting use of appropriated funds, and, if applicable, Disclosure of Lobbying Activities (SF–LLL);

(d) Form HUD–2880, Applicant/Recipient Disclosure/Update Report, as required under subpart A of 24 CFR part 4 (Accountability in the Provision of HUD Assistance); and, if applicable,

(e) Abbreviated Consolidated Plan.

(f) A Section 108 Loan Guarantee application or request, if applicable, consisting of one of the following:

(1) A formal application for Section 108 Loan Guarantee(s), including the documents listed at § 570.704(b);

(2) A brief description of a Section 108 Loan Guarantee application(s) to be submitted within 60 days (with HUD reserving the right to extend such period for good cause on a case-by-case basis) of a notice of CDBG Small Cities grant award. (The CDBG grant award will be conditioned on approval of actual Section 108 Loan Guarantee commitments within a stated period of time.) This description must be sufficient to support the basic eligibility of the proposed project or activities for Section 108 assistance; or

(3) If applicable, a copy of a Section 108 Loan Guarantee approval document with grant number and date of approval.

2. Streamlined Application Requirements for Certain Applicants

Single Purpose applications submitted under the FY 1996 NOFA but not selected for funding will be reactivated for consideration under this NOFA, if the applicant notifies HUD in writing by March 2, 1998 that the applicant wishes the prior application to be considered in this competition. Applications which are reactivated may be updated, amended or supplemented by the applicant provided that such

amendment or supplementation is received no later than the due date for applications under this NOFA. If there is no significant change in the application involving new activities or alteration of proposed activities that will significantly change the scope, location or objectives of the proposed activities or beneficiaries, there will be no further citizen participation requirement to keep the application active for a succeeding round or competition.

D. *Funding Award Process.* In accordance with section 102 of the HUD Reform Act and HUD's regulation in 24 CFR part 4, HUD will notify the public by notice published in the **Federal Register** of all award decisions made by HUD under this competition. In accordance with the requirements of section 102 of the Reform Act and HUD's regulations at 24 CFR part 4, HUD also will ensure that documentation and other information regarding each application submitted under this NOFA is sufficient to indicate the basis upon which assistance was provided or denied. Additionally, in accordance with § 4.5(b) of these regulations, HUD will make this material available for public inspection for a period of 5 years, beginning not less than 30 calendar days after the date on which assistance is provided.

## III. Technical Assistance

Prior to the application deadline, the Buffalo and New York offices will provide technical assistance on request to individual applicants, including explaining and responding to questions regarding program regulations, and defining terms in the application package. In addition, HUD will conduct informational meetings around the State to discuss the Small Cities Program, and will conduct application workshops in conjunction with these meetings. Please contact the New York or Buffalo Office for further information regarding these meetings. Application kits will be available at these meetings, as well as from the New York or Buffalo Offices. In order to ensure that the application deadline is met, it is strongly suggested that applicants begin preparing their applications immediately and not wait for the informational meetings.

## IV. Checklist of Application Submission Requirements

The following checklist is intended to aid applicants in determining whether their application is complete:

**Application Completeness Checklist**

Applicant: _____

Amount Requested $ _____

1. Is amount of funds requested within established maximum?

2. Part I—Needs Description (HUD Form 4124.1).

a. Program Area

_____ Housing

_____ Target Area

_____ Nontarget Area

_____ Public Facilities

_____ Economic Development (If an ''appropriate'' analysis is required but is not included, the application cannot be rated.)

b. Is description of community development needs included in application?

3. Part II—Community Development Activities (HUD Form 4124.2).

a. Has national objective been identified for each activity? b. Will 70 percent of grant funds primarily benefit low-and moderate-income persons? (If not, the application cannot be rated.)

4. Part III—Impact Description (HUD Form 4124.3).

5. Part IV—Outstanding Performance (HUD Form 4124.4).

6. Part V—Program Schedule (HUD Form 4124.5).

7. Part VI—Maps.

a. Location of proposed activities. (Applicants must show the boundaries of the defined area or areas.)

b. Location of areas with minorities by census tract. (If there are no minority areas, state so on the map.)

c. Housing conditions if project involves housing rehabilitation. (Number and location of each standard and substandard unit should be clearly identified.)

8. a. Is Standard Form 424 complete?

Yes No

b. Is original signature on at least one copy?

Yes No

9. Is Certification signed with original signature?

Yes No

10. Has the abbreviated consolidated plan been prepared and submitted to HUD (or included with this application)?

11. Form HUD–2880, Application/Recipient Disclosure/Update Report.

12. Do proposed economic development activities meet the public benefit standards as defined in 24 CFR 570.209?

## V. Corrections to Deficient Applications

Under no circumstances will HUD accept from the applicant unsolicited information regarding the application after the application deadline has passed.

HUD may advise applicants of technical deficiencies in applications and permit them to be corrected. A technical deficiency would be an error or oversight which, if corrected, would not alter, in either a positive or negative fashion, the review and rating of the application. Examples of curable technical deficiencies would be a failure to submit the proper certifications or failure to submit an application containing an original signature by an authorized official. Situations not considered curable would be, for example, a failure to submit program impact descriptions.

HUD will notify applicants in writing of any curable technical deficiencies in applications. Applicants will have 14 calendar days from the date of HUD's correspondence to reply and correct the deficiency. If the deficiency is not corrected within this time period, HUD will reject the application as incomplete.

Applicants should note that if an abbreviated consolidated plan is not submitted, the failure to submit it in a timely manner is not considered a curable deficiency.

## VI. Findings and Certifications

*Paperwork Reduction Act Statement*

The information collection requirements related to this CDBG program have been approved by the Office of Management and Budget (OMB) in accordance with the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520), and have been assigned OMB approval number 2506–0020. *An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless the collection displays a valid control number.*

*Environmental Impact*

This NOFA provides funding under, and does not alter environmental requirements of, a regulation previously published in the **Federal Register**. Accordingly, under 24 CFR 50.19(c)(5), this NOFA is categorically excluded from environmental review under the National Environmental Policy Act. The environmental review provisions of this regulation are in 24 CFR 570.604.

*Federalism*

The General Counsel, as the Designated Official under section 6(a) of Executive Order 12612, *Federalism*, has determined that this NOFA will not have substantial, direct effects on States, on their political subdivisions, or on their relationship with the Federal Government, or on the distribution of power and responsibilities between them and other levels of government. While the NOFA will provide financial assistance to the Small Cities Program of New York State, none of its provisions will have an effect on the relationship between the Federal Government and New York State, or the State's political subdivisions.

*Accountability in the Provision of HUD Assistance*

See Section I.A.4. of this NOFA.

*Prohibition Against Lobbying Activities*

Applicants for funding under this NOFA are subject to the provisions of section 319 of the Department of Interior and Related Agencies Appropriation Act for Fiscal Year 1991 (31 U.S.C. 1352) (the Byrd Amendment) and to the provisions of the Lobbying Disclosure Act of 1995 (Pub. L. 104–65; December 19, 1995).

The Byrd Amendment, which is implemented in regulations at 24 CFR part 87, prohibits applicants for Federal contracts and grants from using appropriated funds to attempt to influence Federal executive or legislative officers or employees in connection with obtaining such assistance, or with its extension, continuation, renewal, amendment or modification. The Byrd Amendment applies to the funds that are the subject of this NOFA. Therefore, applicants must file a certification stating that they have not made and will not make any prohibited payments and, if any payments or agreement to make payments of nonappropriated funds for these purposes have been made, a form SF–LLL disclosing such payments must be submitted. The certification and the SF–LLL are included in the application package.

The Lobbying Disclosure Act of 1995, which repealed section 112 of the HUD Reform Act and resulted in the elimination of the regulations at 24 CFR part 86, requires all persons and entities who lobby covered executive or legislative branch officials to register with the Secretary of the Senate and the Clerk of the House of Representatives and file reports concerning their lobbying activities.

*Prohibition Against Advance Information on Funding Decisions*

HUD's regulations implementing section 103 of the Department of Housing and Urban Development Reform Act of 1989 (42 U.S.C. 3537a), codified in 24 CFR part 4, apply to this funding competition. The regulations continue to apply until the announcement of the selection of successful applicants. HUD employees involved in the review of applications and in the making of funding decisions are limited by the regulations from providing advance information to any person (other than an authorized employee of HUD) concerning funding decisions, or from otherwise giving any applicant an unfair competitive advantage. Persons who apply for assistance in this competition should confine their inquiries to the subject areas permitted under 24 CFR part 4.

Applicants or employees who have ethics related questions, such as whether particular subject matter can be discussed with persons outside HUD, should contact the HUD Office of Ethics (202) 708–3815. (This is not a toll-free number.)

*Catalog of Federal Domestic Assistance*

The Catalog of Federal Domestic Assistance Number for this program is 14.219.

Date: December 11, 1997.

**Fred Karnas, Jr.,**

*Deputy Assistant Secretary for Economic Development.*

[FR Doc. 97–32851 Filed 12–12–97; 9:27 am]

BILLING CODE 4210–29–P

federal register

Tuesday
December 16, 1997

# Part IV

# The President

**Proclamation 7060—Suspension of Entry as Immigrants and Nonimmigrants of Persons Who Are Senior Officials of the National Union for the Total Independence of Angola (''UNITA'') and Adult Members of Their Immediate Families**

**Executive Order 13069—Prohibiting Certain Transactions With Respect to UNITA**

Federal Register
Vol. 62, No. 241
Tuesday, December 16, 1997

# Presidential Documents

**Title 3—**

## The President

**Proclamation 7060 of December 12, 1997**

## Suspension of Entry as Immigrants and Nonimmigrants of Persons Who Are Senior Officials of the National Union for the Total Independence of Angola (''UNITA'') and Adult Members of Their Immediate Families

**By the President of the United States of America**

**A Proclamation**

In light of the failure of the National Union for the Total Independence of Angola (''UNITA'') to comply with its obligations under the ''Accordos de Paz,'' the Lusaka Protocol, and other components of the peace process in Angola, and in furtherance of United Nations Security Council Resolution 1127 of August 28, 1997, 1130 of September 29, 1997, and 1135 of October 29, 1997, I have determined that it is in the foreign policy interests of the United States to restrict the entry into the United States of aliens described in section 1 of this proclamation.

NOW, THEREFORE, I, WILLIAM J. CLINTON, by the power vested in me as President of the United States by the Constitution and the laws of the United States of America, including sections 212(f) and 215 of the Immigration and Nationality Act of 1952, as amended (8 U.S.C. 1182(f) and 1185), and section 301 of title 3, United States Code, hereby find that the entry into the United States of aliens described in section 1 of this proclamation as immigrants or nonimmigrants would, except as provided for in section 2 of this proclamation, be detrimental to the interests of the United States. I do therefore proclaim that:

**Section 1.** The entry into the United States as immigrants and nonimmigrants of senior officials of UNITA and adult members of their immediate families, is hereby suspended.

**Sec. 2.** Section 1 shall not apply with respect to any person otherwise covered by section 1 where the entry of such person would not be contrary to the interests of the United States.

**Sec. 3.** Persons covered by section 1 and 2 shall be identified by the Secretary of State.

**Sec. 4.** In identifying persons covered by section 2, the Secretary shall consider whether a person otherwise covered by section 1 is an official necessary for the full functioning of the Government of Unity and National Reconciliation, the National Assembly, or the Joint Commission, within the meaning of paragraph 4(a) of United Nations Security Council Resolution 1127 of August 28, 1997.

**Sec. 5.** This proclamation is effective immediately and shall remain in effect until such time as the Secretary of State determines that it is no longer necessary and should be terminated.

**Sec. 6.** The Secretary of State is hereby authorized to implement this proclamation pursuant to such procedures as the Secretary of State may establish.

IN WITNESS WHEREOF, I have hereunto set my hand this twelfth day of December, in the year of our Lord nineteen hundred and ninety-seven, and of the Independence of the United States of America the two hundred and twenty-second.

William J. Clinton

[FR Doc. 97–33033
Filed 12–15–97; 10:56 am]
Billing code 3195–01–P

# Presidential Documents

**Executive Order 13069 of December 12, 1997**

## Prohibiting Certain Transactions With Respect to UNITA

By the authority vested in me as President by the Constitution and the laws of the United States of America, including the International Emergency Economic Powers Act (50 U.S.C. 1701 *et seq.*) (IEEPA), the National Emergencies Act (50 U.S.C. 1601 *et seq.*), section 5 of the United Nations Participation Act of 1945, as amended (22 U.S.C. 287c)(UNPA), and section 301 of title 3, United States Code, in view of United Nations Security Council Resolution 1127 of August 28, 1997, and 1130 of September 29, 1997, and in order to take additional steps with respect to the actions and policies of the National Union for the Total Independence of Angola (UNITA) and the national emergency declared in Executive Order 12865, I, WILLIAM J. CLINTON, President of the United States of America, hereby order:

**Section 1.** Except to the extent provided in regulations, orders, directives, or licenses issued pursuant to this order, and notwithstanding the existence of any rights or obligations conferred or imposed by any international agreement or any contract entered into or any license or permit granted prior to the effective date of this order, all UNITA offices located in the United States shall be immediately and completely closed.

**Sec. 2.** Except to the extent provided in regulations, orders, directives, or licenses issued pursuant to this order, and notwithstanding the existence of any rights or obligations conferred or imposed by any international agreement or any contract entered into or any license or permit granted prior to the effective date of this order, the following are prohibited:

(a) the sale, supply, or making available in any form, by United States persons or from the United States or using U.S.-registered vessels or aircraft, of any aircraft or aircraft components, regardless of origin:

(i) to UNITA; or

(ii) to the territory of Angola other than through a point of entry specified pursuant to section 4 of this order;

(b) the insurance, engineering, or servicing by United States persons or from the United States of any aircraft owned or controlled by UNITA;

(c) the granting of permission to any aircraft to take off from, land in, or overfly the United States if the aircraft, as part of the same flight or as a continuation of that flight, is destined to land in or has taken off from a place in the territory of Angola other than one specified pursuant to section 4 of this order;

(d) the provision or making available by United States persons or from the United States of engineering and maintenance servicing, the certification of airworthiness, the payment of new claims against existing insurance contracts, or the provision, renewal, or making available of direct insurance with respect to:

(i) any aircraft registered in Angola other than those specified pursuant to section 4 of this order; or

(ii) any aircraft that entered the territory of Angola other than through a point of entry specified pursuant to section 4 of this order;

(e) any transaction by any United States person or within the United States that evades or avoids, or has the purpose of evading or avoiding, or attempts to violate, any of the prohibitions set forth in this order.

**Sec. 3.** For the purposes of this order:

(a) the term ''person'' means an individual or entity;

(b) the term ''entity'' means a partnership, association, trust, joint venture, corporation, or other organization;

(c) the term ''United States person'' means any United States citizen, permanent resident alien, entity organized under the laws of the United States (including foreign branches), or any person in the United States;

(d) the term ''UNITA'' includes:

(i) the Uniao Nacional para a Independencia Total de Angola (UNITA), known in English as the ''National Union for the Total Independence of Angola;''

(ii) the Forcas Armadas para a Liberacao de Angola (FALA), known in English as the ''Armed Forces for the Liberation of Angola;'' and

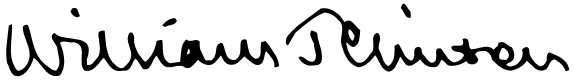
(iii) any person acting or purporting to act for or on behalf of any of the foregoing, including the Center for Democracy in Angola (CEDA).

**Sec. 4.** The Secretary of the Treasury, in consultation with the Secretary of State and, as appropriate, other agencies, is hereby authorized to take such actions, including the specification of places, points of entry, and aircraft registered in Angola for purposes of section 2(a), (c), and (d) of this order, the authorization in appropriate cases of medical emergency flights or flights of aircraft carrying food, medicine, or supplies for essential humanitarian needs, and the promulgation of rules and regulations, and to employ all powers granted to the President by IEEPA and UNPA as may be necessary to carry out the purposes of this order. The Secretary of the Treasury may redelegate any of these functions to other officers and agencies of the United States Government. All agencies of the United States Government are hereby directed to take all appropriate measures within their authority to carry out the provisions of this order, including suspension or termination of licenses or other authorizations in effect as of the effective date of this order.

**Sec. 5.** Nothing contained in this order shall create any right or benefit, substantive or procedural, enforceable by any party against the United States, its agencies or instrumentalities, its officers or employees, or any other person.

**Sec. 6.** (a) This order is effective at 12:01 a.m. eastern standard time on December 15, 1997.

(b) This order shall be transmitted to the Congress and published in the **Federal Register**.



THE WHITE HOUSE,
*December 12, 1997.*

[FR Doc. 97–33034
Filed 12–15–97; 10:57 am]
Billing code 3195–01–P

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