

## Introduction

### DEPARTMENT OF AGRICULTURE

#### Agricultural Marketing Service

#### 7 CFR Part 205

[Docket Number: TMD-00-02-FR]

RIN: 0581-AA40

#### National Organic Program

**AGENCY:** Agricultural Marketing Service, USDA.

**ACTION:** Final Rule with request for comments.

**SUMMARY:** This final rule establishes the National Organic Program (NOP or program) under the direction of the Agricultural Marketing Service (AMS), an arm of the United States Department of Agriculture (USDA). This national program will facilitate domestic and international marketing of fresh and processed food that is organically produced and assure consumers that such products meet consistent, uniform standards. This program establishes national standards for the production and handling of organically produced products, including a National List of substances approved for and prohibited from use in organic production and handling. This final rule establishes a national-level accreditation program to be administered by AMS for State officials and private persons who want to be accredited as certifying agents. Under the program, certifying agents will certify production and handling operations in compliance with the requirements of this regulation and initiate compliance actions to enforce program requirements. The final rule includes requirements for labeling products as organic and containing organic ingredients. This final rule also provides for importation of organic agricultural products from foreign programs determined to have equivalent organic program requirements. This program is authorized under the Organic Foods Production Act of 1990, as amended.

**EFFECTIVE DATE:** This rule becomes effective [60 days after publication in the Federal Register].

Comments: Comments on specified aspects of the final regulations must be submitted on or before [90 days after publication in the Federal Register].

**ADDRESSES:** Interested persons are invited to submit written comments on specified aspects of the final regulation to: Keith Jones, Program Manager, National Organic Program, USDA-AMS-TMP-NOP, Room 2945-So., Ag Stop 0275, P.O. Box 96456, Washington, DC 20090-6456. Comments may also be filed via the Internet through the National Organic Program's homepage at: [www.ams.usda.gov/nop](http://www.ams.usda.gov/nop). Written comments on specified aspects of the final regulations should be identified with the docket number TMD-00-02-FR. To facilitate the timely scanning and posting of comments to the NOP homepage, multiple-page comments submitted by regular mail should not be stapled or clipped.

It is our intention to have all comments to this final rule, whether mailed or submitted via the Internet, available for viewing on the NOP homepage in a timely manner. Comments submitted in response to this final rule will be available for viewing at USDA-AMS,

Transportation and Marketing Programs, Room 2945-South Building, 14th and Independence Avenue, SW, Washington, DC, from 9:00 a.m. to 12:00 noon and from 1:00 p.m. to 4:00 p.m., Monday through Friday (except for official Federal holidays). Persons wanting to visit the USDA South Building to view comments received in response to this final rule are requested to make an appointment in advance by calling (202) 720-3252.

**FOR FURTHER INFORMATION CONTACT:** Richard Mathews, Senior Agricultural Marketing Specialist, USDA-AMS-TMP-NOP, Room 2510-So., P.O. Box 96456, Washington, DC 20090-6456; Telephone: (202) 205-7806; Fax: (202) 205-7808.

#### **SUPPLEMENTARY INFORMATION:**

##### **Prior Documents in this Proceeding**

This final rule is issued pursuant to the Organic Food Production Act of 1990 (Act or

OFPA), as amended (7 U.S.C. 6501 et seq.). This final rule replaces the proposed rule published in the Federal Register March 13, 2000. The public submitted 40,774 comments on the proposed rule. Comments to the proposed rule were considered in the preparation of this final rule.

The following notices related to the National Organic Standards Board (NOSB) and the development of this proposed regulation have been published in the Federal Register. Six notices of nominations for membership on the NOSB were published between April 1991 and June 2000 (56 FR 15323, 59 FR 43807, 60 FR 40153, 61 FR 33897, 64 FR 33240, 65 FR 35317). Two notices of extension of time for submitting nominations were published on September 22, 1995, and September 23, 1996 (60 FR 49246, 61 FR 49725). Twenty notices of meetings of the NOSB were published between March 1992 and November 2000 (57 FR 7094, 57 FR 27017, 57 FR 36974, 58 FR 85, 58 FR 105, 58 FR 171, 59 FR 58, 59 FR 26186, 59 FR 49385, 60 FR 51980, 60 FR 15532, 61 FR 43520, 63 FR 7389, 63 FR 64451, 64 FR 3675, 64 FR 28154, 64 FR 54858, 65 FR 11758, 65 FR 33802, 65 FR 64657). One notice of public hearings on organic livestock and livestock products was published on December 30, 1993 (58 FR 69315). Two notices specifying a procedure for submitting names of substances for inclusion on or removal from the National List of Approved and Prohibited Substances were published on March 27, 1995 (60 FR 15744), and July 13, 2000 (65 FR 43259). A rule proposing the NOP was published on December 16, 1997 (62 FR 65850). An extension of the time period for submitting comments to the proposed rule was published on February 9, 1998 (63 FR 6498). One request for comments on Issue Papers was published on October 28, 1998 (63 FR 57624). A notice of a program to assess organic certifying agencies was published on June 9, 1999 (64 FR 30861). A rule proposing the NOP was published on March 13, 2000 (65 FR 13512). A notice of public meeting and request for comments on organic production and handling of aquatic animals to be labeled as organic was published on March 23, 2000 (65 FR 15579). One advance notice of proposed rulemaking and request for comments on reasonable security for private certifying agents was published on August 9, 2000 (65 FR 48642).

This preamble includes a discussion of the final rule and supplementary information,

including the Regulatory Impact Assessment, Unfunded Mandates Reform Act Statement, Regulatory Flexibility Act Analysis, Federalism Impact Statement, and Civil Justice Impact Statement. The Civil Rights Impact Analysis is not included as an attachment but may be obtained by writing to the address provided above or via the Internet through the National Organic Program's homepage at: <http://www.ams.usda.gov/nop>.

### **Approval of Paperwork Reduction Act Requirements for this Final Rule**

The reporting requirements and recordkeeping burden imposed by this rule were published in the March 13, 2000, Federal Register for public comment. The Agency addressed these comments in the final rule to ensure that the least amount of the burden is placed on the public. The information collection and recordkeeping requirements have been reviewed and approved by the Office of Management and Budget under OMB Number 0581-0191, National Organic Program.

## Definitions -- Preamble

### National Organic Program Overview

#### Subpart A - Definitions

##### Description of Regulations

This subpart defines various terms used in this part. These definitions are intended to enhance conformance with the regulatory requirements through a clear understanding of the meaning of key terms.

We have amended terms and definitions carried over from the proposed rule where necessary to make their wording consistent with the language used in this final rule. We have revised the definitions of the following words for greater clarity: person, practice standard, inert ingredient, processing, tolerance. We have removed the definitions for the following terms because the terms are not used in this final rule or have been determined to be unnecessary: accredited laboratory, estimated national mean, system of organic production and handling. We received comments on some of these definitions that have been deleted. We have not addressed those comments here because the relevant definitions have been deleted.

##### Definitions - Changes Based on Comments

This subpart differs from the proposed rule in several respects as follows:

(1) Many commenters requested changes to the definition of "excluded methods." Comments included requests to use the more common term, "genetically modified organisms(GMO)"; to include the products of excluded methods/GMO's in the definition; to more closely follow the NOSB definition by adding gene deletion, doubling, introduction of a foreign gene, and changing gene position; to include that excluded methods are prohibited by the Act and by the regulations in this part; to change the wording of the reference to "recombinant DNA"; and to add that the definition of excluded methods only covers "intentional use."

We have accepted some of the comments and have modified the definition accordingly. Specifically, we have included reference to the "methods"-gene deletion, gene doubling, changing positions of genes, and introducing foreign genes-that were included in the original NOSB definition. This will make the definition even more closely parallel the NOSB recommendation. We also refer to recombinant DNA technology, which is technically more accurate than the proposed rules reference to recombinant DNA as a "method."

We have not accepted the comments that requested adding the products of excluded methods to the definition. The emphasis and basis of these standards is on process, not product. We have specifically structured the provisions relating to excluded methods to refer to the use of methods. Including the products of excluded methods in the definition would not be consistent with this approach to organic standards as a process-based system. For the same reason, we have retained the term, "excluded methods," to reinforce that process-based approach.

We have also rejected comments requesting that we include the prohibition on excluded methods in the definition and, likewise, those requesting that we refer to "intentional use" of excluded methods. The final rule maintains and clarifies the prohibition on the use of excluded methods in organic production systems. The prohibition is most properly addressed in the appropriate provisions of the regulations, particularly in Section 205.105, and not in the definition. Similarly, although we recognize that a distinction between intentional and unintentional use of excluded

methods may be meaningful, particularly as it pertains to issues of drift, this is an issue that is best handled in the sections of the regulation governing use of excluded methods, not in the definition. The definition for "excluded methods" now reads:

A variety of methods used to genetically modify organisms or influence their growth and development by means that are not possible under natural conditions or processes and are not considered compatible with organic production. Such methods include cell fusion, microencapsulation and macroencapsulation, and recombinant DNA technology (including gene deletion, gene doubling, introducing a foreign gene, and changing the position of genes when achieved by recombinant DNA technology). Such methods do not include the use of traditional breeding, conjugation, fermentation, hybridization, in vitro fertilization, or tissue culture."

(2) Many commenters objected to the definition of "compost" in the proposed rule because it required that compost must be produced in a facility that was in compliance with the Natural Resource Conservation Service's (NRCS) practice standard for a composting facility. We agree with these commenters and removed the requirement to comply with the NRCS practice standard. However, the final rule incorporates new requirements for the production of compost that are included in the definition. The final rule requires that compost must be produced through a process that combines plant and animal materials with an initial C:N ratio of between 25:1 and 40:1. Furthermore, producers using an in-vessel or static aerated pile system must maintain the composting materials at a temperature of between 131F and 170F for 3 days. Producers using a windrow system must maintain the composting materials at a temperature between 131F and 170F for 15 days, during which time, the materials must be turned a minimum of five times. We developed the requirements in the final rule for producing an allowed composted material by integrating standards used by the Environmental Protection Agency (EPA) and USDA's Natural Resources Conservation Service (NRCS). The requirements for the carbon-to-nitrogen (C:N) ratio for composting materials is the same as that found in the NRCS practice standard for a composting facility. The time and temperature requirements for in-vessel, static aerated pile, and window composting systems are consistent with those which EPA regulates under 40 CFR 503 for the production of Class A sewage sludge. Additionally, AMS reviewed these compost production requirements with USDA's Agricultural Research Service (ARS). This subject is discussed further under subpart C, Crop Production, Changes Based on Comment.

(3) Some commenters stated that allowing nonagricultural or synthetic substances as feed supplements contradicted the definition for "feed supplement" in the proposed rule. These commenters stated that the definition stipulated that a feed supplement must, itself, be a feed material and that the proposed definition for "feed" did not include nonagricultural or synthetic substances. These commenters stated that the definition of "feed supplement" needed to be amended to accommodate nonagricultural or synthetic substances, or such substances should not be allowed. We agree with these commenters and amended the definition for "feed supplement" to read "a combination of feed nutrients added to livestock feed to improve the nutritional balance or performance of the total ration." One commenter recommended modifying the definition of "feed additive" to "a substance added to feed in micro quantities to fulfill a specific nutritional need; i.e., essential nutrients in the form of amino acids, vitamins, and minerals." We agree that this modification provides a more precise description of "feed additive" and have included the change. The changes to the definitions for "feed supplement" and "feed additive" are further discussed under item (4) of Livestock Production - Changes Based on Comments.

(4) One commenter stated that the definition for "forage" inaccurately described it as "vegetable matter," and suggested that "vegetative matter" was a more suitable description. We agree with the suggestion and have incorporated the change.

(5) Some commenters stated that the definition for "mulch" implied that all mulch materials must either be organic or included on the National List. These commenters maintained that, if this was the intent of the proposed rule, the provision was too restrictive. They recommended revising the

definition to clarify that natural but nonorganic plant and animal materials, if managed to prevent contamination from prohibited substances, could be used as mulch without being added to the National List. This was the intent in the proposed rule, and we have modified the definition to make this provision clearer.

(6) Many commenters stated that the final rule should include a definition of "organic production" that required that certified operations must preserve or protect biodiversity. These commenters stated that the preservation of biodiversity is a requirement in many existing organic certification standards, including the Codex guidelines. They also stated that the NOSB had included the requirement to preserve biodiversity in its definition of organic. We agree with the intent of these comments but prefer the term, "conserve," to "preserve" because it reflects a more dynamic, interactive relationship between the operation and biodiversity over time. We included a definition for organic production as "a production system that is managed in accordance with the Act and regulations in this part to respond to site-specific conditions by integrating cultural, biological, and mechanical practices that foster cycling of resources, promote ecological balance, and conserve biodiversity." We deleted the definition for "organic system of production and handling" in the final rule.

(7) Several commenters, including the NOSB, were concerned that the definition for "planting stock" as "any plant or plant tissue, including rhizomes, shoots, leaf or stem cuttings, roots, or tubers, used in plant production or propagation" was sufficiently broad to be applied to annual seedlings. We agree that it is important to establish that annual seedlings are not covered by the definition of "planting stock" and amended the definition to exclude them. The definition for planting stock in the final rule states "any plant or plant tissue other than annual seedlings but including rhizomes, shoots, leaf or stem cuttings, roots, or tubers, used in plant production or propagation." The final rule retains the definition for "annual seedling" from the proposed rule.

(8) Several commenters recommended that the definition of "processing" should be amended to include "distilling" as an allowed practice. We agree with this comment and added distilling as an allowed processing practice.

(9) Several commenters recommended that the final rule include a definition for "processing aid" that is consistent with the definition proposed by the NOSB and used by the Food and Drug Administration (FDA). We agree with these commenters and have included a definition for processing aid that is the same as the definition used by FDA and found in 21 CFR Part 101.100(a)(3)(ii).

(10) Many commenters questioned whether the term, "State organic certification program," in the proposed rule included organic programs from States that did not offer certification services. These commenters stated that the final rule should include provisions for all State organic programs regardless of whether they functioned as certifying agents. We agree with these commenters and have amended the final rule by incorporating the term, "State organic program," as "a State program that meets the requirements of section 6506 of the Act, is approved by the Secretary, and is designed to ensure that a product that is sold or labeled as organically produced under the Act is produced and handled using organic methods." The term, "State organic program," encompasses such programs whether they offer certification services or not.

(11) One commenter stated that the definition for "wild crop" only referred to a plant or part of a plant that was harvested from "an area of land." This commenter was concerned that the definition would preclude the certification of operations that produce wild aquatic crops, such as seaweed, and stated that the OFPA does allow for certifying such operations. We agree with this commenter and changed the definition to refer to a plant or part of a plant harvested from a "site."

(12) Many commenters stated that the soil fertility and crop nutrient management practice standard lacked a definition for "manure." These commenters maintained that the different provisions contained in the practice standard for "manure" and "compost" would be difficult to enforce without clear definitions to differentiate between the two materials. We agree with these comments and added a definition for manure as "feces, urine, other excrement, and bedding produced by livestock that has not been composted."

(13) Some commenters stated that the National List in the final rule should include an annotation for narrow range oils to limit their use to a specific subset of such materials recommended by the NOSB. We agree with this comment but, rather than add an annotation, we have included the specifications recommended by the NOSB in a new definition for narrow range oils. Narrow range oils are defined as "petroleum derivatives, predominately of paraffinic and naphthenic fractions with a 50-percent boiling point (10 mm Hg) between 415F and 440F."

(14) Many commenters maintained that the final rule needed a definition of the term, "pasture," to describe the relationship between ruminants and the land they graze. These commenters stated that a meaningful definition of "pasture" must incorporate the nutritional component that it provides livestock, as well as the necessity to manage the land in a manner that protects the natural resources of the operation. We agree with these commenters and have added a definition of "pasture" as "land used for livestock grazing that is managed to provide feed value and maintain or improve soil, water, and vegetative sources."

(15) Many commenters stated that a definition for "split operation" was necessary to prevent commingling between organic and nonorganic commodities on operations that produced or handled both forms of a commodity. We agree with these comments and have included a definition for "split operation" as "an operation that produces or handles both organic and nonorganic agricultural products."

### **Definitions - Changes Requested But Not Made**

This subpart retains from the proposed rule terms and their definitions on which we received comments as follows:

(1) Many commenters objected to the definition of "sewage sludge" because it excluded ash generated in a sewage sludge incinerator and grit and screenings generated during preliminary treatment of domestic sewage in treatment works. We have not changed the definition for "sewage sludge" because it provides the most comprehensive and enforceable description of the types of materials that commenters wanted to prohibit. The definition for "sewage sludge" in the proposed rule arose in response to significant public comment on the first proposed rule for national organic standards (62 Federal Register, No. 241) that recommended prohibiting biosolids in organic production. When incorporating those comments into the proposed rule, we did not use the term, "biosolids," because it does not have a standardized definition under Federal regulations. The term, "biosolids," is commonly used to refer to "sewage sludge," which is the regulatory term established in 40 CFR Part 503. We incorporated the precise definition from 40 CFR Part 503, even though it does not include ash, grit, or screenings, because it provided the clearest description of the types of materials identified in public comment.

While commenters are correct that ash, grit, or screenings from the production of sewage sludge are not prohibited by this definition, these materials are prohibited elsewhere in the regulation. The soil fertility and crop nutrient management practice standard in section 205.203 establishes the universe of allowed materials and practices. These allowed materials and practices are crop rotations, cover crops, plant and animal materials (including their ash), nonagricultural, natural materials, and, under appropriate conditions, mined substances of low and high solubility and synthetic materials included on the National List. Ash, grit, or screenings from the production of

sewage sludge cannot be included in any of these categories and, therefore, cannot be used in organic production. We retained the definition of "sewage sludge" because it most clearly conveys the wide array of commercially available soil amendments that might be considered for organic production but that the final rule expressly prohibits. We have not added specific exclusions for sewage sludge, ash, grit, or screenings because these materials are prohibited through other provisions in the practice standard.

(2) The proposed rule prohibited the handler of an organic handling operation from using ionizing radiation for any purpose. The vast majority of commenters agreed with this prohibition and further recommended that the term, "ionizing radiation," should be defined to identify the specific applications that are prohibited. Most commenters supported a definition based on the FDA requirements in 21 CFR part 179.26 for the treatment or processing of food using ionizing radiation. While agreeing with the prohibition on ionizing radiation, these commenters favored allowing certain forms of irradiation such as the use of X-rays to inspect for debris such as stones that were inadvertently commingled with organically handled food. Other commenters recommended a prohibition on all forms of irradiation, which would include X-rays for inspection purposes, ultraviolet light, and microwaves in addition to ionizing radiation. Finally, a number of commenters stated that ionizing radiation is a safe and effective process for handling food and, therefore, should not be prohibited in organic handling.

We have not added a definition for "ionizing radiation" to the final rule because we have incorporated specific references to the applications that are prohibited in the regulatory text. The final rule prohibits the handler of an organic handling operation from using ionizing radiation as specified under 21 CFR part 179.26. These are the FDA-approved uses of ionizing radiation that commenters most frequently recommended that we prohibit in organic handling operations. They include the use of cobalt-60, cesium-137, and other sources of radiation for the purpose of controlling microbial contaminants, pathogens, and pests in food or to inhibit the growth and maturation of fresh foods. At its June 2000 meeting, the NOSB recommended prohibiting ionizing radiation for the purpose of controlling microbial contaminants, pathogens, parasites, and pests in food, preserving a food, or inhibiting physiological processes such as sprouting or ripening. The final rule does not prohibit the handler of an organic handling operation from using the FDA-approved applications of X-rays for inspecting food. The prohibition on ionizing radiation in the final rule is based solely on consumer preference as reflected in the overwhelming public comment stating that organically handled foods should not be treated in that manner.

(3) Some commenters recommend that the final rule incorporate definitions for the terms, "food additives," "extraction methods," "incidental additive," and "substantially transform." However, these terms are not used in the final rule and do not require a definition.

### **Definitions - Clarifications**

Following our review of the definitions provisions in the proposed rule, we decided to further clarify the following provision in the final rule:

We were concerned that "State entity," the meaning of which encompasses both domestic and foreign political subdivisions, may be confused with "State," the meaning of which is limited to the States of the United States, its territories, the District of Columbia, and Puerto Rico. To avoid any possible confusion as to which provisions in this final rule apply to States and which apply to the broader political subdivisions, we have replaced the term, "State entity," with the term, "governmental entity," while retaining the same definition language in the proposed rule.



## Applicability -- Preamble

### Subpart B - Applicability

This subpart provides an overview of what has to be certified under the National Organic Program (NOP); describes exemptions and exclusions from certification; addresses use of the term, "organic"; addresses recordkeeping by certified production and handling operations; and addresses allowed and prohibited substances, methods, and ingredients in organic production and handling.

### Description of Regulations

Except for exempt and excluded operations, each production or handling operation or specified portion of a production or handling operation that produces or handles crops, livestock, livestock products, or other agricultural products that are intended to be sold, labeled, or represented as "100 percent organic," "organic," or "made with organic (specified ingredients or food group(s))" must be certified. Certified operations must meet all applicable requirements of these regulations.

This final rule becomes effective 60 days after its publication in the Federal Register and will be fully implemented 18 months after its effective date. Eighteen months after the effective date, all agricultural products that are sold, labeled, or represented as "100 percent organic," "organic," or "made with..." must be produced and handled in compliance with these regulations. Products entering the stream of commerce prior to the effective date will not have to be relabeled. The U.S. Department of Agriculture (USDA) seal may not be affixed to any "100 percent organic" or "organic" product until 18 months after the final rule's effective date.

We anticipate that certifying agents and production and handling operations will move as quickly as possible after the effective date of the final rule to begin operating under the national organic standards. Certifying agents must begin certifying organic production and handling operations to the national standards upon receipt of their accreditation from the Administrator. Any production or handling operation or specified portion of a production or handling operation that has been already certified by a certifying agent on the date that the certifying agent receives its accreditation under this part shall be deemed to be certified under the Act until the operation's next anniversary date of certification. We have taken this approach because we believe that such certifying agents will, upon the effective date of the final rule, demonstrate their eligibility for accreditation by applying the national standards to the certification and renewal of certification of their clients. We also believe this approach will provide relief to certified operations which might otherwise have to be certified twice within a 12-month period (prior to their certifying agent's accreditation and again following their certifying agent's accreditation). This relief will only be available to those certified operations certified by a certifying agent that receives its accreditation within 18 months from the effective date of the final rule.

Certifying agents can apply for accreditation anytime after the effective date of the rule. Applications will be processed on a first-come, first-served basis. Those certifying agents who apply for accreditation within the first 6 months after the effective date of the final rule and are determined by the Administrator to meet the requirements for accreditation will be notified of their status approximately 12 months after the final rule's effective date. This approach is being taken because of the market advantage that could be realized by accredited certifying agents if USDA did not announce the accreditations simultaneously.

### Exempt and Excluded Operations

This regulation establishes several categories of exempt or excluded operations. An exempt or excluded operation does not need to be certified. However, operations that qualify as exempt or

excluded operations can voluntarily choose to be certified. A production or handling operation that is exempt or excluded from obtaining certification still must meet other regulatory requirements contained in this rule as explained below.

### **Exempt Operations**

(1) A production or handling operation that has \$5,000 or less in gross annual income from organic sales is exempt from certification. This exemption is primarily designed for those producers who market their product directly to consumers. It will also permit such producers to market their products direct to retail food establishments for resale to consumers. The exemption is not restricted to U.S. producers. However, as a practical matter, we do not envision any significant use of the exemption by foreign producers because: (1) the products from such operations cannot be used as ingredients identified as organic in processed products produced by another handling operation, and (2) it is unlikely that such operations will be selling their products directly to consumers in the United States.

An exempt producer or handler must comply with the labeling requirements of section 205.310 and the organic production and handling requirements applicable to its type of operation. For example, a producer of organic vegetables that performs no handling functions would have to comply with the labeling requirements of section 205.310 and the applicable production requirements in sections 205.202 through 205.207. The labeling and production and handling requirements protect the integrity of organically produced products.

(2) A retail food establishment or portion of a retail food establishment that handles organically produced agricultural products but does not process them is exempt from all of the requirements in these regulations.

(3) A handling operation or portion of a handling operation that handles only agricultural products containing less than 70 percent organic ingredients by total weight of the finished product (excluding water and salt) is exempt from the requirements in these regulations, except the recordkeeping provisions of section 205.101(c); the provisions for prevention of contact of organic products with prohibited substances in section 205.272; and the labeling regulations in sections 205.305 and 205.310. The recordkeeping provisions maintain an audit trail for organic products. The prevention of contact with prohibited substances and the labeling requirements protect the integrity of organically produced products.

(4) A handling operation or portion of a handling operation that uses the word, "organic," only on the information panel is exempt from the requirements in these regulations, except the recordkeeping provisions of section 205.101(c); the provisions for prevention of contact of organic products with prohibited substances as provided in section 205.272; and the labeling regulations in sections 205.305 and 205.310. The recordkeeping provisions maintain an audit trail for organic products. The prevention of contact with prohibited substances and labeling requirements protect the integrity of organically produced products.

As noted above, exempt handling operations producing multiingredient products must maintain records as required by section 205.101(c). This would include records sufficient to: (1) prove that ingredients identified as organic were organically produced and handled and (2) verify quantities produced from such ingredients. Such records must be maintained for no less than 3 years, and the operation must allow representatives of the Secretary and the applicable State program's governing State official access to the records during normal business hours for inspection and copying to determine compliance with the applicable regulations.

### **Excluded Operations**

(1) A handling operation or portion of a handling operation that sells organic agricultural products labeled as "100 percent organic," "organic," or "made with..." that are packaged or otherwise enclosed in a container prior to being received or acquired by the operation, remain in the same package or container, and are not otherwise processed while in the control of the handling operation is excluded from the requirements in these regulations, except for the provisions for prevention of commingling and contact of organic products with prohibited substances in section 205.272. The requirements for the prevention of commingling and contact with prohibited substances protect the integrity of organically produced products.

This exclusion will avoid creating an unnecessary barrier for handlers who distribute nonorganic products and who want to offer a selection of organic products.

(2) A retail food establishment or portion of a retail food establishment that processes on the premises of the retail food establishment raw and ready-to-eat food from certified agricultural products labeled as "100 percent organic," "organic," or "made with..." is excluded from the requirements in these regulations, except for the provisions for prevention of contact of organic products with prohibited substances as provided in section 205.272 and the labeling regulations in section 205.310. The prevention of commingling and contact with prohibited substances and labeling requirements protect the integrity of organically produced products.

Excluded retail food establishments include restaurants; delicatessens; bakeries; grocery stores; or any retail outlet with an in-store restaurant, delicatessen, bakery, salad bar, or other eat-in or carry-out service of processed or prepared raw and ready-to-eat food.

There is clearly a great deal of public concern regarding the handling of organic products by retail food establishments. We have not required certification of retail food establishments at this time because of a lack of consensus as to whether retail food establishments should be certified, a lack of consensus on retailer certification standards, and a concern about the capacity of existing certifying agents to certify the sheer volume of such businesses. Retail food establishments, not exempt under the Act, could at some future date be subject to regulation under the NOP. Any such regulation would be preceded by rulemaking with an opportunity for public comment.

No retailer, regardless of this exclusion and the exceptions found in the definitions for "handler" or "handling operation," may sell, label, or provide market information on a product unless such product has been produced and handled in accordance with the Act and these regulations. Any retailer who knowingly sells or labels a product as organic, except in accordance with the Act and these regulations, will be subject to a civil penalty of not more than \$10,000 per violation under this program.

### **Recordkeeping Requirements for Certified Operations**

A certified operation must maintain records concerning the production and handling of agricultural products that are sold, labeled, or represented as "100 percent organic," "organic," or "made with..." sufficient to demonstrate compliance with the Act and regulations. Such records must be adapted to the particular business that the certified operation is conducting, fully disclose all activities and transactions of the certified operation in sufficient detail to be readily understood and audited, be maintained for not less than 5 years beyond their creation, and be sufficient to demonstrate compliance with the Act and regulations. Certified operations must make the records required by this regulation available for inspection by authorized representatives of the Secretary, the applicable State organic program's (SOP) governing State official, and the certifying agent. Access to such records must be provided during normal business hours.

### **Examples of Records**

Each exempt, excluded, and certified operation should maintain the records which demonstrate compliance with the Act and the regulations applicable to it and which it believes establish an audit trail sufficient to prove to the Secretary, the applicable SOP's governing State official, and the certifying agent that the exempt, excluded, or certified operation is and has been in compliance with the Act and regulations.

Examples of records include: application and supporting documents for certification; organic system plan and supporting documents; purchased inputs, including seeds, transplants, livestock, and substances (fertilizers, pesticides, and veterinary biologics consistent with the livestock provisions of subpart C), cash purchase receipts, receiving manifests (bills of lading), receiving tickets, and purchase invoices; field records (planting, inputs, cultivation, and harvest); storage records (bin register, cooler log); livestock records, including feed (cash purchase receipts, receiving manifests (bills of lading), receiving tickets, purchase invoices, copies of grower certificates), breeding records (calendar, chart, notebook, veterinary documents), purchased animals documentation (cash purchase receipts, receiving manifests (bills of lading), receiving tickets, purchase invoices, copies of grower certificates), herd health records (calendar, notebook, card file, veterinary records), and input records (cash purchase receipts, written records, labels); producer invoice; producer contract; receiving manifests (bills of lading); transaction certificate; producer certificate; handler certificate; weigh tickets, receipts, and tags; receiving tickets; cash purchase receipts; raw product inventory reports and records; finished product inventory reports and records; daily inventories by lot; records as to reconditioning, shrinkage, and dumping; production reports and records; shipping reports; shipping manifests (bills of lading); paid freight and other bills; car manifests; broker's contracts; broker's statements; warehouse receipts; inspection certificates; residue testing reports; soil and water testing reports; cash receipt journals; general ledgers and supporting documents; sales journals; accounts payable journals; accounts receivable journals; cash disbursement journals; purchase invoices; purchase journals; receiving tickets; producer and handler contracts; cash sales receipts; cash purchase journals; sales invoices, statements, journals, tickets, and receipts; account sales invoices; ledgers; financial statements; bank statements; records of deposit; canceled checks; check stubs; cash receipts; tax returns; accountant's or other work papers; agreements; contracts; purchase orders; confirmations and memorandums of sales; computer data; computer printouts; and compilations of data from the foregoing.

### **Allowed and Prohibited Substances**

A certified operation must only use allowed substances, methods, and ingredients for the production and handling of agricultural products that are sold, labeled, or represented as "100 percent organic," "organic," or made with..." for these products to be in compliance with the Act and the NOP regulations. Use of ionizing radiation, sewage sludge, and excluded methods are prohibited in the production and handling of organic agricultural products.

### **Applicability - Changes Based on Comments**

This subpart differs from the proposal in several respects as follows:

(1) Violations of the Act or Regulations. We have amended section 205.100 by adding a new paragraph (c), which addresses violations of the Act and these regulations. A number of commenters advocated for provisions within the final rule describing what legal proceedings USDA would conduct against operations or persons that violate the NOP. We agree that this rule should include provisions addressing violations of the Act and these regulations. Accordingly, we have added at section 205.100 the misuse of label provisions and false statement provisions of section 2120 (7 U.S.C. 6519) of the Act. Specifically, section 205.100(c) provides that persons not in compliance with the labeling requirements of the Act or these regulations are subject to a civil penalty of not more than \$10,000 per violation and that persons making false statements under the Act to the Secretary, a governing State official, or an accredited certifying agent shall

be subject to the provisions of section 1001 of Title 18, United States Code. The provisions of the Act and these regulations apply to all operations or persons that sell, label, or represent their agricultural product as organic.

(2) Prohibition on Use of Excluded Methods. We have moved section 205.600 from subpart G, Administrative, to subpart B, Applicability, and replaced paragraph (d), which referred the reader to section 205.301, with new paragraphs (d) through (g). As amended, this section, redesignated as section 205.105, includes all of the provisions covered under old section 205.600.

The vast majority of commenters strongly supported the prohibition on the use of excluded methods in organic production and handling but raised concerns that they could not point to one provision that prohibited use of excluded methods in all aspects of organic production and handling. To close what they perceived to be "loopholes" in the prohibition, commenters made several suggestions for inclusion of new provisions prohibiting use of excluded methods in particular aspects of organic production and handling that they believed were not covered in the proposed rule. Other commenters pointed to inconsistencies in the way the prohibition on use of excluded methods was described in different sections, raising concerns that these apparent inconsistencies may create confusion for organic operations, certifiers, and consumers.

Although we intended that use of excluded methods would be prohibited in all aspects of organic production and handling, the structure of the proposed rule may not have made that clear. We also share the concerns that, in attempting to identify all aspects of organic production and handling where excluded methods might be used, we may inadvertently have left out some provisions, creating confusion for organic operations, certifying agents, and consumers and creating doubt as to the scope of the prohibition on use of excluded methods. Similarly, to the extent that the prohibition on excluded methods may have been described differently in various sections of the proposed rule, we also share the concern that these inconsistencies could create confusion.

As a result of these concerns, we have created a new provision in section 205.105 that prohibits the use of excluded methods (and ionizing radiation and sewage sludge) generally. This provision should alleviate perceptions that some areas of organic production may not have been covered by the prohibitions in the proposed rule. It also allows us to eliminate from the regulation most of the individual references to the prohibition on use of these methods, thereby eliminating any potential confusion where these provisions may have appeared inconsistent. These changes do not lift the prohibition on use of these methods in those sections. In fact, the purpose of this new provision is to make clear that use of these methods is prohibited in the production and handling of organic products.

(3) Animal Vaccines. The proposed rule specifically asked for public comment on the potential impact of the prohibition on use of excluded methods as it relates to animal vaccines. A number of commenters raised concerns that there may be some critical vaccines that are only available in forms produced using excluded methods. Several commenters requested that we prohibit use of animal vaccines produced using excluded methods but that we provide for a temporary exemption until such time as vaccines produced without using excluded methods are approved for use on the National List. Other commenters requested that we prohibit use of vaccines produced using excluded methods without exception.

We have concluded that the potential impact of prohibiting vaccines produced using excluded methods on animal production systems is still unknown. We do not know of any critical animal vaccine that is only available in a form produced using excluded methods, but it is unclear whether producers and certifying agents are tracking the possible use of such vaccines. There also appears to be no international consensus on the use in organic production systems of animal vaccines produced using excluded methods, although there is precedent for such an exemption.

European Union regulations, for example, allow for use of animal vaccines produced using excluded methods.

Based on comments received and because the potential impact of the prohibition on use of excluded methods is still uncertain, we have created the possibility at section 205.105(e) for the NOSB to exercise one very narrow exception to allow use of animal vaccines produced using excluded methods but only if they are explicitly approved on the National List. We believe the issue of animal vaccines requires further deliberation and that it is most appropriate to consider it through the National List process, which mandates review by the NOSB and Technical Advisory Panels. Consideration of animal vaccines produced using excluded methods is appropriate for the National List review process because animal vaccines, we believe, are most appropriately considered synthetic materials. That is why the provision is structured so that vaccines produced using excluded methods could only be used in organic production if they are affirmatively included on the National List. We do not believe that a broad-based exemption of the type suggested in some comments, even if only temporary, is appropriate.

The Act allows use of animal vaccines in organic livestock production. Given the general prohibition on the use of excluded methods, however, we believe that animal vaccines produced using excluded methods should not be allowed without an explicit consideration of such materials by the NOSB and without an affirmative determination from the NOSB that they meet the criteria for inclusion on the National List. It is for that reason that we have not granted this request of commenters but, rather, provided an opportunity for review of this narrow range of materials produced using excluded methods through the National List process.

It is important to make clear, however, that this provision does not open all potential applications of excluded methods to a case-by-case review in the context of the National List, nor are we proposing that any particular vaccines be reviewed for inclusion on the National List at this time. The prohibition on use of excluded methods applies across the board to all phases of organic production and handling. We are simply responding to comments suggesting that a narrow exception for animal vaccines may be appropriate and providing for the possibility that such an exception could be invoked upon thorough review and recommendation by the NOSB

### **Applicability - Changes Requested But Not Made**

This subpart retains from the proposed rule regulations on which we received comments as follows:

(1) Exemption of Handling Operations Producing Multiingredient Products. Some commenters asserted that only certified handling operations should be allowed to identify ingredients in multiingredient products as organic. These commenters believe that consumers will be misled if noncertified handling operations are allowed to identify ingredients as organic even if the organic claim is limited to the information panel. We do not agree with these assertions and have retained the proposed rule provisions that do not require handler certification when a product only identifies ingredients as organic within the information panel. Although handling operations only making organic claims on the information panel are exempt from certification, these operations are required to use organic product from certified operations. They are also required to prevent contact of organic products with prohibited substances as set forth in section 205.272, adhere to the labeling provisions of sections 205.305 and 205.310, and maintain records in accordance with section 205.101(c). We believe consumers will understand the distinction between products that have the organic nature of the product stated on the principal display panel and those that merely identify an ingredient as organic on the information panel.

(2) Retailer Exclusion from Certification. Many commenters objected to the provisions of section 205.101(b)(2) which exclude retail food establishments from certification. These commenters

assert that only final retailers that do not process agricultural products should be excluded from certification. There is clearly a great deal of public concern regarding the handling of organic products by retail food establishments. We have not required certification of retail food establishments at this time because of a lack of consensus as to whether retail food establishments should be certified, a lack of consensus on retailer certification standards, and a concern about the capacity of existing certifying agents to certify the sheer volume of such businesses. In addition, most existing certification programs do not include retail food establishments, and we do not believe there is sufficient consensus to institute such a significant expansion in the scope of certification at this time. However, since a few States have established procedures for certifying retail food establishments, we will assess their experience and continue to seek consensus on this issue of establishing retailer provisions under the NOP. Any such change would be preceded by rulemaking with an opportunity for public comment. The exclusion of nonexempt retail food establishments from this final rule does not prevent a State from developing an organic retail food establishment program as a component of its SOP. However, as with any component of an SOP, the Secretary will review such components on a case-by-case basis.

(3) Producer Exemption Level. Several commenters advocated for an increase in the producer exemption level above the \$5,000 limit. Comments supporting the exemption suggested increasing the statutory limit for qualifying for the exemption to as high as \$75,000. Other commenters stated that all producers should be certified and opposed the exemption even though it is required by the Act. These commenters were concerned about maintaining the integrity of the organic product and about the lack of verification of the exempt operations.

We have not increased or removed the \$5,000 producer exemption because the exemption is mandated by section 2106(d) (7 U.S.C. 6505(d)) of the Act. Our purpose is to limit the financial burdens of certification on such operations but not to exempt them from the standards for organic production and handling. Accordingly, exempt production and handling operations must comply with the applicable organic production and handling requirements of subpart C and the labeling requirements of section 205.310.

Some of the commenters wanting a change in the producer exemption level suggested that the NOP add provisions for restricting these producers to marketing at farmers markets or roadside stands. We disagree with these comments. While we believe that most producers qualifying for the exemption are indeed likely to be small producers who market their products directly to consumers, we do not believe it is in the best interest of these producers to restrict their market opportunity to a specific sales method.

A few comments suggested that we establish a sliding-scale certification fee based upon either the size of the operation or sales of agricultural product instead of the exemption. The NOP does not establish fees for certification. Certifying agents may establish a sliding-scale system as long as their fees are reasonable and applied in a consistent and nondiscriminatory manner.

Finally, some commenters expressed concern that exempt operations were forbidden from certification. This interpretation is not correct. Any production or handling operation, including an exempt operation, which makes application for certification as an organic operation and meets the requirements for organic certification may be certified.

(4) Handler exemption. Many commenters disagreed with the proposed rule provision providing for an exemption of \$5,000 to handlers. These commenters asked the NOP to remove the phrase, "or handlers," from the exemption provision. The commenters argue that the handler exemption is not authorized by the Act. We disagree with the commenters, and we have retained the handler exemption in the final rule. The Act states that the exemption is available to "persons" selling not more than \$5,000 annually in value of agricultural products. The Act's definition of "persons" includes handlers. Thus, handlers grossing \$5,000 or less qualify for the exemption.

(5) Categories of Income to Qualify for an Exemption. Some commenters want the \$5,000 producer/handler exemption to include all sales of agricultural products, not just sales of organic agricultural products. These commenters perceive this provision to be a loophole for large, split operations. We disagree with these commenters, and we have retained the \$5,000 producer/handler exemption based upon total sales of organic agricultural products. We do not believe there is a significant number of split operations which only gross \$5,000 in annual sales of organic products and, therefore, qualify for this exemption. In setting the exemption levels, the Department sought to maximize the benefits to small producers afforded by the Act while setting a threshold level that minimizes the potential of product mislabeling.

(6) Limiting Handler Exclusions. Many commenters argued that brokers, distributors, warehousemen, and transporters should not be excluded from certification. We do not agree with these commenters. Brokers, distributors, warehousemen and transporters do not alter the product and, in many cases, do not take title to the product. Certifying these handlers would be an unnecessary burden on the industry. Traditionally, distributors and trucking companies have been excluded from State and private certification requirements.

(7) Recordkeeping Requirements for Excluded Operations. Several commenters argued that excluded operations should be required to comply with the same recordkeeping requirements as exempt operations. Some commenters expressed concern over the inability to verify compliance for either exempt or excluded operations and asked that exempt or excluded operations be subject to additional recordkeeping requirements. We disagree with these commenters and have retained the provisions from the proposed rule on recordkeeping for excluded operations. Given the nature of these excluded operations, for example, operations that only sell prepackaged organic products, we believe that extensive recordkeeping requirements would be an unwarranted regulatory burden.

(8) Recordkeeping Burden on Small Certified Operations. Some commenters questioned whether small certified operations have the ability to implement a recordkeeping system which complies with the provisions of section 205.103. These commenters argue that recordkeeping requirements must be tailored to the scale of the operation. We do not believe that the recordkeeping requirements as described in section 205.103 conflict with the suggestions of the commenters. The recordkeeping requirements provide that the records must be adapted to the particular business that the certified operation is conducting and be sufficient to demonstrate compliance with the Act and regulations. It is USDA's intent that each production and handling operation decide for itself what recordkeeping scheme is appropriate, given the complexity and scope of the individual business. These provisions provide considerable latitude for each production and handling operation to decide what records are necessary to demonstrate its compliance with the Act and the NOP regulations.

(9) Public Access to Records. Several commenters asked that the public have full access to any certifying agent record on organic production and/or handling operations. Other commenters expressed concerns about certifying agents divulging confidential business information and asked that records containing confidential business information not be taken from the business' physical location.

We have not changed this provision. The recordkeeping requirements are designed to seek a balance between the public's right to know and a business's right to retain confidential business information. Certifying agents must have access to certain records during their review of the operation to determine the operation's compliance with the NOP. However, certifying agents are required to protect an operation's confidential business information. Requiring full public access could compromise a business' competitive position and place an unfair burden on the organic industry.

(10) Fair Labor Practices on Organic Farms. Many commenters asked the NOP to



develop fair labor practice standards as a part of the final rule. We have not adopted these comments. Other statutes cover labor and worker safety standards. The Act does not provide the authority to include them in these regulations. However, these regulations do not prohibit certifying agents from developing a voluntary certification program, separate from organic certification, that address fair labor and worker safety standards.

(11) "Transitional Organic" Label. Several commenters requested that the NOP adopt regulations on the conversion of operations to organic production and create a "transitional organic" label. We have not included provisions within the final rule that provide for "transitional organic" labeling. Although many commenters requested that we provide for transition labeling, there does not appear to be sufficient consensus to establish such a standard at this time. Given this lack of consensus, it is unclear what marketplace value such a label might have, and we are concerned that allowing such a label at this point might lead to greater consumer confusion rather than providing clarity.

### **Applicability - Clarifications**

Clarification is given on the following issues raised by commenters as follows:

(1) "Genetic" drift. Many commenters raised issues regarding drift of the products of excluded methods onto organic farms. These commenters were concerned that pollen drifting from near-by farms would contaminate crops on organic operations and that, as a result, organic farmers could lose the premium for their organic products through no fault of their own. Many commenters argued that we should use this rule to somehow shift the burden to the technology providers who market the products of excluded methods or the nonorganic farming operations that use their products. Some, for example, suggested that this regulation should require that the nonorganic operations using genetically engineered varieties plant buffer strips or take other steps to avoid drift onto organic farms. Others suggested that the regulation could provide for citizens' right to sue in cases of drift.

While we understand the concerns that commenters have raised, the kind of remedies they suggested are outside the scope of the Act and this regulation. The Act only provides for the regulation of organic operations. We cannot use this regulation to impose restrictions, such as requiring buffer strips or other measures, on operations that are not covered by the Act. Similarly, while citizens may have the ability to bring suit under other laws, the Act itself does not provide for the right to bring suit as a Federal cause of action, and we could not grant it through this regulation.

Drift has been a difficult issue for organic producers from the beginning. Organic operations have always had to worry about the potential for drift from neighboring operations, particularly drift of synthetic chemical pesticides. As the number of organic farms increases, so does the potential for conflict between organic and nonorganic operations.

It has always been the responsibility of organic operations to manage potential contact of organic products with other substances not approved for use in organic production systems, whether from the nonorganic portion of a split operation or from neighboring farms. The organic system plan must outline steps that an organic operation will take to avoid this kind of unintentional contact.

When we are considering drift issues, it is particularly important to remember that organic standards are process based. Certifying agents attest to the ability of organic operations to follow a set of production standards and practices that meet the requirements of the Act and the regulations. This regulation prohibits the use of excluded methods in organic operations. The presence of a detectable residue of a product of excluded methods alone does not necessarily constitute a violation of this regulation. As long as an organic operation has not used excluded

methods and takes reasonable steps to avoid contact with the products of excluded methods as detailed in their approved organic system plan, the unintentional presence of the products of excluded methods should not affect the status of an organic product or operation.

Issues of pollen drift are also not confined to the world of organic agriculture. For example, plant breeders and seed companies must ensure genetic identity of plant varieties by minimizing any cross-pollination that might result from pollen drift. Under research conditions, small-scale field tests of genetically engineered plants incorporate various degrees of biological containment to limit the possibility of gene flow to other sexually compatible plants. Federal regulatory agencies might impose specific planting requirements to limit pollen drift in certain situations. Farmers planting nonbiotechnology-derived varieties may face similar kinds of questions if cross-pollination by biotechnology-derived varieties alters the marketability of their crop. These discussions within the broader agricultural community may lead to new approaches to addressing these issues. They are, however, outside the scope of this regulation by definition.

(2) Additional NOP Standards for Specific Production Categories. Many commenters asked that the NOP include in the final rule certification standards for apiculture, greenhouses, mushrooms, aquatic species, culinary herbs, pet food, and minor animal species (e.g., rabbits) food. The NOP intends to provide standards for categories where the Act provides the authority to promulgate standards. During the 18-month implementation period, the NOP intends to publish for comment certification standards for apiculture, mushrooms, greenhouses and aquatic animals. These standards will build upon the existing final rule and will address only the unique requirements necessary to certify these specialized operations.

Some of the other questions raised by commenters are already addressed in the final rule. For example, feed for minor species is covered by livestock feed provisions within subpart C and the livestock feed labeling provisions within subpart D. The production and utilization of culinary herbs, including herbal teas, is covered by the provisions of the final rule. We do not envision needing to do additional rulemaking on these two categories.

Other requests by commenters have not been addressed. We have not addressed the labeling of pet food within this final rule because of the extensive consultation that will be required between USDA, the NOSB, and the pet food industry before any standards on this category could be considered.

(3) Standards for Cosmetics, Body Care Products, and Dietary Supplements. A few commenters asked that the NOP include in the final rule certification standards for cosmetics, body care products, and dietary supplements. Producers and handlers of agricultural products used as ingredients in cosmetics, body care products, and dietary supplements could be certified under these regulations. Producers and handlers of these ingredients might find an increased market value for their products because of the additional assurance afforded by certification. The ultimate labeling of cosmetics, body care products, and dietary supplements, however, is outside the scope of these regulations.

(4) Private Label Products. Many commenters asked about the certification status of

so-called "private label products." Private label products are items for which a retailer contracts with a processor to produce the product to the retailer's specifications and to be sold under the retailer's name. Commenters believe the proposed rule was unclear on the certification requirements for these products. Any product labeled as "100 organic," "organic," or "made with..." must be certified regardless of the business arrangements under which the product was produced. When a retail operation contracts for the production, packaging, or labeling of organic product, it is the certified production or handling operation that is responsible for complying with the applicable organic production or handling regulations.

(5) State Oversight of Exempt and Excluded Operations. Many commenters asked for clarification on the State's enforcement responsibility for exempt and excluded operations. The NOP is ultimately responsible for the oversight and enforcement of the program, including oversight of exempt and excluded operations and cases of fraudulent or misleading labeling. We expect, however, that States would want to monitor for false claims or misleading labeling under these regulations and would forward any complaints to the NOP. States that have an approved SOP which includes regulation of operations excluded under the NOP would be required to enforce those provisions.

(6) Nonedible Fibers Products in the NOP. Some commenters asked the NOP to clarify the certification status of fibers such as cotton and flax. The final rule allows for certification of organically produced fibers such as cotton and flax. However, the processing of these fibers is not covered by the final rule. Therefore, goods that utilize organic fibers in their manufacture may only be labeled as a "made with..." product; e.g., a cotton shirt labeled "made with organic cotton."

(7) Recordkeeping for Operations That Produce Organic and Nonorganic Product. Several commenters recommended that "split operations," which are operations producing organic and nonorganic agricultural products, be required to maintain separate records. These commenters believe that the proposed rule did not provide adequate provision for the maintenance of separate recordkeeping. The provisions within section 205.103(b)(1) and (b)(2) do indicate that operations which produce both organic and nonorganic agricultural products must maintain a recordkeeping system that differentiates the organic portion of the operations from the records related to other portions of operations.

(8) NOP Program Manual. A few commenters, particularly States, noted that the proposed rule made several references to program manuals as a mechanism for further clarifying certain portions of the rule. These commenters asked whether certifying agents should consider information contained in these manuals as enforceable regulations. NOP program manuals cannot be and are not intended to be the equivalent of regulations. Rather, the NOP envisions development of a program manual to serve as guidance for certifying agents regarding implementation- and certification-related issues. Material contained within the program manual will be designed to address the organic agriculture principles of each final rule section, as appropriate, and to offer information that certifying agents should consider in making certification decisions that will be reliably uniform throughout the country. The use of program manuals as guidance to assist in developing uniform certification decisions is a standard industry practice, and the NOP has compiled examples of program manuals from both large and small certifiers. Because the NOP intends to use the examples it has acquired as the basis for any NOP guidance manual, we believe that most certifying agents will find such NOP manual, when developed, familiar and useful. Additionally, we will use the NOSB public meeting process to seek guidance from industry and the public on what information would be useful in a program manual and to provide input on the program manual as it is developed. Of course, if in developing program guidance, it appears that modifications or changes in the NOP final rule are required, such modifications would be made through notice and comment rulemaking.

(9) Use of Products from Exempt Operations as Organic Ingredients. A few commenters responded to the question in the proposed rule in which we asked whether handlers should be allowed to identify organically produced products produced by exempt production operations as organic ingredients. The proposed rule provided that all ingredients identified as organic in a multiingredient product must have been produced by a production or handling operation certified by an accredited certifying agent.

The commenters supported this position. These commenters believe that the potential for mislabeling outweighed any financial benefit that might accrue to exempt producers through

expanded market opportunities. We concur, and, therefore, have retained the prohibition on using products produced by an exempt production or handling operation as organic ingredients

(10) Exemption of Handling Operations Producing Multiingredient Products. We have amended section 205.101(a)(3) by changing "50 percent" to "70 percent" to make it consistent with the amendments to the labeling provisions. We have also edited section 205.101(a)(4) for clarification purposes. Additionally, we amended sections 205.101(a)(3) and 205.101(a)(4) by citing the labeling requirements of section 205.305. These amendments have been made to clarify that handling operations exempted under these sections are subject to the labeling requirements of section 205.305.

(11) Production and Handling in Compliance with Federal Statutes. We have amended section 205.102 by removing paragraph (c). This paragraph provided that any agricultural product that is sold, labeled, or represented as "100 percent organic," "organic," or "made with organic (specified ingredients)" must be produced and handled in compliance with applicable Federal statutes and their implementing regulations. We have taken this action because the provision is an identical restatement of section 2120(f) (7 U.S.C. 6519(f)) of the Act. The Act makes clear that all production and handling operations are to comply with all applicable Federal statutes and their implementing regulations. Therefore, it is unnecessary to repeat the requirement in these regulations.

(12) Foreign Applicants. We have removed section 205.104, which provided that the regulations in this part, as applicable, apply equally to domestic and foreign applicants for accreditation, accredited certifying agents, domestic and foreign applicants for certification as organic production or handling operations, and certified organic production and handling operations unless otherwise specified. These regulations, as written, apply equally to all applicants for accreditation, accredited certifying agents, applicants for organic certification, and certified organic operations. Accordingly, we have determined that section 205.104 is not necessary.

# Production and Handling -- Preamble

## Subpart C - Organic Crop, Wild Crop, Livestock, and Handling Requirements

### Description of Regulations

#### General Requirements

This subpart sets forth the requirements with which production and handling operations must comply in order to sell, label, or represent agricultural products as "100 percent organic," "organic," or "made with organic (specified ingredients or food group(s))." The producer or handler of an organic production or handling operation must comply with all applicable provisions of subpart C. Any production practice implemented in accordance with this subpart must maintain or improve the natural resources, including soil and water quality, of the operation. Production and handling operations which sell, label, or represent agricultural products as organic in any manner and which are exempt or excluded from certification must comply with the requirements of this subpart, except for the development of an organic system plan.

#### Production and Handling (General)

The Organic Food Production Act of 1990 (OFPA or Act) requires that all crop, wild crop, livestock, and handling operations requiring certification submit an organic system plan to their certifying agent and, where applicable, the State organic program (SOP). The organic system plan is a detailed description of how an operation will achieve, document, and sustain compliance with all applicable provisions in the OFPA and these regulations. The certifying agent must concur that the proposed organic system plan fulfills the requirements of subpart C, and any subsequent modification of the organic plan by the producer or handler must receive the approval of the certifying agent.

The organic system plan is the forum through which the producer or handler and certifying agent collaborate to define, on a site-specific basis, how to achieve and document compliance with the requirements of certification. The organic system plan commits the producer or handler to a sequence of practices and procedures resulting in an operation that complies with every applicable provision in the regulations. Accreditation qualifies the certifying agent to attest to whether an organic system plan comports with the organic standard. The organic system plan must be negotiated, enacted, and amended through an informed dialogue between certifying agent and producer or handler, and it must be responsive to the unique characteristics of each operation.

An organic system plan contains six components. First, the organic system plan must describe the practices and procedures used, including the frequency with which they will be used, in the certified operation. Second, it must list and characterize each substance used as a production or handling input, including the documentation of commercial availability, as applicable. Third, it must identify the monitoring techniques which will be used to verify that the organic plan is being implemented in a manner which complies with all applicable requirements. Fourth, it must explain the recordkeeping system used to preserve the identity of organic products from the point of certification through delivery to the customer who assumes legal title to the goods. Fifth, the organic system plan must describe the management practices and physical barriers established to prevent commingling of organic and nonorganic products on a split operation and to prevent contact of organic production and handling operations and products with prohibited substances. Finally, the organic system plan must contain the additional information deemed necessary by the certifying agent to evaluate site-specific conditions relevant to compliance with these or applicable State program regulations. Producers or handlers may submit a plan developed to

comply with other Federal, State, or local regulatory programs if it fulfills the requirements of an organic system plan.

The first element of the organic system plan requires a narrative or other-descriptive format that identifies the practices and procedures to be performed and maintained, including the frequency with which they will be performed. Practices are tangible production and handling techniques, such as the method for applying manure, the mechanical and biological methods used to prepare and combine ingredients and package finished products, and the measures taken to exclude pests from a facility. Procedures are the protocols established for selecting appropriate practices and materials for use in the organic system plan, such as a procedure for locating commercially available, organically produced seed. Procedures reflect the decision-making process used to implement the organic system plan.

By requiring information on the frequency with which production and handling practices and procedures will be performed, the final rule requires an organic system plan, to include an implementation schedule, including information on the timing and sequence of all relevant production and handling activities. The plan will include, for example, information about planned crop rotation sequences, the timing of any applications of organic materials, and the timing and location of soil tests. Livestock management practices might describe development of a rotational grazing plan or addition of mineral supplements to the feed supply. A handling operation might identify steps involved in locating and contracting with farmers who could produce organic ingredients that were in short supply.

The second element that must be included in an organic system plan is information on the application of substances to land, facilities, or agricultural products. This requirement encompasses both natural and synthetic materials allowed for use in production and handling operations. For natural materials which may be used in organic operations under specific restrictions, the organic plan must detail how the application of the materials will comply with those restrictions. For example, farmers who apply manure to their fields must document in their organic system plans how they will prevent that application from contributing to water contamination. A producer and handler who bases the selection of seed and planting stock material under section 205.204 or an agricultural ingredient under section 205.301 on the commercial availability of that substance must provide documentation in the organic system plan.

The third element of the organic system plan is a description of the methods used to evaluate its effectiveness. Producers and handlers are responsible for identifying measurable indicators that can be used to evaluate how well they are achieving the objectives of the operation. For example, production objectives could be measured through regular tallies of bushels or pounds of product sold from the farm or in numbers of cases sold from a handling operation. Indicators that can identify changes in quality or effectiveness of management practices could be relatively simple, such as the information contained in a standard soil test. The specific indicators used to evaluate a given organic system plan will be determined by the producer or handler in consultation with the certifying agent. Thus, if the organic system plan calls for improvements in soil organic matter content in a particular field, it would include provisions for analyzing soil organic matter levels at periodic intervals. If herd health improvement is an objective, factors such as somatic cell count or observations about changes in reproductive patterns might be used as indicators.

The fourth element of the organic system plan is a description of the recordkeeping system used to verify and document an audit trail, as appropriate to the operation. For each crop or wild-crop harvested, the audit trail must trace the product from the field, farm parcel, or area where it is harvested through the transfer of legal title. A livestock operation must trace each animal from its entrance into through removal from the organic operation. A handling operation must trace each product that is handled and sold, labeled, or represented as organic from the receipt of its constituent ingredients to the sale of the processed product.

The fifth element which must be included in an organic system plan pertains to split production or handling operations. This provision requires an operation that produces both organic and nonorganic products to describe the management practices and physical barriers established to prevent commingling of organic and nonorganic products. This requirement addresses contact of organic products, including livestock, organic field units, storage areas, and packaging to be used for organic products, with prohibited substances.

The specific requirements to be included in an organic system plan are not listed here. The accreditation process provides an assurance that certifying agents are competent to determine the specific documentation they require to review and evaluate an operation's organic system plan. Section 205.200(a)(6) allows a certifying agent to request additional information needed to determine that an organic system plan meets the requirements of this subpart. The site-specific nature of organic production and handling necessitates that certifying agents have the authority to determine whether specific information is needed to carry out their function.

### **Crop Production**

Any field or farm parcel used to produce an organic crop must have been managed in accordance with the requirements in sections 205.203 through 205.206 and have had no prohibited substances applied to it for at least 3 years prior to harvest of the crop. Such fields and farm parcels must also have distinct, defined boundaries and buffer zones to prevent contact with the land or crop by prohibited substances applied to adjoining land.

A producer of an organic crop must manage soil fertility, including tillage and cultivation practices, in a manner that maintains or improves the physical, chemical, and biological condition of the soil and minimizes soil erosion. The producer must manage crop nutrients and soil fertility through rotations, cover crops, and the application of plant and animal materials. The producer must manage plant and animal materials to maintain or improve soil organic matter content in a manner that does not contribute to contamination of crops, soil, or water by plant nutrients, pathogenic organisms, heavy metals, or residues of prohibited substances. Plant and animal materials include raw animal manure, composted plant and animal materials, and uncomposted plant materials. Raw animal manure must either be composted, applied to land used for a crop not intended for human consumption, or incorporated into the soil at least 90 days before harvesting an edible product that does not come into contact with the soil or soil particles and at least 120 days before harvesting an edible product that does come into contact with the soil or soil particles. Composted plant or animal materials must be produced through a process that establishes an initial carbon-to-nitrogen (C:N) ratio of between 25:1 and 40:1 and achieves a temperature between 131F and 170F. Composting operations that utilize an in-vessel or static aerated pile system must maintain a temperature within that range for a minimum of 3 days. Composting operations that utilize a windrow composting system must maintain a temperature within that range for a minimum of 15 days, during which time the materials must be turned five times.

In addition to these practices and materials, a producer may apply a crop nutrient or soil amendment included on the National List of synthetic substances allowed in crop production. The producer may apply a mined substance of low solubility. A mined substance of high solubility may only be applied if the substance is used in compliance with the annotation on the National List of nonsynthetic materials prohibited in crop production. Ashes of untreated plant or animal materials which have not been combined with a prohibited substance and which are not included on the National List of nonsynthetic substances prohibited for use in organic crop production may be used to produce an organic crop. A plant or animal material that has been chemically altered by a manufacturing process may be used only if it is included on the National List of synthetic substances allowed for use in organic production. The producer may not use any fertilizer or composted plant and animal material that contains a synthetic substance not allowed for crop production on the National List or use sewage sludge. Burning crop residues as a means of

disposal is prohibited, except that burning may be used to suppress the spread of disease or to stimulate seed germination.

The producer must use organically grown seeds, annual seedlings, and planting stock. The producer may use untreated nonorganic seeds and planting stock when equivalent organic varieties are not commercially available, except that organic seed must be used for the production of edible sprouts. Seed and planting stock treated with substances that appear on the National List may be used when an organically produced or untreated variety is not commercially available. Nonorganically produced annual seedlings may be used when a temporary variance has been established due to damage caused by unavoidable business interruption, such as fire, flood, or frost. Planting stock used to produce a perennial crop may be sold as organically produced planting stock after it has been maintained under a system of organic management for at least 1 year. Seeds, annual seedlings, and planting stock treated with prohibited substances may be used to produce an organic crop when the application of the substance is a requirement of Federal or State phytosanitary regulations.

The producer is required to implement a crop rotation, including but not limited to sod, cover crops, green manure crops, and catch crops. The crop rotation must maintain or improve soil organic matter content, provide for effective pest management in perennial crops, manage deficient or excess plant nutrients, and control erosion to the extent that these functions are applicable to the operation.

The producer must use preventive practices to manage crop pests, weeds, and diseases, including but not limited to crop rotation, soil and crop nutrient management, sanitation measures, and cultural practices that enhance crop health. Such cultural practices include the selection of plant species and varieties with regard to suitability to site-specific conditions and resistance to prevalent pests, weeds, and diseases. Mechanical and biological methods that do not entail application of synthetic substances may be used as needed to control pest, weed, and disease problems that may occur. Pest control practices include augmentation or introduction of pest predators or parasites; development of habitat for natural enemies; and nonsynthetic controls such as lures, traps, and repellents. Weed management practices include mulching with fully biodegradable materials; mowing; livestock grazing; hand weeding and mechanical cultivation; flame, heat, or electrical techniques; and plastic or other synthetic mulches, provided that they are removed from the field at the end of the growing or harvest season. Disease problems may be controlled through management practices which suppress the spread of disease organisms and the application of nonsynthetic biological, botanical, or mineral inputs. When these practices are insufficient to prevent or control crop pests, weeds, and diseases, a biological or botanical substance or a synthetic substance that is allowed on the National List may be used provided that the conditions for using the substance are documented in the organic system plan. The producer must not use lumber treated with arsenate or other prohibited materials for new installations or replacement purposes that comes into contact with soil or livestock.

A wild crop that is to be sold, labeled, or represented as "100 percent organic," "organic," or "made with organic (specified ingredients or food group(s))" must be harvested from a designated area that has had no prohibited substances applied to it for a period of 3 years immediately preceding the harvest of the wild crop. The wild crop must also be harvested in a manner that ensures such harvesting or gathering will not be destructive to the environment and will sustain the growth and production of the wild crop.

### **Livestock Production**

Any livestock product to be sold, labeled, or represented as organic must be maintained under continuous organic management from the last third of gestation or hatching with three exceptions. Poultry or edible poultry products must be from animals that have been under continuous organic management beginning no later than the second day of life. Milk or milk products must be from



animals that have been under continuous organic management beginning no later than 1 year prior to the production of such products, except for the conversion of an entire, distinct herd to organic production. For the first 9 months of the year of conversion, the producer may provide the herd with a minimum of 80-percent feed that is either organic or produced from land included in the organic system plan and managed in compliance with organic crop requirements. During the final 3 months of the year of conversion, the producer must provide the herd feed in compliance with section 205.237. Once the herd has been converted to organic production, all dairy animals shall be under organic management from the last third of gestation. Livestock used as breeder stock may be brought from a nonorganic operation into an organic operation at any time, provided that, if such livestock are gestating and the offspring are to be organically raised from birth, the breeder stock must be brought into the organic operation prior to the last third of gestation.

Should an animal be brought into an organic operation pursuant to this section and subsequently moved to a nonorganic operation, neither the animal nor any products derived from it may be sold, labeled, or represented as organic. Breeder or dairy stock that has not been under continuous organic management from the last third of gestation may not be sold, labeled, or represented as organic slaughter stock. The producer of an organic livestock operation must maintain records sufficient to preserve the identity of all organically managed livestock and all edible and nonedible organic livestock products produced on his or her operation.

Except for nonsynthetic substances and synthetic substances included on the National List that may be used as feed supplements and additives, the total feed ration for livestock managed in an organic operation must be composed of agricultural products, including pasture and forage, that are organically produced. Any portion of the feed ration that is handled must comply with organic handling requirements. The producer must not use animal drugs, including hormones, to promote growth in an animal or provide feed supplements or additives in amounts above those needed for adequate growth and health maintenance for the species at its specific stage of life. The producer must not feed animals under organic management plastic pellets for roughage or formulas containing urea or manure. The feeding of mammalian and poultry slaughter by-products to mammals or poultry is prohibited. The producer must not supply animal feed, feed additives, or feed supplements in violation of the Federal Food, Drug, and Cosmetic Act.

The producer of an organic livestock operation must establish and maintain preventive animal health care practices. The producer must select species and types of livestock with regard to suitability for site-specific conditions and resistance to prevalent diseases and parasites. The producer must provide a feed ration including vitamins, minerals, protein, and/or amino acids, fatty acids, energy sources, and, for ruminants, fiber. The producer must establish appropriate housing, pasture conditions, and sanitation practices to minimize the occurrence and spread of diseases and parasites. Animals in an organic livestock operation must be maintained under conditions which provide for exercise, freedom of movement, and reduction of stress appropriate to the species. Additionally, all physical alterations performed on animals in an organic livestock operation must be conducted to promote the animals' welfare and in a manner that minimizes stress and pain.

The producer of an organic livestock operation must administer vaccines and other veterinary biologics as needed to protect the well-being of animals in his or her care. When preventive practices and veterinary biologics are inadequate to prevent sickness, the producer may administer medications included on the National List of synthetic substances allowed for use in livestock operations. The producer may not administer synthetic parasiticides to breeder stock during the last third of gestation or during lactation if the progeny is to be sold, labeled, or represented as organically produced. After administering synthetic parasiticides to dairy stock, the producer must observe a 90-day withdrawal period before selling the milk or milk products produced from the treated animal as organically produced. Every use of a synthetic medication or parasiticide must be incorporated into the livestock operation's organic system plan subject to approval by the certifying agent.

The producer of an organic livestock operation must not treat an animal in that operation with antibiotics, any synthetic substance not included on the National List of synthetic substances allowed for use in livestock production, or any substance that contains a nonsynthetic substance included on the National List of nonsynthetic substances prohibited for use in organic livestock production. The producer must not administer any animal drug, other than vaccinations, in the absence of illness. The use of hormones for growth promotion is prohibited in organic livestock production, as is the use of synthetic parasiticides on a routine basis. The producer must not administer synthetic parasiticides to slaughter stock or administer any animal drug in violation of the Federal Food, Drug, and Cosmetic Act. The producer must not withhold medical treatment from a sick animal to maintain its organic status. All appropriate medications and treatments must be used to restore an animal to health when methods acceptable to organic production standards fail. Livestock that are treated with prohibited materials must be clearly identified and shall not be sold, labeled, or represented as organic.

A livestock producer must document in his or her organic system plan the preventative measures he or she has in place to deter illness, the allowed practices he or she will employ if illness occurs, and his or her protocol for determining when a sick animal must receive a prohibited animal drug. These standards will not allow an organic system plan that envisions an acceptable level of chronic illness or proposes to deal with disease by sending infected animals to slaughter. The organic system plan must reflect a proactive approach to health management, drawing upon allowable practices and materials. Animals with conditions that do not respond to this approach must be treated appropriately and diverted to nonorganic markets.

The producer of an organic livestock operation must establish and maintain livestock living conditions for the animals under his or her care which accommodate the health and natural behavior of the livestock. The producer must provide access to the outdoors, shade, shelter, exercise areas, fresh air, and direct sunlight suitable to the species, its stage of production, the climate, and the environment. This requirement includes access to pasture for ruminant animals. The producer must also provide appropriate clean, dry bedding, and, if the bedding is typically consumed by the species, it must comply with applicable organic feed requirements. The producer must provide shelter designed to allow for the natural maintenance, comfort level, and opportunity to exercise appropriate to the species. The shelter must also provide the temperature level, ventilation, and air circulation suitable to the species and reduce the potential for livestock injury. The producer may provide temporary confinement of an animal because of inclement weather; the animal's stage of production; conditions under which the health, safety, or well-being of the animal could be jeopardized; or risk to soil or water quality. The producer of an organic livestock operation is required to manage manure in a manner that does not contribute to contamination of crops, soil, or water by plant nutrients, heavy metals, or pathogenic organisms and optimizes nutrient recycling.

## **Handling**

Mechanical or biological methods can be used to process an agricultural product intended to be sold, labeled, or represented as "100 percent organic," "organic," or "made with organic ingredients" for the purpose of retarding spoilage or otherwise preparing the agricultural product for market. Processed multiingredient products labeled "100 percent organic," may only use wholly organic ingredients, pursuant to paragraph (a) of section 205.301. Nonagricultural substances that are allowed for use on the National List and nonorganically produced agricultural products may be used in or on "organic" and "made with..." products pursuant to paragraphs (b) and (c) of section 205.301, respectively. Documentation of commercial availability of each substance to be used as a nonorganic ingredient in products labeled "organic" must be listed in the organic handling system plan in accordance with section 205.201.

Handlers are prohibited from using: (1) ionizing radiation for the treatment or processing of foods; (2) ingredients produced using excluded methods; or (3) volatile synthetic solvents in or on a

processed product or any ingredient which is sold, labeled, or represented as organic. The prohibition on ionizing radiation for the treatment or processing of foods is discussed under Applicability, section 205.105. This rule does not prohibit an organic handling operation from using Food and Drug Administration (FDA)-approved X-rays for inspecting packaged foods for foreign objects that may be inadvertently commingled in the packaged product.

The two paragraphs on excluded methods and ionizing radiation in section 205.270(c) of the proposed rule are replaced with new paragraph (c)(1) which cross-references those practices under paragraphs (e) and (f) of section 205.105. New section 205.105 clearly specifies that ionizing radiation and excluded methods are two practices that handlers must not use in producing organic agricultural products and ingredients. The prohibition on the use of volatile synthetic solvents, also included under paragraph (c) of section 205.270 does not apply to nonorganic ingredients in "made with..." products.

The practice standard for facility pest management under section 205.271 requires the producer or handler operating a facility to use management practices to control and prevent pest infestations. Prevention practices in paragraph (a) include removing pest habitats, food sources, and breeding areas; preventing access to handling facilities; and controlling environmental factors, such as temperature, light, humidity, atmosphere, and air circulation, to prevent pest reproduction. Permitted pest control methods in paragraph (b) include mechanical or physical controls, such as traps, light, or sound. Lures and repellents using nonsynthetic substances may be used as pest controls. Lures and repellents with synthetic substances that are allowed on the National List also may be used. Prevention and control practices in paragraphs (a) and (b) may be used concurrently.

If the practices in paragraphs (a) and (b) are not effective, amended paragraph (c) provides that handlers may then use a nonsynthetic or synthetic substance consistent with National List. If the measures and substances provided under paragraphs (a), (b), and (c) are not effective, synthetic substances not on the National List may be used to control pest infestations. Under new paragraph (d), the handler and the operation's certifying agent, prior to using such a substance, must agree on the substance to be used to control the pest, measures to be taken to prevent contact with organically produced product, and ingredients that may be in the handling facility.

This rule recognizes that certain local, State, and Federal laws or regulations may require intervention with prohibited substances before or at the same time substances allowed in paragraphs (b) and (c) are used. To the extent that this occurs, this rule permits the handler to follow such laws and regulations to market a product as organically handled, provided that the product does not come into contact with the pest control substance used.

The extent of pest infestation cannot be foreseen when an organic plan is submitted by the certified operation and approved by the certifying agent. A handler who uses any nonsynthetic or synthetic substance to control facility pests must update its organic handling system plan to address all measures taken or intended to be taken to prevent contact between the substance and any organically produced ingredient or finished product.

Section 205.272 provides additional practice standards that must be followed by an organic handling operation to prevent the commingling of organic and nonorganic products and to protect organic products from contact with prohibited substances. An organic handling operation must not use packaging materials and storage containers or bins that contain a synthetic fungicide, preservative, or fumigant in handling an organic product. The operation also must not use or reuse any storage bin or container that was previously in contact with any prohibited substance unless the reusable bin or container has been thoroughly cleaned and poses no risk of prohibited materials contacting the organic product.

## Temporary Variances

This subpart establishes conditions under which certified organic operations may receive temporary variances from the production and handling provisions of this subpart. The Administrator may establish temporary variances due to: (1) Natural disasters declared by the Secretary; (2) unavoidable business interruption caused by natural catastrophes such as drought, wind, fire, flood, excessive moisture, hail, tornado, or earthquake; or (3) to conduct research on organic production and handling techniques or inputs. An SOP's governing State official or a certifying agent may recommend that the Administrator establish a temporary variance for various reasons including an unavoidable business interruption. The Administrator will determine how long a temporary variance will be in effect at the time it is established, subject to such extension as the Administrator deems necessary. Temporary variances may not be issued to allow use of any practice, material, or procedure which is prohibited under section 205.105.

The proposed rule inadvertently omitted the SOP's governing State official as having authority to recommend a temporary variance to the Administrator. We have added that authority in paragraph (b) of section 205.290.

Upon notification by the Administrator that a temporary variance has been established, the certifying agent must inform each production and handling operation it certifies that may be affected by the temporary variance. For example, if a drought causes a severe shortage of organically produced hay, a dairy operation may be permitted to substitute some nonorganic hay for a portion of the herd's diet to prevent liquidation of the herd. The producer must keep records showing the source and amount of the nonorganic hay used and the timeframe needed to restore the total feed ration to organic sources. The certifying agent may require that the next organic plan include contingency measures to avoid the need to resort to nonorganic feed in case of a future shortage.

## General - Changes Based on Comments

This subpart differs from the proposal in several respects as follows: (1) Maintain or Improve Provision for Production Operations Only. A number of commenters questioned whether the requirement in the proposed rule that an operation must "maintain or improve the natural resources of the operation, including soil and water quality" applied to handling as well as production operations. They stated that handling operations are not integrated into natural systems the way that production systems are. As a result, these commenters were uncertain how handlers could fulfill the "maintain or improve" requirement.

The "maintain or improve" requirement addresses the impact of a production operation on the natural resource base that sustains it and, as such, does not apply to handling operations. We have modified the final rule in section 205.200 by limiting the "maintain or improve" requirement to production practices.

(2) Management Practices and Physical Barriers to Prevent Commingling. Many commenters, including numerous certifying agents, stated that the proposed provisions for an organic system plan were not adequate for the task of certifying an operation that produces both organic and nonorganic products. The commenters requested that the final rule incorporate the provisions established in the OFPA for certifying these split operations. These provisions include separate recordkeeping for the organic and nonorganic operations and the implementation of protective practices to prevent the commingling of product and the unintentional contact of organic product with prohibited substances. We have amended the provisions for an organic system plan in section 205.201(a)(5) to require greater accountability regarding the segregation of organic and nonorganic products in a split operation. The changes we made incorporate language from the OFPA ("physical facilities, management practices") to provide clear criteria for producers,

handlers and certifying agents to agree upon an organic system plan that protects the integrity of organic product.

(3) Commercial Availability. The proposed rule required that a raw or processed agricultural product sold, labeled, or represented as organic must contain not less than 95 percent organically produced raw or processed agricultural product. Additionally, section 205.606 of the proposed rule allowed any nonorganically produced agricultural product to be used in the 5 percent nonorganic component of an agricultural product sold, labeled, or represented as organic. Many commenters objected to these provisions and recommended that nonorganically produced agricultural products should only be allowed in an organic product when the organically produced form was not commercially available. Commenters stated that allowing nonorganically produced agricultural products within the 5 percent would significantly weaken demand for many organically produced commodities, especially herbs and spices. These commenters stated that herbs and spices often constitute less than 5 percent of the ingredients in a raw or processed agricultural product and that handlers producing an organic product would instinctively seek out the less expensive nonorganic variety. They also indicated that the 5 percent component is an important market for many products produced from organically produced livestock, such as milk derivatives and meat by-products, that are not typically marketed directly to consumers. Commenters stated that the preponderance of current certification programs use the commercial availability criterion when determining whether a nonorganically produced agricultural product may be used within the 5 percent component. Commenters cited the National Organic Standards Board's (NOSB) recommendation that organic agricultural products be used in this 5 percent component unless they are commercially unavailable and requested that the final rule incorporate the criteria for determining commercial availability that accompanied that NOSB recommendation.

We agree with commenters that a preference for organically produced agricultural commodities, when commercially available, can benefit organic producers, handlers, and consumers in a variety of ways. We believe that the commercial availability requirement may allow consumers to have confidence that processed products labeled as "organic" contain the highest feasible percentage of organic ingredients. Some producers may benefit from any market incentive to supply organically produced minor ingredients that handlers need for their processed products. We recognize that the provision does impose an additional requirement on handlers who must ascertain whether the agricultural ingredients they use are commercially available in organic form. The NOSB recommended that the final rule contain a commercial availability provision based upon the guidelines developed by the American Organic Standards project of the Organic Trade Association. For these reasons, we have amended the final rule to require that an agricultural commodity used as an ingredient in a raw or processed product labeled as organic must be organic when the ingredient is commercially available in an organic form.

While recognizing the potential benefits of applying the commercial availability standard to all agricultural ingredients in a processed product, we are concerned that enforcing this provision could impose an excessive burden on handlers. Although many commenters stated that some existing certifying agents apply a commercial availability standard, we do not have complete information on the criteria used by these certifying agents, and we are unsure whether a consensus exists on criteria for commercial availability within the organic community. Additionally, we are concerned that, unless the standard is clearly articulated and consistently interpreted and enforced, it will not be effective. Disagreement among certifying agents regarding when and under what circumstances an ingredient is commercially available would undermine our intent to create an equitable and enforceable standard.

AMS is soliciting additional comment and information on a number of issues concerning the development of standards for the commercial availability of organically produced agricultural commodities used in processed products labeled as "organic." On the basis of these comments and information and additional recommendations that the NOSB may develop, AMS will develop a commercial availability standard for use in implementing the final rule. AMS intends to develop

the commercial availability standard and incorporate it within the final rule prior to the commencement of certification activities by accredited certifying agents. This approach will provide organic handlers and certifying agents the standard necessary to incorporate the consideration of commercial availability of ingredients in an organic system plan at the time that the USDA organic standard comes into use. Specifically, AMS requests comments and information addressing the following questions:

What factors, such as quantity, quality, consistency of supply, and expense of different sources of an ingredient, should be factored into the consideration of commercial availability? What relative importance should each of these factors possess, and are there circumstances under which the relative importance can change?

What activities and documentation are sufficient to demonstrate that a handler has taken appropriate and adequate measures to ascertain whether an ingredient is commercially available?

How can AMS ensure the greatest possible degree of consistency in the application of the commercial availability standard among multiple certifying agents?

Could potentially adverse effects of a commercial availability standard, such as uncertainty over the cost and availability of essential ingredients, impact or impede the development of markets for organically processed products?

What economic and administrative burdens are imposed by the commercial availability standards found in existing organic certification programs?

How would producers benefit from market incentives to increase use of organic ingredients that result from a commercial availability standard?

Would lack of a commercial availability standard provide a disincentive for handlers of products labeled "organic" to seek out additional organic minor ingredients? What impacts could this have on producers of minor ingredients?

AMS welcomes any new or unpublished research results or information that exists concerning a commercial availability standard. AMS specifically invites comment from establishments which currently operate using commercial availability or a comparable provision in the conduct of their business. AMS will receive comment on this issue until 90 days after publication of the final rule.

(4) Conservation of Biodiversity. Many commenters recommended amending the definition of organic production to include the requirement that an organic production system must promote or enhance biological diversity (biodiversity). Commenters stated that the definitions for organic production developed by the NOSB and the Codex Commission include this requirement. We agree with these commenters and have amended the definition of organic production to require that a producer must conserve biodiversity on his or her operation. The use of "conserve" establishes that the producer must initiate practices to support biodiversity and avoid, to the extent practicable, any activities that would diminish it. Compliance with the requirement to conserve biodiversity requires that a producer incorporate practices in his or her organic system plan that are beneficial to biodiversity on his or her operation.

#### **General - Changes Requested But Not Made**

This subpart retains from the proposed rule regulations on which we received comments as follows:

Organic Plan Excessively Restrictive. One organic inspector was concerned that the requirements of the organic system plan were too prescriptive and would create an excessive paper work burden for producers and handlers. The commenter stated that the excessive specificity of certain requirements (composition and source of every substance used), combined with the ambiguity of others (soil and tissue testing required but with no mention of the frequency), would confuse the working relationship between a producer or handler and his or her certifying agent. The commenter was concerned that strict adherence to the specifications in the organic system plan would compromise the ability of producers and handlers to run their businesses. While agreeing that flexibility in the development of the organic system plan was valuable, the commenter stated that producers and handlers, not the certifying agent, must retain the primary managerial role for their operation. Other commenters maintained that the organic system plan requirements were too ambiguous and would inhibit certifying agents' efforts to review necessary information. For example, a trade association commented that the absence of specific recordkeeping requirements for livestock feed materials, medications, and health care activities would impair compliance monitoring.

The provisions for an organic system plan were one of the most significantly revised components of the proposed rule, and, with minor changes related to split operations, we have retained them in the final rule. These provisions provide ample discretion for producers, handlers, and certifying agents to perform their duties while recognizing that mutual consent is a prerequisite for them to meet their responsibilities. The organic system plan enables producers and handlers to propose and certifying agents to approve site and operation-specific practices that fulfill all applicable program requirements. Producers and handlers retain the authority to manage their operations as they deem necessary, but any actions they undertake that modify their organic system plan must be approved by the certifying agent. With regard to recordkeeping, certifying agents are authorized to require the additional information, such as the livestock records mentioned in the comment, that they deem necessary to evaluate compliance with the regulations.

One certifying agent stated that the requirement to maintain or improve the natural resources of the operation was worthy in principle but unreasonable to achieve. This commenter stated that the long-term consequences of an organic system plan could not be foreseen and recommended requiring that producers "must endeavor" to maintain or improve the operation's natural resources. We have not changed this requirement because the vast majority of commenters supported an organic system plan that mandated the "maintain or improve" principle. A good working relationship between the producer and his or her certifying agent, including the annual inspection and accompanying revisions to the organic system plan, can rectify the unforeseen and unfavorable conditions that arise.

### **Crop Production - Changes Based on Comments**

This subpart differs from the proposal in several respects as follows:

(1) Crop nutrient management. The fundamental requirement of the soil fertility and crop nutrient management practice standard, that tillage, cultivation, and nutrient management practices maintain or improve the physical, chemical, and biological condition of the soil and minimize erosion, remains unaltered. The proposed rule required that a producer budget crop nutrients by properly utilizing manure or other animal and plant materials, mined substances of low or high solubility, and allowed synthetic amendments. Many commenters disagreed with using the term, "budget," which they considered too limiting to characterize nutrient management in organic systems. These commenters recommended that the practice standard instead emphasize the diverse practices used in organic systems to cycle nutrients over extended periods of time.

We agree with these commenters and have amended the final rule to require that producers manage crop nutrients and soil fertility through the use of crop rotations and cover crops in addition to plant and animal materials. Additionally, we clarified that producers may manage crop

nutrients and soil fertility by applying mined substances if they are used in compliance with the conditions established in the National List. Finally, we removed the word, "waste," from our description of animal and plant materials in the proposed rule to emphasize the importance of these resources in organic soil fertility management.

(2) Compost Practice Standard. The proposed rule required that a composted material used on an organic operation must be produced at a facility in compliance with the Natural Resource Conservation Service (NRCS) practice standard. While many commenters agreed with the need for greater oversight of the feedstocks and procedures used to produce compost, most stated that the NRCS practice standard would not be suitable for this purpose. Commenters stated that the requirements in the NRCS practice standard were not designed for organic operations and would prohibit many established, effective composting systems currently used by organic producers. For example, adoption of the NRCS practice standard would prevent producers from using nonfarm wastes as compost feedstocks. Materials such as food processing by-products and leaves from curbside collection programs have long been used with beneficial results.

Commenters also stated that the minimum acceptable requirements for the design, construction, and operation of a composting facility contained in the practice standard were appropriate for a voluntary cost share program but were excessive as a compliance requirement for organic certification. Commenters questioned whether producers could justify the investment of time and resources needed to comply with the multiple design and operation criteria specified in the NRCS practice standard.

We agree with commenters who stated that, given the diversity of composting systems covered by a national organic standard, requiring full compliance with the NRCS practice standard would be overly prescriptive. We maintain, however, that implementation of the OFPA requires a rigorous, quantitative standard for the production of compost. The OFPA contains significant restrictions on applying raw manure that are reflected in the soil fertility and crop nutrient management practice standard. These restrictions pertain to raw manure and do not apply once fresh animal materials are transformed into a composted material. An organic producer using a composted material containing manure must comply with the nutrient cycling and soil and water conservation provisions in his or her organic system plan but is not constrained by the restrictions that apply to raw manure. Therefore, producers intending to apply soil amendments will require clear and verifiable criteria to differentiate raw manure from composted material. We developed the requirements in the final rule for producing an allowed composted material by integrating standards used by the Environmental Protection Agency (EPA) and USDA's Natural Resources Conservation Service (NRCS). The requirements for the carbon-to-nitrogen (C:N) ratio for composting materials are the same as that found in the NRCS practice standard for a composting facility. The time and temperature requirements for in-vessel, static aerated pile, and windrow composting systems are consistent with that EPA regulates under 40 CFR Part 503 for the production of Class A sewage sludge. Additionally, AMS reviewed these compost production requirements with USDA's Agricultural Research Service (ARS).

The conditions in the final rule for producing an allowed composted material begin with the selection of appropriate feedstocks. The producer's first responsibility is to identify the source of the feedstocks used in the composting system. This requirement ensures that only allowed plant and animal materials are included in the composting process, that they are not contaminated with prohibited materials, and that they are incorporated in quantities suitable to the design of the composting system. Certifying agents will exercise considerable discretion for evaluating the appropriateness of potential feedstock materials and may require testing for prohibited substances before allowing their use. For example, a certifying agent could require a producer to monitor off-farm inputs such as leaves collected through a municipal curbside program or organic wastes from a food processing facility. Monitoring may be necessary to protect against contamination from residues of prohibited substances, such as motor oil or heavy metals, or gross inert materials such as glass shards that can enter the organic waste stream.



The final rule further requires that the producer adhere to quantitative criteria when combining and managing the plant and animal materials that are being composted. When combining feedstocks to initiate the process, producers must establish a C:N ratio of between 25:1 and 40:1. This range allows for very diverse combinations of feedstock materials while ensuring that, when properly managed, the composting process will yield high quality material. While some commenters maintained that specifying any C:N ratio in the final rule would be too restrictive, it would be far more problematic not to establish a range. The 25:1 to 40:1 range ensures that producers will establish appropriate conditions under which the additional requirements in this practice standard, most notably the time and temperature criteria, can be achieved with minimal producer oversight. Composting operations using a C:N ratio lower than 25:1 require increasingly intensive management as the ratio drops due to the risk of putrefaction. Operations in excess of the 40:1 range may achieve the minimum temperature but are likely to drop off quickly and result in a finished material that is inadequately mature and deficient in nitrogen. The producer is not required to perform a physical analysis of each feedstock component if he or she can demonstrate that an estimated value is reliable. For example, estimates of the carbon and nitrogen content in specific manures and plant materials are generally recognized. Other feedstocks of consistent quality may be tested once and assumed to approximate that value.

The producer must develop in his or her organic system plan the management strategies and monitoring techniques to be used in his or her composting system. To produce an allowed composted material, the producer must use an in-vessel, static aerated pile, or windrow composting system. Producers using an in-vessel or static aerated pile system must document that the composting process achieved a temperature between 131F and 170F and maintained that level for a minimum of 3 days. Producers using a windrow composting system must document that the composting process achieved a temperature between 131F and 170F and maintained that level for a minimum of 15 days. Compost produced using a windrow system must be turned five times during the process. These time and temperature requirements are designed to minimize the risk from human pathogens contained in the feedstocks, degrade plant pathogens and weed seeds, and ensure that the plant nutrients are sufficiently stabilized for land application.

The final rule does not contain provisions for the use of materials commonly referred to as "compost teas." A compost tea is produced by combining composted plant and animal materials with water and a concentrated nutrient source such as molasses. The moisture and nutrient source contribute to a bloom in the microbial population in the compost, which is then applied in liquid form as a crop pest or disease control agent. The microbial composition of compost teas are difficult to ascertain and control and we are concerned that applying compost teas could impose a risk to human health. Regulation of compost teas was not addressed in the proposed rule. The National Organic Program (NOP) will request additional input from the NOSB and the agricultural research community before deciding whether these materials should be prohibited in organic production or whether restrictions on their use are appropriate.

In addition to managing crop nutrients with raw manure and composted plant and animal materials, a producer may use uncomposted plant materials. These are materials derived exclusively from plant sources that a producer manages in a manner that makes them suitable for application in a cropping system. For example, plant materials that are degraded and stabilized through a vermicomposting process may be used as a soil fertility and crop nutrient amendment.

(3) Mined Substances of High Solubility. The proposed rule treated mined substances of high solubility as a single category of soil amendment and allowed their use where warranted by soil and crop tissue testing. Many commenters objected to the general allowance for this category of substances and were particularly disappointed that the NOSB annotations on two such materials, sodium (Chilean) nitrate and potassium chloride, were not included. Commenters cited the potential detrimental effects of these highly soluble and saline substances on soil quality and stated that several international organic certification programs severely prescribe or prohibit their use. One certifying agent recommended that natural substances of high solubility and salinity be

handled comparably to similar synthetic materials such as liquid fish products and humic acids that appear on the National List, complete with their original NOSB annotations.

At its June 2000 meeting, the NOSB recommended that the NOP delete general references to mined substances of high solubility from the final rule, and incorporate the NOSB's specific annotations for materials of this nature. We have adopted this recommendation by retaining a place for mined substances of high solubility in the soil fertility and crop nutrient management practice standard but restricting their use to the conditions established for the material as specified on the National List of prohibited natural substances. Under this approach, mined substances of high solubility are prohibited unless used in accordance with the annotation recommended by the NOSB and added by the Secretary to the National List. We deleted the provision from the proposed rule that use of the substance be "justified by soil or crop tissue analysis." The final rule contains two materials--sodium nitrate and potassium chloride--that may be used in organic crop production with the annotations developed by the NOSB.

While "mined substances of high solubility" is not a discrete, recognized category such as crop nutrients, the proposed rule mentioned sodium nitrate, potassium chloride, potassium nitrate (niter), langbeinite (sulfate of potash magnesia), and potassium sulfate in this context. Based on the recommendation of the NOSB, the final rule would prohibit use of these materials, unless the NOSB developed recommendations on conditions for their use and the Secretary added them to the National List. The NOP would welcome further guidance from the NOSB on these materials.

(4) Burning crop residues. The proposed rule prohibited burning as a means of crop disposal, except for burning prunings from perennial crops to suppress the spread of disease. Many commenters supported the principle behind the prohibition but maintained that the proposed language was too restrictive and would preclude certain beneficial agronomic practices. Several producers stated that the proposed rule would prevent them from collecting and burning residues from diseased annual crops, which they felt was an effective and beneficial practice. Other producers cited their use of prescriptive burning as a management practice for certain native or wild crops. As evidenced by the allowance for burning to suppress disease with perennial crops, the proposed rule was not designed to preclude the selective use of fire in organic production. We agree with the commenters that a more flexible allowance for the practice is warranted, and we have amended the provision to allow burning of annual and perennial crop residues for the suppression of disease and to stimulate seed germination. Producers must establish their need and procedures for burning in their organic system plan, and the practice cannot be used solely to remove crop debris from fields. (5) Requirement for Organic Seed in Sprout Production. The proposed rule allowed nonorganically produced seeds for all purposes, including sprout production, when the certifying agent concurred with the producer that organically produced seeds were not commercially available. While commenters predominately supported this approach with seed used for planting, they were virtually unanimous in stating that it is never appropriate to allow nonorganically produced and handled seeds in organic sprout production. Commenters cited the NOSB's June 1994 recommendation that seed used for the production of edible sprouts shall be organically produced and stated that existing certification standards do not provide an exemption based on commercial availability. We agree with these commenters and have modified the final rule to require that organic seed must be used for the production of edible sprouts.

(6) Mitigating the Effects of a Biological, Botanical, or Synthetic Substance. The proposed rule required that producers who used a biological or botanical substance or an allowed synthetic substance to control crop pests, weeds, or disease evaluate and mitigate the effects of repetitive use of the same or similar substances. While agreeing that pest resistance and shifts in pest populations were important considerations, commenters stated that managing these issues was beyond the ability of individual operations. Commenters recommended that the NOP develop principles and practices for managing pest resistance and shifts in pest types that would apply to all production operations. We agree with these comments and have deleted the requirement to

evaluate and mitigate the effects of using the same or similar crop pest, weed, or disease control substances. The final rule requires that producers document the use of such substances in their organic systems plans, subject to the approval of their certifying agent.

(7) Prohibition on Use of Treated Lumber. The proposed rule did not specifically address the use of lumber that had been treated with a prohibited substance, such as arsenic, in organic production. Citing the explicit prohibition on these substances in existing organic standards, many commenters felt that treated lumber should be excluded in the final rule. Commenters also cited the NOSB's recommendation to prohibit the use of lumber treated with a prohibited substance for new construction and replacement purposes effective upon publication of the final rule. We have included a modified version of the NOSB's recommendation within the crop pest, weed, and disease management practice standard. This provision prohibits the use of lumber treated with arsenate or other prohibited materials for new installations or replacement purposes in contact with an organic production site. We included this modification to clarify that the prohibition applies to lumber used in direct contact with organically produced and handled crops and livestock and does not include uses, such as lumber for fence posts or building materials, that are isolated from production. The prohibition applies to lumber used in crop production, such as the frames of a planting bed, and for raising livestock, such as the boards used to build a farrowing house. (8) Greater Rigor in the Wild Harvest Production Organic System Plan. A number of commenters stated that the wild-crop harvesting practice standard was insufficiently descriptive and that the proposed rule failed to apply the same oversight to wild harvest operations as it did to those producing crops and livestock. Some commenters maintained that the proposed rule did not require a wild harvest producer to operate under an approved organic system plan. These commenters proposed specific items, including maps of the production area that should be required in a wild harvest operation's organic system plan. One commenter recommended that the definition for "wild crop" be modified to allow the harvest of plants from aquatic environments.

We amended the practice standard for wild-crop harvesting to express the compliance requirements more clearly. Wild-crop producers must comply with the same organic system plan requirements and conditions, as applicable to their operation, as their counterparts who produce crops and livestock. Wild harvest operations are production systems, and they must satisfy the general requirement that all practices included in their organic system plan must maintain or improve the natural resources of the operation, including soil and water quality. We modified the practice standard to emphasize that wild harvest production is linked to a designated site and expect that a certifying agent would incorporate mapping and boundary conditions into the organic system plan requirements. Finally, we changed the definition of "wild crop" to specify that harvest takes place from a "site" instead of "from land," thereby allowing for aquatic plant certification.

### **Crop Production - Changes Requested But Not Made**

This subpart retains from the proposed rule regulations on which we received comments as follows:

(1) Application of Raw Manure. The soil fertility and crop nutrient management practice standard in the proposed rule permitted the application of raw manure to crops not intended for human consumption and established restrictions for applying it to crops used for human food. For human food crops, the proposed rule required a 120-day interval between application and harvest of crops whose edible portion had direct contact with the soil or soil particles, and a 90-day interval for crops that did not. These provisions reflected the recommendations developed by the NOSB at its June 1999 meeting. The practice standard also required that raw manure must be applied in a manner that did not contribute to the contamination of crops, soil, or water by plant nutrients, pathogenic organisms, heavy metals, or residues of prohibited substances.

The majority of commenters supported the provisions for applying raw manure. Some commenters stated that the provisions effectively balanced the benefits of applying raw manure to the soil with the environmental and human health risks associated with its use. These commenters stated that the lengthy intervals between application and harvest would not impose an unreasonable or unfeasible burden on organic producers. The NOSB strongly supported the provisions in the proposed rule, emphasizing that raw manure contributed significant benefits to soil nutrient, structure, and biological activity that other soil fertility practices and materials do not provide. Other commenters stated that the provisions were consistent with the requirements in existing organic standards and added that the restrictions were justifiable because they reflected responsible management practices.

For differing reasons, a number of commenters disagreed with the proposed provisions. Some commenters cited the human health risks associated with pathogenic organisms found in raw manure and stated that the proposed intervals between application and harvest were not adequately protective. These commenters recommended that the NOP conduct more extensive risk assessment procedures before determining what, if any, intervals between application and harvest would adequately protect human health. Some of these commenters identified the risk assessment methodology and pathogen treatment procedures governing the production and use of sewage sludge as the most suitable precedent for guiding the additional work required in this area. Conversely, a number of commenters stated that the provisions in the proposed rule were excessive because they exceeded the minimum 60-day interval between application and harvest established in the OFPA. Many of these commenters recommended eliminating the distinction between crops that come into contact with soil or soil particles and those that don't and applying a uniform 60-day interval between harvest and application for any crop to which raw manure had been applied. Some commenters stated that the 120-day interval severely limited the flexibility of producers who operated in regions such as the Northeast where the growing season lasted only slightly longer. Other commenters maintained that the practice standard did not address specific practices, such as applying raw manure to frozen fields, that they maintained should be expressly prohibited.

The responsibility to use raw manure in a manner that is protective of human health applies to all producers, whether organic or not, who apply such materials. We acknowledge the commenters who noted that the OFPA cites food safety concerns relative to manure use and, therefore, that food safety considerations should be reflected in the practice standard for applying raw manure in the final rule. Some of the commenters favored more extensive risk assessment procedures or lengthening the interval between application and harvest. We have not, however, changed the provisions for applying raw manure.

Although public health officials and others have identified the use of raw manure as a potential food safety concern, at the present time, there is no science-based, agreed-upon standard for regulating the use of raw manure in crop production. The standard in this rule is not a public health standard. The determination of food safety demands a complex risk assessment methodology, involving extensive research, peer review, and field testing for validation of results. The only comparable undertaking in Federal rulemaking has been EPA's development of treatment and application standards for sewage sludge, an undertaking that required years of dedicated effort. The NOP does not have a comparable capacity with which to undertake a comprehensive risk assessment of the safety of applying raw manure to human food crops. To delegate the authority to determine what constitutes safe application of raw manure to certifying agents would be even more problematic. A certifying agent cannot be responsible for establishing a Federal food safety standard. Therefore, the standard in this rule is a reflection of AMS' view and of the public comments that this standard is reasonable and consistent with current organic industry practices and NOSB recommendations for organic food crop production. Should additional research or Federal regulation regarding food safety requirements for applying raw manure emerge, AMS will ensure that organic production practice standards are revised to reflect the most up-to-date food safety standard.

Neither the identification of food safety as a consideration in the OFPA nor the inclusion of this practice standard in the final rule should be construed to suggest that organically produced agricultural products are any safer than nonorganically produced ones. USDA has consistently stated that certification is a process claim, not a product claim, and, as such, cannot be used to differentiate organic from nonorganic commodities with regard to food safety. National organic standards for manure use cannot be used to establish a food safety standard for certified commodities in the absence of a uniform Federal regulation to ensure the safety of all human food crops to which raw manure has been applied. The OFPA was designed to certify a process for informational marketing purposes.

Neither have we changed the practice standard in response to comments that the requirement in the final rule should not exceed the 60-day interval contained in the OFPA. The OFPA clearly establishes that the interval must be no less than 60 days and does not preclude a longer standard. The NOSB has strongly supported the proposed 90- and 120-day intervals, and the vast majority of commenters indicated that these provisions would be feasible for virtually all organic cropping systems. The requirement in the practice standard that raw manure must be applied in a manner that does not contribute to the contamination of crops, soil, or water by plant nutrients, pathogenic organisms, heavy metals, or residues of prohibited substances provides certifying agents the discretion to prohibit specific practices that would not be in compliance. With this discretion, a certifying agent could prohibit practices, such as applying manure to frozen ground or too close to water resources, that many commenters stated were not appropriate for organic production.

(2) No Prohibition on Manure from Nonorganic Operations. The proposed rule identified animal and plant waste materials as important components in soil fertility and crop nutrient management without providing criteria for distinguishing allowed and prohibited sources. A large number of commenters objected to this provision and stated that manure from nonorganic sources may contain residues from prohibited substances, including animal medications. These commenters maintained that some of these residues, such as antibiotics, may remain active for extended intervals, and others, such as heavy metals, could accumulate on the organic operation. Commenters stated that if either or both conditions prevailed, the integrity of the organic operation would be jeopardized. Many producers and certifying agents emphasized that the proposed rule conflicted with the Codex guidelines that prohibit the use of manure from factory farms. These commenters were concerned that failure to restrict the use of manure from nonorganic operations would put their products at a competitive disadvantage, particularly in European markets. When raising this issue, most commenters requested that the final rule either prohibit the use of manure from factory farms or state that certifying agents could regulate the practice by requiring residue testing and restrictions on application.

We have not changed the provisions for using manure from nonorganic operations in the final rule. In many discussions on the subject throughout the years, the NOSB has never recommended that manure from nonorganic farms be prohibited. Existing organic certification standards routinely permit the use of manure from nonorganic operations with appropriate oversight, and the final rule incorporates a similar approach. Under the final rule, a certifying agent can require residue testing when there is reasonable concern that manure, either raw or as a component of compost, contains sufficient quantities of prohibited materials to violate the organic integrity of the operation. Providing certifying agents the discretion to require screening for prohibited materials will minimize the risk of introducing contaminants while maintaining the ecologically important practice of recycling organic material from nonorganic operations. Additionally, the final rule requires that producers apply manure and compost in a manner that maintains or improves the soil and water quality of their operation. This provision provides an additional safeguard that certifying agents may use to ensure that the application of any form of manure protects the natural resources of the operation.

(3) Rotating a Field in and out of Organic Production. Some commenters stated that a producer should not be allowed to rotate fields on their operation in and out of organic production. These commenters were concerned that producers could apply prohibited substances that persisted for many years, such as soil fumigants, and begin harvesting organically produced crops after 3 years. They stated that, without a prohibition on the rotation of fields in this manner, organic producers could effectively use a prohibited substance on their operation.

We have not amended the final rule to prohibit the rotation of a field on an operation in and out of organic production. The statutory prohibition on the application of a prohibited substance is 3 years, and this requirement is contained in section 205.202(b). This prohibition restricts the application of a prohibited substance, not its residual activity. If AMS receives evidence that the rotation of fields in this manner threatens to compromise organic production, the NOP and NOSB will collaborate on developing standards to remedy it. (4) Use of Seed Treatments on the National List. The seed and planting stock practice standard in the proposed rule generated a very diverse array of responses that, while largely favorable, highlighted a potentially disruptive impact on organic producers. The practice standard favored organic seed and planting stock over nonorganically produced but untreated varieties and nonorganically produced, untreated seed and planting stock over nonorganically produced seeds and planting stock treated with an allowed synthetic substance. Producers could use the less preferable seed or planting stock variety if they demonstrated to their certifying agent that an equivalent variety in the preferred form was not commercially available. Most commenters endorsed the principle of requiring organic seed and planting stock and agreed that the proposed provisions were a workable approach to enforcement. They stated that the provisions created an incentive for seed and planting stock providers to develop supplies for organic markets, yet enabled producers who made a good faith effort but failed to locate seed or planting stock in the preferred form the ability to continue producing organically. Most commenters indicated that this approach would support the existing market for organic seed and planting stock while fostering its continued development.

A number of commenters, however, stated that the seed and planting stock practice standard was unreasonable and unworkable and would adversely affect organic producers. These effects would include significantly reduced planting options due to the nonavailability of seed in any allowed form and higher seed costs, which represent a significant percentage of the total production cost for some commodities. These commenters maintained that the three categories of seed and planting stock allowed in the order of preference could not reliably provide producers with many commercial varieties currently being planted. They pointed out that there were no synthetic seed treatments on the National List in the proposed rule, thereby eliminating the use of treated seed in organic production. Commenters stated that producers often rely upon seed and planting stock varieties that are uniquely well adapted for their growing conditions or marketing requirements and that these particular varieties would very often not be available in untreated form. These commenters concluded that the proposed practice standard would compel many producers to abandon many tried and true varieties of seed and planting stock and perhaps phase out organic production entirely. One commenter maintained that the proposed rule's stated intention of using the practice standard to stimulate production of organic seed and planting stock was not within the purpose of the OFPA.

We have not changed the seed and planting stock practice standard in response to these commenters because the prohibition on using synthetic materials not on the National List is a requirement of the OFPA. The final rule cannot allow producers to use synthetic seed treatments that have not been reviewed, favorably recommended by the NOSB, and added to the National List by the Secretary. The practice standard creates incentives for producers to seek out seed and planting stock inputs that are the most compatible with organic production, yet includes allowances when preferred forms are not commercially available. While no seed treatments are included on the National List in the final rule, individuals may petition the NOSB for review of such substances. Additionally, the practice standard creates an incentive for seed and planting stock producers and suppliers to develop natural treatments suitable for organic systems that would not

need to appear on the National List. The objectives of spurring production of organically grown seed and promoting research in natural seed treatments are compatible with the OFPA's purpose of facilitating commerce in organically produced and processed food. We designed the practice standard to pursue these objectives while preventing the disruption that an ironclad requirement for organically produced seed and planting stock may have caused. (5) Practice Standard for Maple Syrup. Many commenters stated that the proposed rule lacked production and handling standards for operations that produce maple syrup. Commenters stated that maple syrup production is a significant enterprise for many organic producers and that the absence of a practice standard in the final rule would adversely affect existing markets for organic products. Many commenters recommended that the final rule incorporate the maple syrup practice standard from an existing certification program or the American Organic Standards.

We have not included a practice standard for the production and handling of maple syrup because the final rule contains sufficient provisions for the certification of these types of operations. After reviewing existing practice standards for maple syrup, we determined that the standards in the final rule for crop production, handling operations, and allowed and prohibited materials on the National List provided comparable guidance.

### **Crop Production - Clarifications**

Clarification is given on the following issues raised by commenters:

(1) Applicability of Crop Rotation Requirement to all Operations. One State program commented that the crop rotation practice standard in the proposed rule was unreasonable for producers who operated in regions where limited rainfall and irrigation resources or unique soil conditions made cover cropping impractical. This commenter stated that certain dryland cropping systems, such as aloe vera production, function as "semi-perennial" systems that do not include rotations, yet fulfill the objectives of the crop rotation practice standard. A certifying agent expressed a similar concern by suggesting that the crop rotation practice standard be changed by adding "may include, but is not limited to" prior to the list of allowed management practices. This commenter felt that the "may include" clause afforded individual growers greater discretion by acknowledging that not every allowed management practice would be applicable to all operations.

We have retained the language from the proposed rule because it already provides the flexibility to develop site-specific crop rotation practices requested by these commenters. The regulation as originally written includes the "but not limited to" clause that allows producers to include alternative management practices in their organic system plan. Additionally, the regulation states that the producer must implement a crop rotation that provides the required functions "that are applicable to the operation." This further establishes that the crop rotation component of an organic system plan must be considered within the context of site-specific environmental conditions including climate, hydrology, soil conditions, and the crops being produced. The final rule requires implementation of a crop rotation, but the producer and certifying agent will determine the specific crops and the frequency and sequencing of their use in that rotation. Crop rotations must fulfill the requirements of this practice standard--to maintain or improve soil organic matter content, provide for pest management, manage deficient or excess plant nutrients, and control erosion--and are not obligated to use any specific management practice. We structured this and other practice standards, as well as the requirements of the organic system plan, to enable producers and certifying agents to develop organic system plans adapted to natural variation in environmental conditions and production systems.

(2) Excluding Annual Seedlings from Planting Stock. The proposed rule allowed a producer to use nonorganically produced seeds and planting stock if organically produced equivalent varieties were not commercially available. Several commenters, including the NOSB, were concerned that the definition of planting stock as "any plant or plant tissue, including rhizomes, shoots, leaf or stem cuttings, roots, or tubers, used in plant production or propagation" was sufficiently broad to

be applied to annual seedlings. While many commenters, including the NOSB, supported the commercial availability exemption in the case of seeds and planting stock, they objected to extending it to annual seedlings. The proposed rule did not intend to include annual seedling within the definition of planting stock and included a separate definition of "annual seedling" as "a plant grown from seed that will complete its life cycle or produce a harvestable crop yield within the same crop year or season in which it is planted." The proposed rule addressed annual seedlings as a distinct category within the seed and planting stock practice standard. There was no allowance for using nonorganically produced annual seedlings based on commercial availability, and such seedlings can only be used when a temporary variance has been issued due to a catastrophic business interruption. The growth of markets for organically produced annual seedlings, unlike those for seeds and planting stock, obviates the need for the commercial availability provision. We have retained this approach in the final rule.

### **Livestock Production - Changes Based on Comments**

This subpart differs from the proposal in several respects as follows:

(1) Whole Herd Conversion. The proposed rule required that livestock receive 1 year of continuous organic management prior to the milk or milk products they produce being labeled as organic. Based on the feed provisions in that proposal, producers would be required to provide a 100-percent organic feed ration (exclusive of National List substances allowed as feed supplements and additives) for that entire year. Many producers, consumers, State certification programs, and certifying agents commented that the full year organic feed requirement created an insurmountable barrier for small and medium-size dairy operations wishing to convert to organic production. They maintained that the added expense of a full year, 100-percent organic feed requirement was economically prohibitive. These commenters stated that "new entry" or "whole herd" conversion provisions in existing certification standards have been instrumental in enabling established nonorganic dairies to make the transition to organic production. Commenters stated that these provisions typically allow producers to provide livestock 80-percent organic or self-raised feed for the first 9 months of a herd's transition, before requiring 100-percent organic feed for the final 3 months. Some commenters stated that many current organic dairies had capitalized on this whole herd conversion provision and that the consistent growth in demand for organic milk and milk products reflected consumer acceptance of the principle.

At its June 2000 meeting, the NOSB reiterated its prior endorsement of the conversion principle for operations that jointly convert dairy herds and the land on which they are raised. The NOSB recommended allowing a producer managing an entire, distinct herd to provide 80-percent organic or self-raised feed during the first 9 months of the final year of conversion, and 100-percent organic feed for the final 3 months. The recommendation further required that dairy animals brought onto an organic dairy must be organically raised from the last third of gestation, except that feed produced on land managed under an organic system plan could be fed to young stock up to 12 months prior to milk production.

While the preponderance of comments supported the whole herd conversion provision, a significant number of individuals, certifying agents, and State certification programs opposed it. Some commenters felt that requiring less than 1 full year of 100-percent organic feed would not satisfy consumer expectations for an organically managed dairy. Other commenters stated that the whole herd conversion merely favored one segment of organic producers over another. They maintained that the full year, 100-percent organic feed requirement would stimulate markets for organically produced hay and grain, thereby rewarding good row crop rotation. One certifying agent was concerned that the conversion provision would create a permanent exemption and that split operation dairies could use it repeatedly to bring nonorganic animals into the organic operation.



The final rule contains a provision for whole herd conversion that closely resembles those found in the NOSB recommendation and the existing certification standards. The final rule requires that an entire, distinct dairy herd must be under organic management for 1 year prior to the production of organic milk. During the first 9 months of that year, the producer must provide a feed ration containing a minimum of 80-percent organic feed or feed that is raised from land included in the organic system plan and managed in compliance with organic crop requirements. The balance of the feed ration may be nonorganically produced, but it must not include prohibited substances including antibiotics or hormones. The producer must provide the herd 100-percent organic feed for the final 3 months before the production of organic milk. The producer must comply with the provisions in the livestock health and living conditions practice standard during the entire year of conversion. After the dairy operation has been certified, animals brought on to the operation must be organically raised from the last third of gestation. We did not incorporate the NOSB's recommendation to provide young stock with nonorganic feed up to 12 months prior to the production of certified milk. By creating an ongoing allowance for using nonorganic feed on a certified operation, this provision would have undermined the principle that a whole herd conversion is a distinct, one-time event.

We anticipate that the provisions added to the final rule will address the concerns of commenters who objected to the conversion principle. Consumers have embraced milk and milk products from dairies certified under private whole herd conversion provisions essentially identical to that in the final rule. While the conversion provision may temporarily reduce demand for organic feed materials, it encourages producers to develop their own supplies of organic feed. The conversion provision also rewards producers for raising their own replacement animals while still allowing for the introduction of animals from off the farm that were organically raised from the last third of gestation. This should protect existing markets for organically raised heifers while not discriminating against closed herd operations. Finally, the conversion provision cannot be used routinely to bring nonorganically raised animals into an organic operation. It is a one-time opportunity for producers working with a certifying agent to implement a conversion strategy for an established, discrete dairy herd in conjunction with the land resources that sustain it.

(2) Organic Management for Livestock from the Last Third of Gestation. The proposed rule required that organically managed breeder and dairy stock sold, labeled, or represented as organic slaughter stock must be under continuous organic management from birth. Many commenters stated that this requirement was an inappropriate relaxation of most existing organic standards, which require organic management for all slaughter stock from the last third of gestation. These commenters cited the NOSB's 1994 recommendation that all slaughter stock must be the progeny of breeder stock under organic management from the last third of gestation or longer. Commenters also recommended extending the organic management provision to cover the last third of gestation to make it consistent with the requirements in section 205.236(a)(4) for the organically raised offspring of breeder stock. We agree with the argument presented by commenters and have changed the final rule to require that breeder or dairy stock be organically raised from the last third of gestation to be sold as organic slaughter stock.

(3) Conversion Period for Nonedible Livestock Products. The proposed rule required that livestock must be under continuous organic management for a period not less than 1 year before the nonedible products produced from them could be sold as organic. Several commenters questioned the basis for creating different origin of livestock requirements based on whether the operation intended to produce edible or nonedible products. These commenters stated that the OFPA does not sanction such a distinction, nor is it contained in existing certification standards. They questioned why the proposed rule created such a provision in the absence of a favorable NOSB recommendation. We agree that the creation of a separate origin of livestock requirement for animals intended to provide nonedible products could be confusing. We have changed this provision in the final rule to require that nonedible products be produced from livestock that have been organically managed from the last third of gestation.

(4) Provisions for Feed Supplements and Feed Additives. The proposed rule provided that nonagricultural products and synthetic substances included on the National List could be used as feed additives and supplements. Many commenters stated that allowing nonagricultural products and synthetic substances as feed supplements contradicted the definition for "feed supplement" found in the proposed rule. That definition stipulated that a feed supplement must, itself, be a feed material, and the definition for "feed" in the proposed rule precluded using nonagricultural products and synthetic substances. These commenters requested that either the definition of "feed supplement" be changed to make it consistent with the allowance for nonagricultural products and synthetic substances or else that the term be dropped from the final rule. The Food and Drug Administration (FDA) recommended modifying the definitions for "feed additive" and "feed supplement" and further specifying the components required in a feed ration under the livestock health care practice standard.

We amended the definition in the final rule to state that a feed supplement is "a combination of feed nutrients added to livestock feed to improve the nutritional balance or performance of the total ration." We retained the second component of the proposed definition, which described how a feed supplement could be offered to livestock. We amended the definition of "feed additive" to "a substance added to feed in micro quantities to fulfill a specific nutritional need; i.e., essential nutrients in the form of amino acids, vitamins, and minerals." The definitions for "feed supplement" and "feed additive" in the proposed rule were originally recommended by the NOSB. While our intent in the proposed rule was to codify as fully as possible the recommendations of the NOSB, we agree with commenters that the proposed definitions were incompatible with the overall provisions for livestock feed. The definitions in the final rule are consistent with the NOSB's objective to create clear distinctions between feed, feed supplements, and feed additives while clarifying the role for each within an organic livestock ration. We also incorporated FDA's recommendation to include protein and/or amino acids, fatty acids, energy sources, and fiber for ruminants as required elements of a feed ration in the livestock health care practice standard. These additions make the livestock health care practice standard more consistent with the National Research Council's Committee on Animal Nutrition's Nutrient Requirement series, which we cited in the proposed rule as the basis for feed requirements.

Many commenters addressed provisions in the proposed rule to allow or prohibit specific materials and categories of materials used in livestock feed. Among these, some commenters questioned whether enzymes were defined as a feed additive and, therefore, allowed. One certifying agent requested guidance on the status of supplementing livestock feed with amino acids. At its October 1999 meeting, the NOSB discussed the Technical Advisory Panel (TAP) reviews on the use of enzymes and amino acids in livestock feed. The NOSB determined that natural sources of enzymes exist and that their use should be allowed in organic production. Their discussion of natural sources of enzymes concluded that enzymes derived from edible, nontoxic plants and nonpathogenic bacteria or fungi that had not been genetically engineered should be allowed as a nonorganic feed additive. The NOSB did not take a position on amino acids during this meeting but indicated that it would revisit the subject in the near future. Based on these recommendations, the final rule allows the use of natural enzymes but not amino acids as nonorganic feed additives. The NOSB's recommendation that natural sources of enzymes existed and were compatible with organic livestock production supports allowing them without adding them to the National List. Some commenters discussed the animal welfare and environmental benefits associated with providing amino acids in livestock feed and supported allowing them. However, without a recommendation from the NOSB that amino acids are natural or should be added to the National List as a synthetic, the final rule does not allow their use.

Commenters questioned whether nonsynthetic but nonagricultural substances, such as ground oyster shells and diatomaceous earth, would be allowed in agricultural feed. In 1994, the NOSB recommended that natural feed additives can be from any source, provided that the additive is not classified as a prohibited natural on the National List. We agree with this recommendation and have amended the final rule to allow such materials as feed additives and supplements. The

only additional constraint on these materials is that every feed, feed additive, and feed supplement be used in compliance with the Federal Food, Drug, and Cosmetic Act, as stated in section 205.237(b)(6).

The NOSB recommended that ruminants maintained under temporary confinement must have access to dry, unchopped hay. Although this position was an NOSB recommendation and not part of the proposed rule, several commenters responded to it. Most of these commenters stated that the language was too restrictive and could preclude the use of many suitable forage products. One dairy producer stated that the requirement would not be practical for operations that mix hay with other feed components. We agree that the NOSB's proposed language is too prescriptive and have not included it in the final rule.

(5) Provisions for Confinement. The proposed rule established the health, nutritional, and behavioral needs of the particular species and breed of animal as the primary considerations for determining livestock living conditions. The proposed rule also identified essential components of the practice standard, including access to shade, shelter, exercise areas, fresh air, and direct sunlight, while stating that species-specific guidelines would be developed in conjunction with future NOSB recommendations and public comment. Finally, the proposed rule outlined the conditions pertaining to animal welfare and environmental protection under which producers could temporarily confine livestock.

While supportive of the underlying principles of this practice standard, the vast majority of commenters stated that the actual provisions suffered from a lack of clarity and specificity. Many commenters were concerned that the proposed rule did not adequately ensure access to the outdoors for all animals. While supportive of the access to pasture requirement for ruminant production, commenters stated that the final rule needed a clear definition of pasture to make the provision meaningful. Conversely, some commenters supported the less prescriptive approach adopted in the proposed rule. The NOSB added considerably to its earlier recommendations on livestock living conditions during its June 2000 meeting.

Many commenters stated that the criteria identified as required elements in the provisions for livestock living conditions did not specifically include access to the outdoors. One commenter stated that the requirement that animals receive direct sunlight could be interpreted to simply require windows in livestock confinement facilities. Commenters were virtually unanimous that, except for the limited exceptions for temporary confinement, all animals of all species must be afforded access to the outdoors. Commenters also maintained that the outdoor area must accommodate natural livestock behavior, such as dust wallows for poultry and, in the case of ruminants, provide substantial nutrition. Many commenters specifically opposed dry lots as an allowable outdoor environment. The NOSB recommended that the final rule state that all livestock shall have access to the outdoors. As a result of these comments, we have revised the final rule to establish that access to the outdoors is a required element for all organically raised livestock.

We further amended the final rule to include a definition of "pasture." The definition of "pasture" we included emphasizes that livestock producers must manage their land to provide nutritional benefit to grazing animals while maintaining or improving the soil, water, and vegetative resources of the operation. The producer must establish and maintain forage species-appropriate for the nutritional requirements of the species using the pasture.

Numerous commenters requested clarification on species-specific living conditions, such as the use of cages for poultry and confinement systems for veal production. The use of continuous confinement systems including cages for poultry and veal production is incompatible with the requirement that organically raised livestock receive access to the outdoors and the ability to engage in physical activity appropriate to their needs. There will be times when producers must temporarily confine livestock under their care, but these instances must be supported by the exemptions to the outdoor access requirement included in the final rule. Other commenters

requested additional guidance on whether confinement for the purpose of finishing slaughter stock would be allowed, and, if so, how long that confinement could last. Commenters who supported an allowance for finishing most often recommended that, in the case of cattle, confinement should not exceed 90 days. The final rule does not include a specific length of time that cattle or other species may be confined prior to slaughter. We will seek additional input from the NOSB and public comment before developing such standards.

Several commenters questioned whether a Federal, State, or local regulation that required confinement would supersede the requirement for outdoor access. These commenters were aware of county ordinances that prohibited free ranging livestock production to protect water quality. Organic operations must comply with all Federal, State, and local regulations. At the same time, to sell, label, or represent an agricultural commodity as "100 percent organic," "organic," or "made with..." the producer or handler must comply with the all applicable requirements set forth in this regulation. Federal, State, or local regulations that prohibit a required practice or require a prohibited one will essentially preclude organic certification of the affected commodity within that jurisdiction.

(6) Prohibition on Parasiticides During Lactation. The proposed rule provided that breeder stock could receive synthetic parasiticides included on the National List, provided that the treatment occurred prior to the last third of gestation for progeny that were to be organically managed. Many commenters supported this principle but were concerned that the wording would allow producers to administer parasiticides to lactating breeder stock while the offspring were still nursing. These commenters felt that such an allowance violated the intent of the provision because offspring could be exposed to systemic parasiticides or their residues through their mother's milk. The NOSB recommended a prohibition on using allowed synthetic parasiticides during lactation for progeny that are organically managed. We agree with these commenters and have modified the final rule to prohibit the treatment of organically managed breeder stock with allowed synthetic parasiticides during the last third of gestation or lactation.

### **Livestock Production - Changes Requested But Not Made**

This subpart retains from the proposed rule regulations on which we received comments as follows:

(1) Prohibition on Factory Farms. Many commenters requested that the final rule prohibit the certification of "factory farms." These commenters stated that factory farms are dependent upon practices and materials that are inconsistent with or expressly prohibited in the OFPA. The final rule does not contain such a prohibition because commenters did not provide a clear, enforceable definition of "factory farm" for use in the final rule. All organic operations, regardless of their size or other characteristics, must develop and adhere to an approved organic system plan that complies with these regulations in order to be certified. (2) Nonorganic Feed Protocol. The proposed rule required that, except for nonagricultural products and synthetic substances included on the National List, a producer must provide livestock with a total feed ration composed of agricultural feed products, including pasture and forage, that is organically produced and, if applicable, handled. It also included provisions for temporary variances that, under very limited circumstances and with the approval of the certifying agent and the Administrator, would provide an exemption from specific production and handling standards. The preamble of the proposed rule described an emergency resulting in the unavailability of organic agricultural feed products as an example of a situation in which a temporary variance could be issued. Many commenters recommended that the final rule require a producer who received a temporary variance for a feed emergency to follow the order of preference for noncertified organic feed developed by the NOSB. This order of preference requires a producer to procure agricultural feed products from sources that are as close to complying with the standards for organic certification as possible. Commenters stated that adherence to the order of preference would most closely conform with

the expectation of consumers that organically raised livestock received organic feed and would create an incentive for livestock feed producers to pursue certification.

We have not included the NOSB's feed emergency order of preference in the final rule because it would be too prescriptive and difficult to enforce during an emergency. Receiving a temporary variance categorically exempts a producer from the provision for which it was issued, although that producer may not substitute any practice, material, or procedure that is otherwise prohibited, although that producer may not substitute any practice, material, or procedure that is otherwise prohibited under section 205.105 . Additionally, certified organic feed is far more available in terms of quantity and affordability than when the NOSB developed its order of preference in 1994. We anticipate that producers whose original supply of organic agricultural feed products is interrupted will be able to fill the shortfall through the marketplace.

(3) Prohibition on Physical Alterations. The proposed rule required that producers perform physical alterations as needed to promote animal welfare and in a manner that minimizes pain and stress. This provision was one component of the health care practice standard that required producers to establish and maintain preventive livestock health care practices. We stated in the preamble that there was insufficient consensus from previous public comment to designate specific physical alterations as allowed or prohibited and envisioned working with producers, certifying agents, and consumers to achieve that goal. We requested comment on techniques to measure animal stress that could be used to evaluate whether specific physical alterations were consistent with the conditions established in the proposed rule.

We received significant numbers of comments both opposing and supporting the provision in the proposed rule for performing physical alterations. Many commenters opposed any allowance for physical alterations and argued that such practices are cruel and debilitating to animals. These commenters maintained that modifications in breed selection, stocking densities, and the configuration of living conditions could achieve results similar to physical alterations without harming the animal. They stated that by adapting their production systems to promote the physical and psychological welfare of animals, producers could obviate the need for physical alterations. In particular, commenters cited physical alterations to the beaks and feet of poultry as unnecessary due to the availability of alternative production systems. Many commenters expressed concern that the allowance for physical alterations would facilitate the certification of large confinement operations. Commenters also stated that performing physical alterations was inconsistent with Codex guidelines and objected to the allowance before full public deliberation on the subject through the NOSB process.

A large number of commenters stated that, if reasonable guidelines could be established, the allowance for physical alterations would be a beneficial, and even necessary, condition for organic livestock production. These commenters maintained that producers engage in physical alterations for the overall welfare of the flock or herd and that the pain and stress of performing them must be weighed against the pain and stress of not doing so. For example, these commenters cited the traumatic effect of cannibalism on poultry flocks that had not undergone beak trimming or the injuries caused by animals whose horns had not been removed. Many of these commenters stated that producers could reduce but not eliminate the need for physical alterations through alternative production practices such as breed selection and stocking densities. The NOSB supported the provision as written in the proposed rule, stating that it met the animal welfare requirements while allowing practices necessary for good animal husbandry.

We have retained the proposed provision for physical alterations without taking any further position on whether specific practices are allowed or prohibited. We did not receive substantial new guidance on techniques to measure stress in animals due to physical alterations and have made no revisions in that regard. The final rule establishes that, when appropriately performed and within the context of an overall management system, specific physical alterations are

allowed. It also mandates that, as an element of a preventative health care program, physical alterations must benefit the ultimate physical and psychological welfare of the affected animal.

(4) Withdrawal for Synthetic Parasiticides in Lactating Livestock. The proposed rule required a 90-day withdrawal period before milk and milk products produced from livestock treated with an allowed synthetic parasiticide could be labeled as organic. Referencing the statement in the preamble to the proposed rule that the 90-day withdrawal period was attributable to "consumer expectations of organically raised animals," a dairy producer commented that the provision ignored animal welfare and farm economic sustainability considerations. The commenter considered the 90-day withdrawal period capricious and problematic since, for bovine dairy operations, it would compel producers to either shorten an animal's natural drying off period, or lose 30 days of organic milk production. The commenter stated that the optimal extended withdrawal period for this situation would be 60 days since this is the approximate duration of a dairy cow's natural dry period. Under this approach, livestock requiring treatment could receive an allowed synthetic parasiticide at the time of drying off, thus allowing the withdrawal period to coincide with the natural 60-day period when the livestock were not lactating. Livestock could complete the withdrawal period prior to the birth of their offspring in approximately 60 days, at which time the mother's milk could again be sold as organic. The commenter maintained that the 60-day period would satisfy consumer expectation for an extended withdrawal period after treatment with an allowed synthetic parasiticide without imposing an unnecessary constraint on the producer.

We have retained the 90-day withdrawal period in the final rule. The provisions in the final rule for treating livestock with an allowed synthetic parasiticide reflect the 90-day withdrawal period recommended by the NOSB at its October 1999 meeting. The NOSB has the authority to reconsider this issue and propose an alternative annotation for the Secretary's consideration.

(5) Delineation of Space Requirements for Animal Confinement. The proposed rule did not establish space requirements for livestock living conditions but stated that a producer must accommodate the health and natural behavior of animals under his or her care. Some commenters stated their preference for space requirements because they are more uniform and enforceable. These commenters stated that some existing certification standards include space requirements in standards for livestock living conditions and that Codex guidelines support this approach. While not disagreeing that space requirements could be an effective certification tool for organic livestock production systems, we have not incorporated any such provisions in the final rule. We anticipate that additional NOSB recommendations and public comment will be necessary for the development of space requirements. At its June 2000 meeting, the NOSB agreed that it would be premature to include space requirements in the final rule.

(6) Access to pasture versus pasture-based. Commenters stated that the proposed rule's requirement that ruminants receive "access to pasture" did not sufficiently characterize the relationship that should exist between ruminants and the land they graze. Many of these commenters recommended that the final rule require that ruminant production be "pasture-based." Many commenters stated that the final rule needed a more explicit description of the relationship between livestock and grazing land. The NOSB shared this perspective and recommended that the final rule require that ruminant production systems be "pasture-based." In contrast, an organic dairy producer maintained that a uniform, prescriptive definition of pasture would not be appropriate in a final rule. This commenter stated that the diversity of growing seasons, environmental variables, and forage and grass species could not be captured in a single definition and that certifying agents should define pasture on a case-by-case basis. This commenter also disagreed with the "pasture-based" requirement, stating that pasture should be only one of several components of balanced livestock nutrition. Singling out pasture as the foundation for ruminant management would distort this balance and deprive other producers of the revenue and rotation benefits they generate by growing livestock feed.

We retained the "access to pasture" requirement because the term, "pasture-based," has not been sufficiently defined to use for implementing the final rule. The final rule does include a definition for pasture, and retention of the "access to pasture" provision provides producers and certifying agents with a verifiable and enforceable standard. The NOP will work with the NOSB to develop additional guidance for managing ruminant production operations.

(7) Stage of Production. The proposed rule contained provisions for temporary confinement, during which time livestock would not receive access to the outdoors. Many commenters were concerned that the stage-of-production justification for temporary confinement could be used to deny animals access to the outdoors during naturally occurring life stages, including lactation. Commenters overwhelmingly opposed such an allowance and stated that the stage of production exemption should be narrowly applied. One commenter stated that a dairy operation, for example, might have seven or eight distinct age groups of animals, with each group requiring distinct living conditions. Under these circumstances, the commenter maintained that a producer should be allowed to temporarily house one of these age groups indoors to maximize use of the whole farm and the available pasture. At its June 2000 meeting, the NOSB stated that the allowance for temporary confinement should be restricted to short-term events such as birthing of newborn or finish feeding for slaughter stock and should specifically exclude lactating dairy animals.

We have not changed the provision in the final rule for the stage-of-production allowance in response to these comments. The NOSB has supported the principle of a stage-of-production allowance but has not provided sufficient guidance for determining, on a species-specific basis, what conditions would warrant such an allowance. Without a clearer foundation for evaluating practices, we have not identified any specific examples of practices that would or would not warrant a stage-of-production allowance. We will continue to explore with the NOSB specific conditions under which certain species could be temporarily confined to enhance their well-being.

In the final rule, temporary confinement refers to the period during which livestock are denied access to the outdoors. The length of temporary confinement will vary according to the conditions on which it is based, such as the duration of inclement weather. The conditions for implementing temporary confinement for livestock do not minimize the producer's ability to restrain livestock in the performance of necessary production practices. For example, it is allowable for a producer to restrain livestock during the actual milking process or under similar circumstances, such as the administration of medication, when the safety and welfare of the livestock and producer are involved.

### **Handling - Changes Based on Comments**

The following changes are made based on comments received.

(1) Commercial Availability. A large number of commenters, including organic handlers and certifying agents, stated that "commercial availability" must be included as a requirement for the 5 percent of nonorganic ingredients that are used in products labeled "organic."

We agree and have added a commercial availability requirement as part of a handler's organic system plan under section 205.201 of this subpart. Up to 5 percent (less water and salt) of a product labeled "organic," may be nonorganic agricultural ingredients. However, handlers must document that organic forms of the nonorganic ingredients are not commercially available before using the nonorganic ingredients.

(2) Prohibited Practices. Commenters were unclear about the extent of the prohibition on use of excluded methods and ionizing radiation. To make that prohibition clear, we have moved the handling prohibitions in proposed rule sections 205.270 (c) to 205.105, Applicability, subpart B.

Paragraphs (c)(1) and (c)(2) which listed excluded methods and ionizing radiation in the proposed rule are combined into paragraph (c)(1) that cross-references new section 205.105.

(3) Use of Predator Pests and Parasites. Paragraph (b)(1) of section 205.271 proposed that predator pests and parasites may be used to control pests in handling facilities. Under FDA's Good Manufacturing Practice, 21 CFR part section 110.35(c), it states that "No pests shall be allowed in any area of a food plant." Some commenters believed use of predator pests in handling facilities is prohibited by the FDA regulation. Other commenters stated that predator pests could be used in certain handling facilities under the FDA regulation. One commenter claimed that the FDA regulation in 21 CFR part 110.19 allows exemptions for certain establishments that only harvest, store, or distribute raw agricultural product. Another commenter suggested that use of predator pests should be allowed when FDA does not prohibit their use.

We do not intend to be inconsistent with the FDA requirement and, thus, have removed proposed paragraph (b)(1) of section 205.271. Use of predator pests in various organic handling and storage areas is subject to FDA's Good Manufacturing Practice. Paragraphs (b)(2) and (b)(3) are redesignated.

(4) Use of Synthetic Pheromone Lures. Proposed paragraph (b)(3) provided for use of nonsynthetic lures and repellent. A few handlers and certifying agents commented that nearly all pheromone lures use synthetic substances. Because pheromone lures do not come into contact with products in a handling facility, commenters argued that such lures should be allowed, provided that the synthetic substance used is on the National List.

We agree and have added "synthetic substances" to redesignated paragraph (b)(2) for use in lures and repellents. The synthetic substances used must be consistent with the National List. (5) Restrict Initial Use of Synthetics to National List Substances. Paragraph (c) in the proposed rule provided for use of any synthetic substance to prevent or control pests. Several handlers and certifying agents stated that use of nonsynthetic and synthetic substances should initially be limited first to substances which are allowed on the National List. This would mean that substances not allowed for use on the National List could not be used initially to control or prevent pest infestations.

We agree with these comments. Use of allowed substance before use of other substances is a fundamental principle of organic agriculture. Therefore, if preferred practices under paragraphs (a) and (b) are not successful in preventing or controlling pest infestations, handlers may then use, under amended paragraph (c), only nonsynthetic or synthetic substances which are allowed for use on the National List.

We have removed the proviso that applications of a pest control substance must be consistent with the product's label instructions. This requirement is readily understood and does not need to be explicitly stated in the regulations.

Because paragraph (c) now provides for use only of allowed National List substances, a new paragraph (d) is added to allow for use of other synthetic substances, including synthetic substances not on the National List, to prevent or control pest infestations. These substances may be used only if the practices in paragraphs (a), (b), and (c) are ineffective. Before the substance is used, the handler and the operation's certifying agent must agree on the synthetic substance to be used and the measures to be taken to prevent contact of the substance with organic products and ingredients in the facility. We expect that this communication can be accomplished with telephone calls or by electronic means.

This regulation does not preempt Federal, State, or local health and sanitation requirements. We recognize that inspectors who monitor compliance with those regulations may require immediate



intervention and use of synthetic substances, not on the National List, before or at the same time as the methods specified in paragraphs (b) and (c). Therefore, to make this clear, we have added a new paragraph (f). To ensure that the use of the substances does not destroy a product's organic integrity, we are requiring that the handler take appropriate measures to prevent contact of the product with the pest control substance used.

(6) Preventing Contact with Prohibited Substances. Commenters recommended that, if prohibited substances are applied by fogging or fumigation, the organic product and packaging material must be required to be completely removed from the facility and reentry of the product or packaging be delayed for a period three times longer than that specified on the pesticide label. Commenters believed removal and reentry should be mandatory, regardless of the organic product or container.

We understand the commenters' concerns. However, their recommendations are not appropriate for all pest infestations. We believe that measures needed to be taken to prevent contact with a synthetic substance must be determined on a case-by-case basis by the handler and certifying agent. As stated earlier, new paragraph (d) of section 205.271 requires a handler and certifying agent to agree on control and prevention measures prior to application of a synthetic substance. We believe that such an agreement will help safeguard a product's organic integrity. Use of a synthetic substance in fogging or fumigation should be based on, among other things, location of the pest relative to the organic products in the facility; the extent of the pest infestation; the substance and application method to be used; the state of the organically produced product or ingredient (raw, unpackaged bulk, canned, or otherwise sealed); and health and sanitation requirements of local, State, and Federal authorities.

Paragraph (e) is changed to clarify that an operation's organic handling plan must be updated to document all measures taken to prevent contact between synthetic pest control substances and organically produced products and ingredients.

(7) Repetitive Use of Pest Control Measures. One commenter suggested a change in the paragraph (e) requirement that handlers' organic plans must include "an evaluation of the effects of repetitive use" of pest prevention and control materials. The commenter believed that the requirement was excessive and beyond what should be expected of handlers. The commenter indicated that handlers' organic plans should address the "techniques that will be used to minimize" the negative effects of repetitive use of pest control materials.

We agree that "an evaluation of the effects of repetitive use" is more than what is reasonable to expect of handlers in their organic plans. We do not agree, however, that an organic plan should be required to address the "techniques" used to minimize the effects of repetitive use of pest control materials. However, we believe that handlers should update their organic handling plans to account for the use of pest control or prevention substances, particularly if the substances are prohibited substances. The update should include a description of the application methods used and the measures taken to prevent contact between the substance used and the organic product. We have added these requirements in redesignated paragraph (e). Proposed paragraph (e) of section 205.271 is removed.

## **Handling - Changes Requested But Not Made**

(1) Exceptions to Handling Processes. A commenter stated that many herbal products are extracted from organically produced herbs but that the extraction of those products "can employ significantly different methods than those used in the manufacture of more traditional foods." To be labeled as "organic" ingredients, substances such as herbs, spices, flavorings, colorings, and other similar substances, must be derived from a certified organic source and be extracted without the use of prohibited substances.

(2) Allowed Synthetics Used in Packaging Materials and Storage Containers. A State department of agriculture commented that section 205.272(b)(1) prohibits use of synthetic fungicides, preservatives, or fumigants in packaging materials and storage containers or bins. The comment stated that it is inconsistent to permit use of allowed substances as ingredients in processed products but prohibit their use as a preservative or fumigant in the packaging materials and storage containers and bins. The commenter suggested that paragraph (b)(1) be amended to permit use of National List-allowed substances in section 205.605, particularly carbon dioxide and ozone, in packaging materials and storage containers or bins.

We understand the commenter's concern. However, section 6510(a)(5) of the Act specifically prohibits use of any packaging materials, storage containers, or bins that contain synthetic fungicides, preservatives, or fumigants.

(3) Additional Measures to Prevent Product Contamination. A few commenters suggested changing paragraph (e) of section 205.271 to require that handlers' organic handling plans specify measures that would be taken to prevent contact between a pest control substance and "packaging materials." This would be in addition to measures preventing contamination of "any ingredient or finished product" in the handling facility.

We understand the commenters' objective. However, for the reasons stated earlier in regard to commenters' request that mandatory removal of product during pest control treatment be required, we believe that such a requirement should not be mandatory for all packaging materials. Measures to prevent contamination of packaging material should be left to the handler and certifying agent to specify in the handling plan.

### **Handling - Clarifications**

Clarification is given on the following issues raised by commenters.

(1) Use of Nonorganic Ingredients in Processed Products. We have corrected paragraph (c) of section 205.270 to clarify what must not be used in or on organically produced ingredients and nonorganically produced ingredients used in processed organic products. The prohibition on use of ionizing radiation, excluded methods, and volatile synthetic solvents applies to all organically produced ingredients. The 5 percent of nonorganic ingredients in products labeled "organic," also are subject to the three prohibited practices. The nonorganic ingredients in products labeled "made with organic ingredients" must not be produced using ionizing radiation or excluded methods but may be produced using volatile synthetic solvents. The nonorganic ingredients in products containing less than 70 percent organically produced ingredients may be produced and processed using ionizing radiation, excluded methods, and synthetic solvents.

(2) Water Quality Used in Processing. A handler questioned whether public drinking water containing approved levels of chlorine, pursuant to the Safe Drinking Water Act, is acceptable for use in processing products labeled "100 percent organic." Water meeting the Safe Drinking Water Act may be used in processing any organically produced products.

### **Temporary Variances - Changes Based on Comments**

Additional Causes for Issuing Temporary Variance. A few State department of agriculture commenters suggested that "drought" should be added to the regulatory text as a natural disaster warranting a temporary variance from regulations.

We agree and have added drought to the regulatory text in paragraph (a)(2) of section 205.290. We have also added "hail" as a natural disaster warranting a temporary variance. Both drought

and hail were mentioned in the preamble of the proposed rule but were unintentionally left out of the regulatory text.

### **Temporary Variances - Changes Requested But Not Made**

Allowance of Temporary Variances. A few commenters suggested that SOP's governing State officials should be able to authorize temporary variances due to local natural disasters which may occur in a State. We do not agree that with these comments. For consistency of application, we believe that only the Administrator should have the authority to grant a temporary variance. Citing local conditions, an SOP's governing State official and certifying agents may recommend a temporary variance to the Administrator. We are committed to providing quick responses to such recommendations.

## Labeling -- Preamble

### Subpart D - Labels, Labeling, and Market Information

The Act provides that a person may sell or label an agricultural product as organically produced only if the product has been produced and handled in accordance with provisions of the Act and these regulations. This subpart sets forth labeling requirements for organic agricultural products and products with organic ingredients based on their percentage of organic composition. For each labeling category, this subpart establishes what organic terms and references can and cannot be displayed on a product package's principal display panel (pdp), information panel, ingredient statement, and on other package panels. Labeling requirements also are established for organically produced livestock feed, for containers used in shipping and storing organic product, and for denoting organic bulk products in market information which is displayed or disseminated at the point of retail sale. Restrictions on labeling organic product produced by exempt operations are established. Finally, this subpart provides for a USDA seal and regulations for display of the USDA seal and the seals, logos, or other identifying marks of certifying agents.

The intent of these sections is to ensure that organically produced agricultural products and ingredients are consistently labeled to aid consumers in selection of organic products and to prevent labeling abuses. These provisions cover the labeling of a product as organic and are not intended to supersede other labeling requirements specified in other Federal labeling regulations. The Food and Drug Administration (FDA) regulates the placement of information on food product packages in 21 CFR parts 1 and 101. USDA's Food Safety and Inspection Service's (FSIS) Federal Meat Inspection Act, Poultry Products Inspection Act, and Egg Products Inspection Act have implementing regulations in 9 CFR part 317 which must be followed in the labeling of meat, poultry, and egg products. The Federal Trade Commission (FTC) regulations under the Fair Packaging and Labeling Act (FLPA) in 16 CFR part 500 and the Alcohol Tobacco and Firearms (ATF) regulations under the Federal Alcohol Administration Act (FAA) in 27 CFR parts 4, 5, and 7, also must be followed, as applicable to the nature of the product. The labeling requirements specified in this subpart must be implemented in a manner so that they do not conflict with the labeling requirements of these and other Federal labeling requirements.

While this regulation does not require labeling of an organic product as organic, we assume that producers and handlers choose to label their organic products and display the USDA seal to the extent allowed in these regulations. They do this to improve the marketability of their organic product.

Under the National Organic Program (NOP), the assembly, packaging, and labeling of multiingredient organic products are considered handling activities. The certification of handling operations is covered in subpart C of this regulation. No claims, statements, or marks using the term, "organic," or display of certification seals, other than as provided in this regulation, may be used. Based on comments received, several important labeling changes from the proposed rule are made in this final rule. (1) The term, "organic," cannot be used in an agricultural product name if it modifies an ingredient that is not organically produced (e.g., "organic chocolate ice cream" when the chocolate flavoring is not organically produced). (2) The 5 percent or less of nonorganic ingredients in products labeled "organic" must be determined not "commercially available" in organic form. (3) Display of a product's organic percentage is changed from required to optional for "organic" and "made with ..." products. (4) The minimum organic content for "made with..." products is increased from 50 percent to 70 percent. (5) In addition to listing individual ingredients, the "made with..." label may identify a food group on the label ("made with organic fruit"). (6) A new section is added to provide labeling of livestock feed that is organically produced. (7) Finally, a revised design for the USDA seal is established. In addition to these changes, we have made a few changes in the regulatory text for clarity and consistency purposes. These do not change the intent of the regulation.

Once a handler makes a decision to market a product as organic or containing organic ingredients, the handler is required to follow the provisions in this subpart regarding use, display, and location of organic claims and certification seals. Handlers who produce and label organic ingredients and/or assemble multiingredient products composed of 70 percent or more organic ingredients must be certified as an organic handling operation. Handlers of products of less than 70 percent organic ingredients do not have to be certified unless the handler actually produces one or more of the organic ingredients used in the product. Repackers who purchase certified organic product from other entities for repackaging and labeling must be certified as an organic operation. Entities which simply relabel an organic product package are subject to recordkeeping requirements which show proof that the product purchased prior to relabeling was, indeed, organically produced and handled. Distributors which receive and transport labeled product to market are not subject to certification or any labeling requirements of this regulation.

Many commenters appealed for "transition" or "conversion" labeling. This issue is discussed under Applicability in subpart B. Transition labeling is not provided for in the Act or the proposed rule and is not provided for in this regulation.

## **Description of Regulations**

### **General Requirements**

The general labeling principle employed in this regulation is that labeling or identification of the organic nature of a product increases as the organic content of the product increases. In other words, the higher the organic content of a product, the more prominently its organic nature can be displayed. This is consistent with provisions of the Act which establish the three percentage categories for organic content and basic labeling requirements in those categories.

Section 205.300 specifies the general use of the term, "organic," on product labels and market information. Paragraph (a) establishes that the term, "organic," may be used only on labels and in market information as a modifier of agricultural products and ingredients that have been certified as produced and handled in accordance with these regulations. The term, "organic," cannot be used on a product label or in market information for any purpose other than to modify or identify the product or ingredient in the product that is organically produced and handled. Food products and ingredients that are not organically produced and handled cannot be modified, described, or identified with the term, "organic," on any package panel or in market information in any way that implies the product is organically produced.

Section 6519(b) of the Act provides the Secretary with the authority to review use of the term, "organic," in agricultural product names and the names of companies that produce agricultural products. While we believe that the term, "organic," in a brand name context does not inherently imply an organic production or handling claim and, thus, does not inherently constitute a false or misleading statement, we intend to monitor the use of the term in the context of the entire label. We will consult with the FTC and FDA regarding product and company names that may misrepresent the nature of the product and take action on a case-by-case basis.

### **Categories of Organic Content**

Section 205.301 establishes the organic content requirements for different labeling provisions specified under this program. The type of labeling and market information that can be used and its placement on different panels of consumer packages and in market information is based on the percentage of organic ingredients in the product. The percentage must reflect the actual weight or fluid volume (excluding water and salt) of the organic ingredients in the product. Four categories of organic content are established: 100 percent organic; 95 percent or more organic; 70 to 95 percent organic; and less than 70 percent organic.

## **100 Percent Organic**

For labeling and market information purposes, this regulation allows a "100 percent organic" label on: (1) agricultural products that are composed of a single ingredient such as raw, organically produced fruits and vegetables and (2) products composed of two or more organically produced ingredients, provided that the individual ingredients are, themselves, wholly organic and produced without any nonorganic ingredients or additives. Only processing aids which are, themselves, organically produced, may be used in the production of products labeled "100 percent organic." With the exception of the description phrase "100 percent" on the pdp, the labeling requirements for "100 percent organic" products are the same as requirements for 95 percent organic products specified in section 205.303.

## **Organic**

Products labeled or represented as "organic" must contain, by weight (excluding water and salt), at least 95 percent organically produced raw or processed agricultural product. The organic ingredients must be produced using production and handling practices pursuant to subpart C. Up to 5 percent of the ingredients may be nonagricultural substances (consistent with the National List) and, if not commercially available in organic form pursuant to section 205.201, nonorganic agricultural products and ingredients in minor amounts (hereinafter referred to as minor ingredients) (spices, flavors, colorings, oils, vitamins, minerals, accessory nutrients, incidental food additives). The nonorganic ingredients must not be produced using excluded methods, sewage sludge, or ionizing radiation.

## **Made with Organic Ingredients**

For labeling and market information purposes, the third category of agricultural products are multiingredient products containing by weight or fluid volume (excluding water and salt) between 70 and 95 percent organic agricultural ingredients. The organic ingredients must be produced in accordance with subpart C and subpart G. Such products may be labeled or represented as "made with organic (specified ingredients or food group(s))." By "specified," we mean the name of the agricultural product(s) or food group(s) forming the organic ingredient(s). Up to three organically produced ingredients or food groups may be named in the phrase.

If one or more food groups are specified in the phrase, all ingredients in the product which belong to the food group(s) identified on the label must be organically produced. For the purposes of this labeling, the following food groups may be identified as organically produced on a food package label: beans, fish, fruits, grains, herbs, meats, nuts, oils, poultry, seeds, spices, sweeteners, and vegetables. In addition, processed milk products (butter, cheese, yogurt, milk, sour creams, etc.) also may be identified as a "milk products" food group. For instance, a vegetable soup made with 85 percent organically produced and handled potatoes, tomatoes, peppers, celery, and onions may be labeled "soup made with organic potatoes, tomatoes, and peppers" or, alternatively, "soup made with organic vegetables." In the latter example, the soup may not contain nonorganic vegetables. For the purposes of this labeling provision, tomatoes are classified, according to food use, as a vegetable.

To qualify for this organic labeling, the nonorganic agricultural ingredients must be produced and handled without use of the first three prohibited practices specified in paragraph (f) of section 205.301, but may be produced or handled using practices prohibited in paragraphs (f)(4) through (f)(7).

Because of the length of the labeling phrase "made with organic (specified ingredients or food group(s))," such products are referred to in this preamble as "made with..." products. The labeling requirements for "made with..." products are specified in section 205.304.

## **Product With Less Than 70 Percent Organic Ingredients**

The final labeling category covers multiingredient products with less than 70 percent organic ingredients (by weight or fluid volume, excluding water and salt). The organic ingredients must be produced in accordance with subparts C and G. The remaining nonorganic ingredients may be produced, handled, and assembled without regard to these regulations (using prohibited substances and prohibited production and handling practices). Organic labeling of these products is limited to the information panel only as provided in section 205.305.

Products that fail to meet the requirements for one labeling category may be eligible for a lower labeling category. For example, if a product contains wholly organic ingredients but the product formulation requires a processing aid or less than 5 percent of a minor ingredient that does not exist in organic form, the product cannot be labeled "100 percent organic" and must be labeled as "organic." If a multiingredient product is 95 percent or more organic but contains a prohibited substance in the remaining 5 percent, the product cannot be labeled as "organic," because of the presence of the prohibited substance, but may be labeled as a "made with..." product. Further, a handler who produces a "100 percent organic" or "organic" product but chooses not to be certified under this program may only display the organic percentage on the information panel and label the ingredients as "organic" on the ingredient statement. The handler must comply with recordkeeping requirements in subpart E.

## **Livestock feed**

All agricultural ingredients used in raw and processed livestock feed that is labeled as "100 percent organic" and "organic" must be organically produced and handled in accordance with the requirements of these regulations. The difference between the two labels is that feed labeled as "100 percent organic" must be composed only of organically produced agricultural ingredients and may not contain nonorganic feed additives or supplements. The agricultural portion of livestock feed labeled as "organic" must contain only organically produced raw and processed agricultural ingredients and may contain feed additives and supplements in conformance with the requirements of section 205.237. Additionally, labeling of livestock feed containers must follow State livestock feed labeling laws.

## **Prohibited Practices**

The labeling of whole products or ingredients as organic is prohibited if those products or ingredients are produced using any of the following production or handling practices: (1) ingredients or processing aids produced using excluded methods; (2) ingredients that have been produced using applications of sewage sludge; (3) ingredients that have been processed with ionizing radiation; (4) synthetic substances not on the National List; (5) sulfites, nitrates, or nitrites added to or used in processing of an organic product in addition to those substances occurring naturally in a commodity (except the use of sulfites in the production of wine); (6) use of the phrase, "organic when available," or similar statement on labels or in market information when referring to products composed of nonorganic ingredients used in place of specified organic ingredients; and (7) labeling as "organic" any product containing both organic and nonorganic forms of an ingredient specified as "organic" on the label.

These seven prohibitions apply to the four labeling categories of products and are not individually repeated as prohibited practices in the following sections. Table 1, Prohibited Production and Handling Practices for Organic Labeling, shows how use of the seven prohibited practices affects the labeling of organically produced products and ingredients used in those products.

## **TABLE 1: PROHIBITED PRODUCTION AND HANDLING PRACTICES FOR LABELING CATEGORIES**

Organic and use label	Use excluded methods	Use sewage sludge	Use ionizing radiation	Use substances not on National List	Contain added sulfites, nitrates, nitrites	Use nonorganic ingredients and label "when available"	Use both organic and nonorganic forms of same ingredient
<b>"100 percent organic"</b> Single/multiingredients completely organic	NO	NO	NO	NO	NO	NO	NO
<b>"Organic"</b>							
Organic ingredients (95% or more)	NO	NO	NO	NO	NO	NO	NO
Nonorganic ingredients (5% or less)	NO	NO	NO	NO	NO	NO	NO
<b>"Made with organic ingredients"</b>							
Organic ingredients (70-95%)	NO	NO	NO	NO	NO-except wine	NO	NO
Nonorganic ingredients (30% or less)	NO	NO	NO	OK	OK	NA*	NA*
<b>Less-than 70% organic ingredients</b>							
Organic Ingredients (30% or less)	NO	NO	NO	NO	NO-except wine	NO	NO
Nonorganic Ingredients (70% or more)	OK	OK	OK	OK	OK	NA*	NA*

\* Not applicable, provided that the nonorganic ingredient is not labeled as "organic" on the ingredient statement and is not counted in the calculation of the product's organic percentage.



## **Calculating the Percentage of Organic Ingredients**

Section 205.302 specifies procedures for calculating the percentage, by weight or fluid volume, of organically produced ingredients in an agricultural product labeled or represented as "organic." The calculation is made by the handler at the time the finished product is assembled.

The organic percentage of liquid products and liquid ingredients is determined based on the fluid volume of the product and ingredients (excluding water and salt). When a product is identified on the pdp or the information panel as being reconstituted with water from a concentrate, the organic content is calculated on the basis of a single-strength concentration.

For products that contain organically produced dry and liquid ingredients, the percentage of total organic ingredients is based on the combined weight of the dry organic ingredient(s) and the weight of the liquid organic ingredient(s) (excluding water and salt). For example, a product may be made using organically produced vegetable oils or grain oils or contain organic liquid flavoring extracts in addition to other organic and nonorganic ingredients. In such cases, the weight of the liquid organic oils or flavoring extracts, less any added water and salt, would be added to other solid organic ingredients in the product, and their combined weight would be the basis for calculating the percentage of organic ingredients.

At the discretion of the handler, the total percentage of all organic ingredients in a food product may be displayed on any package panel of the product with the phrase, "contains X percent organic ingredients," or a similar phrase. If the total percentage is a fraction, it must be rounded down to the nearest whole number. The percentage of each organic ingredient is not required to be displayed in the ingredient statement.

A certified operation that produces organic product may contract with another operation to repackage and/or relabel the product in consumer packages. In such cases, the repacker or relabeler may use information provided by the certified operation to determine the percentage of organic ingredients and properly label the organic product package consistent with the requirements of this subpart.

## **Labeling "100 Percent Organic" and "Organic" Products**

Section 205.303 includes optional, required, and prohibited practices for labeling agricultural products that are "100 percent organic" or "organic." Products that are composed of wholly organic ingredients may be identified with the label statement, "100 percent organic," on any package panel. Products composed of between 95 and 100 percent organic ingredients may be identified with the label statement "organic" on any package panel, and the handler must identify each organic ingredient in the ingredient statement.

The handler may display the following information on the pdp, the information panel, and any other part of the package and in market information representing the product: (1) the term, "100 percent organic" or "organic," as applicable to the content of the product; and (2) for products labeled "organic," the percentage of organic ingredients in the product. The size of the percentage statement must not exceed one-half the size of the largest type size on the panel on which the statement is displayed. It also must appear in its entirety in the same type size, style, and color without highlighting; (3) the USDA seal; and (4) the seal, logo, or other identifying mark of the certifying agent (hereafter referred to as "seal or logo") which certified the handler of the finished product. The seals or logos of other certifying agents which certified organic raw materials or organic ingredients used in the product also may be displayed, at the discretion of the finished product handler. If multiple organic ingredients are identified on the ingredient

statement, the handler of the finished product that combined the various organic ingredients must maintain documentation, pursuant to subpart B of this regulation.

While certifying agent identifications can appear on the package with the USDA seal, they may not appear larger than the USDA seal on the package. There is no restriction on the size of the USDA seal as it may appear on any panel of a packaged product, provided that display of the Seal conforms with the labeling requirements of FDA and FSIS.

If a product is labeled as "100 percent organic" the ingredients may be identified with the term, "organic," but will not have to be so labeled because it is assumed from the 100 percent label that all ingredients are organic. For 95 percent-plus products, each organically produced ingredient listed in the ingredient statement must be identified with the term, "organic," or an asterisk or other mark to indicate that the ingredient is organically produced. Water and salt cannot be identified as "organic" in the ingredient statement.

The handler of these products also must display on the information panel the name of the certifying agent which certified the handling operation that produced the finished product. The handler may include the business address, Internet address, or telephone number of the certifying agent. This information must be placed below or otherwise near the manufacturer or distributor's name.

### **Labeling Products "Made with Organic (specified ingredients or food group(s))"**

With regard to agricultural products "made with..."--those products containing between 70 and 95 percent organic ingredients--this rule establishes, in section 205.304, the following optional, required, and prohibited labeling practices.

Under optional practices, the "made with..." statement is used to identify the organically produced ingredients in the product. The statement may be placed on the pdp and other panels of the package. The same statement can also be used in market information representing the product. However, the following restrictions are placed on the statement: (1) the statement may list up to three ingredients or food group commodities that are in the product; (2) the individually specified ingredients and all ingredients in a labeled food group must be organically produced and must be identified as "organic" in the ingredient statement on the package's information panel; (3) the statement cannot appear in print that is larger than one half (50 percent) of the size of the largest print or type appearing on the pdp; and (4) The statement and optional display of the product's organic percentage must appear in their entirety in the same type size, style, and color without highlighting.

The following food groups can be specified in the "made with" labeling statement: fish, fruits, grains, herbs, meats, nuts, oils, poultry, seeds, spices, sweeteners, and vegetables. In addition, organically produced and processed butter, cheeses, yogurt, milk, sour cream, etc., may be identified as a "milk products" food group. For the purposes of this labeling, tomatoes are considered as vegetables, based on their use in a product. As noted immediately above, all of a product's ingredients that are in the specified food group(s) must be organically produced.

Display of the "made with..." statement on other panels must be similarly consistent with the size of print used on those panels. These restrictions are in accordance with FDA labeling requirements and similar to the recommendations of the National Organic Standards Board (NOSB). This provision helps assure that the "made with..." statement is not displayed in such a manner as to misrepresent the actual organic composition of the product.

The USDA seal may not be displayed on the pdp of products labeled "made with organic ingredients." However, at the handler's option and consistent with any contract agreement

between the organic producer or handler and the certifying agent, the certifying agent's seal or logo may be displayed on the pdp and other package panels.

Packages of "made with..." products may display on the pdp, information panel, or any package panel, the total percentage of organic ingredients in the product. Any organically produced ingredient, including any ingredient that is a member of a food group listed on the "made with..." statement, must be identified in the ingredient statement with the term, "organic." Alternatively, an asterisk or other mark may be placed beside each organically produced ingredient in the ingredients statement with an explanation that the mark indicates the ingredient is organically produced.

The name of the certifying agent which certified the handler of the finished product must be displayed below or otherwise near the manufacturer or distributor's name. The statement may include the phrase, "Certified organic by..." or "Ingredients certified as organically produced by...." to help distinguish the certifying agent from the manufacturer or distributor. The handler may include the business address, Internet address, or telephone number of the certifying agent which certified the handler of the finished product.

If the percentage of organic ingredients in the product is displayed, the handler who affixes the label to the product package is responsible for determining the percentage. The handler may use information provided by the certified operation in determining the percentage. As part of the certifying agent's annual certification of the handler, the certifier must verify the calculation and labeling of packages.

### **Labeling Products with Less Than 70 Percent Organic Ingredients**

Section 205.305 covers the final labeling category of packaged multiingredient agricultural products containing less than 70 percent organic ingredients.

Handlers of "less than 70 percent" multiingredient products, who choose to declare the organic nature of their product, may do so only in the ingredient statement by identifying the organically produced ingredients with the term, "organic," or with an asterisk or other mark. If the handler identifies the ingredients that are organically produced, the handler also may declare the percentage of organic content in the product. The percentage may only be placed on the information panel so that it can be viewed in relation to the ingredient statement.

Processed products composed of less than 70 percent organic content cannot display the USDA seal or any certifying agent's organic certification seal or logo anywhere on the product package or in market information.

Handlers of such products are subject to this regulation in the following ways. Those handlers who only purchase organic and nonorganic ingredients and assemble a finished product of less than 70 percent organic content do not have to be certified as organic handlers. However, they are responsible for appropriate handling and storage of the organic ingredients (section 205.101(a)(3)) and for maintaining records verifying the organic certification of the ingredients used in the product (section 205.101(c)). To the extent that the packaging process includes affixing the label to finished product package, those handlers are responsible for meeting the labeling requirements of this subpart. The nonorganic ingredients may be produced, handled, and assembled without regard to the requirements of this part.

Table 2, Labeling Consumer Product Packages, provides a summary of the required and prohibited labeling practices for the four labeling categories.

### **TABLE 2: LABELING CONSUMER PRODUCT PACKAGES**

Labeling category	Principle display panel	Information panel	Ingredient statement	Other package panels
"100 percent Organic"  (Entirely organic; whole, raw or processed product)	"100 percent organic" (optional)  USDA seal and certifying agent seal(s) (optional)	"100% organic" (optional)  Certifying agent name (required); business/Internet address, tele. # (optional)	If multiingredient product, identify each ingredient as "organic" (optional)	"100 percent organic" (optional)  USDA seal and certifying agent seal(s) (optional)
"Organic"  (95% or more organic ingredients)	"Organic" (plus product name) (optional) "X% organic" (optional) USDA seal and certifying agent seal(s) (optional)	"X % organic" (optional)  Certifying agent name (required); business/Internet address, tele. # (optional)	Identify organic ingredients as "organic" (required if other organic labeling is shown)	X% organic" (optional)  USDA seal and certifying agent seal(s) (optional)
"Made with Organic Ingredients" (70 to 95% organic ingredients)	"made with organic (ingredients or food group(s))" (optional)  "X % organic" (optional)  Certifying agent seal of final product handler (optional)  <u>Prohibited: USDA seal</u>	"X % organic ingredients" (optional)  Certifying agent name (required); business/Internet address, tele. # (optional)  <u>Prohibited: USDA seal</u>	Identify organic ingredients as "organic" (required if other organic labeling is shown)	"made with organic (ingredients or food group(s))" (optional)  "X % organic" (optional)  Certifying agent seal of final product handler (optional)  <u>Prohibited: USDA seal</u>
Less-than 70% organic ingredients	<u>Prohibited: Any reference to organic content of product</u>  <u>Prohibited: USDA seal &amp; certifying agent seal</u>	"X % organic" (optional)  <u>Prohibited: USDA seal &amp; certifying agent seal</u>	Identify organic ingredients as "organic" (optional) (required if % organic is displayed)	<u>Prohibited: USDA seal &amp; certifying agent seal</u>

Misrepresentation in Labeling of Organic Products. The labeling requirements of this final rule are

intended to assure that the term, "organic," and other similar terms or phrases are not used on a product package or in marketing information in a way that misleads consumers as to the contents of the package. Thus, we intend to monitor the use of the term, "organic," and other similar terms and phrases. If terms or phrases are used on product packages to represent "organic" when the products are not produced to the requirements of this regulation, we will proceed to restrict their use.

Handlers may not qualify or modify the term, "organic," using adjectives such as, "pure" or "healthy," e.g., "pure organic beef" or "healthy organic celery." The term, "organic," is used in labeling to indicate a certified system of agricultural production and handling. Terms such as "pure," "healthy," and other similar adjectives attribute hygienic, compositional, or nutritional characteristics to products. Use of such adjectives may misrepresent products produced under the organic system of agriculture as having special qualities as a result of being produced under the organic system. Furthermore, use of such adjectives would incorrectly imply that products labeled in this manner are different from other organic products that are not so labeled.

Moreover, "pure," "healthy," and other similar terms are regulated by FDA and FSIS. These terms may be used only in accordance with the labeling requirements of FDA and FSIS. The prohibition on use of these terms to modify "organic" does not otherwise preclude their use in other labeling statements as long as such statements are in accordance with other applicable regulations. Representations made in market information for organic products are also subject to the requirements and restrictions of other Federal statutes and applicable regulations, including the Federal Trade Commission Act, 15 U.S.C. 45 et seq.

### **Labeling Organically Produced Livestock Feed Products**

New section 205.306 is added to provide for labeling of the two categories of livestock feed that are organically produced under this regulation. Feed labeled "100 percent organic" may contain only organically produced agricultural product. Such feed must not contain feed additives, supplements, or synthetic substances. Feed labeled "organic" must contain only organically produced agricultural products and may contain feed additives and supplements in accordance with section 205.237, Livestock Feed, and section 205.603 of the National List. This rule does not limit the percentage of such additives and supplements in organic feed products, which may be required under various State laws.

Livestock feed labeled "100 percent organic" and "organic" may, at the handler's option, display the USDA seal and the seal or logo of the certifying agent. The organic ingredients listed on the ingredient statement may be identified with the word, "organic," or other reference mark. The name of the certifying agent must be displayed on the information panel. The business address, Internet address, and other contact information for the certifying agent may be displayed. These are the only labeling options to indicate that livestock feed that is organically produced.

### **Labeling of Products Shipped in International Markets**

Domestically produced organic products intended for export may be labeled to meet the requirements of the country of destination or any labeling requirements specified by a particular foreign buyer. For instance, a product label may require a statement that the product has been certified to, or meets, certain European Union (EU) organic standards. Such factual statements regarding the organic nature of the product are permitted. However, those packages must be exported and cannot be sold in the United States with such a statement on the label because the statement indicates certification to standards other than are required under this program. As a safeguard for this requirement, we require that shipping containers and bills of lading for such exported products display the statement, "for export only," in bold letters. Handlers also are expected to maintain records, such as bills of lading and U.S. Customs Service documentation,

showing export of the products. Only products which have been certified and labeled in accordance with the requirements of the NOP may be shipped to international markets without marking the shipping containers "for export only."

Organically produced products imported into the United States must be labeled in accordance with the requirements of this subpart. Labeling and market representation of the product cannot imply that the product is also certified to other organic standards or requirements that differ from this national program.

### **Labeling Nonretail Containers**

Section 205.307 provides for labeling nonretail containers used to ship or store raw or processed organic agricultural products that are labeled "100 percent organic," "organic," and "made with organic..." Labeling nonretail containers as containing organically produced product should provide for easy identification of the product to help prevent commingling with nonorganic product or handling of the product which would destroy the organic nature of the product (fumigation, etc.). These labeling provisions are not intended for shipping or storage containers that also are used in displays at the point of retail sale. Retail containers must meet labeling provisions specified in section 205.307.

Containers used only for shipping and storage of any organic product labeled as containing 70 percent or more organic content may, at the handler's discretion, display the following information: (1) the name and contact information of the certifying agent which certified the handler of the finished product; (2) the term, "organic," modifying the product name; (3) any special handling instructions that must be followed to maintain the organic integrity of the product; and (4) the USDA seal and the appropriate certifying agent seal. This information is available to handlers if they believe display of the information helps ensure special handling or storage practices which are consistent with organic practices.

Containers used for shipping and storage of organic product must display a production lot number if such a number is used in the processing and handling of the product. Much of this information may overlap information that the handler normally affixes to shipping and storage containers or information that is required under other Federal labeling regulations. There are no restrictions on size or display of the term, "organic," or the certifying agent seal unless required by other Federal or State statutes.

### **Labeling Products at the Point of Retail Sale**

Section 205.308 applies to organically produced "100 percent organic" and "organic" products that are not packaged prior to sale and are presented in a manner which allows the consumer to select the quantity of the product purchased.

The terms, "100 percent organic" and "organic," as applicable, may be used to modify the name of the product in retail displays, labeling, and market information. The ingredient statement of a product labeled "organic" displayed at retail sale must identify the organic ingredients. If the product is prepared in a certified facility, the retail materials may also display the USDA seal and the seal or logo of the certifying agent. If shown, the certifying agent seal must not be larger than the USDA seal.

Section 205.309 addresses "made with..." products that are not packaged prior to sale and are presented in a manner which allows the consumer to select the quantity of the product purchased. These products include, but are not limited to, multiingredient products containing between 70 and 95 percent organic ingredients. The "made with..." label may be used to modify the name of the product in retail displays, labeling, and market information. Up to three organic

ingredients or food groups may be identified in the statement. If such statement is declared in market information at the point of retail sale, the ingredient statement and market information must identify the organic ingredients. Retail display and market information of bulk products cannot display the USDA seal but may, if the product is prepared in a certified facility, display the seal or logo of the certifying agent which certified the finished product. The certifying agent's seal or logo may be displayed at the option of the retail food establishment.

Products containing less than 70 percent organic ingredients may not be identified as organic or containing organic ingredients at retail sale. The USDA seal and any certifying agent seal or logo may not be displayed for such products.

### **Labeling Products Produced in Exempt or Excluded Operations**

Section 205.310 provides limited organic labeling provisions for organic product produced or handled on exempt and excluded operations. Such operations would include retail food establishments, certain manufacturing facilities, and production and handling operations with annual organic sales of less than \$5,000. These operations are discussed more thoroughly in subpart B, Applicability.

Any such operation that is exempt or excluded from certification or which chooses not to be certified may not label its organically produced products in a way which indicates that the operation has been certified as organic. Exempt producers may market whole, raw organic product directly to consumers, for example, at a farmers market or roadside stand as "organic apples" or "organic tomatoes." Exempt producers may market their products to retail food establishments for resale to consumers. However, no terms may be used which indicate that such products are "certified" as organic. Finally, exempt organic producers cannot sell their product to a handler for use as an ingredient or for processing into an ingredient that is labeled as organic on the information panel.

These provisions are truth in labeling provisions because display of a certification seal indicates that the product has been certified. We believe this requirement helps differentiate between certified and uncertified products and helps maintain the integrity of certified products while providing organic labeling opportunities for exempt and excluded operations.

### **USDA Organic Seal**

This final rule establishes a USDA seal that can be placed on consumer packages, displayed at retail food establishments, and used in market information to show that certified organic products have been produced and handled in accordance with these regulations. The USDA seal can only be used to identify raw and processed products that are certified as organically produced. It cannot be used for products labeled as "made with organic ingredients" (70 to 95 percent organic ingredients) or on products with less than 70 percent organic ingredients.

The USDA seal is composed of an outer circle around two interior half circles with an overlay of the words "USDA Organic." When used, the USDA seal must be the same form and design as shown in figure 1 of section 205.311 of this regulation. The USDA seal must be printed legibly and conspicuously. On consumer packages, retail displays, and labeling and market information, the USDA seal should be printed on a white background in earth tones with a brown outer circle and separate interior half circles of white (upper) and green (lower). The term, "USDA," must appear in green on the white half circle. The term, "organic," must appear in white on the green half circle. The handler may print the USDA seal in black and white, using black in the place of green and brown. Size permitting, the green (or black) lower half circle may have four light lines running from left to right and disappearing at the right horizon, to resemble a cultivated field. The

choice between these two color schemes is left to the discretion of the producer, handler, or retail food establishment.

### **Labeling - Changes Based on Comments**

The following changes are made based on comments received.

(1) Use of "Organic" in Product Names. The NOSB, State organic program (SOP) managers, certifying agents, and a large number of individual commenters strongly recommended that USDA prohibit use of the term, "organic," to modify an ingredient in a product name if the ingredient, itself, is not produced organically. The examples offered were "organic chocolate ice cream" and "organic cherry sweets" in which the ice cream and candy are at least 95 percent organic but the chocolate and cherry flavoring is not organically produced.

We agree with commenters that such product names can be misleading and would be a violation of section 205.300(a). In the examples, the word, "organic," precedes the words, "chocolate" and "cherry," and clearly implies that those ingredients are organically produced. The chocolate and cherry flavorings must be organically produced to be used in this way. If the product is at least 95 percent organically produced but the flavoring is nonorganic, the word sequence must be reversed or the word, "flavored," must be added to the name; e.g., "chocolate organic ice cream" or "chocolate flavored organic ice cream." A sentence has been added to section 205.300(a) to specify that the term, "organic," may not be used in a product name to identify an ingredient that is not organically produced.

A similar comment was received asking how a single product with two separately wrapped components can be labeled if one of the components is organically produced and the other is not. The commenter's example was a carrot and dip snack pack in which the carrots are organically produced and the dip is a conventional product. Another example is ready-to-eat tossed green salad in which the salad greens are organically produced but the separately pouched salad dressing is a nonorganic component of the product.

Such products also must be labeled in accordance with section 205.300(a). It would be misleading to label the snack pack "organic carrots and dip" or "organic green salad and ranch dressing," if the dip and ranch dressing are not produced with organic ingredients. The salad may be labeled "organic green salad with ranch dressing."

Section 6519(b) of the Act provides the Secretary with the authority to take action against misuse of the term, "organic." USDA will monitor use of the term, "organic," in product names and will restrict use of the term in names that are determined to be deliberately misleading to consumers. Such determinations must be made on a case-by-cases basis.

(2) Labeling Livestock Feed. In the definition of "agricultural product," the Act includes product marketed for "livestock consumption." This means that NOP regulations have applicability to livestock feed production. The Association of American Feed Control Officials (AAFCO) and a few States departments of agriculture commented that the proposed provisions conflict with widely followed standards for livestock feed labeling. AAFCO's "Model Bill and Regulation" standards are incorporated in many State feed laws. The commenters claimed that the requirement to identify organic ingredients in the ingredient statement conflicts with feed regulations which prohibit reference to an ingredient's "quality or grade." They also claimed that the percentage of organic content requirement is a quantitative claim that must be verified by independent sources (e.g., sources other than the certifying agent). The commenters suggested that a provision be added to address labeling of commercial livestock feed.



We have added new paragraph (e) of section 205.301 which provides for two kinds of feed that can be labeled as "organic." The first is feed that contains only organically produced agricultural ingredients and contains no added nutrients or supplements. The second organic feed category also must contain only organically produced agricultural ingredients but may contain feed additives and supplements that are needed to meet the nutritional and health needs of the livestock for which the feed is intended. Feed labeled as "organic" must conform with the requirements of section 205.237, Livestock feed. That section provides that feed additives and supplements produced in conformity with section 205.603 of the National List may be used. The NOP requires that livestock under organic management must only be fed organically produced agricultural ingredients.

We also have added new section 205.306 to address commenters' labeling concerns. The new section provides for optional display of a feed's organic percentage and optional identification of the feed ingredients that are organically produced. The labeling requirements are not intended to supersede the general feed labeling requirements established in the FFDCA and those found under various State laws. Handling processes, feed formulations and recordkeeping must be sufficient to meet the requirements of applicable State regulations.

We believe the provisions in new paragraph (e) of section 205.301 on feed content and new section 205.306 on labeling will allow livestock feed producers to produce and label organic livestock feed that is in accordance with these regulations and State requirements.

(3) Organic Processing Aids. Several industry leaders and SOP managers questioned whether the proposed rule intended to exclude the use of certified organic processing aids in the creation of "100 percent organic" products. Commenters pointed out that a handler should be able to use organically produced processing aids to create products that are labeled as "100 percent organic." The processing aid can be a by-product of an organic agricultural product; e.g., a filter made of rice hulls from organically produced rice. AMS concurs. Accordingly, a change is made in paragraph (f)(4) of section 205.301 to provide for use of organically produced processing aids in products labeled "100 percent organic."

To help clarify this and correct an incomplete reference in the proposed rule preamble, we have changed the column heading of the fourth prohibited practice in the preamble table 1.

(4) Content of "100 Percent Organic Products." Certifying agents and several industry commenters called attention to the regulatory text of section 205.301(a) describing 100 percent organic products. They argued that the proposed rule would allow products with one or more 95 percent-plus "organic" ingredients to be combined as components and have the resulting product be labeled as "100 percent organic."

We did not intend to allow any ingredient that is less than 100 percent organic to be used in a product labeled "100 percent organic." To leave no doubt as to the nature of any product labeled "100 percent organic," we have changed the wording of paragraph (a) of section 205.301 to clarify that a multiingredient "100 percent organic" product must be comprised entirely of 100 percent organic ingredients.

(5) Labeling of Organic Percentage. We received many comments requesting clearer display of a product's percentage of organic content. Most suggested that any product containing less than 100 percent organic ingredients should be required to display the organic percentage on the pdp. They argued that display of the organic percentage on the front of the package would enable consumers to more easily determine organic content, compare competing products, and make better purchase decisions. The NOSB did not recommend display of organic percentage on the pdp for all products containing organic ingredients.

We also received several comments from handlers concerned that the required display of a product's organic percentage can be a burden on handlers. They stated that, to save packaging and printing costs, handlers order bulk quantities of printed packages, labels, and other printed marketing materials. When printed in advance of a growing season and harvest, the handler may not be able to assemble a product that is exactly consistent with the preprinted labeling information, particularly the percentage of organic content. One commenter representing a commodity association opposed the required percentage labeling because the association believes consumers will not understand any organic claim if a percentage of less than 100 percent is displayed.

We believe that display of the percentage of organic content is important product information that can be very helpful to consumers in their purchase decisions. We also believe that the opportunity to display the percentage content of organically produced ingredients can be a positive factor in encouraging handlers to use more organic ingredients in their multiingredient products. At the same time, we understand the financial commitment involved in preprinting bulk quantities of packages and labels well in advance of harvests, which determine availability of needed ingredients.

This final rule implements changes in sections 205.303 and 205.304 for products labeled "organic" and "made with organic ingredients." The requirement to display the percentage of organic content on the information panel is removed. That requirement is replaced with optional labeling of the product's organic percentage on the pdp or any other package panels. This will allow those handlers to display the percentage of their product's organically produced contents on the pdp where it will be most immediately visible to consumers. Handlers who cannot, with certainty, display their product's organic percentage or who choose not to display the percentage, are not required to do so.

This revised labeling provision also removes the requirement in section 205.305 that products with less than 70 percent organic content display the product's organic percentage on the information panel. Under this final rule, that percentage labeling is optional but is still restricted to the information panel. The percentage of a less than 70 percent organic product may not be displayed on the pdp and may not be displayed if the organic ingredients are not identified in the ingredient statement.

(6) Designation of Organically Produced Ingredients. A certifying agent suggested that identification of organic ingredients in ingredient statements should be allowed to be made with an asterisk or similar mark, with the asterisk defined on the information panel. The commenter stated that the repetitive use of the word, "organic," may cause space problems on some small packages and that use of a mark is a common industry practice. We agree with the comment and have changed sections 205.303(b)(1), 205.304(b)(1), and 205.305(a)(i) of the regulatory text accordingly. Thus, organic ingredients may be identified in the ingredient statement with either the term, "organic," or an asterisk or other mark, provided that the asterisk or other mark is defined on the information panel adjacent to the ingredient statement.

(7) Minimum Organic Percentage for Labeling. In the proposed rule's preamble, we asked for public comment on whether the 50 percent minimum organic content for pdp labeling should be increased. The 50 percent minimum content was established in section 6505(c) of the Act. However, the Act also provides the Secretary with the authority to require such other terms and conditions as are necessary to implement the program. Thus, the minimum organic content level for pdp labeling could be changed if the change would further the purposes of the Act.

Comments to the first (1997) proposal and to the revised proposed rule suggested that the minimum organic content for labeling purposes should be increased. All comments received, including comments from certifying agents, a leading organic association, the EU and other international commenters recommended that the minimum organic content to qualify for pdp

labeling should be raised to 70 percent, which is the EU's minimum. All comments stated that the increase is necessary to make the NOP standards consistent with international organic standards. Commenters also pointed to advances in organic production and processing technologies and to increases in the availability of organically produced products and processed ingredients. These factors should make it easier for handlers to assemble food products with higher organic content.

We concur with the comments. We view this as a tightening of labeling requirements in that pdp labeling now requires a higher percentage of organic ingredients and makes the U.S. standard consistent with international norms.

In the proposed rule's preamble, we also asked for specific public comment on whether a minimum percentage of total product content should be required for any single organic ingredient that is included in the pdp statement "made with organic (specified ingredients)." No commenters responded to this question. Therefore, no required minimum percentage for a single organic ingredient in "made with..." products is established.

(8) "Made With Organic (Specified Food Groups)." Several industry organizations suggested that, as an alternative to listing up to three organic ingredients in the "made with..." label, the rule should also allow for identification of food "groups" or "classes" of food in the "made with" label. Commenters suggested, for instance, that a soup (with 70 percent or more organic ingredients, less water and salt) containing organically produced potatoes, carrots, and onions may be labeled as "soup made with organic potatoes, carrots, and onions" or, alternatively, "soup made with organic vegetables."

We agree that this label option offers handlers of such multiingredient products with more flexibility in their labeling. All ingredients in the identified food group must be organically produced and must be identified in the ingredient statement as "organic." In the above example, if soup also contains conventionally produced cauliflower, only "soup made with organic potatoes, carrots, and onions" can be displayed.

We also believe that some parameters must be established as to what are considered as food groups or classes of food. For the purposes of this regulation, products from the following food groups may be labeled as "organic" in a "made with..." label: beans, fruits, grains, herbs, meats, nuts, oils, poultry, seeds, spices, and vegetables. In addition, organically produced and processed butter, cheeses, yogurt, milk, sour cream, etc. may be combined in a product and identified as "organic milk products." Organically produced and processed sugar cane, sugar beets, corn syrup, maple syrup, etc. may be used in a product and identified as "organic sweeteners."

Finally, to be consistent with the "made with..." labeling for individual ingredients, up to three food groups can be identified in the "made with..." statement. Section 205.304 is changed accordingly.

(9) Labeling Products from Exempt and Excluded Operations. A change is made in redesignated section 205.310 which provides for labeling of organic products produced by exempt and excluded operations. SOP managers and an organic handler pointed out that the preamble suggested restrictions on labeling that would prevent exempt and excluded operations from identifying their products as "organic." After review of the proposed rule, we have revised redesignated section 205.310 to more clearly specify labeling opportunities for exempt operations. The regulatory text more clearly states that such operations may not label or represent their organic products as being "certified" as organic and that such exempt and excluded operations must comply with applicable production and handling provisions of subpart C. Labeling must be consistent with the four labeling categories based on the product's organic content.

A State organic advisory board recommended that proposed section 205.309 be revised to apply to exempt and excluded operations which choose to be certified under this program. We do not believe it is necessary to provide separate regulatory text for exempt and excluded operations that are certified. An exempt operation is not precluded from organic certification, if qualified.

(10) Redesigned USDA Seal. Leading industry members, certifying agents, SOP managers, and many individual commenters opposed the proposed wording and design of the USDA seal. Comments generally stated the following points: (1) the proposed Seal wording indicates that USDA is the certifying agent rather than accredited certifiers; (2) international Organization for Standardization (ISO) Guide 61 prohibits government bodies from acting or appearing as certifying agents; and (3) The shield or badge design indicates a certification of product "quality" and assurance of safety which is inconsistent with the NOP's claim to be a certification of "process" only. Commenters suggested several alternative seal statements, including: "Certified Organic - USDA Accredited," "Certified Organic - USDA Approved," "USDA Certified Organic Production," "Meets USDA Organic Production Requirements."

Based on comments received, we are implementing a revised USDA seal which is shown in the regulatory text under section 301.311. It is a circular design with the words, "USDA Organic." The color scheme is a white background, brown outer circle, white and green inner semicircles, and green and white words. A black and white color scheme also may be used if preferred by the handler.

Some commenters suggested changing the shape of the USDA seal to a circle or triangle which, they state, is more in keeping with recognized recycling and sustainability logos. We did not choose a triangle design because processors have commented that triangle designs may cause tears in shrink wrap coverings at the points of the triangle.

### **Labeling - Changes Requested But Not Made**

(1) "Organic" in Company Names. Many commenters stated that the term, "organic," must not be used as part of a company name if the company does not market organically produced foods. They are concerned that the term in a company name would incorrectly imply that the product, itself, is organically produced.

While we understand commenter concerns, we do not know the extent of the problem. We do not believe those concerns require such a prohibition in the regulations at this time. These regulations may not be the best mechanism to address the issue. Section 6519(b) of the Act provides the Secretary with the authority to take action against misuse of the term, "organic." USDA will monitor use of the term, "organic," in company names and will work with the FTC to take action against such misuse of the term. These determinations must be made on a case-by-case basis. The proposed rule did not specifically address this issue. We have added a sentence to paragraph (a) of section 205.300 to this effect.

(2) The "100 Percent Organic" Label. A large number of commenters opposed the "100 percent organic" label for different reasons. A few claimed that the label is not authorized under the Act. Several commenters suggested that consumers will not understand the difference between multiingredient products labeled "100 percent organic" and "organic." Others raised the concern that the "100 percent organic" phrase to modify raw, fresh fruits and vegetables in produce sections and farmers markets may be confusing to consumers.

Regarding the first comment, the term is not specifically provided for in the Act. However, the Secretary has the authority under section 6506(a)(11) to require other terms and conditions as may be necessary to develop a national organic program. When a product is wholly organic, pursuant to the production and handling requirements of the NOP, we believe the handler should

have the option to differentiate it from products which, by necessity, are less than 100 percent organic. We believe the label meets the purposes of the Act.

Regarding consumer confusion, we believe consumers will understand the difference between the two kinds of organic products and will make their organic purchases accordingly.

Regarding the labeling of raw, fresh product as "100 percent organic," organically produced products can be labeled to a lower labeling category. Raw, fresh fruits and vegetables which qualify for a "100 percent organic" label may be labeled simply as "organic," if the producer or retail operator believes that label is best for marketing purposes.

(3) Explain Why Product Is Not 100 Percent Organic. A large number of commenters also suggested any "product that is less than 100 percent organic should carry that information on the main display panel..." By "that information," we assume the commenters are referring to the reasons why a product cannot be certified as "100 percent organic."

AMS believes such a labeling requirement is impractical. Products may fail to qualify for a "100 percent organic" label for very technical, or little understood, reasons. Contemporary food processing often uses ingredients, processing technologies, and product formulations that are complicated, technical, and probably not of interest to the general organic consumer. Such information is not required on nonorganically produced products for the simple reason that it is not considered useful to consumers. Explanations of the different processing technologies used in food products would be cumbersome and would interfere with other product labeling.

We believe the optional display of the organic percentage and required identification of organic ingredients on the information panel provides sufficient information for consumers to make purchase decisions. Other descriptive information regarding processing substances and procedures may, of course, be provided at the handler's option and placed in accordance with other Federal labeling requirements.

(4) Check the Appropriate Organic Category. One commenter suggested that packages of organically produced product display a small box listing the four organic label categories and a check mark beside the category which fits the product.

We understand the simplicity and comparative nature of such a standardized organic label that allows easy comparison of similar products. However, we believe that the optional display of the product's organic percentage and required identification of organic ingredients will be more helpful to consumers and makes the grid box redundant.

(5) Nonorganic Ingredients in Organic Products. A large number of comments were received on the composition and use of nonorganic ingredients in products labeled "made with..." and on conventional products with less than 50 (now 70) percent organic ingredients. Several industry commenters suggested that nonorganic ingredients in "made with..." products must be "natural" (nonsynthetic agricultural substances) and not be artificially produced. Commenters argued that all ingredients in "made with..." and less than 70 percent products should be produced in accordance with the prohibited practices under sections 205.105 and 205.301(f). A significant number of commenters opposed identification of organic ingredients in what they called "natural food" products.

First, we do not agree that the nonorganic ingredients in "made with..." products must be restricted to only "natural" products. Such restrictions on the composition of nonorganic ingredients would significantly reduce handlers' options in producing those products and, thus, reduce consumers' options in purchasing products with organic ingredients.

Regarding prohibited practices, this rule implements the strong industry and consumer demand that the prohibited practices found under section 205.105 (excluded methods, irradiation, and sewage sludge) not be used in nonorganic ingredients in "made with..." products. However, we do not believe that restrictions on use of the other prohibited practices, found in section 205.301(f), would further the purposes of the Act. Application of all prohibited practices on the nonorganic ingredients in the "made with..." and less-than 70 percent organic products would essentially require that those products be organically produced. The Act allows for products that are not wholly organic. We believe the "made with..." label and the labeling restrictions on the less-than 70 percent organic products clearly states to consumers that only some of the ingredients in those products are organically produced.

If accepted, these comments would unnecessarily restrict a handler's ability to truthfully represent and market a conventionally produced agricultural product with some organic ingredients. A handler should not be prohibited from making a truthful claim about some ingredients in a less than 70 percent organic product.

(6) Alternative "Made With..." Labels. A few SOP managers commented that the phrase, "made with...", is confusing. They stated that many processed foods contain at least 50 percent organic ingredients but do not make an organic claim on the pdp. They believe the label would be less confusing if it stated a minimum organic percentage rather than identifying the organic ingredients. They suggest the labeling category be changed to "contains at least 50 percent organic ingredients (or, as revised in this rule, "contains at least 70 percent organic ingredients").

We disagree. Identification of up to three organically produced ingredients or food groups on the pdp gives consumers useful, specific information about the product's organic ingredients. This label, combined with the optional display of the percentage content on the pdp and required identification of organic ingredients, should provide enough information for consumers to make good decisions.

A few commenters contended that the statement "made with organic (specified ingredients)" is unclear and "open ended" and that consumers may assume the entire product is organically produced. The "made with..." labeling claim refers only to the organic ingredients and not to the whole product. We do not believe that consumers will be confused by the label. (7) Use of Other Terms as Synonymous for "Organic". A few commenters representing international organic standards suggested that use of the terms, "biologic" and "ecologic," which are synonymous with "organic" in other countries, should be allowed under the NOP. Commenters claimed these terms are approved by Codex and their inclusion in this regulation would facilitate international trade and equivalency agreements.

These terms were addressed in the proposed rule and are not accepted. Under the NOP, these terms may be used as eco-labels on a product package but may not be used in place of the term, "organic." Although such terms may be considered synonymous with "organic" in other countries, they are not widely used or understood in this country. We believe their use as synonymous for "organic" would only lend to consumer confusion. Regarding the Codex labeling standard, we point out that Codex also provides that terms commonly used in a country may be used in place of "biologic" and "ecologic." Thus, the use of "organic" in the United States is consistent with Codex standards.

With regard to the commenters' claim that the alternate labels would facilitate international trade, this regulation allows alternative labeling of products which are being shipped to international markets. Thus, a certified organic operation in the United States may produce a product to meet contracted organic requirements of a foreign buyer, label the product as "biologic" or "ecologic" on the pdp consistent with the market preferences of the receiving country, and ship the product to the foreign buyer.

Other terms were suggested by commenters as alternatives to the term, "organic," including "grown by age-old, natural methods," "grown without chemical input," and "residue Free." These phrases may be consumer friendly but clearly do not convey the extensive and complex nature of contemporary organic agriculture. These phrases may be used as additional, eco-labels, provided they are truthful labeling statements. They are not permitted as replacements for the term, "organic."

(8) Reconstituted Organic Concentrates. A certifying agent objected to paragraph (a)(2) of section 205.302, which allows labeling of an organically produced concentrate ingredient which is reconstituted with water during assembly of the processed product. The commenter claimed that this provision gives consumers the message that reconstituted juice is equivalent to fresh juice when, the commenter claims, it is not the same.

AMS disagrees. This labeling is consistent with current industry practices. The Act does not prohibit such labeling of concentrates. We believe it is in the interest of the program to allow labeling of organically produced concentrates, provided that the process to produce the concentrate and the reconstitution process is consistent with organic principles and the National List.

(9) Calculating Reconstituted Versus Dehydrated Weight. Several comments were received regarding specific problems encountered in the calculation of the percentage of organic content as provided under section 295.302. A handler claimed the reconstituted weight of an organically produced spice should be counted in the percentage calculation rather than the dehydrated weight of the spice used in the formulation. A similar comment was received from a food cooperative suggesting that, if an organically produced concentrate (in powdered form) is added to the same organically produced ingredient in its organic liquid form (not from concentrate), then the product's organic percentage should be calculated based on the concentrate's single-strength reconstituted weight plus the weight of the natural organic liquid.

AMS disagrees with these comments. This regulation provides for an ingredient's weight to be calculated, excluding added water and salt. If an organically produced spice is added to a product in its natural form, the weight of the spice is calculated. If the spice ingredient is in dehydrated, powdered form when added in the product formulation, the dehydrated weight of the spice must be the basis for its percentage of content calculation. If an organically produced dehydrated spice is reconstituted with water prior to product assembly, the spice must still be calculated at its dehydrated weight because percentage calculations are based on the ingredient weight, excluding water and salt. It would be misleading to calculate the weight of the concentrate ingredient in its reconstituted form.

Likewise, if a powdered ingredient is added to the same organically produced ingredient in its natural, liquid form, the weight of the powdered ingredient must be used. Using the reconstituted weight of the powdered ingredient would increase the percentage of the ingredient above the actual weight of the ingredient in the product. We believe that if the comment were accepted, the handler would be able to use less natural organic liquid than the organic percentage and ingredient statement indicates.

(10) Calculate Organic Percentage in Tenths of a Percent. A trade organization suggested that the organic percentage be rounded to tenths of one percent to accommodate products that may contain a minor ingredient or additive that comprises less than 1 percent of the product. The example provided was Vitamin D in milk. The comment suggested that it is misleading to consumers to suggest that 1 percent of a milk product is nonorganic when the Vitamin D additive may be comprise only a few tenths of one percent of the product.

AMS disagrees. Rounding down the percentage to a whole number is sufficient for consumer information and does not misrepresent the product's organic content. A handler may add a qualifying statement regarding the minor ingredient's weight in relation to the whole product weight.

(11) Verifying Calculations. A State department of agriculture comment suggested that the paragraph (c) of section 205.302 be revised slightly to provide that percentage calculations must be verified "to the satisfaction" of the certifying agent. The commenter believes that the suggested language allows the handler the flexibility to determine the number calculations that need to be checked in order to verify that the organic percentage calculation is correct.

We do not believe the suggested change is necessary. We assume that any use of a certifying agent's seal on a product means that the certifying agent has checked and approves of the method of calculating the product's organic percentage. If the calculations are not to the certifying agent's satisfaction, the agent would not certify the handling process.

While we appreciate the point made by the commenter, we do not believe the suggested change means what the commenter intends. Paragraph (c) of section 205.302 does not specify the number and methods of calculations that need to be carried out by a certifying agent because that will depend on the handling process being certified and the ingredients in the product. We leave that to the discretion of the certifying agent. Also, the basis for a product's organic percentage calculation should be clarified in the organic plan. It is assumed that the certifying agent will either be satisfied that the methodology for calculating organic percentage is correct or the methodology will be changed.

(12) Labeling Nonretail Shipping Containers. A few State departments of agriculture commented that shipping and storage containers with organic products should be required to be labeled as containing organic product. Other commenters recommended that shipping containers be required to display the name of the grower and the certifying agent. They cite these requirements as current industry practice.

This regulation does not require organic labeling on shipping and storage containers because those containers are not used in the marketplace. The only information required by the NOP is the production lot number of the product, if a lot number exists for the particular product. Product content and shipper information may be displayed, as required by other Federal or State regulations or at the discretion of the handler. Proper identification of the organic nature of a product with special instructions for shipment or storage could prevent exposure to prohibited substances that would lead to subsequent loss of the shipment as an organic product.

(13) Disclaimers on Organic Products. Several commenters complained that consumers are misled by the organic labeling and the NOP. They claimed that when science-based technologies (genetic engineering, irradiation, chlorination, etc.) are not used on products, the food is less safe than conventionally produced foods. Some of the commenters suggested that a disclaimer regarding food safety and nutritional value be required on packages with organic labeling.

AMS disagrees. The USDA seal indicates only that the product has been certified to a certain production and/or handling "process" or "system." The seal does not convey a message of food safety or more nutritional value. The NOP prohibitions on use of excluded methods, ionizing radiation, sewage sludge, and some substances and materials are not intended to imply that conventionally produced products made by those methods or containing those prohibited substances are less safe or nutritious than organically produced products. We do not believe that organic food packages or labeling should carry disclaimers of what the USDA seal or a certifying agent's seal does not represent. Other Federal and State seals and marketing claims are placed on consumer products, including food products, without disclaimers regarding those seals and



claims. A disclaimer displayed in relation to USDA seal or a certifying agent's seal would confuse consumers. Finally, disclaimer statements also would present space problems on small product packages.

## **Labeling - Clarifications**

Clarification is given on the following issues raised by commenters:

(1) Certification Is to an Organic Process, Not Organic Product. Several commenters suggested that the final rule more clearly state that the NOP provides for certification of an organic process or system of agriculture and not certification of products, themselves, as "organic." They stated that the phrase "...contain or be created using..." in paragraphs (a), (b), and (c) of section 205.301 implies certification of the product's content and not to the processed-based, organic system of agriculture.

We agree and have revised the wording in those paragraphs to clarify that such products must be organically produced in accordance with organic production and handling requirement of this regulation.

(2) Phasing Out Use of Old Labels and Packages. Citing FDA regulations, the NOSB, certifying agents, and some State agencies suggested a minimum 18-month period for handlers to use up their current supplies of packages and labels before complying with the new labeling requirements.

This rule provides for an interim period of 18 months between publication of the final rule and the implementation date of the program. Publication of this final rule serves notice to certified producers and handlers that they should begin planning for phasing out use of labels that are not in accordance with these requirements.

The implementation process is discussed in Applicability, subpart B. An organic operation will automatically be certified under this program when its certifying agent is accredited by AMS. At that time, the operation may begin following these labeling requirements but may not display the new USDA seal until the implementation date. AMS assumes that certifying agents and their client certified operations will maintain frequent contact as to the status of the agent's application for accreditation so that the certified operation may schedule the phasing out of old labels and purchase of new labels and packages. AMS expects to accredit all currently operating certifying agents by the implementation date of this regulation. Stick-on labels to comply with the new requirements are acceptable.

Newly established organic operations certified for the first time must immediately begin using labels in accordance with this program.

(3) Labeling of Products With Minor Ingredients. Several commenters questioned how the minor ingredients (spices, flavors, colorings, preservatives, oils, vitamins, minerals, accessory nutrients, processing aids, and incidental food additives) needed for formulation or processing of many multiingredient products will be treated under the "100 percent organic" and "organic" labeling categories. Because minor ingredients may not exist or are difficult to obtain in organic form, their use in a product can affect the labeling of the product, even though the percentage of the ingredient is extremely small compared to the rest of the product's ingredients.

Minor ingredients and processing aids must be treated as any other ingredient or substance which is used as an ingredient in or in the processing of an organically produced product. To be added as an ingredient or used in the processing of a product labeled "100 percent organic," a minor ingredient must be extracted from a certified organic source without the use of chemicals or

solvents. To be added as an ingredient or used in the processing of a product labeled "organic," a minor ingredient must be from an organic agricultural source, if commercially available. If not commercially available, the ingredient must be an agricultural product or a substance consistent with the National List.

(4) Reusing Containers. A commenter complained that small producers should not be subjected to costly packaging and labeling requirements when their products are sold directly to the public at farmers markets and roadside stands. The commenter requested that small producers be able to reuse retail boxes and labels. The commenter did not specify which labeling provisions presented burdensome costs on small entities.

We agree that costs for exempt operations, indeed all organic operations, should be kept to a minimum. NOP does not prohibit reuse of containers provided their labeling does not misrepresent product and does not allow organic product to come into contact with prohibited substances from the container's previous contents.

(5) Clarifying Prohibited Labeling Practices. Commenters identified a few inconsistencies between the preamble and regulatory text regarding the seven prohibited production and processing practices now specified in section 205.301(f). We have made the following changes to clarify the intent of the regulation.

A commenter correctly pointed out that the regulatory text of paragraph (f) incorrectly refers only to ingredients that cannot be produced using the seven prohibited production and handling practices listed in the paragraph. That text is not consistent with the preamble, which correctly states that whole products, as well as ingredients, labeled as "organic" cannot be produced or processed using the seven prohibited practices. The term, "whole products," is added to the introductory sentence of new section 205.301(f).

A few commenters pointed out that all seven practices are prohibited in the production of nonorganic ingredients used in products labeled as "organic." The second sentence of proposed paragraph (b) of section 205.301 (products labeled "organic") incorrectly listed only the first three prohibited practices. A phrase is added to the introductory sentence of new paragraph (f) to specify that the 5 percent or less of nonorganic ingredients in products labeled as "organic" may not be produced or handled using any of the seven prohibited practices.

Finally, with the addition of the commercial availability requirement in section 205.201, a conforming change is needed in section 205.301(f)(6) regarding use of nonorganic ingredients when organically produced ingredients are available.

(6) Consistency with State Labeling Requirements. One State organic association commented that the State's law requires identification of the certifying agent if the term, "certified organic," appears on the label. The comment was not clear about where on the package the certifier must be identified; e.g., with the "certified organic" term on the pdp or anywhere on the package. The commenter did not specifically suggest changing the labeling provisions to include the certifying agent on the pdp.

This regulation allows a handler the option of displaying the certifying agent's seal or logo on the pdp for products with 70 percent or more organically produced ingredients. This regulation also requires identification of the certifying agent on the information panel of all products containing 70 percent or more organically produced ingredients. The identification must include an address or contact information and be placed adjacent to identification of the manufacturer, required by FDA. We believe these provisions are sufficient to meet the State's labeling requirements. The NOP will be available to consult with States regarding alternative labeling required to be used in the State.

(7) Clarifying Labeling of Products in Other Than Packaged Form. We have modified sections 205.308 and 205.309 to clarify that products in other than packaged form at the point of retail sale that are prepared by an exempt or excluded operation may be labeled as "100 percent organic," "organic," or "made with..." as appropriate. Consistent with the general restrictions on the labeling of products from such operations, which are found in section 205.310, such products may not display the USDA seal or any certifying agent's seal or other identifying mark or otherwise be represented as a certified organic product.

## Certification -- Preamble

### Subpart E - Certification

This subpart sets forth the requirements for a national program to certify production and handling operations as certified organic production or handling operations. This certification process will be carried out by accredited certifying agents.

### Description of Regulations

#### General Requirements

Production and handling operations seeking to receive or maintain organic certification must comply with the Act and applicable organic production and handling regulations. Such operations must establish, implement, and annually update an organic production or handling system plan that is submitted to an accredited certifying agent. They must permit on-site inspections by the certifying agent with complete access to the production or handling operation, including noncertified production and handling areas, structures, and offices.

As discussed in subpart B, certified operations must maintain records concerning the production and handling of agricultural products that are sold, labeled, or represented as "100 percent organic," "organic," or "made with organic (specified ingredients or food group(s))" sufficient to demonstrate compliance with the Act and regulations. Records applicable to the organic operation must be maintained for not less than 5 years beyond their creation. Authorized representatives of the Secretary, the applicable State organic program's (SOP) governing State official, and the certifying agent must be allowed access to the operation's records during normal business hours. Access to the operation's records will be for the purpose of reviewing and copying the records to determine compliance with the Act and regulations.

Certified operations are required to immediately notify the certifying agent concerning any application, including drift, of a prohibited substance to any field, production unit, site, facility, livestock, or product that is part of the organic operation. They must also immediately notify the certifying agent concerning any change in a certified operation or any portion of a certified operation that may affect its compliance with the Act and regulations.

#### Certification Process

To obtain certification, a producer or handler must submit an application for certification to an accredited certifying agent. The application must contain descriptive information about the applicant's business, an organic production and handling system plan, information concerning any previous business applications for certification, and any other information necessary to determine compliance with the Act.

Applicants for certification and certified operations must submit the applicable fees charged by the certifying agent. An applicant may withdraw its application at anytime. An applicant who withdraws its application will be liable for the costs of services provided up to the time of withdrawal of the application.

The certifying agent will decide whether to accept the applicant's application for certification. A certifying agent must accept all production and handling applications that fall within its area(s) of accreditation and certify all qualified applicants to the extent of its administrative capacity to do so. In other words, a certifying agent may decline to accept an application for certification when the certifying agent is not accredited for the area to be certified or when the certifying agent lacks

the resources to perform the certification. However, the certifying agent may not decline to accept an application on the basis of race, color, national origin, gender, religion, age, disability, political beliefs, sexual orientation, or marital or family status.

Upon acceptance of an application for certification, a certifying agent will review the application to ensure completeness and to determine whether the applicant appears to comply or may be able to comply with the applicable production or handling regulations. As part of its review, the certifying agent will verify that an applicant has submitted documentation to support the correction of any noncompliances identified in a previously received notification of noncompliance or denial of certification. We anticipate that at a future date the certifying agent will also review any available U.S. Department of Agriculture (USDA) data on production and handling operations for information concerning the applicant.

We anticipate using data collected from certifying agents to establish and maintain a password-protected Internet database only available to accredited certifying agents and USDA. This database would include data on production and handling operations issued a notification of noncompliance, noncompliance correction, denial of certification, certification, proposed suspension or revocation of certification, and suspension or revocation of certification. Certifying agents would use this Internet database during their review of an application for certification. This data will not be available to the general public because much of the data would involve ongoing compliance issues inappropriate for release prior to a final determination.

After a complete review of the application, which shall be conducted within a reasonable time, the certifying agent will communicate its findings to the applicant. If the review of the application reveals that the applicant may be in compliance with the applicable production or handling regulations, the certifying agent will schedule an on-site inspection of the applicant's operation to determine whether the applicant qualifies for certification. The initial on-site inspection must be conducted within a reasonable time following a determination that the applicant appears to comply or may be able to comply with the requirements for certification. The initial inspection may be delayed for up to 6 months to comply with the requirement that the inspection be conducted when the land, facilities, and activities that demonstrate compliance or capacity to comply can be observed.

The certifying agent will conduct an initial on-site inspection of each production unit, facility, and site that produces or handles organic products and that is included in the applicant's operation. As a benchmark, certifying agents should follow auditing guidelines prescribed by the International Organization for Standardization Guide 10011-1, "Guidelines for auditing quality systems - Part 1: Auditing" (ISO Guide 10011-1).<sup>(1)</sup> The certifying agent will use the on-site inspection in determining whether to approve the request for certification and to verify the operation's compliance or capability to comply with the Act and regulations. Certifying agents will conduct on-site inspections when an authorized representative of the operation who is knowledgeable about the operation is present. An on-site inspection must also be conducted when land, facilities, and activities that demonstrate the operation's compliance with or capability to comply with the applicable production or handling regulations can be observed.

The on-site inspection must verify that the information provided to the certifying agent accurately reflects the practices used or to be used by the applicant or certified operation and that prohibited substances have not been and are not being applied to the operation. Certifying agents may use the collection and testing of soil; water; waste; plant tissue; and plant, animal, and processed products samples as tools in accomplishing this verification.

The inspector will conduct an exit interview with an authorized representative of the operation who is knowledgeable about the inspected operation to confirm the accuracy and completeness of inspection observations and information gathered during the on-site inspection. The main purpose of this exit interview is to present the inspection observations to those in charge of the

firm in such a manner so as to ensure they clearly understand the results of the inspection. The firm is not required to volunteer any information during the exit interview but would be required to respond to questions or requests for additional information. The inspector will raise and discuss during the exit interview any known issues of concern, taking into account their perceived significance. As a general rule, the inspector will not make recommendations for improvements to the operation during the exit interview. However, the certifying agent will have the discretion to decide the extent to which an inspector may discuss any compliance issue. At the time of the inspection, the inspector shall provide the operation's authorized representative with a receipt for any samples taken by the inspector. There shall be no charge to the inspector for the samples taken.

The certifying agent shall, within a reasonable time, provide the inspected operation with a copy of the on-site inspection report, as approved by the certifying agent, for any on-site inspection performed and provide the operation with a copy of the test results for any samples taken by an inspector.

### **Notification of Approval**

A certifying agent will review the on-site inspection report, the results of any analyses for substances, and any additional information provided by the applicant within a reasonable time after completion of the initial on-site inspection. The certifying agent will grant certification upon making two determinations: (1) that the applicant's operation, including its organic system plan and all procedures and activities, is in compliance with the Act and regulations and (2) that the applicant is able to conduct operations in accordance with its organic systems plan.

Upon determining the applicant's compliance and ability to comply, the agent will grant certification and issue a "certificate of organic operation." The certification may include requirements for the correction of minor noncompliances within a specified time period as a condition of continued certification. A certificate of organic operation will specify the name and address of the certified operation; the effective date of certification; the categories of organic operation, including crops, wild crops, livestock, or processed products produced by the certified operation; and the name, address, and telephone number of the certifying agent. Once certified, a production or handling operation's organic certification continues in effect until surrendered by the organic operation or suspended or revoked by the certifying agent, the SOP's governing State official, or the Administrator.

### **Denial of Certification**

Should the certifying agent determine that the applicant is not able to comply or is not in compliance with the Act, the certifying agent will issue a written notification of noncompliance to the applicant. The notification of noncompliance will describe each noncompliance, the facts on which the notification is based, and the date by which rebuttal or correction of each noncompliance must be made. Applicants who receive a notification of noncompliance may correct the noncompliances and submit, by the date specified, a description of correction and supporting documentation to the certifying agent. As an alternative, the applicant may submit a new application to another certifying agent, along with the notification of noncompliance and a description of correction of the noncompliances and supporting documentation. Applicants may also submit, by the date specified, written information to the issuing certifying agent to rebut the noncompliance described in the notification of noncompliance. When a noncompliance cannot be corrected, a notification of noncompliance and a "notification of denial of certification" may be combined in one notification.

The certifying agent will evaluate the applicant's corrective actions taken and supporting documentation submitted or the written rebuttal. If necessary, the certifying agent will conduct a

followup on-site inspection of the applicant's operation. When the corrective action or rebuttal is sufficient for the applicant to qualify for certification, the certifying agent will approve certification. When the corrective action or rebuttal is not sufficient for the applicant to qualify for certification, the certifying agent will issue the applicant a written notice of denial of certification. The certifying agent will also issue a written notice of denial of certification when an applicant fails to respond to the notification of noncompliance. The notice of denial of certification will state the reasons for denial and the applicant's right to reapply for certification, request mediation, or file an appeal.

An applicant who has received a notification of noncompliance or notice of denial of certification may apply for certification again at any time with any certifying agent. When the applicant submits a new application to a different certifying agent, the application must include, when available, a copy of the notification of noncompliance or notice of denial of certification. The application must also include a description of the actions taken, with supporting documentation, to correct the noncompliances noted in the notification of noncompliance. When a certifying agent receives such an application, the certifying agent will treat the application as a new application and begin a new application process.

A certifying agent has limited authority to deny certification without first issuing a notification of noncompliance. This authority may be exercised when the certifying agent has reason to believe that an applicant for certification has willfully made a false statement or otherwise purposefully misrepresented its operation or its compliance with the requirements for certification.

### **Continuation of Certification**

Each year, the certified operation must update its organic production or handling system plan and submit the updated information to the certifying agent and pay the certification fees to continue certification. The updated organic system plan must include a summary statement, supported by documentation, detailing deviations from, changes to, modifications to, or other amendments to the previous year's organic system plan. The updated organic system plan must also include additions to or deletions from the previous year's organic system plan, intended to be undertaken in the coming year. The certified operation must update the descriptive information about its business and other information as deemed necessary by the certifying agent to determine compliance with the Act and regulations. The certified operation must also provide an update on the correction of minor noncompliances previously identified by the certifying agent as requiring correction for continued certification.

Following receipt of the certified operation's updated information, the certifying agent will, within a reasonable time, arrange and conduct an on-site inspection of the certified operation. When it is impossible for the certifying agent to conduct the annual on-site inspection following receipt of the certified operation's annual update of information, the certifying agent may allow continuation of certification and issue an updated certificate of organic operation on the basis of the information submitted and the most recent on-site inspection conducted during the previous 12 months. However, the annual on-site inspection must be conducted within the first 6 months following the certified operation's scheduled date of annual update. As a benchmark, certifying agents should follow auditing guidelines prescribed by ISO Guide 10011-1. Upon completion of the inspection and a review of updated information, the certifying agent will determine whether the operation continues to comply with the Act and regulations. If the certifying agent determines that the operation is in compliance, certification will continue. If any of the information specified on the certificate of organic operation has changed, the certifying agent will issue an updated certificate of organic operation. If the certifying agent finds that the operation is not complying with the Act and regulations, a written notification of noncompliance will be issued as described in section 205.662.

In addition to annual inspections, a certifying agent may conduct additional on-site inspections of certified operations that produce or handle organic products to determine compliance with the Act

and regulations. The Administrator or SOP's governing State official may also require that additional inspections be performed by the certifying agent to determine compliance with the Act and regulations. Additional inspections may be announced or unannounced and would be conducted, as necessary, to obtain information needed to determine compliance with identified requirements.

Such on-site inspections would likely be precipitated by reasons to believe that the certified operation was operating in violation of one or more requirements of the Act or these regulations. The policies and procedures regarding additional inspections, including how the costs of such inspections are handled, would be the responsibility of each certifying agent. Misuse of such authority would be subject to review by USDA during its evaluation of a certifying agent for reaccreditation and at other times in response to complaints. Certified production and handling operations can file complaints with USDA at any time should they believe a certifying agent abuses its authority to perform additional inspections.

### **Certification After Suspension or Revocation of Certifying Agent's Accreditation**

When the Administrator revokes or suspends a certifying agent's accreditation, affected certified operations will need to make application for certification with another accredited certifying agent. The certification of the production or handling operation remains in effect during this transfer of the certification. The certified production or handling operation may seek certification by any qualified certifying agent accredited by the Administrator. To minimize the burden of obtaining the new certification, the Administrator will oversee transfer of the original certifying agent's file on the certified operation to the operation's new certifying agent.

Upon initiation of suspension or revocation of a certifying agent's accreditation or upon suspension or revocation of a certifying agent's accreditation, the Administrator may initiate proceedings to suspend or revoke the certification of operations certified by the certifying agent. The Administrator's decision to suspend or revoke a producer's or handler's certification in light of the loss of its certifying agent's accreditation would be made on a case-by-case basis. Actions such as fraud, bribery, or collusion by the certifying agent, which cause the Administrator to believe that the certifying agent's clients do not meet the standards of the Act or these regulations, might require the immediate initiation of procedures to suspend or revoke certification from some or all of its client base. Removal of accreditation, regardless of the reason, in no way affects the appeals rights of the certifying agent's clients. Further, a certified operation's certification will remain in effect pending the final resolution of any proceeding to suspend or revoke its certification.

A private-entity certifying agent must furnish reasonable security for the purpose of protecting the rights of operations certified by such certifying agent. This security is to ensure the performance of the certifying agent's contractual obligations. As noted elsewhere in this rule, the specific amount and type of security that must be furnished by a private certifying agent will be the subject of future rulemaking by USDA. We anticipate that the amount of the security will be tied to the number of clients served by the certifying agent and the anticipated costs of certification that may be incurred by its clients in the event that the certifying agent's accreditation is suspended or revoked. We anticipate that the security may be in the form of cash, surety bonds, or other financial instrument (such as a letter of credit) administered in a manner comparable to cash or surety bonds held under the Perishable Agricultural Commodities Act.

### **Certification - Changes Based on Comments**

This subpart differs from the proposal in several respects as follows:



(1) Access to Production and Handling Operation. We have amended section 205.400(c) by changing "noncertified areas and structures" to "noncertified production and handling areas, structures, and offices." A commenter requested that section 205.400(c) be amended to allow for access to farm-related structures only. The commenter believes that the requirements of section 205.400(c) could be interpreted as giving inspectors access to residential property. We agree with the commenter that residential privacy should be maintained. However, if a certified operation conducts business from or stores records at a residential property, the certified operation will be considered to be maintaining an office at the residential property. The records in such office shall be made accessible for review and copying. Accordingly, we have amended section 205.400(c) to further clarify which areas and structures are to be made accessible during an on-site inspection.

(2) Application for Certification. We have amended the first paragraph of section 205.401 by replacing the word, "request," each time it occurred with the word, "application." A commenter recommended that we amend the first paragraph of section 205.401 by replacing the word, "request," with "application." We have accepted the commenter's recommendation because the amendment makes the language in the first paragraph consistent with the title and the requirements of the section.

(3) Verification of Correction of Noncompliances. To make section 205.402(a)(3) consistent with section 205.401(c) we have amended the language in section 205.402(a)(3) to require that the certifying agent verify that an applicant who previously applied to another certifying agent and received a notification of denial of certification has submitted documentation to support the correction of any noncompliances identified in the notification of denial of certification. A commenter recommended that section 205.402(a)(3) be amended by inserting "or denial of certification" after the phrase, "notification of noncompliance." We have accepted the commenter's recommended amendment because it is consistent with the requirements of section 205.401(c). Section 205.401(c) requires an applicant for certification to include the name(s) of any organic certifying agent(s) to which application has previously been made, the year(s) of application, and the outcome of the application(s) submission. The applicant is also required to include, when available, a copy of any notification of noncompliance or denial of certification issued to the applicant for certification. The words, "when available," have been added to this requirement in this final rule to satisfy concerns regarding the status of applicants who cannot find or no longer have a copy of any notification of noncompliance or denial of certification previously received. We see no down side to relaxing this requirement since the applicant must still comply with each of the other provisions in section 205.401(c), including the requirement that the applicant include a description of the actions taken to correct the noncompliances noted in any notification of noncompliance or denial of certification, including evidence of such correction. Further, the certifying agent will be using USDA's database of certification actions during its review of an application for certification.

(4) Timely Communication to the Applicant. We have amended section 205.402(b), by requiring at paragraph (b)(1) that the certifying agent, within a reasonable time, review the application materials received and communicate its findings to the applicant. A commenter requested that we amend section 205.402(b) which required a certifying agent to communicate to the applicant its findings on the review of application materials submitted by the applicant. Specifically, the commenter requested that section 205.402(b) be amended by adding to the end thereof, "in a timely manner so as to prevent the avoidable tillage of native habitat that had been identified in the application as lands for organic production."

We concur that certification decisions should be timely. There are many reasons (e.g., financial and contractual) for why certification must be timely. It would be impractical, however, to attempt to address all of the reasons for timely certification in these regulations. We have, therefore, amended section 205.402(b) as noted above. This amendment is consistent with the requirement in section 205.402(a) that the certifying agent, upon acceptance of an application for certification, review the application for completeness, determine by a review of the application materials

whether the applicant appears to comply or may be able to comply with the requirements for certification, and schedule an on-site inspection. The "upon acceptance" requirement necessitates that the certifying agent review the application for certification and provide feedback to the applicant in a timely manner.

(5) On-site Inspections. We have amended section 205.403(a)(1) by specifying that the initial and annual on-site inspections of each production unit, facility, and site in an operation applies to those units, facilities, and sites that produce or handle organic products. A commenter recommended that section 205.403(a)(1) be amended to specify that on-site inspections of each production unit, facility, and site will include just those that produce or handle organic products. The commenter stated that this change was necessary because some retail corporations choose to certify all store locations regardless of whether the location sells organic products. The commenter went on to say that, if a location does not stock any organic products, the certifying agent should have the discretion to modify the inspection requirement.

We have excluded all retail food establishments from certification. The exclusion is found in section 205.101(b)(2). Accordingly, the commenter's recommendation is not applicable to retail food establishments. We have, however, made the recommended amendment to section 205.403(a)(1) because of its potential applicability to other operations which may apply for certification.

(6) Scheduling Initial On-site Inspection. We have amended section 205.403(b) to provide that the initial inspection may be delayed for up to 6 months to comply with the requirement that the inspection be conducted when the land, facilities, and activities that demonstrate compliance or capacity to comply with the organic production and handling requirements can be observed. We received a comment stating that if an application is received in January for a crop that will be planted in May, it would be necessary to delay the inspection until late May or June to observe the crop in the field. The commenter went on to say that the alternative would be to conduct the initial inspection before the crop is planted, in order to meet the "within a reasonable time" requirement, and then conduct a reinspection during the growing season. The commenter recommended amending section 205.403(b) to allow the certifying agent to delay the initial on-site inspection until the land, facilities, and activities that demonstrate compliance or capacity to comply can be observed.

We have accepted the recommendation because there may be situations where a later on-site inspection will prove mutually beneficial to the certifying agent and the operation to be inspected. However, certifying agents are reminded that the operation may be certified following a demonstration that the operation is able to comply with the organic production and handling requirements found in subpart C of these regulations. Accordingly, certifying agents should not unnecessarily delay the certification of an organic production or handling operation by insisting that the inspection only be performed when the operation can demonstrate its actual compliance with the organic production and handling requirements. Applicants who believe that the certifying agent is abusing its authority to delay the on-site inspection may file a complaint with the Administrator.

We have also amended the second sentence in section 205.403(b) by inserting the word, "all," and removing both references to "applicant" to clarify that the provision applies to all on-site inspections.

(7) Exit Interview. We have amended section 205.403(d) by requiring that the inspector conduct an exit interview with "an authorized representative of the operation who is knowledgeable about the inspected operation" rather than "an authorized representative of the inspected operation" as required in the proposed rule. This amendment is consistent with the requirement in section 205.403(b) that an on-site inspection be conducted when an authorized representative of the operation who is knowledgeable about the operation is present.

A commenter requested that we define "authorized representative." Another commenter recommended changing the term, "authorized representative," to "responsible executive." Our amendment of section 205.403(d) responds to both of these comments by clarifying the qualifications of an authorized representative.

A third commenter stated that an exit interview is not a practical requirement and that an initial interview is often preferred. The commenter stressed that verification that the inspector has correctly understood what is presented is ongoing. This commenter also expressed the belief that there may be times when it may not be appropriate for the inspector to address issues of concern and that such issues may be best left to the certifying agent. The commenter recommended that the requirement for an exit interview be deleted or presented as an option. Another commenter suggested that issues of concern are often identified and discussed with the operation's representative during the course of the inspection. This commenter believes that it is unnecessarily confrontational to require an exit interview during which these issues of concern are repeated. This commenter recommended replacing the required exit interview with a communications provision that would require the inspector to discuss the need for any additional information as well as any issues of concern. The recommended provision would also authorize the certifying agent to provide the applicant with a summary of the inspector's areas of concern.

While we agree that the language in section 205.403(d) needed clarification, we do not agree that the exit interview is impractical or unnecessarily confrontational. The exit interview is intended to give the inspector an opportunity to confirm the accuracy and completeness of inspection observations and information gathered during the on-site inspection, to request any additional information necessary to establish eligibility for certification, and to raise and discuss any known issues of concern. Issues of concern that may involve compliance issues will be handled as authorized by the certifying agent. The exit interview is also intended to give the inspected operation's authorized representative general information concerning the inspector's observations. Such exit interviews are required under ISO Guide 10011-1. Accordingly, requiring exit interviews is consistent with ISO standards and our expectation, as stated earlier in this preamble, that certifying agents benchmark their on-site inspection procedures to ISO Guide 10011-1.

(8) On-site Inspection Documentation. We have amended section 205.402(b) by adding the requirements that the certifying agent: (1) provide the applicant with a copy of the on-site inspection report, as approved by the certifying agent, for any on-site inspection performed and (2) provide the applicant with a copy of the test results for any samples taken by an inspector. We have also amended section 205.403 by adding a new paragraph (e) that requires the inspector, at the time of the inspection, to provide the operation's authorized representative with a receipt for any samples taken by the inspector. This new paragraph also addresses the requirement that the certifying agent provide the operation inspected with a copy of the inspection report and any test results. Having the certifying agent issue the on-site inspection report to the operation inspected is consistent with ISO Guide 65, section 11(b).

Several commenters recommended that section 205.403 be amended to require that the inspector issue a copy of the on-site inspection report to the operation at the exit interview. They also recommended that the inspector be required to provide the operation with a receipt for samples collected for testing. The commenters, further, recommended that the certifying agent be required to provide the operation with a written report on the results of the testing performed on the samples taken. A commenter also recommended that the operation be paid for any samples taken. One of the commenters recommended that section 205.403 be amended by adding protocol for an exit interview.

We concur that the applicant for certification and certified operations should be provided with a copy of the on-site inspection report, a receipt for samples taken, and a copy of the test results for samples taken. Accordingly, we have amended sections 205.402(b) and 205.403 as noted above.

The protocol for an exit interview will be set forth in the certifying agent's procedures to be used to evaluate certification applicants, make certification decisions, and issue certification certificates. The NOP is available to respond to questions and to assist certifying agents in the development of these procedures which are required under section 205.504(b)(1). Accordingly, AMS is not amending the section to include a protocol for exit interviews. AMS is also not including a requirement that the certifying agent pay the applicant for samples taken, since such charges would just be charged back to the applicant as a cost for processing the applicant's application for certification.

(9) Granting Certification. We have amended the last sentence of section 205.404(a) by removing the word, "restrictions," and replacing it with "requirements for the correction of minor noncompliances within a specified time period." A commenter suggested that the last sentence of section 205.404(a) be amended to read: "The approval may include restrictions or requirements as a condition of continued certification, which includes a time line for fulfilling the requirement." Another commenter requested that we define "restrictions." This commenter also recommended amending section 205.404(a) to clarify the meaning of "restrictions" and to require corrective action by the operator within a specific time period. We agree with the commenters that the last sentence of section 205.404(a) was in need of further clarification. We also agree that it is appropriate for the regulations to require that the requirements for correction include a specified time period within which the corrections must be made. Accordingly, we amended section 205.404(a) as noted above. The certifying agent will make the determination of whether a violation of the Act and regulations is minor. Minor noncompliances are those infractions that, by themselves, do not preclude the certification or continued certification of an otherwise qualified organic producer or handler. The certifying agent would be free to modify the time period for correction should it believe it to be appropriate.

We have also made editorial changes to section 205.404(a) consistent with suggestions we received on section 205.506. In the title to section 205.404 we have replaced "Approval of" with "Granting." In section 205.404(a) we have replaced "approve" with "grant" and "approval" with "certification." This change makes the language in section 205.404 consistent with ISO Guide 65, section 4.6, which addresses the granting of certification.

(10) Payment of Fees. We have amended the introductory statement within section 205.406(a) by adding the requirement that, to continue certification, a certified operation annually pay the certifying agent's certification fees. A commenter recommended amending section 205.404(c) by adding a sentence providing that a certified operation's failure to pay the certifying agent's certification fees may be a cause for suspension or revocation of certification. We agree that the issue of payment of fees should be addressed but not in section 205.404(c), which deals with the duration of a certified operation's certification. We believe the issue of payment of certification fees is more appropriately addressed in section 205.406, which deals with continuation of certification. Accordingly, we have amended section 205.406(a) to require payment of the certifying agent's fees as a condition of continued certification. This addition would allow a certifying agent to initiate suspension or revocation proceedings against any operation that fails to pay the required fees. The certifying agent is not required to initiate suspension or revocation proceedings for failure to pay the fees. In fact, the certifying agent is encouraged to use one or more of the legal debt collection alternatives available to it.

(11) Denial of Certification. We have amended section 205.405 to include noncompliance and resolution provisions originally included by cross-reference to section 205.662(a). We have made this amendment in response to a comment that these regulations do not provide an opportunity for a hearing upon denial of certification. We disagree with the commenter's assessment but have amended section 205.405(a) to eliminate confusion that may result from the cross-reference to section 205.662(a). We have determined that section 205.662(a) may cause confusion for certification applicants because the section does not specifically address applicants.

As amended, section 205.405(a) required a written notification of noncompliance that describes each noncompliance, the facts on which the noncompliance is based, and the date by which the applicant must rebut or correct each noncompliance and submit supporting documentation of each such correction when correction is possible. Section 205.405(b) lists the options available to the applicant, including the options of correcting the noncompliance or submitting written information to rebut the noncompliance. Successful correction or rebuttal will result in an approval of certification. When the corrective action or rebuttal is not sufficient for the applicant to qualify for certification, the certifying agent will issue a written notice of denial of certification. This notice will state the reason(s) for denial and the applicant's right to request mediation in accordance with section 205.663 or to file an appeal in accordance with section 205.681.

(12) Rebuttal of a Noncompliance. We have amended section 205.405(b)(3) to clarify that rebuttal of a noncompliance shall be submitted to the certifying agent that issued the notification of noncompliance. We made this amendment in response to a commenter's question about who has authority to evaluate a written rebuttal.

(13) Correction of Minor Noncompliances. We have amended section 205.406(a) by adding a new paragraph (3) which requires the certified operation to include with its annual reporting an update on the correction of minor noncompliances previously identified by the certifying agent as requiring correction for continued certification. A commenter recommended adding at 205.406(a) a requirement that the certified operation address any restrictions that have been applied to its certification under 205.404(a). We agree with the commenter that the annual reporting by the certified operation should include an update addressing the certified operation's compliance with the certifying agent's requirements for the correction of minor noncompliances. Accordingly, we amended section 205.406(a) as noted above and redesignated paragraph (3) as paragraph (4). The certifying agent will make the determination of whether a violation of the Act and regulations is minor. Minor noncompliances are those infractions that, by themselves, do not preclude the certification or continued certification of an otherwise qualified organic producer or handler.

(14) Scheduling Annual On-site Inspections. We have amended section 205.406(b) to provide that, when it is impossible for the certifying agent to conduct the annual on-site inspection following receipt of the certified operation's annual update of information, the certifying agent may allow continuation of certification and issue an updated certificate of organic operation on the basis of the information submitted and the most recent on-site inspection conducted during the previous 12 months. The annual on-site inspection, required by section 205.403, must, however, be conducted within the first 6 months following the certified operation's scheduled date of annual update.

A commenter expressed the belief that the requirement for an on-site inspection after receipt of the certified operation's annual update of information would have required that all annual on-site inspections be performed at the same time of the year. The commenter went on to express the belief that, to avoid inspecting certified operations twice a year, certifying agents would have to schedule the annual update to occur during the growing season in order to comply with the requirement for timing inspections when normal production activities can be observed. The commenter stated that certifying agents should be given more flexibility for scheduling inspections and conducting their certification programs according to management procedures best suited to their agency. The commenter recommended amending section 205.406(b) by adding to the end thereof: "or base the decision regarding eligibility for renewal on an on-site inspection conducted during the previous 12 months."

We agree with the commenter that certifying agents should be given more flexibility for scheduling on-site inspections so as to best meet the management needs of the certifying agent. Accordingly, we have amended section 205.406(b) to allow continuation of certification and issuance of an updated certificate of organic operation on the basis of the information submitted and the most recent on-site inspection conducted during the previous 12 months. This option will

be available to the certifying agent when renewal is scheduled for a time when it is impossible to conduct the annual on-site inspection following receipt of the annual update and at a time when land, facilities, and activities that demonstrate the operation's compliance or capability to comply can be observed. This change does not affect the requirement in section 205.403(a)(1) that the certifying agent conduct an annual on-site inspection of each certified operation. Further, the annual on-site inspection must be conducted within the first 6 months following the certified operation's scheduled date of annual update.

### **Certification - Changes Requested But Not Made**

This subpart retains from the proposed rule regulations on which we received comments as follows:

(1) Number of On-site Inspections. A commenter recommended that section 205.403(a)(1) be amended by adding a requirement that production operations be under active organic management for the last year of the 3-year land conversion period and that two on-site inspections be performed prior to organic certification.

Section 205.403(a)(1) provides that the certifying agent must conduct an initial on-site inspection of each production unit, facility, and site that produces or handles organic products and that is included in an operation for which certification is requested. The requirement does not preclude a certifying agent from conducting additional on-site inspections, if necessary, to establish the applicant's eligibility for certification. The Act requires a 3-year period immediately preceding harvest, during which the production operation must be free from the application of prohibited substances. The Act does not, however, require that land be under active organic management during this period, and we do not believe such a requirement in these regulations is necessary. Such a requirement, for example, would necessitate some process for verifying that an operation is under active organic management, which would, in effect, require a certification-type decision a year before certification is granted and the operation can begin to label products as certified organic. Accordingly, we disagree with the commenter's recommendation that an operation be under active organic management for the last year of the 3-year land conversion and that two on-site inspections be required.

(2) Unannounced Inspections. A commenter recommended that section 205.403(a)(2)(iii) be amended to require additional unannounced inspections either by defining the circumstances under which the inspections should be undertaken or by setting a minimum percentage of unannounced inspections. The commenter claimed that 5 percent is a common percentage adopted by certifying agents around the world.

Section 205.403 requires an initial on-site inspection, annual on-site inspection, and additional on-site inspections to determine compliance with the Act and regulations, to verify that information provided reflects actual practices, and to verify, through testing if necessary, that prohibited substances are not used by the operation. Because of the widely disparate nature of certified operations, we believe the certifying agent is in the best position to determine the need for additional on-site inspections. Accordingly, we have rejected the commenter's request that the regulations require additional unannounced visits either by defining the circumstances under which these should be undertaken or by setting a minimum percentage.

(3) Timeliness of Certifying Agent Review Information. A commenter requested that section 205.404(a) be amended to specify a timeframe of 60 days rather than "Within a reasonable time" as the time by which the certifying agent must review the on-site inspection report, the results of any analyses for substances, and any additional information requested from or supplied by the applicant.

Section 205.404(a) requires the certifying agent, within a reasonable time after completion of the initial on-site inspection, to review the on-site inspection report, the results of any analyses for substances conducted, and any additional information requested from or supplied by the applicant. Section 205.504(b)(1) requires the certifying agent to submit a copy of the procedures to be used to evaluate certification applicants, make certification decisions, and issue certification certificates. Such procedures and the certifying agent's performance in making timely certification decisions will be subject to review during accreditation and reaccreditation of the certifying agent. Certifying agents are expected to make timely decisions regarding whether to certify an applicant and whether a certified operation is in compliance with the Act and regulations. Applicants with complaints regarding timeliness of service could forward their complaints to the Administrator. Accordingly, timely service will be in the best interest of certifying agents since such complaints could have an impact on their reaccreditation or continued accreditation. Further, our original position is consistent with those commenters requesting flexibility in determining what constitutes reasonable time. Accordingly, we have not amended section 205.404(a) as requested.

(4) Categories of Organic Operation. We received a variety of comments regarding the requirement that the certifying agent issue a certificate of organic operation which specifies the categories of organic operation, including crops, wild crops, livestock, or processed products produced by the certified operation. One commenter recommended that section 205.404(b)(3) be amended, with regard to processing, to only require a processing category to be specified on the certificate, such as food processing or feed processing. The commenter stated that it should not be necessary to list every product on the certificate. Specifically, the commenter recommended amending section 205.404(b)(3) by inserting the words, "general categories of," immediately in front of the word, "processed." Another commenter recommended amending section 205.404(b)(3) to require the identity of specific crops and the specific processing operations certified. Still another commenter requested that section 205.404(b) be amended by adding a new paragraph requiring that the certificate include the number of livestock of each species produced on the certified operation. This same commenter also recommended the addition of a new paragraph requiring that the certificate identify the specific location of each certified organic field and handling operation. We also received support for section 205.404(b)(3) as written. This commenter does not support the addition of information regarding the number of livestock or the location of fields.

We disagree with the suggestion that the certificate list every crop, wild crop, livestock, or processed product produced by the certified operation. We believe that listing categories of organic operation is sufficient. This does not, however, prevent the certifying agent, in cooperation with the certified operation, from listing specific crops, livestock, or processed products on the certificate. Such information could always be listed on the certificate when requested by the certified operation. We also disagree with the commenter who requested that certifying agents display the number of livestock of each species produced by the certified operation and the specific location of each certified organic field and handling operation. We do not believe it is necessary to list the quantity of product to be produced or handled at a certified operation, nor do we believe it is necessary to list the location of a certified operation's fields or facilities. Such information may, however, be listed on the certificate upon the written request of the certified operation. By requiring the name, address, and telephone number of the certifying agent, the certificate would provide interested persons with a contact for obtaining releasable information concerning the certified operation. Further, the certifying agent is the first line of compliance under this program and, as such, is the person to whom all questions and concerns should be addressed about certified operations.

(5) Annual Renewal of Certification. Numerous commenters requested that section 205.404(b)(2) be amended to provide for the placement of an expiration date on the certificate of organic operation. The commenters want yearly expiration of certification and yearly expiration of the certificate of organic operation. Commenters also requested that section 205.404(c) be amended to provide that once certified, a production or handling operation's organic certification continues

in effect until the expiration date on the certificate, until surrendered by the organic operation, or until suspended or revoked by the certifying agent, the SOP's governing State official, or the Administrator. Some commenters recommended the addition of a new paragraph 205.406(e) that would provide for automatic suspension of a certification if the certified operation did not provide the information required in paragraph 205.406(a) by the expiration date to be placed on the certificate of organic operation.

We disagree with the commenters who have requested annual renewal of certification and that the certified operation's certification and its certificate of organic operation expire annually. We prefer continuous certification due to the very real possibility that the renewal process might not always be completed before expiration of the certification period. Expiration of the certification period would result in termination of the operation's certification. Even a short period of interruption in an operation's organic status could have severe economic ramifications. Further, we believe that a regular schedule of expiration of certification is unnecessary inasmuch as all certified operations are required to annually update their organic system plan and submit any changes to their certifying agent. More importantly, unlike accreditation, where the Act provides for expiration and renewal, the Act does not provide for an expiration or renewal of certification. Therefore, it is also our position that once granted certification the production or handling operation retains that certification until voluntarily surrendered or removed, following due process, for violation of the Act or these regulations.

(6) Denial of Certification. A commenter recommended that section 205.405(e) be amended to place a time restriction on reapplication for certification after denial of certification. The commenter suggested a 3-year period. We disagree with this recommendation because the reasons for denial include a wide range of noncompliances. The ability to correct noncompliances will vary as will the time needed to correct the noncompliances.

(7) Production and Handling Operation Certification Following Suspension or Revocation of Certifying Agent Accreditation. A few commenters requested amendment of section 205.406 through the addition of a new paragraph (f). Specifically, the commenters requested provisions that would provide for USDA notification of certified operations regarding the suspension or revocation of their certifying agent's accreditation. Some of these commenters requested that the provisions also allow the affected certified operation to use current market labels for a maximum period of 12 months, provided the certified operation made application for certification with another USDA-accredited certifying agent within 3 months of being notified of their certifying agent's suspension or revocation of accreditation. Another commenter requested that the new paragraph provide that the affected certified operation will continue to operate as if certified by the USDA and will be allowed to use current market labels for a maximum period of 12 months. The commenter stated that this amendment would provide the certified operation with the time needed to obtain recertification by an accredited certifying agent and to prepare new labels.

We disagree with the recommendations. USDA does not perform organic certification activities under any circumstance, including upon surrender, suspension, or revocation of an accredited certifying agent's accreditation. Operations certified by a certifying agent that surrenders or loses its USDA accreditation will be notified by USDA and given an opportunity to immediately begin seeking certification by the USDA-accredited certifying agent of their choice. Certified operations shall not affix the seal or other representation of a certifying agent to any product that they produce after the certifying agent has surrendered or had its accreditation revoked. The certified operation may use the USDA organic seal. In the case of suspension of the certifying agent, the reasons for the suspension and the terms of the suspension will determine whether the certifying agent's certified operations will have to seek recertification or stop affixing the certifying agent's seal or other representation to their products. USDA will announce the suspension or revocation of a certifying agent's accreditation, and the announcement will address the status of operations certified by the certifying agent.



## **Certification - Clarifications**

Clarification is given on the following issues raised by commenters as follows:

(1) Recordkeeping. A commenter stated that most computerized recordkeeping systems used at retail and wholesale are set up to save the data for a maximum of 2 years; adding 3 additional years to that requirement would be extremely costly as systems modifications and additional hardware and support would be required to meet the mandate. The commenter suggested that since food product is generally sold and consumed within a matter of months (if not weeks), shortening this requirement to 2 years should meet the goal for tracking of any product through the distribution system. This commenter was referring to the requirement in section 205.400(d) that records be maintained for not less than 5 years beyond their creation.

Section 205.103 requires that a certified operation maintain records; that the records be adapted to the particular business that the certified operation is conducting, fully disclose all activities and transactions of the certified operation in sufficient detail as to be readily understood and audited, be maintained for not less than 5 years beyond their creation, and be sufficient to demonstrate compliance with the Act and the regulations in this part; and that the certified operation must make such records available for inspection and copying during normal business hours by authorized representatives of the Secretary, the applicable SOP's governing State official, and the certifying agent. The requirements do not state in what form (i.e., paper, electronic, film) that the records must be maintained. Therefore, in answer to the commenter's concern, database records more than 2 years old could be stored in any form, including on an electronic storage device, which would permit retrieval upon request.

(2) Application Fees. A commenter recommended that section 205.401 be amended by adding a new paragraph (e) which would require an applicant for certification to include, along with the other required application information, the application fees required by the certifying agent.

The requested language is unnecessary because section 205.400(e) requires submission of the applicable fees charged by the certifying agent as a general requirement for certification.

(3) Applicant Identification. In reference to section 205.401(c) a commenter stated that an applicant that is a corporation could easily change the name of the corporation in order to avoid having to report applications submitted and denied under the previous name. The commenter went on to state that there must be a database available to certifying agents that includes names and location addresses of operations that have received a notification of noncompliance, denial of certification, or a suspension or revocation of certification.

Section 205.401(b) requires the applicant to include in its application the name of the person completing the application; the applicant's business name, address, and telephone number; and, when the applicant is a corporation, the name, address, and telephone number of the person authorized to act on the applicant's behalf.

As we stated in the preamble to the proposed rule, we anticipate using the data collected under section 205.501(a)(15) to establish and maintain two Internet databases. The first Internet database would be accessible to the general public and would include the names and other appropriate data on certified organic production and handling operations. The second Internet database would be password protected and only available to accredited certifying agents and USDA. This second database would include data on production and handling operations issued a notification of noncompliance, noncompliance correction, denial of certification, certification, proposed suspension or revocation of certification, and suspension or revocation of certification. Certifying agents would use the second Internet database during their review of an application for certification.

(4) Withdrawal of Application. Several commenters expressed the belief that allowing an applicant to voluntarily withdraw its application will be used as a tool to avoid denial of certification. They expressed concern that voluntary withdrawal before denial of certification will allow the applicant to make application with a different certifying agent with a clean record. These commenters were responding to the provision in section 205.402(e) which allows an applicant for certification to withdraw its application at any time.

We continue to believe that operations should not be unnecessarily stigmatized because they applied for certification before the operation was ready to meet all requirements for certification. While some operations may use voluntary withdrawal as a means to avoid the issuance of a notification of noncompliance or a notice of denial of certification, this should not adversely affect the National Organic Program (NOP) because all certifying agents are responsible for using qualified personnel in the certification process and for ensuring an applicant's eligibility for certification. Further, all applicants for certification are required under section 205.401(c) to include in their application the name(s) of any organic certifying agent(s) to which application has previously been made, the year(s) of application, and the outcome of the application(s) submission.

(5) On-site Inspections. Section 205.403(a)(2)(ii) provides that the Administrator or SOP's governing State official may require that additional inspections be performed by the certifying agent for the purpose of determining compliance with the Act and the regulations in this part. In commenting on this provision, a commenter asked, "Who is running this program: State or Federal officials?"

This is a national organic program administered by the Agricultural Marketing Service of the United States Department of Agriculture. States may administer their own organic program. However, all SOP's are subject to USDA approval. The National Organic Standards and a State's organic standards under a USDA-approved SOP are the National Organic Standards for that State. The State, under USDA's approval of the SOP, has enforcement responsibilities for the Federal and State components of the organic program within the State.

(6) Verification of Information. A commenter stated that section 205.403(c) is insufficiently comprehensive. The commenter stated that organic inspection is assessment of a process evaluated against comprehensive standards and, as such, it requires specific rules to provide confidence in the quality of the inspection. The commenter recommended amending section 205.403(c) by including requirements on minimum verification methods.

Section 205.403(c) identifies what must be verified during the on-site inspection. The details on how the verification will be accomplished will be set forth in the certifying agent's procedures to be used to evaluate certification applicants, make certification decisions, and issue certification certificates and the certifying agent's procedures for reviewing and investigating certified operation compliance with the Act and regulations. The NOP is available to respond to questions and to assist certifying agents in complying with the on-site inspection requirements, including those for the verification of information.

(7) Notifying Customers of Change in Certification Status. A commenter stated that the regulations do not indicate when a certified organic producer must stop using the organic seal or whether they must notify customers of their denial of certification. The commenter recommended amending section 205.405 to include a provision for notifying customers of a certified operation's change in certification status.

Any producer or handler who plans to sell, label, or represent its product as "100 percent organic," "organic," or "made with..." must be certified unless exempted under the small operation exemption under section 205.101(a)(1) or not regulated under the NOP (i.e., a producer of dog

food). Only certified operations may represent themselves as certified. Operations denied certification may not represent their products as "100 percent organic," "organic," or "made with..." Operations that have had their certification suspended or revoked will be subject to the terms and conditions of their suspension or revocation relative to the labeling of product produced prior to the suspension or revocation. No product produced by an operation after suspension or revocation of certification may be sold, labeled, or represented as "100 percent organic," "organic," or "made with..."

Buyers of organic product can request to see the producer's or handler's certificate of organic operation. Operations that have lost their organic status will be unable to obtain an updated certificate. Buyers with questions regarding an operation's organic status may also contact the certifying agent identified on a certificate of organic operation. Further, as previously noted, we anticipate using the data collected under section 205.501(a)(15) to establish and maintain an Internet database accessible to the general public that will include the names and other appropriate data on certified organic production and handling operations.

(8) Continuation of Certification. A few commenters recommended amending section 205.406 to include a safety net for producers who are certified by a certifying agent that does not become accredited by USDA. They stated that the rule must clearly state that a certified organic producer will have the full 18-month implementation period starting from the effective date of the final rule to get recertified if their certifying agent is not accredited. One of the commenters stated that because the NOP anticipates that the accreditation process will require 12 months, producers will, in effect, have 6 months to be certified by a new certifying agent should the producer's certifying agent not be accredited.

Certification under the NOP will become mandatory 18 months after the effective date of the final rule. Applications for accreditation will be processed on a first-come, first-served basis. Accreditations will be announced approximately 12 months after the effective date of the final rule for those qualified certifying agents who apply within the first 6 months following the effective date and for any other applicants that AMS determines eligible. Certifying agents will begin the process of certifying organic production and handling operations to the national standards upon receipt of their USDA accreditation. All production and handling operations certified by an accredited certifying agent will be considered certified to the national standards until the certified operation's anniversary date of certification. This phase-in period will only be available to those certified operations certified by a certifying agent that receives its accreditation within 18 months from the effective date of the final rule. We anticipate that certifying agents and production and handling operations will move as quickly as possible to begin operating under the national organic standards. Operations certified by a certifying agent, which fails to apply for or fails to meet the requirements for USDA accreditation under the NOP, must seek and receive certification by a USDA-accredited certifying agent before they can sell, label, or represent their products as organic, effective 18 months after the effective date of the final rule.

1. ISO Guide 10011-1 is available for viewing at USDA-AMS, Transportation and Marketing Programs, Room 2945-South Building, 14th and Independence Ave., SW, Washington, DC, from 9:00 a.m. to 4:00 p.m., Monday through Friday (except official Federal holidays). A copy may be obtained from the American National Standards Institute, 11 West 42d Street, New York, NY 10036; Website: [www.ansi.org](http://www.ansi.org); E-mail: [ansionline@ansi.org](mailto:ansionline@ansi.org); Telephone: 212-642-4900; Facsimile: 212-398-0023.

## Accreditation -- Preamble

### Subpart F - Accreditation of Certifying Agents

This subpart sets forth the requirements for a national program to accredit State and private entities as certifying agents to certify domestic or foreign organic production or handling operations. This subpart also provides that USDA will accept a foreign certifying agent's accreditation to certify organic production or handling operations if: (1) USDA determines, upon the request of a foreign government, that the standards under which the foreign government authority accredited the foreign certifying agent meet the requirements of this part; or (2) the foreign governmental authority that accredited the certifying agent acted under an equivalency agreement negotiated between the United States Government and the foreign government.

This National Organic Program (NOP) accreditation process will facilitate national and international acceptance of U.S. organically produced agricultural commodities. The accreditation requirements in these regulations will, upon announcement of the first group of accredited certifying agents, replace the voluntary fee-for-service organic assessment program, established by AMS under the Agricultural Marketing Act of 1946. That assessment program verifies that State and private organic certifying agents comply with the requirements prescribed under the International Organization for Standardization/International Electrotechnical Commission Guide 65, "General Requirements for Bodies Operating Product Certification Systems" (ISO Guide 65).<sup>(1)</sup> ISO Guide 65 provides the general requirements that a certifying agent would need to meet to be recognized as competent and reliable. That assessment program was originally established to enable organic certifying agents in the absence of a U.S. national organic program to comply with European Union (EU) requirements beginning on June 30, 1999. That assessment program verifies that State and private organic certifying agents are operating third-party certification systems in a consistent and reliable manner, thereby facilitating uninterrupted exports of U.S. organic agricultural commodities to the EU. ISO Guide 65 was used as a benchmark in developing the accreditation program described in this final rule. Certifying agents accredited under the NOP that maintain compliance with the Act and these regulations will meet or exceed the requirements of ISO Guide 65; therefore, the organic assessment program is no longer needed.

Participation in the NOP does not preclude the accredited certifying agent from conducting other business operations, including the certification of agricultural products, practices, and procedures to standards that do not make an organic claim. An accredited certifying agent may not, however, engage in any business operations or activities which would involve the agent in a violation of or in a conflict of interest under the NOP.

### Description of Regulations

The Administrator will accredit qualified domestic and foreign applicants in the areas of crops, livestock, wild crops, or handling or any combination thereof to certify domestic or foreign production or handling operations as certified organic operations. Qualified applicants will be accredited for 5 years.

### Application Process

Certifying agents will apply to the Administrator for accreditation to certify production or handling operations operating under the NOP. The certifying agent's application must include basic business information, must identify each area of operation for which accreditation is requested and the estimated number of each type of operation to be certified annually, and must include a list of each State or foreign country where it currently certifies production or handling operations and where it intends to certify such operations. Certifying agents must also submit personnel,

administrative, conflict of interest, current certification, and other documents and information to demonstrate their expertise in organic production or handling techniques, their ability to comply with and implement the organic certification program, and their ability to comply with the requirements for accreditation. Certifying agents planning to certify production or handling operations within a State with an approved State organic program (SOP) must demonstrate their ability to comply with the requirements of the SOP.

The administrative information submitted by the applicant must include copies of its procedures for certifying operations, for ensuring compliance of its certified operations with the Act and regulations, for complying with recordkeeping requirements, and for making information available to the public about certified operations. The procedures for certifying operations encompass the processes used by the certifying agent to evaluate applicants, make certification decisions, issue certification certificates, and maintain the confidentiality of any business information submitted by the certified operation. The procedures for ensuring compliance of the certified operations will include the methods used to review and investigate certified operations, for sampling and residue testing, and to report violations.

The personnel information submitted with the application must demonstrate that the applicant uses a sufficient number of adequately trained personnel to comply with and implement the organic certification program. The certifying agent will also have to provide evidence that its responsibly connected persons, employees, and contractors with inspection, analysis, and decision-making responsibilities have sufficient expertise in organic production or handling techniques to successfully perform the duties assigned. They must also show that all persons who review applications for certification perform on-site inspections, review certification documents, evaluate qualifications for certification, make recommendations concerning certification, or make certification decisions and that all parties responsibly connected to the certifying agent have revealed existing or potential conflicts of interest.

Applicants who currently certify production or handling operations must also submit a list of the production and handling operations currently certified by them. For each area in which the applicant requests accreditation, the applicant should furnish copies of inspection reports and certification evaluation documents for at least three operations. If the applicant underwent any other accrediting process in the year previous to the application, the applicant should also submit the results of the process.

Certifying agents are prohibited from giving advice or providing consultancy services to certification applicants or certified operations for overcoming identified barriers to certification. This requirement does not apply to voluntary education programs available to the general public and sponsored by the certifying agent.

The Administrator will provide oversight of the fees to ensure that the schedule of fees filed with the Administrator is applied uniformly and in a nondiscriminatory manner. The Administrator may inform a certifying agent that its fees appear to be unreasonable and require that the certifying agent justify the fees. The Administrator will investigate the level of fees charged by an accredited certifying agent upon receipt of a valid complaint or under compelling circumstances warranting such an investigation.

### **Statement of Agreement.**

Upon receipt of the certifying agent's application for accreditation, the Administrator will send a statement of agreement to the person responsible for the certifying agent's day-to-day operations for signature. The statement of agreement affirms that, if granted accreditation as a certifying agent under this subpart, the applicant will carry out the provisions of the Act and the regulations

in this part. Accreditation will not be approved until this statement is signed and returned to the Administrator.

The statement of agreement will include the applicant's agreement to accept the certification decisions made by another certifying agent accredited or accepted by USDA pursuant to section 205.500 and the applicant's agreement to refrain from making false or misleading claims about its accreditation status, the USDA accreditation program, or the nature or qualities of products labeled as organically produced. Further, the statement will include the applicant's agreement to pay and submit the fees charged by AMS and to comply with, implement, and carry out any other terms and conditions determined by the Administrator to be necessary. Applicants are also required to affirm through this statement of agreement that they will: (1) conduct an annual performance evaluation of all persons who review applications for certification, perform on-site inspections, review certification documents, evaluate qualifications for certification, make recommendations concerning certification, or make certification decisions and implement measures to correct any deficiencies in certification services; and (2) have an annual program review conducted of their certification activities by their staff, an outside auditor, or a consultant who has expertise to conduct such reviews and implement measures to correct any noncompliances with the Act and the regulations in this part that are identified in the evaluation.

A private entity certifying agent must additionally agree to hold the Secretary harmless for any failure on the agent's part to carry out the provisions of the Act and regulations. A private entity certifying agent's statement will also include an agreement to furnish reasonable security for the purpose of protecting the rights of operations certified by such certifying agent. Such security will be in an amount and according to such terms as the Administrator may by regulation prescribe. A private entity certifying agent must agree to transfer all records or copies of records concerning its certification activities to the Administrator if it dissolves or loses its accreditation. This requirement for the transfer of records does not apply to a merger, sale, or other transfer of ownership of a certifying agent. A private entity certifying agent must also agree to make such records available to any applicable SOP's governing State official.

### **Granting Accreditation.**

Upon receiving all the required information, including the statement of agreement, and the required fee, the Administrator will determine if the applicant meets the requirements for accreditation. The Administrator's determination will be based on a review of the information submitted and, if necessary, a review of the information obtained from a site evaluation. The Administrator will notify the applicant of the granting of accreditation in writing. The notice of accreditation will state the area(s) for which accreditation is given, the effective date of the accreditation, any terms or conditions for the correction of minor noncompliances, and, for a private-entity certifying agent, the amount and type of security that must be established.

Certifying agents who apply for accreditation and do not meet the requirements for accreditation will be provided with a notification of noncompliance which will describe each noncompliance, the facts on which the notification is based, and the date by which the applicant must rebut or correct each noncompliance and submit supporting documentation of each such correction when correction is possible. If the applicant is successful in its rebuttal or provides acceptable evidence demonstrating correction of the noncompliances, the NOP Program Manager will send the applicant a written notification of noncompliance resolution and proceed with further processing of the application. If the applicant fails to correct the noncompliances, fails to report the corrections by the date specified in the notification of noncompliance, fails to file a rebuttal by the date specified in the notification of noncompliance, or is unsuccessful in its rebuttal, the Program Manager will issue a written notification of accreditation denial to the applicant. An applicant who has received written notification of accreditation denial may apply for accreditation again at any time or file an appeal of the denial of accreditation with the Administrator by the date specified in the notification of accreditation denial.

Once accredited, a certifying agent may establish a seal, logo, or other identifying mark to be used by certified production and handling operations. However, the certifying agent may not require use of its seal, logo, or other identifying mark on any product sold, labeled, or represented as organically produced as a condition of certification. The certifying agent also may not require compliance with any production or handling practices other than those provided for in the Act and regulations as a condition for use of its identifying mark. However, certifying agents certifying production or handling operations within a State with more restrictive requirements, approved by the Administrator, shall require compliance with such requirements as a condition of use of their identifying mark by such operations.

### **Site Evaluations.**

One or more representatives of the Administrator will perform site evaluations for each certifying agent in order to examine the certifying agent's operations and to evaluate compliance with the Act and regulations. Site evaluations will include an on-site review of the certifying agent's certification procedures, decisions, facilities, administrative and management systems, and production or handling operations certified by the certifying agent. A site evaluation of an accreditation applicant will be conducted before or within a reasonable time after issuance of the applicant's notification of accreditation. Certifying agents will be billed for each site evaluation conducted in association with an initial accreditation, amendments to an accreditation, and renewals of accreditation. Certifying agents will not be billed by USDA for USDA-initiated site evaluations conducted to determine compliance with the Act and regulations.

As noted above, a certifying agent may be accredited prior to a site evaluation. If the Program Manager finds, following the site evaluation, that an accredited certifying agent is not in compliance with the Act or regulations, the Program Manager will issue the certifying agent a written notification of noncompliance. If the certifying agent fails to correct the noncompliances, report the corrections by the date specified in the notification of noncompliance, or file a rebuttal by the date specified in the notification of noncompliance, the Administrator will begin proceedings to suspend or revoke the accreditation. A certifying agent that has had its accreditation suspended may at any time, unless otherwise stated in the notification of suspension, submit a request to the Secretary for reinstatement of its accreditation. The request must be accompanied by evidence demonstrating correction of each noncompliance and corrective actions taken to comply with and remain in compliance with the Act and regulations. A certifying agent whose accreditation is revoked will be ineligible for accreditation for a period of not less than 3 years following the date of such determination.

### **Peer Review Panels.**

The Administrator shall establish a peer review panel pursuant to the Federal Advisory Committee Act (FACA) (5 U.S.C. App. 2 et seq.). The peer review panel shall be composed of not fewer than three members who shall annually evaluate the NOP's adherence to the accreditation procedures in subpart F of these regulations and ISO/IEC Guide 61<sup>(2)</sup>, General requirements for assessment and accreditation of certification/registration bodies, and the NOP's accreditation decisions. This will be accomplished through the review of: (1) accreditation procedures, (2) document review and site evaluation reports, and (3) accreditation decision documents or documentation. The peer review panel shall report its finding, in writing, to the NOP Program Manager.

### **Continuing Accreditation.**

An accredited certifying agent must submit annually to the Administrator, on or before the anniversary date of the issuance of the notification of accreditation, the following reports and fees: (1) a complete and accurate update of its business information, including its fees, and information

evidencing its expertise in organic production or handling and its ability to comply with these regulations; (2) information supporting any changes requested in the areas of accreditation; (3) a description of measures implemented in the previous year and any measures to be implemented in the coming year to satisfy any terms and conditions specified in the most recent notification of accreditation or notice of renewal of accreditation; (4) the results of the most recent performance evaluations and annual program review and a description of adjustments to the certifying agent's operation and procedures implemented or to be implemented in response to the performance evaluations and program review; and (5) the required AMS fees.

Certifying agents will keep the Administrator informed of their certification activities by providing the Administrator with a copy of: (1) any notice of denial of certification, notification of noncompliance, notification of noncompliance correction, notification of proposed suspension or revocation, and notification of suspension or revocation issued simultaneously with its issuance and (2) a list, on January 2 of each year, including the name, address, and telephone number of each operation granted certification during the preceding year.

One or more site evaluations will occur during the 5-year period of accreditation to determine whether an accredited certifying agent is complying with the Act and regulations. USDA will establish an accredited certifying agent compliance monitoring program, which will involve no less than one randomly selected site evaluation of each certifying agent during its 5-year period of accreditation. Larger and more diverse operations, operations with clients marketing their products internationally, and operations with a history of problems should expect more frequent site evaluations by USDA. Operations with clients marketing their products internationally will be annually site evaluated to meet the ISO-Guide 61 requirement for periodic surveillance of accredited certifying agents. USDA may also conduct site evaluations during investigations of alleged or suspected violations of the Act or regulations and in followup to such investigations. Such investigations will generally be the result of complaints filed with the Administrator alleging violations by the certifying agent. Compliance site evaluations may be announced or unannounced at the discretion of the Administrator. Certifying agents will not be billed by USDA for USDA-initiated site evaluations conducted to determine compliance with the Act and regulations.

An accredited certifying agent must provide sufficient information to persons seeking certification to enable them to comply with the applicable requirements of the Act and these regulations. The certifying agent must maintain strict confidentiality with respect to its clients and not disclose to third parties (with the exception of the Secretary or the applicable SOP's governing State official or their authorized representatives) any business-related information concerning any client obtained while implementing these regulations except as authorized by regulation. A certifying agent must make the following information available to the public: (1) certification certificates issued during the current and 3 preceding calendar years; (2) a list of producers and handlers whose operations it has certified, including for each the name of the operation, type(s) of operation, products produced, and the effective date of the certification, during the current and 3 preceding calendar years; and (3) the results of laboratory analyses for residues of pesticides and other prohibited substances conducted during the current and 3 preceding calendar years. A certifying agent may make other business information available to the public if permitted in writing by the producer or handler. This information will be made available to the public at the public's expense.

An accredited certifying agent must maintain records according to the following schedule: (1) records obtained from applicants for certification and certified operations must be maintained for not less than 5 years beyond their receipt; (2) records created by the certifying agent regarding applicants for certification and certified operations must be maintained for not less than 10 years beyond their creation; and (3) records created or received by the certifying agent pursuant to the accreditation requirements, excluding any records covered by the 10-year requirement, must be maintained for not less than 5 years beyond their creation or receipt. Examples of records



obtained from applicants for certification and certified operations include organic production system plans, organic handling system plans, application documents, and any documents submitted to the certifying agent by the applicant/certified operation. Examples of records created by the certifying agent regarding applicants for certification and certified operations include certification certificates, notices of denial of certification, notification of noncompliance, notification of noncompliance correction, notification of proposed suspension or revocation, notification of suspension or revocation, correspondence with applicants and certified operations, on-site inspection reports, documents concerning residue testing, and internal working papers and memorandums concerning applicants and certified operations. Examples of records created or received by the certifying agent pursuant to the accreditation requirements include operations manuals; policies and procedures documents (personnel, administrative); training records; annual performance evaluations and supporting documents; conflict of interest disclosure reports and supporting documents; annual program review working papers, memorandums, letters, and reports; fee schedules; annual reports of operations granted certification; application materials submitted to the NOP; correspondence received from and sent to USDA; and annual reports to the Administrator.

The certifying agent must make all records available for inspection and copying during normal business hours by authorized representatives of the Secretary and the applicable SOP's governing State official. In the event that the certifying agent dissolves or loses its accreditation, it must transfer to the Administrator and make available to any applicable SOP's governing State official all records or copies of records concerning its certification activities. This requirement for the transfer of records does not apply to a merger, sale, or other transfer of ownership of a certifying agent.

Certifying agents are also required to prevent conflicts of interest and to require the completion of an annual conflict of interest disclosure report by all persons who review applications for certification, perform on-site inspections, review certification documents, evaluate qualifications for certification, make recommendations concerning certification, or make certification decisions and all parties responsibly connected to the certifying agent. Coverage of the conflict of interest provisions extends to immediate family members of persons required to complete an annual conflict of interest disclosure report. A certifying agent may not certify a production or handling operation if the certifying agent or a responsibly connected party of such certifying agent has or has held a commercial interest in the production or handling operation, including an immediate family interest or the provision of consulting services, within the 12-month period prior to the application for certification. A certifying agent may certify a production or handling operation if any employee, inspector, contractor, or other personnel of the certifying agent has or has held a commercial interest, including an immediate family interest or the provision of consulting services, within the 12-month period prior to the application for certification. However, such persons must be excluded from work, discussions, and decisions in all stages of the certification process and the monitoring of the entity in which they have or have held a commercial interest. The acceptance of payment, gifts, or favors of any kind, other than prescribed fees, from any business inspected is prohibited. However, a certifying agent that is a not-for-profit organization with an Internal Revenue Code tax exemption or, in the case of a foreign certifying agent, a comparable recognition of not-for-profit status from its government, may accept voluntary labor from certified operations. Certifying agents are also prohibited from giving advice or providing consultancy services to certification applicants or certified operations for overcoming identified barriers to certification. To further ensure against conflict of interest, the certifying agent must ensure that the decision to certify an operation is made by a person different from the person who conducted the on-site inspection.

The certifying agent must reconsider a certified operation's application for certification when the certifying agent determines, within 12 months of certifying the operation, that a person participating in the certification process and covered under section 205.501(c)(11)(ii) has or had a conflict of interest involving the applicant. If necessary, the certifying agent must perform a new

on-site inspection. All costs associated with a reconsideration of an application, including onsite inspection costs, shall be borne by the certifying agent. When it is determined that, at the time of certification, a conflict of interest existed between the applicant and a person covered under section 205.501(c)(11)(i), the certifying agent must refer the certified operation to a different accredited certifying agent for recertification. The certifying agent must also reimburse the operation for the cost of the recertification.

No accredited certifying agent may exclude from participation in or deny the benefits of the NOP to any person due to discrimination because of race, color, national origin, gender, religion, age, disability, political beliefs, sexual orientation, or marital or family status. Accredited certifying agents must accept all production and handling applications that fall within their areas of accreditation and certify all qualified applicants, to the extent of their administrative capacity to do so, without regard to size or membership in any association or group.

### **Renewal of Accreditation.**

To avoid a lapse in accreditation, certifying agents must apply for renewal of accreditation at least 6 months prior to the fifth anniversary of issuance of the notification of accreditation and each subsequent renewal of accreditation. The Administrator will send the certifying agent a notice of pending expiration of accreditation approximately 1 year prior to the scheduled date of expiration. The accreditation of certifying agents who make timely application for renewal of accreditation will not expire during the renewal process. The accreditation of certifying agents who fail to make timely application for renewal of accreditation will expire as scheduled unless renewed prior to the scheduled expiration date. Certifying agents with an expired accreditation must not perform certification activities under the Act and these regulations.

Following receipt of the certifying agent's annual report and fees and the results of a site evaluation, the Administrator will determine whether the certifying agent remains in compliance with the Act and regulations and should have its accreditation renewed. Upon a determination that the certifying agent is in compliance with the Act and regulations, the Administrator will issue a notice of renewal of accreditation. The notice of renewal will specify any terms and conditions that must be addressed by the certifying agent and the time within which those terms and conditions must be satisfied. Renewal of accreditation will be for 5 years. Upon a determination that the certifying agent is not in compliance with the Act and regulations, the Administrator will initiate proceedings to suspend or revoke the certifying agent's accreditation. Any certifying agent subject to a proceeding to suspend or revoke its accreditation may continue to perform certification activities pending resolution of the proceedings to suspend or revoke the accreditation.

### **Amending accreditation.**

An accredited certifying agent may request amendment to its accreditation at any time. The application for amendment must be sent to the Administrator and must contain information applicable to the requested change in accreditation, a complete and accurate update of the certifying agent's application information and evidence of expertise and ability, and the applicable fees.

### **Accreditation - Changes Based on Comments**

This subpart differs from the proposal in several respects as follows:

(1) Advice and Consultancy Services. We have amended section 205.501(a)(11)(iv) to clarify that certifying agents are to prevent conflicts of interest by not giving advice or providing consultancy services to applicants for certification and certified operations for overcoming identified barriers to

certification. This amendment has been made in response to a commenter who stated that the provisions of section 205.501(a)(11)(iv), as proposed, seemed to preclude the providing of advice and educational workshops and training programs. It was not our intent to prevent certifying agents from sponsoring in-house publications, conferences, workshops, informational meetings, and field days for which participation is voluntary and open to the general public. The provisions as originally proposed and as amended are intended to prohibit certifying agents from telling applicants and certified operations how to overcome barriers to certification identified by the certifying agent. It would be a conflict of interest for a certifying agent to tell an operation how to comply inasmuch as the certifying agents impartiality and objectivity will be lost should the advice or consultancy prove ineffective in resolving the noncompliance. The provisions of section 205.501(a)(11)(iv) are consistent with ISO Guide 61.

To further clarify this issue, we have also amended section 205.501(a)(16) by adding "for certification activities" after the word, "charges."

(2) Conflicts of Interest - Persons Covered. We have amended section 205.501(a)(11)(v) to limit the completion of annual conflict of interest disclosure reports to all persons who review applications for certification, perform on-site inspections, review certification documents, evaluate qualifications for certification, make recommendations concerning certification, or make certification decisions and all parties responsibly connected to the certifying agent. A commenter recommended amending section 205.501(a)(11)(v) to have it apply to all persons with direct oversight of or participation in the certification program rather than all persons identified in section 205.504(a)(2). Section 205.504(a)(2) includes all personnel to be used in the certification operation, including administrative staff, certification inspectors, members of any certification review and evaluation committees, contractors, and all parties responsibly connected to the certifying agent. We have decided that completion of annual conflict of interest disclosure reports by persons not involved in the certification process or responsibly connected to the certifying agent is unnecessary. As amended, section 205.501(a)(11)(v) includes all persons with the opportunity to influence the outcome of a decision on whether to certify a specific production or handling operation. Completed conflict of interest disclosure reports will be used by certifying agents to identify persons with interests in applicants for certification and certified operations that may affect the impartiality of such persons.

(3) Reporting Certifications Granted. We have amended section 205.501(a)(15)(ii) (formerly section 205.501(a)(14)(ii)) by replacing "a quarterly calendar basis" with "January 2 of each year." A commenter stated that the requirement that certifying agents report certifications that they have granted on a quarterly basis to the Administrator is burdensome. The commenter requested that section 205.501(a)(14)(ii) be amended to require a midyear or end-year reporting. Section 205.501(a)(15)(ii) now requires the certifying agent to submit a list, on January 2 of each year, including the name, address, and telephone number of each operation granted certification during the preceding year. Certifying agents can fulfill this requirement by providing an up-to-date copy of the list of producers and handlers required to be made available to the public by section 205.504(b)(5)(ii).

(4) Notification of Inspector. We have added a new section 205.501(a)(18) requiring the certifying agent to provide the inspector, prior to each on-site inspection, with previous on-site inspection reports and to notify the inspector of the certifying agent's decision relative to granting or denying certification to the applicant site inspected by the inspector. Such notification must identify any requirements for the correction of minor noncompliances. We have made this addition because we agree with the commenter that such information should be provided to the inspector and because the requirements are consistent with ISO Guide 61.

(5) Acceptance of Applications. We have added a new section 205.501(a)(19) requiring the certifying agent to accept all production or handling applications for certification that fall within the certifying agent's areas of accreditation and to certify all qualified applicants, to the extent of their

administrative capacity to do so, without regard to size or membership in any association or group. We have made this addition because we agree with the many commenters who requested that certifying agents be required to certify all qualified applicants. We recognize, however, that there may be times when the certifying agent's workload or the size of its client base might make it necessary for the certifying agent to decline acceptance of an application for certification within its area of accreditation. This is why we have included the proviso, "to the extent of their administrative capacity to do so." We have included "without regard to size or membership in any association or group" to address commenter concerns about discrimination in the providing of certification services. This addition is consistent with ISO Guide 61.

(6) Ability to Comply with SOP. We have added a new section 205.501(a)(20) requiring the certifying agent to demonstrate its ability to comply with an SOP, to certify organic production or handling operations within the State. This change, as pointed out by a State commenter, is necessary to clarify that a certifying agent must be able to comply with an SOP to certify production or handling operations within that State.

(7) Performance Evaluation. We have amended section 205.501(a)(6) by replacing "appraisal" with "evaluation" and expanding the coverage from inspectors to persons who review applications for certification, perform on-site inspections, review certification documents, evaluate qualifications for certification, make recommendations concerning certification, or make certification decisions. Corresponding amendments have also been made to section 205.510(a)(4). Further, we have amended section 205.501(a)(6) to clarify that the deficiencies to be corrected are deficiencies in certification services. We changed "appraisal" to "evaluation" at the request of a State commenter who pointed out that State inspectors generally perform other duties in addition to the inspection of organic production or handling operations. We concur that this change will help differentiate between the State's employee performance appraisal for all duties as a State employee and the evaluation of certification services provided under the NOP. Expanding the coverage from inspectors to all persons involved in the certification process makes the regulation consistent with ISO Guide 61. Sections 205.505(a)(3) and 205.510(a)(4) have been amended to make their language consistent with the changes to section 205.501(a)(6).

(8) Annual Program Evaluation. We have amended section 205.501(a)(7) by replacing "evaluation" with "review" and by replacing "evaluations" with "reviews." A commenter suggested amending section 205.501(a)(7) by replacing the requirement of an annual program evaluation with an annual review of program activities. We agree that "review" is a more appropriate term than "evaluate" since to review is to examine, report, and correct while evaluate is more in the nature of assessing value. We have not, however, accepted that portion of the commenter's suggestion which would have removed the reference to the review being conducted by the certifying agent's staff, an outside auditor, or a consultant who has the expertise to conduct such reviews. We have not accepted this suggestion because the comment would have limited the review to being conducted by the certifying agent with no requirement that the certifying agent be qualified to conduct the review. Another commenter wanted to change the requirement to an annual assessment of the quality of the inspection system. We have not accepted this suggestion because it can be interpreted as narrowing the scope of the review from the full certification program to just the inspection component of the certification program. This commenter would also have limited the review to being conducted by the certifying agent with no requirement that the certifying agent be qualified to conduct the review. We believe that narrowing the scope of the review would be inconsistent with ISO Guide 65. It is also inconsistent with our intent that the entire certification program be reviewed annually. We also received a comment stating that it is a violation of ISO Guide 65 to have staff perform an internal review. We disagree with this commenter. ISO Guide 65 provides that the certification body shall conduct periodic internal audits covering all procedures in a planned and systematic manner. Sections 205.505(a)(4) and 205.510(a)(4) have been amended to make their language consistent with the changes to section 205.501(a)(7).

(9) Certification Decision. We have added a new section 205.501(a)(11)(vi) that requires the certifying agent to ensure that the decision to certify an operation is made by a person different from the person who carried out the on-site inspection. Commenters requested that this provision be added to the requirement that certifying agents prevent conflicts of interest. We concur with the request because it clearly separates the act of inspecting an organic operation from the act of granting certification. This addition is also consistent with ISO Guide 65, section 4.2(f), which requires that the certification body ensure that each decision on certification is taken by a person different from those who carried out the evaluation.

(10) Determination of Conflict of Interest. We have added a new section 205.501(a)(12) addressing situations where a conflict of interest present at the time of certification is identified after certification. Several commenters requested the addition of a provision that, if a conflict of interest is identified within 12 months of certification, the certifying agent must reconsider the application and may reinspect the operation if necessary. We agree with the commenters that the issue of conflicts of interest present at the time of certification but identified after certification need to be addressed in the regulations. Accordingly, we have provided that an entity accredited as a certifying agent must reconsider a certified operation's application for certification and, if necessary, perform a new on-site inspection when it is determined, within 12 months of certifying the operation, that any person participating in the certification process and covered under section 205.501(a)(11)(ii) has or had a conflict of interest involving the applicant. Because the certifying agent is responsible for preventing conflicts of interest, all costs associated with a reconsideration of application, including onsite inspection costs, must be borne by the certifying agent. Further, a certifying agent must refer a certified operation to a different accredited certifying agent for recertification when it is determined that any person covered under section 205.501(a)(11)(i) at the time of certification of the applicant had a conflict of interest involving the applicant. Because the certifying agent is responsible for preventing conflicts of interest, the certifying agent must reimburse the operation for the cost of the recertification. Sections 205.501(a)(12) through 205.501(a)(17) have been redesignated as sections 205.501(a)(13) through 205.501(a)(18), respectively.

(11) Financial Security. We published an advanced notice of proposed rulemaking and request for comments regarding financial security in the August 9, 2000, issue of the Federal Register. We issued a news release announcing the Federal Register publication on August 9, 2000. Numerous commenters expressed concern about reasonable security relative to its amount and impact on small certifying agents. A few commenters requested a definition for reasonable security. Others stated that the formula for determining the amount of security should be published in the Federal Register. The March 13, 2000, NOP proposed rule stated that the amount and terms of reasonable financial security would be the subject of additional rulemaking. The August 9, 2000, advanced notice of proposed rulemaking solicited comments on all aspects of reasonable security and protection of the rights of program participants. We requested comments from any interested parties, including producers and handlers of organic agricultural products, certifying agents, importers and exporters, the international community, and any other person or group. Six questions were provided to facilitate public comment on the advanced notice of proposed rulemaking. Comments addressing other relevant issues were also invited. The questions posed in the advanced notice of proposed rulemaking were:

(1) From what risks or events might a customer of a private certifying agent require reasonable security?

(2) What are the financial instrument(s) that could provide the reasonable security to protect customers from these events?

(3) What dollar amounts of security would give reasonable protection to a customer of a private certifying agent?

(4) What are the financial costs to private certifiers, especially small certifiers, of providing reasonable security?

(5) Do the risks or events provided in response to question #1 necessarily require financial compensation?

(6) Are there situations in which reasonable security is not needed?

Following analysis of the comments received, we will publish a proposed rule on reasonable security in the Federal Register. The public will again be invited to submit comments. The proposed rule will include the proposed regulation, an explanation of the decision-making process, an analysis of the costs and benefits, the effects on small businesses, and an estimate of the paperwork burden imposed by the regulation.

(12) Use of Identifying Mark. We have amended section 205.501(b)(2) to clarify that all certifying agents (private and State) certifying production or handling operations within a State with more restrictive requirements, approved by the Secretary, shall require compliance with such requirements as a condition of use of their identifying mark by such operations. Numerous commenters stated that they wanted USDA to permit higher production standards by private certifying agents. See also item 17 under Accreditation - Changes Requested But Not Made. This amendment is intended to further clarify our position that no certifying agent (State or private) may establish or require compliance with its own organic standards. It is an SOP, not a State certifying agent, that receives approval from the Secretary for more restrictive requirements. See also item 7 under Accreditation - Clarifications.

(13) Transfer of Records. To address the issues of a merger, sale, or other transfer of ownership, we have added the following to the end of section 205.501(c)(3); "Provided, That, such transfer shall not apply to a merger, sale, or other transfer of ownership of a certifying agent." Commenters suggested amending section 205.501(c)(3) to provide for the transfer of records accumulated from the time of accreditation to the Administrator or his or her designee, another accredited certifying agent, or an SOP's governing State official in a State where such official exists. It was also stated that this section needs to take into account a certifying agent's decision to merge or transfer accounts to another certifying agent in the case of loss of accreditation. Under the NOP, should a certifying agent dissolve or lose its accreditation, its certified operations will be free to seek certification with the accredited certifying agent of their choice. Accordingly, it would be inappropriate to automatically transfer an operation's records to another certifying agent as requested by the commenters. However, in analyzing the comments, we realized that a provision was needed for a merger, sale, or other transfer of ownership of a certifying agent; thus, the amendment to section 205.501(c)(3). Section 205.505(b)(3) has been amended to make its language consistent with the changes to section 205.501(c)(3).

(14) Fees for Information. We have amended section 205.504(b)(5) by inserting "including any fees to be assessed" after the word, "used." This change is made in response to the question of whether fees may be charged for making information available to the public. It is our intent that certifying agents may charge reasonable fees for document search time, duplication, and, when applicable, review costs. We anticipate that review costs will most likely be incurred when the information requested is located within documents which may contain confidential business information.

(15) Information Available to the Public. We have amended section 205.504(b)(5)(ii) by adding products produced to the information to be released to the public. This addition responds in an alternate way to commenters who wanted the information included on certificates of organic operation. That request was denied; see item 4, Changes Requested But Not Made, under subpart E, Certification. This addition is consistent with ISO Guide 61.

(16) Equivalency of Certification Decisions and Statement of Agreement. We have amended sections 205.501(a)(12) (redesignated as 205.501(a)(13)) and 205.505(a)(1) by deleting the words, "USDA accredited" and "as equivalent to its own," and adding to the end thereof: "accredited or accepted by USDA pursuant to section 205.500." We have made this amendment to clarify that the provision applies to certification decisions by domestic certifying agents as well as foreign certifying agents accredited or accepted by USDA pursuant to section 205.500.

There were many comments in support of section 205.501(a)(12) as written. However some did not agree that certifying agents should have to recognize another agent's decision as equivalent to their own. These commenters want to maintain the right and ability not to use their seal on a product that does not meet their standards. The most strongly voiced comment stated: "delete section 205.501(a)(12) and section 205.505(a)(1). The requirements constitute a "taking" in violation of the Fifth Amendment and are unnecessary to accomplish the goal of establishing a consistent standard and facilitating trade."

We do not concur with the commenters who want to change sections 205.501(a)(12) and 205.505(a)(1). We also do not agree with the comment that sections 205.501(a)(12) and 205.505(a)(1) constitute a taking in violation of the Fifth Amendment and are unnecessary to accomplish the goal of establishing a consistent standard and facilitating trade. We believe that, to accomplish the goal of establishing a consistent standard and to facilitate trade, it is vital that an accredited certifying agent accept the certification decisions made by another certifying agent accredited or accepted by USDA pursuant to section 205.500. All domestic organic production and handling operations, unless exempted or excluded under section 205.101, must be certified to these national standards and, when applicable, any State standards approved by the Secretary. All domestic certified operations must be certified by a certifying agent accredited by the Administrator. No USDA-accredited certifying agent, domestic or foreign, may establish or require compliance with its own organic standards. Certifying agents are not required to have an identifying mark for use under the NOP. However, if a certifying agent is going to use an identifying mark under the NOP, the use of such mark must be voluntary and available to all of the certifying agent's clients certified under the NOP. Accordingly, we have not changed the requirement that a certifying agent accept the certification decisions made by another USDA-accredited certifying agent. We have, however, as noted above, amended both sections to require that USDA-accredited certifying agents accept the certification decisions made by another certifying agent accredited or accepted by USDA pursuant to section 205.500.

(17) Granting Accreditation. We have made editorial changes to section 205.506 consistent with the suggestion that we replace "approval of accreditation" with "granting of accreditation." In the title to section 205.506, we have replaced "Approval of" with "Granting." In section 205.506(a), we have replaced "approved" with "granted," and in section 205.506(b), we have replaced "approval" with "the granting." We have made these change because, under the NOP, we grant accreditation rather than approve accreditation.

(18) Correction of Minor Noncompliances. We have added a new section 205.506(b)(3) providing that the notification granting accreditation will state any terms and conditions for the correction of minor noncompliances. Commenters requested the addition of language to section 205.506(b) which would clarify that the Administrator may accredit with required corrective actions for minor noncompliances. In the proposed rule, we addressed accreditation subject to the correction of minor noncompliances at section 205.510(a)(3). We agree with commenters that, for the purposes of clarity, this issue should also be addressed in section 205.506 on the granting of accreditation. Accordingly, we have added new section 205.506(b)(3) as noted above. We have also retained the provisions of section 205.510(a)(3), which requires certifying agents to annually report on actions taken to satisfy any terms and conditions addressed in the most recent notification of accreditation or notice of renewal of accreditation. Section 205.506(b)(3) has been redesignated as section 205.506(b)(4).

(19) Denial of Accreditation. We have amended section 205.507 to include noncompliance and resolution provisions originally included by cross-reference to section 205.665(a). This cross-reference created confusion for commenters, regarding section 205.665's applicability to applicants for accreditation because the section does not specifically address applicants. Rather than specifically identifying applicants within section 205.665, we believe the issue is best clarified by addressing noncompliance and resolution within section 205.507. As amended, section 205.507 now states in paragraph (a) that the written notification of noncompliance must describe each noncompliance, the facts on which the notification is based, and the date by which the applicant must rebut or correct each noncompliance and submit supporting documentation of each such correction when correction is possible. This rewrite of paragraph (a) also enabled us to eliminate paragraph (b) since its provisions are addressed in amended paragraph (a). The section also provides, at new paragraph (b), that when each noncompliance has been resolved, the Program Manager will send the applicant a written notification of noncompliance resolution and proceed with further processing of the application. We have also clarified the applicant's appeal rights by adding "or appeal the denial of accreditation in accordance with section 205.681 by the date specified in the notification of accreditation denial" to the end of paragraph (c).

(20) Reinstatement of Accreditation. We have amended section 205.507(d) by removing the requirement that a certifying agent that has had its accreditation suspended reapply for accreditation in accordance with section 205.502. In its place, we provide that the certifying agent may request reinstatement of its accreditation. Such request may be submitted at any time unless otherwise stated in the notification of suspension. Amended section 205.507(d) also provides that the certifying agent's request must be accompanied by evidence demonstrating correction of each noncompliance and corrective actions taken to comply with and remain in compliance with the Act and the regulations in this part. We have made this change because unlike revocation, suspension does not terminate a certifying agent's accreditation. Accordingly, requiring a new application for accreditation is unnecessary and burdensome on the certifying agent. This change is consistent with changes to sections 205.662(f) and 205.665(g)(1), which were made based on comments received on section 205.662(f).

(21) Ineligible for accreditation. We have amended section 205.507(d) by deleting "private entity" from the third sentence. The amended sentence provides that "A certifying agent whose accreditation is revoked will be ineligible for accreditation for a period of not less than 3 years following the date of such determination." Several commenters recommended deletion of "private entity" so that private certifying agents would be regulated on an equivalent basis with State certifying agents. It is our intent to regulate private and State certifying agents on an equivalent basis. Accordingly, we made the recommended change.

(22) Peer Review. We have amended section 205.509. As amended, the section requires that the Administrator establish a peer review panel pursuant to FACA (5 U.S.C. App. 2 et seq.). The peer review panel will be composed of not less than 3 members who will annually evaluate the NOP's adherence to the accreditation procedures in subpart F of these regulations and ISO/IEC Guide 61, General requirements for assessment and accreditation of certification/registration bodies, and the NOP's accreditation decisions. This will be accomplished through the review of accreditation procedures, document review and site evaluation reports, and accreditation decision documents and documentation. The peer review panel will report its finding, in writing, to the NOP's Program Manager. We developed this approach to peer review as a means of addressing the suggestions of the commenters and the need for administration of an effective and timely accreditation program.

Many commenters wanted the opening language in the first sentence of section 205.509 changed from "The Administrator may" to the "The Administrator shall" establish a peer review panel to assist in evaluating applicants for accreditation, amendment to an accreditation, and renewal of accreditation as certifying agents. One of the most frequent comments, including a comment by the NOSB, was that peer reviewers should be compensated for their time and expenses. Many



commenters believe also that the peer review process should be collaborative. Some commenters who wanted this change recognized that a collaborative process where confidential information was shared could run into problems because FACA (P.L. 92-463, 5 U.S.C. App.) meetings are open to the public. They advised creating a FACA panel but restricting public access during discussion of confidential business information based on 5 U.S.C. Section 522b(c)(4) of the Government in the Sunshine Act.

As requested, amended section 205.509 requires the formation of a peer review panel. Also as requested, peer reviewers, who will serve as a FACA committee, will be reimbursed for their travel and per diem expenses. The reviewers will also work collaboratively. We have not, however, provided for collaborative review of each applicant for accreditation by the peer review panel because of the administrative burden that an outside collaborative review process would place on the NOP. Currently, there are 36 private and 13 State certifying agencies. It is, therefore, likely that USDA will receive approximately 50 applications for accreditation the first year of the program. Given the need to make accreditation decisions in a timely, organized fashion, it would be infeasible to convene a panel of peers for each applicant for accreditation prior to rendering a decision on accreditation. However, as noted above, we have provided that a peer review panel will annually evaluate the NOP's adherence to the accreditation procedures in subpart F of these regulations and ISO/IEC Guide 61, General requirements for assessment and accreditation of certification/registration bodies, and validate the NOP's accreditation decisions.

We have also amended current section 205.510(c)(3) by removing the reference to reports submitted by a peer review panel to make that section consistent with the rewrite of section 205.509.

(23) Expiration of accreditation. We have added a new section 205.510(c)(1) which provides that the Administrator shall send the accredited certifying agent a notice of pending expiration of accreditation approximately 1 year prior to the scheduled date of expiration. A commenter suggested USDA notification of certifying agents at least 1 year prior to the scheduled expiration of accreditation. We have made the suggested change because we believe notification about 1 year prior to expiration will facilitate the timely receipt of applications for renewal. We have redesignated sections 205.510(c)(1) and 205.510(c)(2) as 205.510(c)(2) and 205.510(c)(3), respectively.

(24) Amendments to Accreditation. We have added a new section 205.510(f) to provide that an amendment to an accreditation may be requested at any time. The application for amendment must be sent to the Administrator and must contain information applicable to the requested change in accreditation. The application for amendment must also contain a complete and accurate update of the information submitted in accordance with section 205.503, Applicant information; and section 205.504, Evidence of expertise and ability. The applicant must also submit the applicable fees required in section 205.640. We have added this new section because we agree with the commenter who expressed concern that the regulations were not clear regarding amendments to accreditation. This addition is consistent with section 205.510(a)(2) which allows certifying agents to request amendment of their accreditation as part of their annual report to the Administrator.

### **Accreditation - Changes Requested But Not Made**

This subpart retains from the proposed rule, regulations on which we received comments as follows:

(1) Accreditation by USDA. A commenter stated that ISO/IEC Guide 61 specifies, but the proposed rule did not specify, the requirements for USDA to assess and accredit certifying agents. The commenter questioned USDA's acceptance internationally as a competent

accreditation body. A few commenters requested that USDA provide certifying agents with assurance of international trade acceptance of the USDA's accreditation program prior to implementation of the final rule. We do not believe that it is necessary to include in these regulations detailed procedures by which USDA will operate its accreditation program. USDA has developed its accreditation and certification programs with the intent that they meet or exceed international guidelines. Every country will make its own decision regarding acceptance of this accreditation program. Accordingly, while we do not anticipate problems with acceptance of our accreditation program, we cannot provide assurance against problems as requested by the commenters.

(2) Equivalency at the European Community (EC) Level. A commenter requested confirmation that an equivalency agreement would be negotiated at the EC level since the EC legislation provides for the basic rules while accreditation of certifying agents is a task for each member state. Another commenter pointed out that because Switzerland has the same regulations as the EC, equivalency would have to be done in close coordination with the EC. The commenter went on to say that according to Swiss and European practice, not only the organic product, but also the bodies involved will be mutually accepted. This commenter also stated that, due to Swiss import provisions, brokers must be subject to a certain control. Equivalency will be negotiated between the United States and the foreign government authority seeking the equivalency agreement.

(3) Period of Accreditation. It was suggested that accreditation should be for a 4-year period with full reevaluation occurring once every 4 years and annual surveillance visits in the intervening years. We do not concur with changing the period of accreditation from 5 years to 4 years as suggested. The 5-year period that we have provided that accreditation is consistent with the Act, which provides that accreditation shall be for a period of not to exceed 5 years. The commenter claims that the international norm is for full reevaluations to take place once every 4 years with annual surveillance visits in the intervening years. ISO Guide 61, section 3.5.1, provides that the accreditation body shall have an established documented program, consistent with the accreditation granted, for carrying out periodic surveillance and reassessment at sufficiently close intervals to verify that its accredited body continues to comply with the accreditation requirements. We believe that accreditation for 5 years is a reasonable period of time. Further, we believe that a 5-year period of accreditation is consistent with ISO Guide 61 inasmuch as we require an annual evaluation of the certification program; annual review of persons associated with the certification process, including inspectors; annual reporting with a complete and accurate update of information required for accreditation; and one or more site evaluations during the period of accreditation in addition to the initial site evaluation for the period of accreditation. Accordingly, we have not made the recommended change.

(4) Accreditation by Private-Sector Accreditation Bodies. Numerous commenters wanted language added to section 205.500(c) that would allow private sector accreditation bodies to accredit foreign certifying agents. For example, several commenters suggested adding a provision reading as follows: "The foreign certifying agent is accredited by a private accreditation body recognized by the USDA as defined by an equivalency agreement negotiated between the USDA and the accreditation body." Commenters also wanted us to amend section 205.502(a) to recognize accreditation by private accreditation programs.

USDA is the accrediting body for all accreditations under the NOP. USDA will not recognize nongovernmental accrediting bodies. USDA will recognize foreign certifying agents accredited by a foreign government authority when USDA determines that the foreign government's standards meet the requirements of the NOP or when an equivalency agreement has been negotiated between the United States and a foreign government.

(5) Requirements for Accreditation. Some commenters requested more specificity in the requirements for accreditation. For example, one recommended that section 205.501(a)(1) should

include the requirement that inspectors demonstrate completion of a specified training program or internship or ongoing education and/or licensing. Another commenter wanted baseline criteria for denying an application due to expertise. Still others wanted a definition for (1) "experience and training pertaining to organic/sustainable agricultural methods and their implementation on farm or in processing facilities," (2) "trained certifying agent personnel," and (3) "reasonable time." Finally, one wanted recordkeeping and evaluative parameters. AMS does not believe that it is necessary to present the requirements for accreditation to the extent of detail requested by the commenters. The intent is to provide flexibility to the certifying agents such that they can tailor their policies and procedures to the nature and scope of their operation. The NOP is available to respond to questions and to assist certifying agents in complying with the requirements for accreditation.

(6) Volunteer Board Members. Some commenters suggested amending section 205.501(a)(5) to include a reference to committees and to expand "sufficient expertise" to "sufficient balance of interests and expertise." The commenters proposed the amendment to create a firewall between those persons involved in decision making and the volunteer board members. However, the purpose of section 205.501(a)(5) is to ensure that the persons used by the certifying agent to assume inspection, analysis, and decision-making responsibilities have sufficient expertise in organic production or handling techniques to successfully perform the duties assigned. Therefore, we have not made the suggested changes. Conflict of interest guidelines are found at section 205.501(a)(11).

(7) Confidentiality. A commenter stated that Texas law prevents the Texas Department of Agriculture from guaranteeing confidentiality to its clients. Accordingly, the commenter requested that section 205.501(a)(10) be amended by adding to the end thereof: "or as required by State statutes." We have not made the suggested change because the Act requires that the certifying agent maintain strict confidentiality with respect to its clients under the NOP and not disclose any business-related information concerning such client obtained while implementing the Act. To be accredited under the NOP, certifying agents must fully comply with the requirements of the Act and these regulations. Further, no SOP will be approved which does not comply with the NOP.

(8) Certifying Agent Fees. Several commenters requested that the regulations prohibit royalty formulas (i.e., fees from every certified sale) for certifying agent fees. It is not our intent to regulate how a certifying agent sets its fees beyond their being reasonable and nondiscriminatory.

(9) Conflicts of Interest. We received numerous comments stating that section 205.501(a)(11)(i) was too restrictive and unnecessary due to the provisions of section 205.501(a)(11)(ii) to prevent conflicts of interest. Some argued that these conflict of interest provisions are beyond ISO requirements and place an undue burden on membership based certifying agents and the entities they serve. They requested a conflict of interest policy enabling membership-based certification organizations to continue operating. A commenter suggested that section 205.501(a)(11) be amended to require that a certifying agent's board members sign an affidavit listing potential conflicts of interest, identify issues where an organization decision might help them personally, and exclude themselves from decision-making that would assist them personally. This commenter proposed the amendment for the purpose of creating a firewall between those persons involved in certification decision-making and the volunteer board members.

We do not believe that the conflict of interest provisions are too restrictive. These provisions are very similar to conflict of interest provisions under other USDA programs involving public-private partnerships (e.g., grain inspection). The certifying agent and its responsibly connected parties, including volunteer board members, hold positions of influence over the certifying agent's employees and persons with whom the certifying agent contracts for such services as inspection, sampling, and residue testing. Therefore, we continue to believe that avoiding such conflicts of interest is necessary to maintain the integrity of the organic certification process.

(10) Conflicts of Interest and Prohibition on Certification. A commenter requested that we include an "or" between sections 205.501(a)(11)(i) and 205.501(a)(11)(ii). We have not made the recommended change because both sections must be complied with; they are not mutually exclusive. Section 205.501(a)(11)(i) prohibits the certification of an applicant when the certifying agent or a responsibly connected party of such certifying agent has or has held a commercial interest in the applicant for certification, including an immediate family interest or the provision of consulting services, within the 12-month period prior to the application for certification. When the certifying agent and its responsibly connected persons are free of any conflict of interest involving the applicant for certification, the applicant may be certified if qualified. However, section 205.501(a)(11)(ii) requires the certifying agent to exclude any person (employees and contractors who do not meet the definition of responsibly connected), including contractors, with conflicts of interest from work, discussions, and decisions in all stages of the certification process and the monitoring of certified production or handling operations for all entities in which such person has or has held a commercial interest, including an immediate family interest or the provision of consulting services, within the 12-month period prior to the application for certification.

(11) Gifts and Contributions. Commenters recommended that section 205.501(a)(11)(iii) be amended to allow not-for-profit organizations to accept gifts and contributions from certified operations for those programs not directly related to the certifying agent's organic certification activities. They also wanted it clarified that not-for-profit organizations can accept voluntary labor from certified operations for those programs not directly related to the certifying agent's organic certification activities. We have not made the requested changes. First, the acceptance of gifts and contributions would constitute a conflict of interest and would be contrary to ISO Guide 61. Certifying agents must have the financial stability and resources to perform their certification duties without relying on gifts and contributions from those they serve. Second, we have not added the requested provision on voluntary labor because section 205.501(a)(11)(iii) already addresses the acceptance of voluntary labor by not-for-profit organizations from certified operations.

(12) Conflicts of Interest - Determination Period. Commenters wanted to increase the conflict determination period from 12 months to 24 months. Some also wanted the period to extend for 2 years after, with the exception of those who have left the employ of the certifying agent or are no longer under contract with the certifying agent.

We disagree with the recommendations calling for a longer precertification conflict of interest prohibition period. We continue to believe that 12 months is a sufficient period to ensure that any previous commercial interest would not create a conflict of interest situation for two reasons. First, this time period is consistent with similar provisions governing conflicts of interest for government employees. Second, section 205.501(a)(11)(v) requires the completion of an annual conflict of interest disclosure report by all personnel designated to be used in the certification operation, including administrative staff, certification inspectors, members of any certification review and program evaluation committees, contractors, and all parties responsibly connected to the certification operation. This requirement will assist certifying agents in complying with the requirements to prevent conflicts of interest. We also continue to believe that a longer prohibition period would have the effect of severely curtailing most certifying agents' ability to comply with the Act's requirement that they employ persons with sufficient expertise to implement the applicable certification program. Accordingly, we have not made the recommended change.

The change recommended by the commenters who requested that the conflict of interest determination period extend for 2 years after certification is unnecessary. Certifying agents and their responsibly connected parties, employees, inspectors, contractors, and other personnel are prohibited from engaging in activities or associations at any time during their affiliation with the certifying agent which would result in a conflict of interest. While associated with the certifying agent, all employees, inspectors, contractors, and other personnel are expected to disclose to the certifying agent any offer of employment they have received and not immediately refused. They

are also expected to disclose any employment they are seeking and any arrangement they have concerning future employment with an applicant for certification or a certified operation. The certifying agent would then have to exclude that person from work, discussions, and decisions in all stages of the certification or monitoring of the operation making the employment offer. If a certifying agent or a responsibly connected party of the certifying agent has received and not immediately refused an offer of employment, is seeking employment, or has an arrangement concerning future employment with an applicant for certification, the certifying agent may not accept or process the application. Further, certifying agents and responsibly connected parties may not seek employment or have an arrangement concerning future employment with an operation certified by the certifying agent while associated with that certifying agent. Certifying agents and responsibly connected parties must sever their association with the certifying agent when such person does not immediately refuse an offer of employment from a certified operation. Accordingly, we have decided not to include a postcertification prohibition period in this final rule.

(13) False and Misleading Claims. A commenter asked who will determine what is a misleading claim about the nature or qualities of products labeled as organically produced. This same commenter recommended amending section 205.501(a)(13) by removing the prohibition against making false or misleading claims about the nature or qualities of products labeled as organically produced.

We disagree with this recommendation. Claims regarding accreditation status, the USDA accreditation program for certifying agents, and the nature and quality of products labeled as organically produced all fall under the authority of the Act. Accordingly, USDA will determine what is a misleading claim. We believe that the requirements are needed to prevent the dissemination of inaccurate or misleading information to consumers about organically produced products. We further believe that the change suggested by the commenter would undermine the goal of a uniform NOP by allowing certifying agents to make claims that would state or imply that organic products produced by operations that they certify are superior to those of operations certified by other certifying agents. These requirements would not prohibit certifying agents from sharing factual information with consumers, farmers, processors, and other interested parties regarding verifiable attributes of organic food and organic production systems. Accordingly, we have not made the recommended change to what is now section 205.501(a)(14).

(14) Certifying Agent Compliance With Terms and Conditions Deemed Necessary. A commenter recommended that we remove section 205.501(a)(17). This section requires that certifying agents comply with and implement other terms and conditions deemed necessary by the Secretary. This requirement is consistent with section 6515(d)(2) of the Act, which requires a certifying agent to enter into an agreement with the Secretary under which such agent shall agree to such other terms and conditions as the Secretary determines appropriate. Accordingly, we have not accepted the commenter's recommendation. This requirement is located at current section 205.501(a)(21).

(15) Limitations on the Use of Certifying Agent's Marks. Numerous commenters stated that they wanted USDA to permit higher production standards by private certifying agents. A common argument for allowing higher standards was that practitioners must be allowed to "raise the bar" through superior ecological on-farm practices or pursuit of other social and ecological goals. Some commenters recommended that the language in section 205.501(b)(2) be replaced with provisions that would allow certifying agents to issue licensing agreements with contract specifications that clearly establish conditions for use of the certifying agent's identifying mark.

We believe the positions advocated by the commenters are inconsistent with section 6501(2) of the Act, which provides that a stated purpose of the Act is to assure consumers that organically produced products meet a consistent national standard. We believe that, to accomplish the goal of establishing a consistent standard and to facilitate trade, it is vital that an accredited certifying agent accept the certification decisions made by another certifying agent accredited or accepted

by USDA pursuant to section 205.500. All organic production and handling operations, unless exempted or excluded under section 205.101 or not regulated under the NOP (i.e., a producer of dog food), must be certified to these national standards and, when applicable, any State standards approved by the Secretary. All certified operations must be certified by a certifying agent accredited by the Administrator. No accredited certifying agent may establish or require compliance with its own organic standards. Accredited certifying agents may establish other standards outside of the NOP. They may not, however, refer to them as organic standards nor require that applicants for certification under the NOP or operations certified under the NOP comply with such standards as a requirement for certification under the NOP. Use of the certifying agent's identifying mark must be voluntary and available to all of its clients certified under the NOP. However, a certifying agent may withdraw a certified operation's authority to use its identifying mark during a compliance process. The certifying agent, however, accepts full liability for any such action.

The national standards implemented by this final rule can be amended as needed to establish more restrictive national standards. Anyone may request that a provision of these regulations be amended by submitting a request to the NOP Program Manager or the Chairperson of the NOSB. Requests for amendments submitted to the NOP Program Manager will be forwarded to the NOSB for its consideration. The NOSB will consider the requested amendments and make its recommendations to the Administrator. When appropriate, the NOP will conduct rulemaking on the recommended amendment. Such rulemaking will include an opportunity for public comment.

(16) Evidence of Expertise and Ability. A commenter stated that section 205.504, which addresses the documentation necessary to establish evidence of expertise and abilities, requires too much paperwork. We believe the amount of paperwork is appropriate for the task at hand, verifying a certifying agent's expertise in and eligibility for accreditation to certify organic production and handling operations to the NOP. We further believe that the level of paperwork is necessary to meet international guidelines for determining whether an applicant is qualified for accreditation as a certifying agent.

(17) Procedures for Making Information Available to the Public. Comments on section 205.504(b)(5) were mixed. Some commenters felt that the proposal fell short of the OFPA requirement to "Provide for public access to certification documents and lab analysis." Others thought that too much confidential information would be released.

The Act requires public access, at section 2107(a)(9), to certification documents and laboratory analyses pertaining to certification. Accordingly, we disagree with those commenters who requested that such documents not be released to the public. We also disagree with the commenters who contend that the requirement for public disclosure falls short of what is required by the Act. Section 205.504(b)(5) meets the requirements of the Act by requiring the release of those documents cited in section 2107(a)(9) of the Act. The section also authorizes the release of other business information as authorized in writing by the producer or handler.

(18) Accreditation Prior to Site Evaluation. Numerous commenters recommended that we require site visits prior to accreditation. Some commenters cited ISO Guide 61, section 2.3.1, in their arguments for site visits prior to accreditation. ISO Guide 61, section 2.3.1., provides that the decision on whether to accredit a body shall be made on the basis of the information gathered during the accreditation process and any other relevant information. Section 3.3.2 of ISO Guide 61 provides that the accreditation body shall witness fully the on-site activities of one or more assessments or audits conducted by an applicant body before an initial accreditation is granted.

We do not concur with the commenters. These regulations provide for assessment of the applicant's qualifications and capabilities through a rigorous review of the application and supporting documentation. Following this review, an initial site evaluation shall be conducted before or within a reasonable period of time after issuance of the applicant's "notification of

accreditation." In cases where the document review raises concerns regarding the applicant's qualifications and capabilities and the Administrator deems it necessary, a preapproval site evaluation will be conducted. We have further provided that a site evaluation shall be conducted after application for renewal of accreditation but prior to renewal of accreditation.

Our purpose in allowing for initial accreditation prior to a site evaluation is to facilitate implementation of the NOP and to provide a means for newly established certifying agents to obtain a client base to demonstrate that they can meet the requirements of the NOP regulations. We believe this is consistent with the intent of ISO Guide 61, section 2.3.1. and fits within its "and any other relevant information" provision. Accordingly, we restate our position that accreditation approval without a site evaluation is appropriate, necessary in the case of established certifying agents that may need to make adjustments in their operations to comply with the NOP regulations, and necessary in the case of newly established certifying agents who will have to obtain a client base to demonstrate beyond the paperwork that they can meet the requirements of the NOP regulations.

(19) Ineligibility After Revocation of Accreditation. Section 205.507(d) provides that a certifying agent whose accreditation is revoked will be ineligible for accreditation for a period of not less than 3 years following the date of such determination. A commenter stated that the 3-year period of ineligibility is overly long and effectively puts the certifying agent out of business. The commenter suggested that a 6- to 12-month period might be reasonable. We have not accepted the suggested 6- to 12-month ineligibility period because the Act requires a period of ineligibility of not less than 3 years following revocation of accreditation.

(20) Qualifications of the Site Evaluator. A commenter recommended amending section 205.508(a) to indicate the required qualifications of the site evaluator. We have not accepted the recommendation. We do not believe that it is necessary to specify the required qualifications of site evaluators in these regulations. All USDA employees who will perform site evaluations under the NOP are quality systems auditors trained in accordance with internationally recognized protocols.

(21) Complaint Process. A commenter recommended that section 205.510 include a complaint process for complaints by certified operations regarding the performance of a certifying agent or inspector. The commenter also recommended that section 205.510 include a complaint process for the public should they feel that a certifying agent is not in compliance.

We do not believe that it is necessary to include a complaint process in the regulations. All interested parties are free to file a complaint with an accredited certifying agent, SOP's governing State official, or the Administrator at any time. We will provide guidance to accredited certifying agents and SOP's governing State officials regarding the type of information to gather when receiving a complaint. SOP's governing State officials will include in their request for approval of their SOP information on their collection of complaint information. Certifying agents will include details regarding the collection of complaint information and the investigation of complaints involving certified operations in their procedures for reviewing and investigating certified operation compliance (section 205.504(b)(2)). This will include maintaining records of complaints and remedial actions relative to certification as well as documentation of followup actions. Further, certifying agents will include details regarding the collection of complaint information and the investigation of complaints involving inspectors and other personnel employed by or contracted by the certifying agents in their policies and procedures for training, evaluating, and supervising personnel (section 205.504(a)(1)).

(22) Recordkeeping by Certifying Agents. A commenter stated that the 10-year recordkeeping requirement of section 205.510(b)(2) for records created by the certifying agent regarding applicants for certification and certified operations is excessive. The commenter recommended a 5-year retention period. We have not accepted the recommended 5-year records retention period

for records created by the certifying agent regarding applicants for certification and certified operations because the Act requires the retention of such records for 10 years.

(23) Reaccreditation. A commenter recommended that section 205.510(c)(1) be amended to require reaccreditation every 3 years. We have provided that accreditation will be for a period of 5 years. This is consistent with the Act which provides that accreditation shall be for a period of not to exceed 5 years. The commenter believes that a 5-year period is not consistent with ISO Guide 61, section 3.5.1, which provides that the accreditation body shall have an established documented program, consistent with the accreditation granted, for carrying out periodic surveillance and reassessment at sufficiently close intervals to verify that its accredited body continues to comply with the accreditation requirements. We believe that accreditation for 5 years is a reasonable period of time. Further, we believe that a 5-year period of accreditation is consistent with ISO Guide 61 inasmuch as we require an annual evaluation of the certification program; annual review of persons associated with the certification process, including inspectors; annual reporting with a complete and accurate update of information required for accreditation; and one or more site evaluations during the period of accreditation in addition to the initial site evaluation for the period of accreditation. Accordingly, we have not made the recommended change. This requirement is located at current section 205.510(c)(2).

(24) Notice of Renewal of Accreditation. A commenter recommended that section 205.510(d) be amended to include a timeframe within which the Administrator must notify an applicant of its renewal of accreditation. We believe that a mandated timeframe for notifying the applicant of renewal of accreditation is inappropriate. We plan to process all applications for renewal of accreditation in the order in which they are received, to confirm the receipt of each application, and to establish a dialog with the applicant upon confirmation of receipt of an application for renewal of accreditation. The length of the renewal process will depend in large part on the nature of the operation seeking renewal of accreditation. To minimize the chances that an accreditation will expire during the renewal process, we have: (1) provided that the Administrator shall send the accredited certifying agent a notice of pending expiration of accreditation approximately 1 year before the date of expiration of the certifying agent's accreditation, (2) required that an application for renewal of accreditation must be received at least 6 months prior to expiration of the certifying agent's accreditation, and (3) provided that the accreditation of a certifying agent who makes timely application for renewal of accreditation will not expire during the renewal process. Accordingly, we have not made the recommended amendment.

### **Accreditation - Clarifications**

Clarification is given on the following issues raised by commenters as follows:

(1) Accreditation of Foreign Certifying Agents. A commenter suggested that section 205.500 be amended to provide that if there is a government system operating in a foreign country then the government is the appropriate pathway for that country to apply for accreditation.

USDA will accept an application for accreditation to perform certification activities under the NOP from any private entity or governmental entity certifying agent and accredit such applicant upon proof of qualification for accreditation. USDA will provide for USDA accreditation of certifying agents and acceptance of a foreign government's accreditation of certifying agent within the same country. This maximizes opportunity for certifying agents without the potential for confusion and overlap in documentation. Further, we believe these requirements facilitate world trade.

(2) State Approval of Product From Foreign Countries. A commenter stated that any product making claims of organic agricultural ingredients to be sold in California shall fall under the jurisdiction of the California Organic Program for enforcement, inspection, and certification direction. The commenter further stated that, should any foreign certifying agents be accepted,



they too shall be subject to the sovereign rights of the State of California to protect and enforce the laws of the State of California and to protect agricultural claims in this State.

Any organic program administered by a State will have to be approved by the Secretary. Approval of an SOP will be contingent upon the State's agreeing to accept the certification decisions made by certifying agents accredited or accepted by USDA pursuant to section 205.500.

(3) Equivalency. A commenter stated that USDA should declare in section 205.500 that there are no alternative methods of production that meet the Congressional purpose "to assure consumers that organically produced products meet a consistent standard." The commenter went on to state that, if USDA proceeds with equivalency then the regulations should be amended to provide for: (1) no importing until final determination, (2) no final determination until Federal Register publication and public comment, (3) audit of foreign agency and production sites, and (4) revocation of accreditation for violations. The commenter also recommended that foreign certifying agents be reviewed with the same frequency as State certifying agents.

We disagree that there are no alternative methods of production that assure consumers that organically produced products meet a consistent standard. Accordingly, we will negotiate equivalency agreements with foreign governments. A final equivalency agreement will be required before affected product may be imported into the United States and sold, labeled, or represented as organic. Equivalency agreements will be announced to the public through a notice in the Federal Register and a news release. Site evaluations are a possibility. Foreign certifying agents that receive USDA accreditation, rather than recognition through their government, will have to fully comply with the NOP and will be treated the same as domestic accredited certifying agents.

(4) Evaluation of Equivalency. Commenters asked how equivalency would be evaluated and recommended basing equivalency, not on a check of formalities, but on the finding of substantive equivalence and equivalent effectiveness of certifying systems.

The negotiation of an equivalency agreement will involve meetings between representatives of the foreign government seeking equivalency and representatives of USDA's Agricultural Marketing Service and Foreign Agricultural Service. Support will be provided by the Office of the U.S. Trade Representative. The process will also include the review of documents and possibly one or more site evaluations. Equivalency agreements will be announced to the public through a notice in the Federal Register and a news release.

(5) Treatment of Certifying Agents Operating in More Than One Country. A few commenters requested that we amend section 205.500(c) by adding a provision to clarify the issue of how the international activities of foreign or domestic certifying agents will be treated when they operate in more than one country.

We believe that the requested provision is unnecessary. Certifying agents, domestic and foreign, accredited under the NOP will be expected to comply fully with the requirements of the NOP regardless of where they operate. The only exception would be when they operate in a country in which the Secretary has negotiated an equivalency agreement.

(6) Accreditation of Foreign Certifying Agents. A commenter requested that we amend section 205.500(c) to exempt foreign applicants from having to be accredited certifying agents in USDA's program if the exporting country's national organic program meets international standards; e.g., Codex guidelines.

We have provided for USDA accreditation of qualified foreign certifying agents upon application. We have also provided that USDA will accept a foreign certifying agent's accreditation to certify

organic production or handling operations if it determines, upon the request of a foreign government, that the standards under which the foreign government authority accredited the foreign certifying agent meet the requirements of this part. We have further provided that USDA will accept a foreign certifying agent's accreditation to certify organic production or handling operations if the foreign government authority that accredited the foreign certifying agent acted under an equivalency agreement negotiated between the United States and the foreign government. These recognitions of foreign government programs, however, do not extend to international standards such as Codex guidelines. In either case, we are recognizing the ability of a foreign government's program to meet U.S. standards, not some other international standard.

(7) States with an Organic Statute. A commenter stated that a State with an organic statute or regulations that does not certify organic producers or organic handlers should not have to be accredited.

The NOP requires the Secretary's approval of SOP's whether or not the State has a State certifying agent. A State may have an SOP but not have a State certifying agent. In this case the SOP must be approved by the Secretary. A State may have a State certifying agent but no SOP. In this case, the State certifying agent must apply for and receive accreditation to certify organic production or handling operations. Finally, a State may have an SOP and a State certifying agent. In this case, the SOP must be approved by the Secretary, and the State certifying agent must apply for and receive accreditation to certify organic production or handling operations.

(8) Nondiscriminatory Services. A commenter wanted the addition of a provision in section 205.501(a) requiring certifying agents to provide nondiscriminatory services. We have not included the suggested addition in this final rule because the provision already exists in section 205.501(d).

(9) Release of Information. A few commenters requested that we amend section 205.501(a)(10) to include a general exclusion allowing the release of any information with the client's permission. We have not included the suggested addition in this final rule because section 205.504(b)(5)(iv) already addresses the allowed release of other business information as permitted in writing by the producer or handler.

(10) Use of the Term, "Certified Organic." In commenting on section 205.501(b)(1), a commenter stated that if the term, "certified organic," is included on a label, it must state by whom, according to Maine State law. We do not believe that the requirements of section 205.501(b)(1) would preclude a certified operation from complying with a State law requiring identification of the certifying agent on a product sold, labeled, or represented as "certified organic." Further, these regulations do not require a certified operation to use the word, "certified," on its label.

(11) Holding the Secretary Harmless. In commenting on the requirements of section 205.501(c)(1), a commenter stated that certifying agents are responsible for representing USDA but seem to have no recourse. Another commenter asked, what happens if a certifying agent is found in violation of the Act but the violation was due to information or direction that came from USDA?

Under the NOP, accredited certifying agents are required to comply with and carry out the requirements of the Act and these regulations. If they fail to do so, they are responsible for their actions or failures to act. This would not be true if the action or failure to act was at the direction of the Secretary.

(12) Self-evaluation of Ability to Comply. A commenter requested that section 205.504 be amended to provide clarity on the baseline requirements that would allow a certifying agent to conduct a self-evaluation to determine its ability to comply. The commenter stated that there

should be some type of baseline acceptance of expertise and ability. The commenter wants details regarding the "training" or "experience" requirements necessary to qualify for accreditation. This commenter also stated that criteria for inspector and reviewer training should be added and enlarged.

We do not believe that it is necessary to present the requirements for accreditation to the extent of detail requested by the commenter. The intent is to provide flexibility to the certifying agents such that they can tailor their policies and procedures to the nature and scope of their operation. The NOP is available to respond to questions and to assist certifying agents in complying with the requirements for accreditation.

(13) Evidence of Expertise and Ability. Commenters stated that important elements of ISO Guide 65 are missing from section 205.504. They cite the maintenance of a complaints register and a register of precedents and provisions for subcontracting and a documents control policy or a document register.

Certifying agents grant certification, deny certification, and take enforcement action against a certified operation's certification. Certifying agents are required to maintain records applicable to all such actions and to report such actions to the Administrator. Certifying agents may contract with qualified individuals for the performance of services such as inspection, sampling, and residue testing. Certifying agents are required to submit personnel information (employed and contracted) and administrative policies and procedures to the Administrator. All such documents must be updated annually. The regulations also require the maintenance of records according to specified retention periods. All of these factors will be considered in granting or denying accreditation. We believe these requirements meet or exceed the ISO Guide 65 guidelines.

(14) Personnel Evidence of Expertise. A commenter inquired about the frequency at which the personnel information, required by section 205.504(a) and used to establish evidence of expertise and ability, is to be updated. Section 205.510 requires that the certifying agent annually submit a complete and accurate update of the information required in section 205.504.

(15) Responsibly Connected. A commenter stated that the term, "responsibly connected," as used in section 205.504(a)(2) is a broad sweep. The commenter believes the term would include everyone they do business with.

Section 205.504(a)(2) requires the certifying agent to provide the name and position description of all personnel to be used in the certification operation. The section assists the certifying agent in meeting the requirement by identifying categories of persons covered by the requirement including persons responsibly connected to the certifying agent. Responsibly connected does not include everyone that the certifying agent does business with. Responsibly connected is defined in the Definitions subpart of this final rule as "any person who is a partner, officer, director, holder, manager, or owner of 10 percent or more of the voting stock of an applicant or a recipient of certification or accreditation." This definition has not changed.

(16) Independent Third-Party Inspectors. A commenter recommended amending section 205.504(a)(3)(l) to provide for the use of independent third-party inspectors. We believe that this recommended amendment is unnecessary since nothing in these regulations precludes a certifying agent from contracting with independent third parties for inspection services.

(17) Response to Accreditation Applicant. A commenter requested that section 205.506(a)(3) be amended to provide a timeframe within which the Administrator has to respond to the accreditation application. While section 205.506(a)(3) identifies the information to be reviewed by the Administrator prior to the granting of accreditation, we assume the commenter is seeking a specific time limit by which the Administrator will acknowledge receipt of an application for

accreditation. In the alternative, the commenter may have been seeking a specific time limit by which the Administrator must grant or deny accreditation. We believe that a regulation-mandated timeframe for notifying the applicant of receipt of an application or for granting or denying accreditation is unnecessary. We plan to process all applications in the order in which they are received, to confirm the receipt of each application upon receipt, and to establish a dialog with the applicant upon confirmation of receipt of an application for accreditation. We will work with each applicant to complete the accreditation process as expeditiously as possible. A firm timeframe, however, cannot be set for granting or denying accreditation due to the anticipated uniqueness of each applicant and its application for accreditation.

(18) Duration of Accreditation and Certification. A commenter asked, "How can certification be essentially in perpetuity and accreditation have a time restraint?" The commenter's question does not indicate a preference for certification or accreditation longevity. The commenter correctly points out that certification and accreditation, both of which must be updated annually, are granted for different time periods. The Act limits the period of accreditation to 5 years but does not establish a limit to the period of certification. We believe the requirement that the certified operation submit an annual update of its organic plan negates the need for a certification expiration date.

(19) Denial of Accreditation. In commenting on section 205.507, a commenter stated that the regulations need to address what happens to a certifying agent's clients when the certifying agent fails to qualify for accreditation on its first attempt.

Section 205.507(c) provides that an applicant who has received written notification of accreditation denial may apply for accreditation again at any time in accordance with section 205.502. Upon implementation of the certification requirements of the NOP, production and handling operations planning to sell, label, or represent their products as organic must be certified by a USDA-accredited certifying agent before selling, labeling, or representing their products as organic. If a producer's or handler's choice of certifying agents does not receive USDA accreditation, the producer or handler must seek and receive certification under the NOP from a USDA-accredited certifying agent before selling, labeling, or representing their products as organic. Producers and handlers not so certified may not sell, label, or represent their products as organic. Any producer or handler who violates this requirement will be subject to prosecution under section 2120 of the Act.

(20) Loss of Accreditation After Initial Site Visit. Commenting on section 205.508(b), a commenter stated the belief that accreditation before a site visit may cause problems if the certifying agent does not meet the requirements and, subsequently, loses its accreditation. We believe the problems will be no greater than will occur at any other time when it becomes necessary to revoke a certifying agent's accreditation, including when it becomes necessary to initiate proceedings to suspend or revoke the certification of one or more of the certifying agent's certified operations. However, just because revocation of a certifying agent's accreditation may be justified, it may not be necessary to suspend or revoke the certification of one or more of its clients. An operation certified by a certifying agent that has lost its accreditation must make application with a new certifying agent if it is going to continue to sell, label, or represent its products as organic.

(21) Prohibition on Certification After Expiration of Accreditation. A commenter stated that, "USDA should allow certifying agents to apply the same provisions to expiration of certification of a certified operation." The provision referenced by the commenter is the section 205.510(c)(1) (current section 205.510(c)(2)) requirement that certifying agents with an expired accreditation must not perform certification activities under the Act and these regulations. We have not accepted the commenter's request that the same prohibition be applied to production and handling operations with an expired certification because certification does not expire.

(22) Expiration of Accreditation. Many commenters requested that we amend section 205.510(c)(1) to require annual reports and "minivisits." The commenters cited ISO Guide 61, section 3.5.1. We do not believe that annual "minivisits" are necessary to meet the requirements of ISO Guide 61 or to assure compliance with the NOP. One or more site evaluations will be conducted during the period of accreditation. The certifying agent's annual report will be used as a determining factor in whether to conduct a site evaluation. A request for amendment to a certifying agent's area of accreditation will also result in a site evaluation. This requirement is located at current section 205.510(c)(2).

(23) Update and Review of Inspector Lists. In commenting on section 205.510(c)(1) (current section 205.510(c)(2)) several commenters stated that updating and review of inspector lists must occur more frequently than every 5 years. They cited ISO Guide 61, section 3.5.1.

Section 205.510(a)(1) requires that the certifying agent annually update the information required in section 205.504. This includes the inspector information required by paragraphs 205.504(a)(2) and 205.504(a)(3)(i).

1. ISO/IEC Guide 65 is available for viewing at USDA-AMS, Transportation and Marketing Programs, Room 2945-South Building, 14th and Independence Ave., SW, Washington, DC, from 9:00 a.m. to 4:00 p.m., Monday through Friday (except official Federal holidays). A copy may be obtained from the American National Standards Institute, 11 West 42d Street, New York, NY 10036; Website: [www.ansi.org](http://www.ansi.org); E-mail: [ansionline@ansi.org](mailto:ansionline@ansi.org); Telephone: 212-642-4900; Facsimile: 212-398-0023.

2. ISO/IEC Guide 61 is available for viewing at USDA-AMS, Transportation and Marketing Programs, Room 2945-South Building, 14th and Independence Ave., SW, Washington, DC, from 9:00 a.m. to 4:00 p.m., Monday through Friday (except official Federal holidays). A copy may be obtained from the American National Standards Institute, 11 West 42d Street, New York, NY 10036; Website: [www.ansi.org](http://www.ansi.org); E-mail: [ansionline@ansi.org](mailto:ansionline@ansi.org); Telephone: 212-642-4900; Facsimile: 212-398-0023.

# National List -- Preamble

## Subpart G Administrative

### The National List of Allowed and Prohibited Substances

#### Description of Regulations

##### General Requirements

This subpart contains criteria for determining which substances and ingredients are allowed or prohibited in products to be sold, labeled, or represented as "organic" or "made with organic (specified ingredients or food group(s))." It establishes the National List of Allowed and Prohibited Substances (National List) and identifies specific substances which may or may not be used in organic production and handling operations. Sections 6504, 6510, 6517, and 6518 of the Organic Foods Production Act (OFPA) of 1990 provide the Secretary with the authority to develop the National List. The contents of the National List are based upon a Proposed National List, with annotations, as recommended to the Secretary by the National Organic Standards Board (NOSB). The NOSB is established by the OFPA to advise the Secretary on all aspects of the National Organic Program (NOP). The OFPA prohibits synthetic substances in the production and handling of organically produced agricultural products unless such synthetic substances are placed on the National List.

Substances appearing on the National List are designated using the following classifications:

1. Synthetic substances allowed for use in organic crop production
2. Nonsynthetic substances prohibited for use in organic crop production
3. Synthetic substances allowed for use in organic livestock production
4. Nonsynthetic substances prohibited for use in organic livestock production
5. Nonagricultural (nonorganic) substances allowed as ingredients in or on processed products labeled as "organic" or "made with organic (specified ingredients or food group(s))"
6. Nonorganically produced agricultural products allowed as ingredients in or on processed products labeled as organic" or "made with organic (specified ingredients or food group(s))"

This subpart also outlines procedures through which an individual may petition the Secretary to evaluate substances for developing proposed National List amendments and deletions.

The NOSB is responsible for making the recommendation of whether a substance is suitable for use in organic production and handling. The OFPA allows the NOSB to develop substance recommendations and annotations and forward to the Secretary a Proposed National List and any subsequent proposed amendments. We have made every effort to ensure the National List in this final rule corresponds to the recommendations on allowed and prohibited substances made by the NOSB. In developing their recommendations, the NOSB evaluates synthetic substances for the National List utilizing the criteria stipulated by the Act. Additionally, criteria for evaluating synthetic processing ingredients have been implemented by the NOSB. These criteria are an interpretation and application of the general evaluation criteria for synthetic substances contained in the OFPA that the NOSB will apply to processing aids and adjuvants. The NOSB adopted these criteria as internal guidelines for evaluating processing aids and adjuvants. The adopted

criteria do not supersede the criteria contained in the OFPA or replace the Food and Drug Administration's (FDA) regulations related to food additives and generally recognized as safe (GRAS) substances. The NOSB has also provided recommendations for the use of synthetic inert ingredients in formulated pesticide products used as production inputs in organic crop or livestock operations. The Environmental Protection Agency (EPA) regulates and maintains the EPA Lists of Inert ingredients used for pesticide. In this final rule, EPA Inerts List 1 and 2 are prohibited, EPA List 3 is also prohibited unless specifically recommended as allowed by the NOSB, and EPA List 4 Inerts are allowed unless specifically prohibited.

In this final rule, only EPA List 4 Inerts are allowed as ingredients in formulated pesticide products used in organic crop and livestock production. The allowance for EPA List 4 Inerts only applies to pesticide formulations. Synthetic ingredients in any formulated products used as organic production inputs, including pesticides, fertilizers, animal drugs, and feeds, must be included on the National List. As sanctioned by OFPA, synthetic substances can be used in organic production and handling as long as they appear on the National List. The organic industry should clearly understand that NOSB evaluation of the wide variety of inert ingredients and other nonactive substances will require considerable coordination between the NOP, the NOSB, and industry. Materials review can be anticipated as one of the NOSB's primary activities during NOP implementation. Considering the critical nature of this task, the organic industry should make a collaborative effort to prioritize for NOSB review those substances that are essential to organic production and handling. The development and maintenance of the National List has been and will be designed to allow the use of a minimal number of synthetic substances that are acceptable to the organic industry and meet the OFPA criteria.

We expect the maintenance of the National List to be a dynamic process. We anticipate that decisions on substance petitions for the inclusion on or deletion from the National List will be made on an annual basis. Any person seeking a change in the National List should request a copy of the petition procedures that were published in the Federal Register (65 Fed Reg 43259 - 43261) on July 13, 2000, from the NOP. The National List petition process contact information is: Program Manager, National Organic Program, USDA/AMS/TMP/NOP, Room 2945-S, Ag Stop 0268, P.O. Box 96456, Washington, DC 20090-6456 or visit the NOP website: [www.ams.usda.gov/nop](http://www.ams.usda.gov/nop). Substances petitioned for inclusion on the National List will be reviewed by the NOSB, which will forward a recommendation to the Secretary. Any amendments to the National List will require rulemaking and must be published for comment in the Federal Register.

Nothing in this subpart alters the authority of other Federal agencies to regulate substances appearing on the National List. FDA issues regulations for the safe use of substances in food production and processing. USDA's Food Safety and Inspection Service (FSIS) has the authority to determine efficacy and suitability regarding the production and processing of meat, poultry, and egg products. FDA and FSIS restrictions on use or combinations of food additives or GRAS substances take precedence over the approved and prohibited uses specified in this final rule. In other words, any combinations of substances in food processing not already addressed in FDA and FSIS regulations must be approved by FDA and FSIS prior to use. FDA and FSIS regulations can be amended from time to time under their rulemaking procedures, and conditions of safe use of food additives and GRAS substances can be revised by the amendment. It is important that certified organic producers and handlers of both crop and livestock products consult with FDA regulations in 21 CFR parts 170 through 199 and FSIS regulations in this regard. All feeds, feed ingredients, and additives for feeds used in the production of livestock in an organic operation must comply with the Federal Food, Drug, and Cosmetic Act (FFDCA). Animal feed labeling requirements are published in 21 CFR Part 501, and new animal drug requirements and a listing of approved animal drugs are published in 21 CFR Parts 510-558. Food (feed) additive requirements, a list of approved food (feed) additives generally recognized as safe substances, substances affirmed as GRAS, and substances prohibited from use in animal food or feed are published in 21 CFR 570-571, 21 CFR 573, 21 CFR 582, 21 CFR 584, and 21 CFR 589, respectively. Furthermore, the Food and Drug Administration has worked closely with the

Association of American Feed Control Officials (AAFCO) and recognizes the list of additives and feedstuffs published in the AAFCO Official Publication, which is updated annually.

Under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), EPA regulates the use of all pesticide products, including those that may be approved for use in the NOP. In registering a pesticide under FIFRA, EPA approves the uses of each pesticide product. It is a violation of FIFRA to use a registered product in a manner inconsistent with its labeling. The fact that a substance is on the National List does not authorize use of a pesticide product for that use if the pesticide product label does not include that use. If the National List and the pesticide labeling conflict, the pesticide labeling takes precedence and may prohibit a practice allowed on the National List.

### **National List - Changes Based On Comments**

This subpart differs from the proposal in several respects as follows:

(1) Comprehensive Prohibition on Excluded Methods. Many commenters supported a comprehensive prohibition on the use of excluded methods in organic production and handling. These commenters stated that the proposed language on excluded methods could have allowed some uses since the general prohibition described in section 205.301 of the proposed rule could be interpreted as applying only to multiingredient products. In order to provide a comprehensive prohibition on the use of excluded methods, we incorporated a new provision within section 205.105. A more comprehensive discussion of this issue is found in subpart B, Applicability.

(2) Substance Evaluation Criteria for the National List. Commenters stated that the final rule should include in the regulation text the evaluation criteria utilized by the NOSB for the development of substance recommendations. We agree, and we have inserted the substance evaluation criteria developed by the NOSB for processing ingredients and cited the criteria within the Act (7 U.S.C. 6518(m)) for crops and livestock production as new provisions for section 205.600, which is now entitled "Evaluation criteria for allowed and prohibited substances, methods, and ingredients."

(3) Substances Approved for Inclusion on the National List. Commenters stated that the National List did not contain all of the substances recommended by the NOSB for inclusion on the National List of Allowed and Prohibited Substances. We agree and have added the following substances consistent with the most recent NOSB recommendations:

#### Crop Production:

Lime sulfur as a plant disease control substance

Elemental sulfur as a plant or soil amendment

Copper as a plant or soil micronutrient

Streptomycin sulfate as plant disease control substances with the annotation " for fire blight control in apples and pears only"

Terramycin (oxytetracycline calcium complex) as a plant disease control substance with the annotation "for fire blight control only"

Magnesium sulfate as a plant or soil amendment with the annotation "allowed with a documented soil deficiency"



Ethylene as a plant growth regulator, with the annotation "for regulation of pineapple flowering"

We have added sodium nitrate and potassium chloride to the National List as nonsynthetic substances prohibited for use in crop production unless used in accordance with the substance annotations. Sodium nitrate is prohibited unless use is restricted to no more than 20 percent of the crop's total nitrogen requirement. Potassium chloride is prohibited unless derived from a mined source and applied in a manner that minimizes chloride accumulation in the soil. These additions are discussed further in item 3 under Changes Based on Comments, subpart C.

#### Livestock Production:

Oxytocin with the annotation "for use in postparturition therapeutic applications"

EPA List 4 inert ingredients as synthetic inert ingredients for use with nonsynthetic substances or synthetic substances allowed in organic livestock production.

Several commenters recommended that the final rule should specify which nonsynthetic substances are prohibited for use in livestock production. These commenters stated that the proposed rule prohibited six such substances for use in crop production and maintained that an analogous list for livestock operations would be beneficial. Of the six nonsynthetic substances in the proposed rule prohibited for use in crop production, four were based on NOSB recommendations (strychnine, tobacco dust, sodium fluoaluminate (mined), and ash from burning manure) and two were based on statutory provisions in the OFPA (arsenic and lead salts). After reviewing these substances and the NOSB recommendations, we determined that the prohibition for one, strychnine, also applies to livestock production. Individuals may petition the NOSB to have additional nonsynthetic substances prohibited for use in organic crop and livestock production.

#### Organic Handling (Processing):

Tribasic calcium phosphate

Nonsynthetic colors

Flavors, with the annotation "nonsynthetic sources only and must not be produced using synthetic solvents and carrier systems or any artificial preservatives"

Nonsynthetic waxes, carnauba wax, wood resin

Cornstarch (native), gums, kelp, lecithin and pectin were moved from section 205.605 to section 205.606

(4) Substance Removed from the National List. Commenters stated that certain substances on the National List in the proposed rule had not been recommended by the NOSB. We agree with the comment that the NOSB did not recommend that magnesium should be allowed as a plant or soil micronutrient and have removed it from the National List.

(5) Changes in Substance Annotations on the National List. Commenters stated that certain annotations in the proposed rule did not capture the precise recommendations of the NOSB. We agree and have amended the annotations within the National List as follows:

The annotation for hydrated lime as a plant disease control substance now states, "must be used in a manner that minimizes accumulation of copper in the soil."

The annotation for horticultural oils as an insecticide substance and as a plant disease control substance now states, "Narrow range oils as dormant, suffocating, and summer oils."

The annotation for hydrated lime in livestock production now states, "not permitted for soil application or to cauterize physical alterations or deodorize animal wastes."

The annotation for the allowed synthetic parasiticide Ivermectin has been modified to state that the substance may not be used during the lactation period of breeding stock.

The annotation for trace minerals and vitamins allowed as feed additives has been modified and now states, "used for enrichment or fortification when FDA approved."

The annotation for magnesium sulfate in organic handling now states, "nonsynthetic sources only."

The annotation for EPA List 4 Inerts allowed in crop and livestock production has been modified to state, "...for use with nonsynthetic substances or synthetic substances listed in this section..."

(6) Sulfur Dioxide for Organic Wines. Many commenters recommended that this final rule should allow for the use of sulfur dioxide in wine labeled "made with organic grapes." They argued that sulfur dioxide is necessary in organic wine production and that prohibiting its use would have a negative impact on organic grape production and wineries that produce wine labeled "made with organic grapes." The prohibition on the use of sulfur dioxide in the proposed rule was based upon the requirement in the Act that prohibited the addition of sulfites to organically produced foods. However, a change in the Act now allows the use of sulfites in wine labeled as "made with organic grapes." Therefore, we have added sulfur dioxide to the National List with the annotation, "for use only in wine labeled 'made with organic grapes,' Provided, That, total sulfite concentration does not exceed 100 ppm." The label for the wine must indicate the presence of sulfites. This addition to the National List is also in agreement with the NOSB recommendation for allowing the use of sulfur dioxide in producing wine to be labeled as "made with organic grapes."

### **National List - Changes Requested But Not Made**

This subpart retains from the proposed rule regulations on which we received comments as follows:

(1) Restructuring the National List. Commenters requested a restructuring of the National List to improve its clarity and ease of use. Some of the commenters asked for minor changes involving the wording of section titles. Other commenters were opposed to the categories used in the National List because the categories are not in compliance with the Act. In its June 2000 meeting, the NOSB asked the NOP to review a proposal from a research institute proposing that processing materials for the National List be categorized according to industry standards. This proposal recommended including new sections for substances used in "made with..." and substances used in the 5-percent nonorganic portion of "organic" multiingredient products. We agree that the present structure of the National List may not have optimum clarity and ease of use. However, extensive restructuring of the National List without additional NOSB consideration and public discussion would be a significant variation from the policy that established the National List for this final rule. The NOP will work with the NOSB and the public to refine the National list consistent with industry norms and public expectations.

(2) Use of EPA List 4 Inerts. The proposed rule allowed EPA List 4 Inerts to be used as synthetic inert ingredients with allowed synthetic active ingredients in crop production. Some commenters stated that certain substances among the EPA List 4 inerts should not be allowed in organic production. Some commenters went further and recommended that the allowance for synthetic

inert ingredients should be limited to the subset of materials that the EPA designates as List 4A. We do not agree with these commenters and have retained the allowance for all inerts included on EPA List 4. List 4 inerts are classified by EPA as those of "minimal concern" and, after continuing consultation with EPA, we believe there is no justification for a further restriction to List 4A. If commenters believe that a particular List 4 inert should not be allowed in formulated products used in organic production, they can petition the NOSB to have that substance prohibited.

(3) Removing Vaccines from the National List. Some commenters asserted that vaccines should not be included on the National List because the NOSB had never favorably recommended their use in livestock production. However, the OFPA authorizes the use of vaccines, and in 1995, the NOSB recommended allowing their use. The NOSB stated that use of vaccines may be necessary to ensure the health of the animal and to remain in compliance with Federal, State, or regional regulations. We agree with the NOSB's recommendation and have retained vaccines as an allowed substance in livestock medication.

(4) Adding Amino Acids to the National List. Some commenters recommended that amino acids should be added to the National List as allowed synthetic substances for livestock production. We have not added amino acids to the National List because the NOSB has not recommended that they should be allowed. This subject is discussed further in item 4, Livestock - Changes Based on Comments, subpart C.

(5) Creating a Category for Prohibited Nonsynthetic Seed Treatments. A commenter stated that the National List of nonsynthetic substances prohibited for use in crop production should include provisions for seed treated with a nonsynthetic substance. This commenter stated that the final rule should acknowledge that a nonsynthetic seed treatment could be prohibited on the National List. We do not believe it is necessary to include a separate category for seed treatments under the prohibited nonsynthetic section of the National List. An individual may petition the NOSB to have a particular nonsynthetic seed treatments placed on the prohibited list without creating a new category for seed treatments.

(6) Creating a Category for Treated Seed and Toxins Derived from Bacteria. Commenters stated that the National List of synthetic substances allowed in crop production should include categories for treated seed and toxins derived from bacteria. These commenters stated that these categories are sanctioned by the OFPA, and failure to consider them would place a significant burden on organic producers. We believe it is unnecessary to include these categories on the National List. Specific substances from these categories could be incorporated in existing categories that reflect their function, such as plant disease control or insecticide. An individual may submit petitions to the NOSB to have specific substances from these categories considered for inclusion on the National List.

(7) Remove Categories for Feed Supplements. A commenter stated that it was inappropriate for the National List of synthetic substances allowed in livestock production to contain categories for feed supplements and feed additives because they are not authorized in the OFPA. We disagree with this commenter because the identification of categories on the National List does not mean that all substances within that category are allowed. The categories help to clarify which types of materials may be included on the National List. The substances included under the categories of feed supplements and feed additives were recommended by the NOSB and added to the National List with the Secretary's approval.

(8) Neurotoxic Substances on the National List. Many commenters requested that the NOP remove particular substances from section 205.605 of the National List. They stated these substances were sources of neurotoxic compounds that negatively effect human health. The substances cited were yeast (autolysate and brewers), carrageenan, and enzymes. Moreover, these commenters argued against including on the National List some amino acids or their

derivatives which the commenters claim have neurotoxic side effects. These commenters requested that amino acids should be prohibited from the National List due to the possibility that neurotoxic substances could be utilized for either organic agricultural production or handling.

We do not agree with the requests of the commenters and we have not made the requested changes. There are no amino acids currently on the National List; therefore, synthetic sources of amino acids are prohibited. Unless recommended for use by the NOSB, synthetic amino acids will not be included on the National List. The NOP has established a petition process for substances to be evaluated for inclusion on or removal from the National List of Allowed and Prohibited Substances in organic production and handling. Anyone seeking to have a particular substance removed from the National List may file a substance petition to amend the National List.

(9) EPA List 4 Inerts for Organic Processing. A few commenters recommended that substances in EPA List 4 inerts that are allowed for use in crop production also be allowed for use as processing materials. We do not agree, and we have not included EPA List 4 Inerts on the National List for organic handling. Inerts listed on EPA List 4 have been evaluated and approved for use in pesticide formulations, not for use as processing materials. Inerts that are included on EPA List 4 would have to be further evaluated to determine whether such materials meet the criteria for inclusion on the National List.

(10) Modifying Annotations of Organic Processing Substances. One commenter requested that the Department modify the annotation for phosphoric acid to include its use as a processing aid. We have not made the suggested change. Any change in the annotation of a substance can only occur through an NOSB recommendation. Individuals or groups can use the petition process to submit substance petitions to the NOSB for the evaluation to be included on or removed from the National List.

(11) Nutritional Supplementation of Organic Foods. Some commenters asserted that 21 CFR 104.20 is not an adequate stand-alone reference for nutritional supplementation of organic foods. As a result, these commenters recommended that the final rule include as additional cites 21 CFR 101.9(c)(8) for FDA-regulated foods and 9 CFR 317.30(c), 318.409(c)(8) for foods regulated by FSIS to support 21 CFR 104.20. We did not implement the suggested changes of the commenters. Section 205.605(b)(20) in the proposed rule allowed the use of synthetic nutrient vitamins and minerals to be used in accordance with 21 CFR 104.20, Nutritional Quality Guidelines For Foods, as ingredients in processed products to be sold as "organic" or "made with..." The commenters recommended cites, 21 CFR 101.9(c)(8) for FDA-regulated foods and 9 CFR 317.30(c); section 318.409(c)(8) did not provide provisions for nutritional supplementation of foods. Instead, these suggested cites were particularly aimed toward: (1) the declaration of nutrition information on the label and in labeling of a food; (2) labeling, marking devices, and containers; (3) entry into official establishments; and (4) reinspection and preparation of products. The NOP, in consultation with FDA, considers 21 CFR 104.20 to be the most appropriate reference regarding nutritional supplementation for organic foods.

(12) National List Petition Process as Part of the Final Rule.

Commenters have requested that the National List Petition Process, approved by the NOSB at its June 2000 meeting (and published in the Federal Register on July 13, 2000), be included in the final rule. We do not agree with the commenters, and we have retained the National List Petition Process regulation language from the proposed rule. We have separated the specific petition process from the regulation to provide for maximum flexibility to change and clarify the petition process to accommodate new considerations developed during the NOP implementation. If this process were part of this final rule, updates to the petition process would require notice and comment rulemaking. Any changes in the National List that may be a result of the petition process, however, would require notice and comment rulemaking.

(13) Nonapproved Substance Amendments to the National List. Commenters also requested to have many substances that are not on the National List and that have not been recommended by the NOSB for use in organic production and handling be added to the National List. We do not agree. Amendments to the National List must be petitioned for NOSB consideration, must have an NOSB recommendation, and must be published for public comment in the Federal Register.

### **National List - Clarifications**

Clarification is given on the following issues raised by commenters as follows:

(1) Inerts Use in Botanical or Microbial Pesticides. Commenters expressed concern that the prohibition on the use of EPA List 3 inerts would prevent organic producers from using certain botanical or microbial formulated products that are currently allowed under some certification programs. These commenters requested that the NOP and the NOSB expedite the evaluation of List 3 inerts used in nonsynthetic formulated products to prevent the loss of certain formulated products. The prohibition of List 3 inerts was based on the recommendation of the NOSB to add only those substances from List 4 to the National List. The NOSB also recommended that individual inert substances included on List 3 could be petitioned for addition to the National List. The NOP has requested that the NOSB identify for expedited review those List 3 inerts that are most important in formulated products used in organic production. Individuals may petition to have these inerts considered for inclusion on the National List. Additionally, the NOP will work with the EPA and the registrants of formulated products to expedite review of List 3 inerts currently included in formulated products used in organic production. Unless List 3 inerts are moved to List 4 or individually added to the National List, they are prohibited for use in organic production.

(2) Prohibiting Ash, Grit, and Screenings Derived from Sewage Sludge. Many commenters recommended that the ash, grit, and screenings derived from the production of sewage sludge should be added to the National List as nonsynthetic materials prohibited for use in crop production. While the use of sewage sludge, including ash, grit, and screenings, is prohibited in organic production, we did not add them to the National List as prohibited nonsynthetic substances. This subject is discussed further under subpart A, Definitions - Changes Requested But Not Made.

(3) Allowed Uses for Pheromones. Some commenters were concerned that the annotation for using pheromones as "insect attractants" was too limiting and would not include uses such as mating disruption, trapping, and monitoring. The annotation for pheromones does not preclude any use for a pheromone that is otherwise allowed by Federal, State, or local regulation.

(4) Nonagricultural Products as Livestock Feed Ingredients. Some commenters questioned whether nonsynthetic, nonagricultural substances such as fishmeal and crushed oyster shell needed to be added to the National List to be used in livestock feed. Nonsynthetic substances do not have to appear on the National List and may be used in organic livestock feed, provided that they are used in compliance with the FFDCRA. This subject is discussed further under item 4, Livestock - Changes Based on Comments, subpart C.

(5) Chlorine Disinfectant Limit Annotation for Organic Production and Handling. Some commenters requested clarification on the annotation for using chlorine materials as an allowed synthetic substance in crop and handling operations. The annotation in the proposed rule, which has been retained in the final rule, stated that "residual chlorine levels in the water shall not exceed the maximum residual disinfectant limit under the Safe Water Drinking Act." With this annotation, the residual chlorine levels at the point where the waste water stream leaves the production or handling operation must meet limits under the Safe Drinking Water Act.

(6) Tobacco Use in Organic Production. One commenter questioned whether forms of tobacco other than tobacco dust, such as water extracts or smoke, were prohibited nonsynthetic substances. The technical advisory panel (TAP) review on which the NOSB based its recommendation to prohibit tobacco dust identified nicotine sulfate as the active ingredient. Therefore, any substance containing nicotine sulfate as an active ingredient is prohibited in crop production.

(7) Nonsynthetic Agricultural Processing Aids on the National List. A commenter requested clarification from the NOP on whether processing aids (e.g., defoaming agents), which are nonsynthetic and nonorganic agricultural substances (e.g., soybean oil), must appear on the National List when used in processing. In this regulation, a nonsynthetic and nonorganic agricultural product, such as soybean oil, used as a processing aid does not have to appear on the National List. Such products are included in the provision in section 205.606 that nonorganically produced agricultural products may be used in accordance with any applicable restrictions when the substance is not commercially available in organic form.

(8) Transparency of the National List Petition Process. Some commenters stated the petition process for amending the National List appears to have limited public access and should be more transparent. These commenters advocate that any amendments to the National List should be subject to notice and comment. They also requested clarity on how petitions are prioritized and reviewed and the timeframes for review. Additionally, these commenters asked the NOP to expedite the review of materials for the National List. On July 13, 2000, AMS published in the Federal Register (Vol. 65, 43259-43261) guidelines for submitting petitions for the evaluations of substances for the addition to or removal from the National List. In this notice, the NOP stated that most petition information is available for public inspection with the exception of information considered to be "confidential business information." The notice also specified that any changes to the National List must be published in the Federal Register for public comment. The published petition notice has also provided an indication to the industry about the urgency of the need for substance review and that the industry should provide pertinent information to the NOSB to expedite the review of materials not on the National List.

## State Programs -- Preamble

### State Organic Programs

The Act provides that each State may implement an organic program for agricultural products that have been produced and handled within the State, using organic methods that meet the requirements of the Act and these regulations. The Act further provides that a State organic program (SOP) may contain more restrictive requirements for organic products produced and handled within the State than are contained in the National Organic Program (NOP). All SOP's and subsequent amendments thereto must be approved by the Secretary.

A State may have an SOP but not have a State certifying agent. A State may have a State certifying agent but no SOP. Finally, a State may have an SOP and a State certifying agent. In all cases, the SOP's must be approved by the Secretary. In all cases, the State certifying agent must apply for and receive accreditation to certify organic production or handling operations pursuant to subpart F.

In States with an approved SOP, the SOP's governing State official is responsible for administering a compliance program for enforcement of the NOP and any more restrictive requirements contained in the SOP. The SOP governing State officials may review and investigate complaints of noncompliance involving organic production or handling operations operating within their State and, when appropriate, initiate suspension or revocation of certification. The SOP governing State officials may also review and investigate complaints of noncompliance involving accredited certifying agents operating within their State. They must report the findings of any review and investigation of a certifying agent to the NOP Program Manager along with any recommendations for appropriate action. States that do not have an SOP will not be responsible for compliance under the NOP, except that an accredited State certifying agent operating within such State will have compliance responsibilities under the NOP as a condition of its accreditation.

The sections covering SOP's, beginning with section 205.620, establish: (1) the requirements for an SOP and amending such a program and (2) the process for approval of an SOP and amendments to the SOP's. Review and approval of an SOP will occur not less than once during each 5-year period. Review related to compliance matters may occur at any time.

### Description of Regulations

#### State Organic Program Requirements

A State may establish an SOP for production and handling operations within the State that produces and handles organic agricultural products. The SOP and supporting documentation must demonstrate that the SOP meets the requirements for organic programs specified in the Act.

An SOP may contain more restrictive requirements governing the production and handling of organic products within the State. Such requirements must be based on environmental conditions or specific production or handling practices particular to the State or region of the United States, which necessitates the more restrictive requirement. More restrictive requirements must be justified and shown to be consistent with and to further the purposes of the Act and the regulations in this part. Requirements necessitated by an environmental condition that is limited to a specific geographic area of the State should only be required of organic production and handling operations operating within the applicable geographic area. If approved by the Secretary, the more restrictive requirements will become the NOP regulations for organic producers and handlers in the State or applicable geographical area of the State. All USDA-

accredited certifying agents planning to operate within a State with an SOP will be required to demonstrate their ability to comply with the SOP's more restrictive requirements.

No provision of an SOP shall discriminate against organic agricultural products produced by production or handling operations certified by certifying agents accredited or accepted by USDA pursuant to section 205.500. Specifically, an SOP may not discriminate against agricultural commodities organically produced in other States in accordance with the Act and the regulations in this part. Further, an SOP may not discriminate against agricultural commodities organically produced by production or handling operations certified by foreign certifying agents operating under: (1) standards determined by USDA to meet the requirements of this part or (2) an equivalency agreement negotiated between the United States and a foreign government.

To receive approval of its SOP, a State must assume enforcement obligations in the State for the requirements of this part and any more restrictive requirements included in the SOP and approved by the Secretary. Specifically, the State must ensure compliance with the Act, the regulations in this part, and the provisions of the SOP by certified production and handling operations operating within the State. The SOP must include compliance and appeals procedures equivalent to those provided for under the NOP.

An SOP and any amendments thereto must be approved by the Secretary prior to implementation by the State.

### **State Organic Program Approval Process**

An SOP and subsequent amendments thereto must be submitted to the Secretary by the SOP's governing State official for approval prior to implementation. A request for approval of an SOP must contain supporting materials that include statutory authorities, program descriptions, documentation of environmental or ecological conditions or specific production and handling practices particular to the State which necessitate more restrictive requirements than the requirements of this part, and other information as may be required by the Secretary. A request for amendment of an approved SOP must contain supporting materials that include an explanation and documentation of the environmental or ecological conditions or specific production practices particular to the State or region, which necessitate the proposed amendment. Supporting material also must explain how the proposed amendment furthers and is consistent with the purposes of the Act and the regulations in this part.

Each request for approval of an SOP or amendment to an SOP and its supporting materials and documentation will be reviewed for compliance with the Act and these regulations. Within 6 months of receiving the request for approval, the Secretary will notify the SOP's governing State official of approval or disapproval. A disapproval will include the reasons for disapproval. A State receiving a notice of disapproval of its SOP or amendment to its SOP may submit a revised SOP or amendment to its SOP at any time.

### **Review of State Organic Programs**

SOP's will be reviewed at least once every 5 years by the Secretary as required by section 6507(c)(1) of the Act. The Secretary will notify the SOP's governing State official of approval or disapproval of the program within 6 months after initiation of the review.

### **State Organic Programs - Changes Based on Comments**

This portion of subpart G differs from the proposal in several respects as follows:



(1) Publication of SOP's and Consideration of Public Comments. Some commenters assert that the USDA should not publish SOP provisions for public comment in the Federal Register. These commenters argued that it is not appropriate for the NOP to have nonresidents commenting on a particular State program as nearly all States have a mechanism to ensure full public participation in their regulation promulgation. They believe the comment process set forth in the proposed rule is a redundant and unacceptable intrusion on State sovereignty.

We will not publish for public comment the provisions of SOP's under review by the Secretary in the Federal Register. We have removed the provision from this final rule, described in section 205.621(b), requiring the Secretary to publish in the Federal Register for public comment a summary of the SOP and a summary of any amendment to such a program. Alternatively, we will announce which SOP's are being reviewed through the NOP website. The NOP will issue public information notices that will announce each approved SOP and any approved amendments to an existing State program. The notices will identify the characteristics of the approved State program that warranted the more restrictive organic production or handling requirements. We also will include a summary of the new program on the NOP website.

(2) NOP Oversight of SOP's. Several commenters stated that, in the proposed rule, the provisions did not provide a comprehensive description of organic programs operated by States that would be under NOP authority. Some commenters implied that the proposed rule would only include States with organic certification programs, while other commenters inquired whether the sections 205.620 to 205.622 included other SOP activities beyond certification.

To address the commenters' concerns, we have modified the section heading by adding the term, "organic," and removing the term, "certification," from the description and definition of SOP's. We have taken this action to clarify that, while certification is one component of the requirements, it does not define the extent of evaluation of State programs that will be conducted by the NOP. SOP's can choose not to conduct certification activities under their existing organic program. State programs whose provisions fall within the scope of the eleven general provisions described in the Act (7 U.S.C. 6506) will require Departmental review.

States may conduct other kinds of organic programs that will not need review and approval by the NOP. Examples of these other programs may include: organic promotion and research projects, marketing; transition assistance or cost share programs, registration of State organic production and handling operations, registration of certifying agents operating within the State, or a consumer referral program. The NOP will not regulate such State activities. Such programs may not advertise, promote, or otherwise infer that the State's organic products are more organic or better than organic product produced in other States. Such programs and projects would be beyond the scope of this national program and will not be subject to the Secretary's review.

### **State Organic Programs - Changes Requested But Not Made**

(1) Limitations on SOP More Restrictive Requirements. Commenters expressed concern that limiting a State's ability to craft a regulation designated as a more restrictive requirement to environmental conditions or specific production and handling practices would hinder the ongoing development of SOP's. They were concerned that any State legislation modifying the SOP would need to be preapproved by the Secretary.

We have retained the provision limiting the scope of more restrictive requirements States can include in their organic program as described in section 205.620(c). We believe the language contained in the provision is broad enough to facilitate the development of SOP's without hindering development or State program implementation and enforcement. Section 6507(b)(1) of the Act provides that States may establish more restrictive organic certification requirements; paragraph (b)(2) establishes parameters for those requirements. More restrictive SOP

requirements must: further the purposes of the Act, be consistent with the Act, not discriminate against other State's agricultural commodities, and be approved by the Secretary before becoming effective. We expect that a State's more restrictive requirements are likely to cover specific organic production or handling practices to address a State's specific environmental conditions. The Secretary will approve State's requests for more restrictive State requirements that are consistent with the purposes of the Act. However, we believe requests from States for more restrictive requirements will be rare. Although SOP's can impose additional requirements, we believe States will be reluctant to put their program participants at a competitive disadvantage when compared to producers and handlers in other States absent compelling environmental conditions or a compelling need for special production and handling practices. While preapproval of State legislation modifying an existing SOP is not required, the NOP envisions a close consultation with States with existing programs to ensure consistency with the final rule.

(2) SOP Enforcement Obligations. Some commenters expressed concern about States having adequate resources available to implement enforcement activities that they are obligated to conduct under the NOP. A few of these commenters argue that the enforcement obligation will result in their State programs being discontinued. A few commenters cited a lack of federal funding to support State enforcement obligations and suggested the NOP provide funding for enforcement activities.

The proposed rule indicated that States with organic programs must assume enforcement obligations for this regulation within their State. We have retained this enforcement obligation in section 205.620(d). Many States currently have organic programs with the kind of comprehensive enforcement and compliance mechanisms necessary for implementing any State regulatory program. Assuming those enforcement activities are consistent with the NOP, this final rule adds no additional regulatory burden to the SOP's. The costs associated with the enforcement activities of an approved SOP should be similar to the enforcement costs associated with the existing State program. Additional clarification of SOP enforcement obligations is in the Accreditation, Appeals, and Compliance preamble discussions.

(3) SOP Evaluation Notification Period. A few commenters indicated that the SOP review and decision notification period described in section 205.621(b) of the proposed rule could hinder a State's ability to develop or implement an SOP. These commenters cited potential cases in which particular States have requirements for regulatory promulgation that must occur within 6 months under a State legislative session that is held once every 2 years. These commenters suggested the NOP should reduce the notification time to 1 to 3 months.

We disagree with the commenters. In the proposed rule in section 205.621(b), the Secretary is required to notify the SOP's governing State official within 6 months of receipt of submission of documents and information regarding the approval of the SOP. We have retained this time period. We will review SOP applications as quickly as possible and will endeavor to make decisions in less than 6 months whenever possible. However, some SOP's may be very complex and require more review time. The NOP envisions working closely with the States and State officials to ensure a smooth transition to the requirements of this final rule.

### **State Organic Programs - Clarifications**

(1) Discrimination Against Organic Products. Several commenters requested the addition of a provision prohibiting an SOP from discriminating against agricultural commodities organically produced in other States. Discrimination by a State against organically produced agricultural products produced in another State is prevented in two ways. First, any organic program administered by a State must meet the requirements for organic programs specified in the Act and be approved by the Secretary. Finally, a USDA-accredited certifying agent must accept the certification decisions made by another USDA-accredited certifying agent as its own.

(2) Potential Duplication Between the Accreditation and SOP Review Process. Some commenters asked about possible duplication between the process for reviewing SOP's and the process of accreditation review. These commenters have asked the NOP to eliminate any duplication that may exist between the two review processes. The NOP will be conducting a review process for SOP's and a separate review process for accrediting State and private certifying agents. The two reviews are different. The SOP review is the evaluation of SOP compliance with the Act and the NOP regulations. If approved, the SOP becomes the NOP standards for the particular State with which all certifying agents operating in that State must comply. Approved SOP's must be in compliance with the Act and the NOP regulations. They cannot have weaker standards than the NOP. States can have more restrictive requirements than the NOP if approved by the Secretary.

The accreditation review is an evaluation of the ability of certifying agents to carry out their responsibilities under the NOP. This review is a measure of the competency of certifying agents to evaluate compliance to national organic standards. Certifying agents will not be unilaterally establishing regulations or standards related to the certification of organic products. They will only provide an assessment of compliance.

Thus, SOP reviews and accreditation reviews are separate evaluations of different procedures. We acknowledge some of the information for the two evaluations may be similar; e.g., compliance procedures. The reviews do not duplicate the same requirements. However, the NOP envisions working with States to ensure documentation is not duplicated.

(3) Scope of Enforcement by States. A number of State commenters have requested clarification on the proposed rule provision specifying that approved SOP's must assume enforcement obligations in their State for the requirements of the NOP and any additional requirements approved by the Secretary. These commenters have indicated that they remain uncertain as to what is expected by the term, "enforcement obligation."

Approved SOP's will have to administer and provide enforcement of the requirements of the Act and the regulations of the NOP. The administrative procedures used by the State in administering the approved SOP should have the same force and effect as the procedures use by AMS in administering this program. This final rule specifies that the requirements for environmental conditions or for special production and handling practices are necessary for establishing more restrictive requirements. These factors establish our position that a State must agree to incurring increased enforcement responsibilities and obligations to be approved as an SOP under the NOP. For instance, a State with an approved organic program will oversee compliance and appeals procedures for certified organic operations in the State. Those procedures must provide due process opportunities such as rebuttal, mediation, and correction procedures. Once approved by the Secretary, the State governing official of the SOP must administer the SOP in a manner that is consistent and equitable for the certified parties involved in compliance actions.

(4) SOP's That Do not Certify and NOP Oversight. A few commenters requested that the NOP develop new provisions to include State programs that have organic regulations but do not conduct certification activities. These commenters argue that any SOP that has a regulatory impact on organic producers, regardless of whether or not the program includes certification, be approved by the Secretary.

This regulation, in section 205.620(b), provides for NOP oversight of SOP's that do not conduct certification activities.

(5) State's Use of Private Certifying Agents. Some commenters have requested that the NOP provide clarification of the proposed rule sections 205.620 through 205.622 on how these

sections will affect States that delegate certification activities to private certifying agents. These commenters asked how the NOP intends to oversee this type of State activity.

The NOP intends to give considerable latitude to States in choosing the most appropriate system or procedures to structure their programs. This may include a State establishing its own certifying agent or relying on private certifying agents. However, States will not be accrediting certifying agents operating in their State. Accreditation of all certifying agents operating in the United States is the responsibility of USDA. Establishment of a single national accreditation program is an essential part of the NOP. As stated elsewhere in this final rule, any accreditation responsibilities of a State's current organic program will cease with implementation of this program. Pursuant to the Compliance provisions of this subpart, the governing State official charged with compliance oversight under the SOP may investigate and notify the NOP of possible compliance violations on the part of certifying agents operating in the State. However, the State may not pursue compliance actions or remove accreditation of any certifying agent accredited by the Secretary. That authority is the sole responsibility of the Secretary. If more restrictive State requirements are approved by the Secretary, we will review certifying agent qualifications in the State, as provided by section 205.501(a)(20), and determine whether they are able to certify to the approved, more restrictive requirements. Our accreditation responsibilities include oversight of both State and private certifying agents, including any foreign certifying agents that may operate in a State.

## Fees -- Preamble

### Subpart G - Fees

This portion of subpart G sets forth the regulations on fees and other charges to be assessed for accreditation and certification services under the National Organic Program (NOP). These regulations address the kinds of fees and charges to be assessed by the U.S. Department of Agriculture (USDA) for the accreditation of certifying agents, the level of such fees and charges, and the payment of such fees and charges. These regulations also address general requirements to be met by certifying agents in assessing fees and other charges for the certification of producers and handlers as certified organic operations. Finally, these regulations address the Secretary's oversight of a certifying agent's fees and charges for certification services.

### Description of Regulation

#### Fees and Other Charges for Accreditation

Fees and other charges will be assessed and collected from applicants for initial accreditation and accredited certifying agents submitting annual reports or seeking renewal of accreditation. Such fees will be equal as nearly as may be to the cost of the accreditation services rendered under these regulations. Fees-for-service will be based on the time required to render the service provided calculated to the nearest 15-minute period. Activities to be billed on the basis of time used include the review of applications and accompanying documents and information, evaluator travel, the conduct of on-site evaluations, review of annual reports and updated documents and information, and the preparation of reports and any other documents in connection with the performance of service. The hourly rate will be the same as that charged by the Agricultural Marketing Service (AMS), through its Quality System Certification Program, to certification bodies requesting conformity assessment to the International Organization for Standardization "General Requirements for Bodies Operating Product Certification Systems" (ISO Guide 65).

Applicants for initial accreditation and accredited certifying agents submitting annual reports or seeking renewal of accreditation during the first 18 months following the effective date of subpart F will receive service without incurring an hourly charge for such service.

Applicants for initial accreditation and renewal of accreditation must pay at the time of application, effective 18 months following the effective date of subpart F, a nonrefundable fee of \$500.00. This fee will be applied to the applicant's fees-for-service account.

When service is requested at a place so distant from the evaluator's headquarters that a total of one-half hour or more is required for the evaluator(s) to travel to such a place and back to the headquarters or from a place of prior assignment on circuitous routing requiring a total of one-half hour or more to travel to the next place of assignment on the circuitous routing, the charge for such service will include all applicable travel charges. Travel charges may include a mileage charge administratively determined by USDA, travel tolls, or, when the travel is made by public transportation (including hired vehicles), a fee equal to the actual cost thereof. If the service is provided on a circuitous routing, the travel charges will be prorated among all the applicants and certifying agents furnished the service involved. Travel charges will become effective for all applicants for initial accreditation and accredited certifying agents on the effective date of subpart F. The applicant or certifying agent will not be charged a new mileage rate without notification before the service is rendered.

When service is requested at a place away from the evaluator's headquarters, the fee for such service shall include a per diem charge if the employee(s) performing the service is paid per diem in accordance with existing travel regulations. Per diem charges to applicants and certifying

agents will cover the same period of time for which the evaluator(s) receives per diem reimbursement. The per diem rate will be administratively determined by USDA. Per diem charges shall become effective for all applicants for initial accreditation and accredited certifying agents on the effective date of subpart F. The applicant or certifying agent will not be charged a new per diem rate without notification before the service is rendered.

When costs, other than fees-for-service, travel charges, and per diem charges, are associated with providing the services, the applicant or certifying agent will be charged for these costs. Such costs include but are not limited to equipment rental, photocopying, delivery, facsimile, telephone, or translation charges incurred in association with accreditation services. The amount of the costs charged will be determined administratively by USDA. Such costs will become effective for all applicants for initial accreditation and accredited certifying agents on the effective date of subpart F.

### **Payment of Fees and Other Charges**

Applicants for initial accreditation and renewal of accreditation must remit the nonrefundable fee along with their application. Remittance must be made payable to the Agricultural Marketing Service, USDA, and mailed to: Program Manager, USDA-AMS-TMP-NOP, Room 2945-South Building, P.O. Box 96456, Washington, DC 20090-6456 or such other address as required by the Program Manager. All other payments for fees and other charges must be received by the due date shown on the bill for collection, made payable to the Agricultural Marketing Service, USDA, and mailed to the address provided on the bill for collection. The Administrator will assess interest, penalties, and administrative costs on debts not paid by the due date shown on a bill for collection and collect delinquent debts or refer such debts to the Department of Justice for litigation.

### **Fees and Other Charges for Certification**

Fees charged by a certifying agent must be reasonable, and a certifying agent may charge applicants for certification and certified production and handling operations only those fees and charges that it has filed with the Administrator. The certifying agent must provide each applicant with an estimate of the total cost of certification and an estimate of the annual cost of updating the certification. The certifying agent may require applicants for certification to pay at the time of application a nonrefundable fee that must be applied to the applicant's fees-for-service account. A certifying agent may set the nonrefundable portion of certification fees; however, the nonrefundable portion of certification fees must be explained in the fee schedule submitted to the Administrator. The fee schedule must explain what fee amounts are nonrefundable and at what stage during the certification process the respective fees become nonrefundable. The certifying agent must provide all persons inquiring about the application process with a copy of its fee schedule.

### **Fees - Changes Based on Comments**

This subpart differs from the proposal in the following respects:

Nonrefundable Portion of Certification Fees. Commenters were not satisfied with the provision in section 205.642 that stated, "The certifying agent may require applicants for certification to pay at the time of application a nonrefundable fee of no more than \$250.00, which shall be applied to the applicant's fee for service account." Some commenters believed we were requiring the certifying agents to bill fees for inspection services separately. One State agency expressed a concern that we were placing a limit on the initial fee the certifying agent could collect. As a result, the State agency commented that by not being allowed to collect the full certification fee at the time of application, the certifying agent, in effect, would be extending credit to the applicant. Commenters

reported that some State agencies are prevented by statute from extending credit and are required to collect all fees at the time of application. Several commenters stated that the amount of \$250.00 was too low and would not cover the costs the certifying agents could incur during the certification process. One organization noted that we should consider prorating the amount of the fee to be refunded when an applicant for certification withdraws before the completion of the certification process. The organization recommended that the amount of the prorated fee should be based on how far along in the certification process the applicant had progressed before withdrawal. Another commenter believed it was inappropriate for USDA to set any fees for private certification programs and that the fees should be market driven.

It was not our intent to limit the initial amount that certifying agents could collect from the applicant for certification. Our intent was to limit the portion of the fee that would be nonrefundable in order to reduce the potential liability for the small producer/handler who may need to withdraw prematurely from the certification process. However, we acknowledge that this provision could be misinterpreted. We also realize that certifying agents may incur initial costs during the preliminary stage of the certification process that may be more or less than the \$250.00 application rate proposed. As a result, we have removed the provision that stated certifying agents could collect a nonrefundable fee of not more than \$250.00 at the time of application from applicants for certification.

Certifying agents may set the nonrefundable portion of their certification fees. However, the nonrefundable portion of their certification fees must be explained in the fee schedule submitted to the Administrator. The fee schedule must explain what fee amounts are nonrefundable and at what stage during the certification process the respective fees become nonrefundable. Certifying agents will also provide all persons inquiring about the application process with a copy of its fee schedule.

### **Fees - Changes Requested But Not Made**

This subpart retains from the proposed rule regulations on which we received comments as follows:

(1) Farm Subsidy/Transition Program. Many commenters asked that USDA subsidize or develop a cost-share program for small farmers/producers who are certified or who are in transition to organic farming. Some commenters wanted these costs to be fully subsidized; a few commenters suggested that USDA pay for any extra site visit costs; and many others wanted USDA to pay premium prices to farmers for their products during the period of transition to organic production. In addition, many commenters argued that USDA should fully fund certification costs. Finally, many commenters suggested that the USDA should provide additional financial support to the organic industry because the industry is relatively young and composed of a large number of small, low-resource businesses.

We have considered the commenters requests but have not made the suggested changes. The NOP under AMS is primarily a user-fee-based Federal program. Section 2107(a)(10) of the Organic Food Production Act of 1990 (OFPA) requires that the NOP provide for the collection of reasonable fees from producers, certifying agents, and handlers who participate in activities to certify, produce, or handle agricultural products as organically produced. Therefore, under the statutory authority of OFPA, it is outside of the scope of the NOP to provide for the subsidization of producers, handlers, and certifying agents as desired by some commenters. We have, however, established provisions in this part that we believe will minimize the economic impact of the NOP on producers, handlers, and certifying agents.

(2) Small Farmer Exemption Versus Lower Certification Fees. Many commenters suggested that certification fees be lowered or based on a sliding scale rather than instituting an exemption from certification for small farmers and handlers.

We have not accepted the commenters' suggestion. We cannot remove the small farmer exemption because section 2106(d) of the Act requires that small farmers be provided an exemption from organic certification if they sell no more than \$5,000 annually in value of agricultural products. Also, certification fees cannot be lowered by USDA because NOP under AMS is primarily a user-fee-based Federal agency. It is not our goal or objective to make a profit on our accreditation activities. However, our fees associated with the accreditation process are targeted toward recovering costs incurred during the accreditation process. Commenters expressed a concern that the accreditation fees charged by USDA would have an impact on the certification fees prescribed by certifying agents to operations seeking organic certification. We understand the commenters' concern that accreditation fees charged to certifying agents will most likely be calculated into the fees that certifiers charge their clients. However, we believe that our provision to waive the hourly service charges for accreditation during the first 18 months of implementation of the NOP should help reduce accreditation costs of the certifying agent and should, therefore, result in lower certification fees charged by certifying agents. As provided by the Act and the regulations in this part, fees charged by certifying agents must be reasonable. Also, certifying agents must submit their fee schedule to the Administrator and may only charge those fees and charges filed with the Administrator. In addition, certifiers are required to provide their approved fee schedules to applicants for certification. Therefore, applicants for certification will be able to base their selection of a certifying agent on price if they choose. Moreover, there are no provisions in the regulations that preclude certifying agents from pricing their services on a sliding scale, as long as their fees are consistent and nondiscriminatory and are approved during the accreditation process.

(3) Accreditation Fees. Many industry commenters suggested that we reevaluate our accreditation fee structure. They believe the hourly accreditation rate proposed is unacceptable. Commenters were concerned that high accreditation costs would lead to high certification costs, which would have a greater impact on small operations. Some industry commenters also noted that we should be required to provide a fee schedule such as the certifiers are required to do. They stated that unless USDA provided a fee schedule that included travel costs, they would not be able to accurately budget for these costs. A few commenters wanted USDA to forgo charging travel costs or not charge travel time at the full rate. Several commenters also stated that the hourly rate stated in the proposal is much higher than what the people who actually perform the accreditations will earn. However, a large majority of the commenters favored the 18-month period in which AMS will not charge the hourly accreditation rate to applicants.

As stated in the proposal, the hourly rate will be the same as that of AMS' Quality Systems Certification Program. Due to the fact that AMS' Quality Systems Certification Program publishes one rate that is readily available to the public, it is our belief that it is unnecessary for the NOP to set up a separate fee schedule. The NOP will notify accredited certifying agents and applicants for accreditation of any proposed rate changes and final actions on such rates by AMS. We will also periodically report the status of fees to the National Organic Standards Board.

Those applicants and certifying agents who need accreditation cost estimates, including travel, for budgetary or other reasons may notify the NOP. The NOP staff will provide the applicant with a cost estimate, based on information provided by the applicant. As stated in an earlier response (( 2) - Changes Requested But Not Made), the objective of the fee that is charged to accredit certifying agents is not to gain a profit for accreditation activities but to recover costs incurred during the accreditation process. As such, these costs include but are not limited to salaries, benefits, clerical help, equipment, supplies, etc.



## Compliance -- Preamble

This portion of subpart G sets forth the enforcement procedures for the National Organic Program (NOP). These procedures describe the compliance responsibilities of the NOP Program Manager, State organic programs' (SOP) governing State officials, and State and private certifying agents. These provisions also address the rights of certified production and handling operations and accredited certifying agents operating under the NOP. The granting and denial of certification and accreditation are addressed under subparts E and F.

### Description of Regulations

The Secretary is required under the Act to review the operations of SOP's, accredited certifying agents, and certified production or handling operations for compliance with the Act and these regulations. The Program Manager of the NOP may carry out compliance proceedings and provide oversight of compliance proceedings on behalf of the Secretary and the Administrator. The Program Manager will initiate proceedings to suspend or revoke a certified operation's certification if a certifying agent or SOP's governing State official fails to take appropriate enforcement action. The Program Manager may also initiate proceedings to suspend or revoke a certified operation's certification if the operation is found to have been erroneously certified by a certifying agent whose accreditation has been suspended or revoked. We anticipate, however, that most investigations, reviews, and analyses of certification noncompliance and initiation of suspension or revocation will be conducted by the certified operation's certifying agent. With regard to certifying agents, the Program Manager will, when appropriate, initiate proceedings to suspend or revoke the accreditation of a certifying agent for noncompliance with the Act and these regulations.

In States with an approved SOP, the SOP's governing State official is responsible for administering a compliance program for enforcement of the NOP/SOP. SOP's governing State officials may review and investigate complaints of noncompliance involving organic production or handling operations operating within their State and, when appropriate, initiate suspension or revocation of certification. SOP's governing State officials may also review and investigate complaints of noncompliance involving accredited certifying agents operating within their State. They must report the findings of any review and investigation of a certifying agent to the Program Manager along with any recommendations for appropriate action.

The compliance provisions of the NOP are consistent with the requirements of the Administrative Procedure Act (APA) (5 U.S.C. 553-559) in that this program provides for due process including an opportunity for hearing, appeal procedures, written notifications of noncompliance, and opportunities to demonstrate or achieve compliance before any suspension or revocation of organic certification or accreditation is invoked. A compliance action regarding certification carried out under an approved SOP's compliance procedures will have the same force and effect as a certification compliance action carried out under these NOP compliance procedures. The notification process for denying certification and accreditation is laid out in subparts E and F, respectively.

Each notification of noncompliance, rejection of mediation, noncompliance resolution, proposed suspension or revocation, and suspension or revocation issued under these regulations must be sent to the recipient's place of business via a delivery service which provides return receipts. Certified operations and certifying agents must respond to all compliance notifications via a delivery service which provides return receipts.

### Noncompliance Procedure for Certified Operations

The Act provides for the enforcement of certification requirements. Statutory oversight of production and handling operations by certifying agents includes review of organic plans, on-site inspections, residue and tissue testing, authority to conduct investigations and initiate suspension or revocation actions, and responsibility to report violations.

### **Notification of Noncompliance**

A written notification of noncompliance will be sent to the certified operation when an inspection, review, or investigation reveals any noncompliance with the Act or these regulations. A noncompliance notification may encompass the entire operation or a portion of the operation. For instance, a violation at one farm may not warrant loss of certification at other farms of the certified operation not affected by the violation. The notification of noncompliance will provide: (1) a description of each condition, action, or item of noncompliance; (2) the facts upon which the notification is based; and (3) the date by which the certified operation must rebut the notification or correct the noncompliance and submit supporting documentation of the correction. A certified operation may continue to sell its product as organic upon receiving a notification of noncompliance and throughout the compliance proceeding and any appeal procedure which might follow the compliance proceeding unless otherwise notified by a State or Federal government agency.

If a certified operation believes the notification of noncompliance is incorrect or not well-founded, the certified operation may submit a rebuttal to the certifying agent or SOP's governing State official, as applicable, providing supporting data to refute the facts stated in the notification. The opportunity for rebuttal is provided to allow certifying agents and certified operations to informally resolve noncompliance issues. The rebuttal process should be helpful in resolving differences which may be the result of misinterpretation of requirements, misunderstandings, or incomplete information. Alternatively, the certified operation may correct the identified noncompliances and submit proof of such corrections. When the certified operation demonstrates that each noncompliance has been corrected or otherwise resolved, the certifying agent or SOP's governing State official, as applicable, will send the certified operation a written notification of noncompliance resolution.

### **Proposed Suspension or Revocation of Certification**

If the noncompliance is not resolved or is not in the process of being resolved by the date specified in the notification of noncompliance, the certifying agent or SOP's governing State official will send the certified operation a written notification of proposed suspension or revocation of certification for the entire operation or a portion of the operation affected by the noncompliance. The notification will state: (1) the reasons for the proposed suspension or revocation; (2) the proposed effective date of the suspension or revocation; (3) the impact of the suspension or revocation on the certified operation's future eligibility for certification; and (4) that the certified operation has a right to request mediation or to file an appeal. The impact of a proposed suspension or revocation may include the suspension or revocation period or whether the suspension or revocation applies to the entire operation or to a portion or portions of the operation.

If a certifying agent or SOP's governing State official determines that correction of a noncompliance is not possible, the notification of noncompliance and the proposed suspension or revocation of certification may be combined in one notification of proposed suspension or revocation. The certified operation will have an opportunity to appeal the proposed suspension or revocation.

If a certifying agent or SOP's governing State official has reason to believe that a certified operation has willfully violated the Act or regulations, a notification of proposed suspension or

revocation will be sent to the certified operation. The proposed suspension or revocation will be for the entire operation or a portion of the operation. This notification, because it involves a willful violation, will be sent without first issuing a notification of noncompliance.

## **Mediation**

A production or handling operation may request mediation of any dispute regarding denial of certification or proposed suspension or revocation of certification. Mediation is not required prior to filing an appeal but is offered as an option which may resolve the dispute more quickly than the next step, which is filing an appeal. When mediation is requested, it must be requested in writing to the applicable certifying agent. The certifying agent will have the option of accepting or rejecting the request for mediation. If the certifying agent rejects the request for mediation, the certifying agent must provide written notification to the applicant for certification or certified operation. The written notification must advise the applicant for certification or certified operation of the right to request an appeal in accordance with section 205.681. Any such appeal must be requested within 30 days of the date of the written notification of rejection of the request for mediation. If mediation is accepted by the certifying agent, such mediation must be conducted by a qualified mediator mutually agreed upon by the parties to the mediation. If an SOP is in effect, the mediation procedures established in the SOP, as approved by the Secretary, must be followed. The parties to the mediation will have no more than 30 days to reach an agreement following a mediation session. If mediation is unsuccessful, the production or handling operation will have 30 days from termination of mediation to appeal the denial of certification or proposed suspension or revocation in accordance with the appeal procedures in section 205.681.

Any agreement reached during or as a result of the mediation process must be in compliance with the Act and these regulations. The Secretary reserves the right to review any mediated agreement for conformity to the Act and these regulations and to reject any agreement or provision not in conformance with the Act or these regulations

## **Suspension or Revocation**

The certifying agent or SOP's governing State official will suspend or revoke the certified operation's certification when the operation fails to resolve the issue through rebuttal or mediation, fails to complete needed corrections, or does not file an appeal. The operation will be notified of the suspension or revocation by written notification. The certifying agent or SOP's governing State official must not send a notification of suspension or revocation to a certified operation that has requested mediation or filed an appeal while final resolution of either is pending.

The decision to suspend or revoke certification will be based on the seriousness of the noncompliance. Such decisions must be made on a case-by-case basis. Section 6519 of the Act establishes that willful violations include making a false statement, knowingly affixing a false label, or otherwise violating the purposes of the Act.

In addition to suspension or revocation, a certified operation that knowingly sells or labels a product as organic, except in accordance with the Act, will be subject to a civil penalty of not more than \$10,000 per violation. Further, a certified operation that makes a false statement under the Act to the Secretary, an SOP's governing State official, or a certifying agent will be subject to the provisions of section 1001 of title 18, United States Code.

A certified operation whose certification has been suspended under this section may at any time, unless otherwise stated in the notification of suspension, submit a request to the Secretary for reinstatement of its certification. The request must be accompanied by evidence demonstrating

correction of each noncompliance and corrective actions taken to comply with and remain in compliance with the Act and the NOP.

A certified operation or a person responsibly connected with an operation that has had its certification revoked will be ineligible to receive certification for an operation in which such operation or person has an interest for 5 years following the date of revocation. Accordingly, an operation will be ineligible for organic certification if one of its responsibly connected parties, was a responsibly connected party of an operation that had its certification revoked. The Secretary may, when in the best interest of the certification program, reduce or eliminate the period of ineligibility.

### **Noncompliance Procedure for Certifying Agents**

The Program Manager, on behalf of the Secretary, may initiate a compliance action against an accredited certifying agent who violates the Act or these regulations. Compliance proceedings may be initiated as a result of annual reviews for continuation of accreditation, site evaluations, or investigations initiated in response to complaints of noncompliant activities. Compliance proceedings also may be initiated on recommendation of an SOP's governing State official.

A written notification of noncompliance will be sent by the Program Manager to an accredited certifying agent when an inspection, review, or investigation of such person reveals any noncompliance with the Act or these regulations. A notification of noncompliance will provide a description of each noncompliance found and the facts upon which the notification is based. Additionally, the notification will provide the date by which the certifying agent must rebut or correct each noncompliance described and submit supporting documentation of each correction.

When documentation received by the Program Manager demonstrates that each noncompliance has been resolved, the Program Manager will send the certifying agent a written notification of noncompliance resolution.

If a noncompliance is not resolved by rebuttal or correction, the Program Manager will issue a notification of proposed suspension or revocation of accreditation. The notification will state whether the suspension or revocation will be for the certifying agent's entire accreditation, that portion of the accreditation applicable to a particular field office, or a specific area of accreditation. For instance, if a certifying agent with field offices in different geographic areas is cited for a compliance violation at one field office, the Program Manager could determine that only that portion of the accreditation applicable to the noncompliant field office should be suspended or revoked.

If the Program Manager determines that the noncompliance cannot be immediately or easily corrected, the Program Manager may combine the notification of noncompliance and the proposed suspension or revocation in one notification.

The notification of proposed suspension or revocation of accreditation will state the reasons and effective date for the proposed suspension or revocation. Such notification will also state the impact of a suspension or revocation on future eligibility for accreditation and the certifying agent's right to file an appeal.

If the Program Manager has reason to believe that a certifying agent has willfully violated the Act or regulations, the Program Manager will issue a notification of proposed suspension or revocation of accreditation. The proposed suspension or revocation may be for the certifying agent's entire accreditation, that portion of the accreditation applicable to a particular field office, or a specified area of accreditation. This notification, because it involves a willful violation, will be sent without first issuing a notification of noncompliance.

The certifying agent may file an appeal of the Program Manager's determination pursuant to section 205.681. If the certifying agent fails to file an appeal of the proposed suspension or revocation, the Program Manager will suspend or revoke the certifying agent's accreditation. The certifying agent will be notified of the suspension or revocation by written notification.

A certifying agent whose accreditation is suspended or revoked must cease all certification activities in each area of accreditation and in each State for which its accreditation is suspended or revoked. Any certifying agent whose accreditation has been suspended or revoked must transfer to the Secretary all records concerning its certification activities that were suspended or revoked. The certifying agent must also make such records available to any applicable SOP's governing State official. The records will be used to determine whether operations certified by the certifying agent may retain their organic certification.

A certifying agent whose accreditation is suspended by the Secretary may at any time, unless otherwise stated in the notification of suspension, submit a request to the Secretary for reinstatement of its accreditation. Such request must be accompanied by evidence demonstrating correction of each noncompliance and actions taken to comply with and remain in compliance with the Act and regulations. A certifying agent whose accreditation is revoked by the Secretary will be ineligible to be accredited as a certifying agent under the Act and regulations for a period of not less than 3 years following the date of revocation.

### **State Organic Programs' Compliance Procedures**

An SOP's governing State official may initiate noncompliance proceedings against certified organic operations operating in the State. Such proceedings may be initiated for failure of a certified operation to meet the production or handling requirements of this part or the State's more restrictive requirements, as approved by the Secretary.

The SOP's governing State official must promptly notify the Program Manager of commencement of noncompliance proceedings initiated against certified operations and forward to the Program Manager a copy of each notice issued. A noncompliance proceeding, brought by an SOP's governing State official against a certified operation may be appealed in accordance with the appeal procedures of the SOP. There will be no subsequent rights of appeal to the Secretary. Final decisions of a State may be appealed to the United States District Court for the district in which such certified operation is located.

An SOP's governing State official may review and investigate complaints of noncompliance with the Act or regulations concerning accreditation of certifying agents operating in the State. When such review or investigation reveals any noncompliance, the SOP's governing State official must send a written report of noncompliance to the Program Manager. The SOP's governing State official's report must provide a description of each noncompliance and the facts upon which the noncompliance is based.

### **Compliance - Changes Based On Comments**

This portion of subpart G differs from the proposal in several respects as follows:

(1) Written Notifications. We have added a new paragraph (d) to section 205.660. The preamble to the proposed rule stated that all written notifications sent by certifying agents and SOP's governing State officials, as well as rebuttals, requests for mediation, and notices of correction of noncompliances sent by certified operations, will be sent to the addressee's place of business by a delivery service which provides dated return receipts. The assurance of completed communications and timely compliance procedures was given as the reason for delivery by a service which provides dated return receipts. The addition of paragraph (d) at section 205.660 is

one of the actions that we have taken in response to requests from commenters that we further clarify the compliance process. Paragraph (d) requires that each notification of noncompliance, rejection of mediation, noncompliance resolution, proposed suspension or revocation, and suspension or revocation issued in accordance with sections 205.662, 205.663, and 205.665 and each response to such notification must be sent to the recipient's place of business via a delivery service which provides return receipts. This action will facilitate the effective administration of the compliance process by assuring a verifiable time line on the issuance and receipt of compliance documents and the response given to each such document.

(2) Determination of Willful. The preamble statement that "only the Program Manager or governing State official may make the final determination that a violation is willful" was incorrect and inconsistent with the regulatory language in section 205.662(d). Section 205.662(d) provides that, "if a certifying agent or State organic program's governing State official has reason to believe that a certified operation has willfully violated the Act or regulations in this part, the certifying agent or State organic program's governing State official shall send the certified operation a notification of proposed suspension or revocation of certification of the entire operation or a portion of the operation, as applicable to the noncompliance." Accordingly, as recommended by a commenter, the incorrect statement has been deleted from the preamble to this final rule.

(3) Proposed Suspension or Revocation. We have amended sections 205.662(c) and 205.665(c) by removing the redundant phrase "or is not adequate to demonstrate that each noncompliance has been corrected" from the first sentence of each section.

(4) Suspension or Revocation. We have amended section 205.662(e)(2) by adding "while final resolution of either is pending" to the end thereof. The language of section 205.662(e)(2) now reads: "A certifying agent or State organic program's governing State official must not send a notification of suspension or revocation to a certified operation that has requested mediation pursuant to section 205.663 or filed an appeal pursuant to section 205.681 while final resolution of either is pending." We have made this change because we agree with those commenters who expressed the belief that section 205.662(e)(2) needed to be amended to clarify the duration of the stay on the issuance of a notification of suspension or revocation when mediation is requested or an appeal is filed. Several commenters stated that section 205.662(e)(2) needed to be amended to clarify that requesting mediation or filing an appeal does not indefinitely stop the suspension or revocation process.

(5) Eligibility After Suspension or Revocation of Certification. We have amended section 205.662(f) such that it now parallels section 205.665(g) which addresses suspension and revocation of certifying agents. We have also changed the title of section 205.662(f) from "Ineligibility" to "Eligibility" to parallel section 205.665(g). A few commenters referred to the provisions in section 205.665(g), which addresses eligibility after suspension or revocation of accreditation, and requested clarification of the difference between suspension and revocation of certification. Upon reviewing section 205.662(f), we decided that amendment was needed to clarify the difference between suspension and revocation of certification relative to eligibility for certification. Accordingly, we added a new paragraph (1) which provides that a certified operation whose certification has been suspended under this section may at any time, unless otherwise stated in the notification of suspension, submit a request to the Secretary for reinstatement of its certification. The paragraph also provides that the request must be accompanied by evidence demonstrating correction of each noncompliance and corrective actions taken to comply with and remain in compliance with the Act and the regulations in this part. We also amended what is now paragraph (2) of section 205.662(f) to clarify that the period of ineligibility following revocation of certification is 5 years unless reduced or eliminated by the Secretary.

Further, we have amended section 205.665(g)(1) to clarify that a certifying agent that has had its accreditation suspended may request reinstatement of its accreditation rather than submit a new request for accreditation. The amendment also clarifies that the reinstatement may be requested

at any time unless otherwise stated in the notification of suspension. This amendment makes section 205.665(g)(1) similar to new paragraph (1) of section 205.662(f). This amendment is also consistent with commenter desires that the noncompliance procedures for certified operations and accredited certifying agents be similar.

(6) Penalties for Violations of the Act. We have amended section 205.662 by adding a new paragraph (g) which incorporates therein the provisions of paragraphs (a) and (b) of section 2120, 7 U.S.C. 6519, Violations of Title, of the Act. Specifically, paragraph (g) provides that, in addition to suspension or revocation, any certified operation that knowingly sells or labels a product as organic, except in accordance with the Act, shall be subject to a civil penalty of not more than \$10,000 per violation. This paragraph also provides that any certified operation that makes a false statement under the Act to the Secretary, an SOP's governing State official, or a certifying agent shall be subject to the provisions of section 1001 of title 18, United States Code. Commenters requested regulatory language citing section 2120, 7 USC 6519, Violations of Title, of the Act. Commenters also requested a clearer description of enforcement. Specifically, they want provisions describing how USDA will deal with operations that make false claims or do not meet the NOP requirements. Further, numerous commenters expressed concern that there are no penalties in the regulations other than suspension and revocation. The European Community stated that it did not find, in the proposal, requirements for penalties to be applied by certifying agents when irregularities or infringements are found. The European Community went on to say that the European Union requires such penalties.

The Act provides for suspension and revocation of certification and the civil and criminal penalties addressed in 7 U.S.C. 6519. Certified operations are also required through the compliance program set forth in these regulations, to correct all noncompliances with the Act or regulations as a condition of retaining their certification. Furthermore, to get a suspended certification reinstated, an operation must submit a request to the Secretary. The request must be accompanied by evidence demonstrating correction of each noncompliance and corrective actions taken to comply with and remain in compliance with the Act and the regulations in this part. An operation or a person responsibly connected with an operation whose certification has been revoked will be ineligible to receive certification for a period of not more than 5 years.

We believe adding paragraph (g) will help clarify that there are penalties which may be imposed on certified operations that violate the Act and these regulations in addition to suspension or revocation.

The provisions of the Act and these regulations apply to all persons who sell, label, or represent their agricultural product as organic. Accordingly, persons who falsely sell, label, or represent their product as organic, are subject to the provisions of paragraphs (a) and (b) of section 2120, 7 USC 6519, of the Act. To clarify this, we have added a new paragraph (c) to section 205.100 of the Applicability subpart.

Certifying agents, SOP's governing State officials, and USDA will receive complaints alleging violations of the Act or these regulations. Certifying agents will review all complaints that they receive to determine if the complaint involves one of their clients. If the complaint involves a client of the certifying agent, the agent will handle the complaint in accordance with its procedures for reviewing and investigating certified operation compliance. If the complaint involves a person who is not a client of the certifying agent, the certifying agent will refer the complaint to the SOP's governing State official, when applicable, or, in the absence of an applicable SOP's governing State official, the Administrator. SOP's governing State officials will review all complaints that they receive in accordance with their procedures for reviewing and investigating alleged violations of the NOP and SOP. The SOP's governing State official's review of the complaint could result in referral of the complaint to a certifying agent when the complaint involves a client of the certifying agent, dismissal, or investigation by the SOP's governing State official. SOP's governing State officials will, as appropriate, investigate allegations of violations of the Act by noncertified

operations operating within their State. USDA will review all complaints that it receives in accordance with its procedures for reviewing and investigating alleged violations of the NOP. USDA will refer complaints alleging violations of the NOP/SOP to the applicable SOP's governing State official, who may, in turn, refer the complaint to the applicable certifying agent. In States without an approved SOP, USDA will refer complaints to the applicable certifying agent. USDA will, as appropriate, investigate allegations of violations of the Act by noncertified operations operating in States where there is no approved SOP.

(7) Mediation. We have amended section 205.663 by providing that a dispute with respect to proposed suspension or revocation of certification may, rather than shall, be mediated. We have also provided that mediation must be requested in writing to the applicable certifying agent. The certifying agent will have the option of accepting or rejecting the request for mediation. If the certifying agent rejects the request for mediation, the certifying agent must provide written notification to the applicant for certification or certified operation. The written notification must advise the applicant for certification or certified operation of the right to request an appeal within 30 days of the date of the written notification of rejection of the request for mediation. If mediation is accepted by the certifying agent, such mediation must be conducted by a qualified mediator mutually agreed upon by the parties to the mediation.

Several commenters wanted section 205.663 amended to provide that disputes "may," rather than "shall," be mediated. The commenters advocated allowing the certifying agent to determine when mediation is a productive option. Several State commenters wanted to amend the second sentence to read as follows: "If a State organic program is in effect, the mediation procedures established in the State organic program, as approved by the Secretary, will be followed for cases involving the State organic program and its applicants or certified parties." Another commenter wanted to retain the requirement that disputes "shall" be mediated but wanted disputes mediated in accordance with 7 CFR Part 11 and section 205.681 of these regulations.

We concur that certifying agents should be authorized to reject a request for mediation, especially when they believe that the noncompliance issue is not conducive to mediation. Accordingly, we amended section 205.663 as noted above. We disagree, however, with the State commenters who want to amend the second sentence. We believe that the recommended change would exclude the clients of private-sector certifying agents operating within the State. USDA approval of an SOP will require that all certified operations operating within the State have the same opportunities for mediation, regardless of whether they are certified by a private or State certifying agent. If an approved SOP provides for mediation, such mediation must be available to all certified operations operating within the State. We also disagree with the commenter who requested that disputes be mediated in accordance with 7 CFR Part 11 and section 205.681 of these regulations. First, we believe that States with an approved SOP must be allowed to establish their own mediation program and procedures. Second, the Act and its implementing regulations are subject to the APA for adjudication. The provisions of the APA generally applicable to agency adjudication are not applicable to proceedings under 7 CFR Part 11, National Appeals Division Rules of Procedure. Even if 7 CFR Part 11 were applicable, it does not address mediation procedures. Mediation is merely addressed in 7 CFR Part 11 as an available dispute resolution method along with its impact on the filing of an appeal.

(8) Noncompliance Procedure for Certifying Agents. We have amended section 205.665(a)(3) to clarify that, like certified operations, certifying agents must submit supporting documentation of each correction of a noncompliance identified in a notification of noncompliance. This amendment to section 205.665(a)(3) was made in response to commenter concerns that the noncompliance procedures for certified operations and certifying agents be similar. It had been our intent that certifying agents would have to document their correction of noncompliances and that the noncompliance procedures for certified operations and certifying agents would be similar.

#### **Compliance - Changes Requested But Not Made**



This subpart retains from the proposed rule, regulations on which we received comments as follows:

(1) Funding for Enforcement. Several commenters stated that USDA should provide funding to the States for the cost of performing enforcement activities. Others asked who should fund investigations and enforcement actions if certifying agents (State and private) are enforcing compliance with a Federal law. Numerous commenters requested information on how enforcement will be funded. The National Organic Standards Board (NOSB) recommended that the NOP examine existing models for capturing enforcement fees such as the State of California's registration program for all growers, handlers, and processors who use the word, "organic," in marketing their products.

We disagree with the commenters who stated that USDA should fund enforcement activities (State and private). Costs for compliance under the NOP will be borne by USDA, States with approved SOP's, and accredited certifying agents. Each of the entities will bear the cost of their own enforcement activities under the NOP. AMS anticipates that States will consider the cost of enforcing their SOP's prior to seeking USDA approval of such programs. We also anticipate that certifying agents will factor the cost of compliance into their certification fee schedules.

We agree that there may be alternatives, such as the State of California's registration program, available to raise funds for enforcing the NOP. We will help identify existing models and potential options that may be available in the future at the Federal, State, or certifying agent level. In the interim, we believe that SOP's should explore funding options at their level and that certifying agents should factor the cost of enforcement into their certification fees structure.

(2) Stop Sale. A number of commenters requested that the regulations include the ability to stop sales or recall misbranded or fraudulently produced products. The Act does not authorize the NOP to stop sales or recall misbranded or fraudulently produced product. Accordingly, USDA cannot authorize stop sales or the recall of product. We also believe that the certified operation's right to due process precludes a stop sale or recall prior to full adjudication of the alleged noncompliance. However, the Food and Drug Administration (FDA) and the USDA's Food Safety Inspection Service (FSIS) have stop sale authority that may be used in certain organic noncompliance cases. Further, States may, at their discretion, be able to provide for stop sale or recall of misbranded or fraudulently produced products produced within their State. While the Act does not provide for stop sale or recall, it does provide at 7 U.S.C. 6519 that any person who: (1) knowingly sells or labels a product as organic, except in accordance with the Act, shall be subject to a civil penalty of not more than \$10,000 and (2) makes a false statement under the Act to the Secretary, an SOP's governing State official, or a certifying agent shall be subject to the provisions of section 1001 of title 18, United States Code.

(3) Notification of Proposed Suspension or Revocation. A commenter recommended replacing "notification of proposed suspension or revocation" in section 205.662(d) with "notification of suspension or revocation." Certification cannot be suspended or revoked without due process. Accordingly, the issuance of a written notification of proposed suspension or revocation is necessary to provide the certified operation with information regarding the alleged noncompliance(s) and its right to answer the allegations. For this reason we have not accepted the commenter's recommendation.

(4) Mediation for Certifying Agents. Several commenters recommended amending section 205.665(c)(4) to provide for mediation between a certifying agent and the Program Manager when a proposed suspension or revocation is disputed by the certifying agent. We have not accepted the recommendation. USDA uses 7 CFR Part 1, Rules of Practice Governing Formal Adjudicatory Proceedings Instituted by the Secretary Under Various Statutes, for adjudicatory proceedings involving the denial, suspension, and revocation of accreditation.

(5) Revocation of Accreditation. A commenter stated that revocation of accreditation for 3 years is excessive. The commenter stated that a period of 6 to 12 months might be reasonable. We have not amended section 205.665(g)(2) because the Act requires that the period of revocation for certifying agents, who violate the Act and these regulations, be for not less than 3 years. Suspension is available to the Secretary to address less egregious noncompliances. A certifying agent whose accreditation is suspended may at any time, unless otherwise stated in the notification of suspension, submit a request to the Secretary for reinstatement of its accreditation. The request must be accompanied by evidence demonstrating correction of each noncompliance and corrective actions taken to comply with and remain in compliance with the Act and these regulations.

(6) Appeals Under SOP's. Several commenters recommended amending 205.668(b) by adding at the end thereof: "unless the State program's appeals procedures include judicial review through the State District Court." Another commenter wanted 205.668(b) amended by removing "of the State organic certification program. There shall be no subsequent rights of appeal to the Secretary. Final decisions of a State may be appealed to the United States District Court for the district in which such certified operation is located," and inserting in its place "at 7 CFR part 11 and 205.681 of this chapter." We have not accepted the recommendations because the Act at 7 U.S.C. 6520 provides that a final decision of the Secretary may be appealed to the United States District Court for the district in which the person is located. We consider an approved SOP to be the NOP for that State. As such, we consider the SOP's governing State official of such approved SOP to be the equivalent of a representative of the Secretary for the purposes of the appeals procedures under the NOP. Accordingly, the final decision of the SOP's governing State official of an approved SOP is considered the final decision of the Secretary and, as such, is appealable to the United States District Court for the district in which the person is located, not a State's District Court.

We also disagree with the commenter who wanted all appeals to be made to the National Appeals Division under the provisions at 7 CFR Part 11 and section 205.681 of these regulations. First, we believe that States with an approved SOP must be allowed to establish their own appeal procedures. Such procedures would have to comply with the Act, be equivalent to the procedures of USDA, and be approved by the Secretary. Second, as noted elsewhere in this preamble, the Act and its implementing regulations are subject to the APA for adjudication. The provisions of the APA generally applicable to agency adjudication are not applicable to proceedings under 7 CFR Part 11.

### **Compliance - Clarifications**

Clarification is given on the following issues raised by commenters:

(1) Complaints, Investigations, Stop Sales, and Penalties. Many commenters wanted USDA to spell out the responsibilities and authorities of States, State and private certifying agents, Federal agencies, and citizens to make complaints, investigate violations, halt the sale of products, and impose penalties. Anyone may file a complaint, with USDA, an SOP's governing State official, or certifying agent, alleging violation of the Act or these regulations. Certifying agents, SOP's governing State officials, and USDA will receive, review, and investigate complaints alleging violations of the Act or these regulations as described in item 6 above under Changes Based on Comments. Citizens have no authority under the NOP to investigate complaints alleging violation of the Act or these regulations.

As noted elsewhere in this preamble, the Act does not authorize USDA to stop the sale of product. Accordingly, USDA cannot authorize stop sales by accredited certifying agents. We also believe that the certified operation's right to due process precludes a stop sale prior to full adjudication of the alleged noncompliance. However, FDA and FSIS have stop sale authority that may be used in the event of food safety concerns. Further, States may, at their discretion, be able

to provide for stop sale of product produced within their State. Citizens have no authority under the NOP to stop the sale of a product.

The Act and these regulations provide for suspension or revocation of certification by certifying agents, SOP's governing State officials, and the Secretary. Only USDA may suspend or revoke a certifying agent's accreditation. All proposals to suspend or revoke a certification or accreditation are subject to appeal as provided in section 205.681. The Act provides at 7 U.S.C. 6519 that any person who: (1) knowingly sells or labels a product as organic, except in accordance with the Act, shall be subject to a civil penalty of not more than \$10,000 and (2) makes a false statement under the Act to the Secretary, an SOP's governing State official, or a certifying agent shall be subject to the provisions of section 1001 of title 18, United States Code. Only USDA may bring an action under 7 U.S.C. 6519.

(2) Certifying Agent's Identifying Mark. The NOSB reaffirmed its recommendation which would allow private certifying agents to prevent the use of their service mark (seal) upon written notification that: (1) certification by the private certifying agent has been terminated, and (2) the certifying agent has 30 days to appeal the certifying agent's decision to the Secretary of Agriculture. We will neither prohibit nor approve a certifying agent's actions to withdraw a certified operation's authority to use the certifying agent's identifying mark for alleged violations of the Act or regulations. We stand fast in our position that all certified operations are to be given due process prior to the suspension or revocation of their certification. The reader is also reminded that the certifying agent cannot terminate, suspend, or revoke a certification if the certified operation files an appeal with an SOP's governing State official, when applicable, or the Administrator as provided for in the notification of proposed suspension or revocation. The certifying agent accepts full liability for any action brought as a result of the withdrawal of a certified operation's authority to use the certifying agent's identifying mark.

(3) Loss of Certification. A commenter posed several questions regarding the loss of certification. The commenter's questions and our responses are as follows.

How will consumers and affected regulatory agencies know if a grower or handler loses its certification? We will provide public notification of suspensions and revocations of certified operations through means such as the NOP website.

What will the effect of a lost certification be? Suspension or revocation of a producer's or handler's certification will require that the producer or handler immediately cease its sale, labeling, and representation of agricultural products as organically produced or handled as provided in the suspension or revocation order. A production or handling operation or a person responsibly connected with an operation whose certification has been suspended may at any time, unless otherwise stated in the notification of suspension, submit a new request for certification in accordance with section 205.401. The request must be accompanied by evidence demonstrating correction of each noncompliance and corrective actions taken to comply with and remain in compliance with the Act and the regulations in this part. An operation or a person responsibly connected with an operation whose certification has been revoked will be ineligible to receive certification for a period of not more than 5 years following the date of such revocation, as determined by the Secretary. Any producer or handler who sells, labels, or represents its product as organic contrary to the provisions of the suspension or revocation order would be subject to prosecution under 7 U.S.C. 6519 of the Act.

Will the certifying agent give a future effective date for loss of certification, or could the loss of certification be immediate or even retroactive? Suspension or revocation will become effective as specified in the suspension or revocation order once it becomes final and effective. The operation, upon suspension or revocation, will be prohibited from selling, labeling, and representing its product as organic per the provisions of the suspension or revocation order.

If organic products already on the market were grown or handled by someone whose certification is revoked or suspended, would USDA require that the products be recalled and relabeled?

USDA will not, unless the noncompliance involves a food safety issue under FSIS, require the recall or relabeling of product in the channels of commerce prior to the issuance of a suspension or revocation order. First, at the time the product was produced, it may have been produced in compliance with the Act and these regulations. Second, USDA does not have the authority, under the Act, to issue a stop sale order for product sold, labeled, or represented as organic and placed in the channels of commerce prior to suspension or revocation of a certified operation's certification. The Act, however, provides at 7 U.S.C. 6519(a) for the prosecution of any person who knowingly sells or labels a product as organic, except in accordance with the Act. Such persons shall be subject to a civil penalty of not more than \$10,000 per violation.

(4) Investigations. A commenter suggested that we amend section 205.661(a) to require that all complaints must be investigated in accordance with the certifying agent's complaints policy. The commenter also stated that the Administrator should know which complaints were not investigated. We disagree that all complaints must be investigated since, upon review of the alleged noncompliance, some complaints may lack grounds for investigation. For example, a concerned citizen could allege that an organic producer was seen applying a pesticide to a specific field. Upon review of the allegation, the certifying agent could determine that the producer in question was a split operation and that the field in question was part of the conventional side of the production operation. Accordingly, there would be no need for an investigation. However, the certifying agent will be expected to: (1) take each allegation seriously, (2) review each complaint received, (3) make a determination as to whether there may be a basis for conducting an investigation, (4) investigate all allegations when it is believed that there may be a basis for conducting the investigation, and (5) maintain a detailed log of all complaints received and their disposition. The actions taken by the certifying agent must be in conformance with the certifying agent's procedures for reviewing and investigating certified operation compliance.

(5) Deadline for the Correction of a Noncompliance. Several commenters requested that 205.662(a)(3) be amended by adding: "The deadline for correction of the noncompliance may be extended at the discretion of the certifier if substantial progress has been made to correct the noncompliance." We believe that the requested amendment is unnecessary. Section 205.662(a)(3) requires that the notification of noncompliance include a date by which the certified operation must rebut or correct each noncompliance and submit supporting documentation of each correction when correction is possible. There is no prohibition preventing the certifying agent from extending the deadline specified when the certifying agent believes that the certified operation has made a good faith effort at correcting each noncompliance.

(6) Compliance with SOP. Several States requested that section 205.665 be amended to clarify how States may handle a private certifying agent found to be in noncompliance with SOP's approved by the Secretary. A majority of these commenters also asked if NOP intends to suspend or revoke the accreditation of certifying agents on a State-by-State basis. Section 205.668(c) authorizes an SOP's governing State official to review and investigate complaints of noncompliance with the Act or regulations concerning accreditation of certifying agents operating in the State. When such review or investigation reveals any noncompliance, the SOP's governing State official shall send a written report of noncompliance to the NOP Program Manager. The report shall provide a description of each noncompliance and the facts upon which the noncompliance is based. The NOP Program Manager will then employ the noncompliance procedures for certifying agents as found in section 205.665. This may include additional investigative work by AMS. Only USDA may suspend or revoke a certifying agent's accreditation.

SOP's must meet the general requirements for organic programs specified in the Act and be at least equivalent to these regulations. Accordingly, noncompliances worthy of suspension or revocation would in all probability be worthy of national suspension or revocation of accreditation for one or more areas of accreditation. Therefore, USDA does not anticipate suspending or

revoking accreditations, or areas of accreditation, on a State-by-State basis. It is possible, however, that the Secretary may decide to only suspend or revoke a certifying agent's accreditation or an area of accreditation to certify producers or handlers within a given State. Such a decision would in all probability be tied to a State's more restrictive requirements.

# Residue Testing -- Preamble

## Inspection and Testing, Reporting, and Exclusion from Sale

This portion of subpart G sets forth the inspection and testing requirements for agricultural products that have been produced on organic production operations or handled through organic handling operations.

Residue testing plays an important role in organic certification by providing a means for monitoring compliance with the National Organic Program (NOP) and by discouraging the mislabeling of agricultural products. This testing program provides State organic programs' (SOP) governing State officials and certifying agents with a tool for ensuring compliance with three areas for testing: (1) preharvest residue testing, (2) postharvest residue testing, and (3) testing for unavoidable residual environmental contamination levels.

## Description of Regulations

### General Requirements

Under the residue testing requirements of the NOP, all agricultural products sold, labeled, or represented as organically produced must be available for inspection by the Administrator, SOP's governing State official, or certifying agent. Organic farms and handling operations must be made available for inspection under subpart E, Certification. In addition, products from the aforementioned organic operations may be required by the SOP's governing State official or certifying agent to undergo preharvest or postharvest testing when there is reason to believe that agricultural inputs used in organic agriculture production or agricultural products to be sold or labeled as organically produced have come into contact with prohibited substances or have been produced using excluded methods. The cost of such testing will be borne by the applicable certifying agent and is considered a cost of doing business. Accordingly, certifying agents should make provisions for the cost of preharvest or postharvest residue testing when structuring certification fees.

### Preharvest and Postharvest Residue Testing

The main objectives of the residue testing program are to: (1) ensure that certified organic production and handling operations are in compliance with the requirements set forth in this final rule and (2) serve as a means for monitoring drift and unavoidable residue contamination of agricultural products to be sold or labeled as organically produced. Any detectable residues of a prohibited substance or a product produced using excluded methods found in or on samples during analysis will serve as a warning indicator to the certifying agent.

The Administrator, SOP's governing State official, or certifying agent may require preharvest or postharvest testing of any agricultural input used in organic agricultural production or any agricultural product to be sold or labeled as "100 percent organic," "organic," or "made with organic (specified ingredients or food group(s))." It is based on the Administrator's, SOP's governing State official's, or certifying agent's belief that an agricultural product or agricultural input has come into contact with one or more prohibited substances or has been produced using excluded methods. Certifying agents do not have to conduct residue tests if they do not have reason to believe that there is a need for testing. Certifying agents must ensure, however, that certified organic operations are operating in accordance with the Act and the regulations set forth in this part.

The "reason to believe" could be triggered by various situations, for example: (1) the applicable authority receiving a formal, written complaint regarding the practices of a certified organic operation; (2) an open container of a prohibited substance found on the premises of a certified organic operation; (3) the proximity of a certified organic operation to a potential source of drift; (4) suspected soil contamination by historically persistent substances; or (5) the product from a certified organic operation being unaffected when neighboring fields or crops are infested with pests. These situations do not represent all of the possible occurrences that would trigger an investigation. Preharvest or postharvest residue testing will occur on a case-by-case basis.

In each case, an inspector representing the Administrator, SOP's governing State official, or certifying agent or will conduct sampling. According to subpart F, Accreditation, private or State entities accredited as certifying agents under the NOP must ensure that its responsibly connected persons, employees, and contractors with inspection, analysis, and decision-making responsibilities have sufficient expertise to successfully perform the duties assigned. Therefore, all inspectors employed by certifying agents to conduct sampling must have sufficient expertise in methods of chain-of-custody sampling. Moreover, testing for chemical residues must be performed in an accredited laboratory. When conducting chemical analyses, the laboratory must incorporate the analytical methods described in the most current edition of the Official Methods of Analysis of the AOAC International or other current applicable validated methodology for determining the presence of contaminants in agricultural products. Results of all analyses and tests performed under section 205.670 must be promptly provided to the Administrator, except, that, where an SOP exists, all test results and analyses should be provided to the SOP's governing State official by the applicable certifying party that requested testing. Residue test results and analyses must also be, according to section 205.403(e)(2), provided to the owner of the certified organic operation whose product was tested. All other parties desiring to obtain such information must request it from the applicable certifying agent.

OFPA requires certifying agents, to the extent of their awareness, to report violations of applicable laws relating to food safety to appropriate health agencies such as EPA and FDA. When residue testing indicates that an agricultural product contains pesticide residues or environmental contaminants that exceed either the EPA tolerance level or FDA action level, as applicable, the certifying agent must promptly report data revealing such information to the Federal agency whose regulatory tolerance or action level has been exceeded.

### **Residue Testing and Monitoring Tools**

When testing indicates that an agricultural product to be sold or labeled as organically produced contains residues of prohibited substances, certifying agents will compare the level of detected residues with 5 percent of the Environmental Protection Agency (EPA) tolerance for the specific residue detected on the agricultural product intended to be sold as organically produced. This compliance measure, 5 percent of EPA tolerance for the detected prohibited residue, will serve as a standard for the Administrator, SOP's governing State officials, and certifying agents to assist in monitoring for illegal use violations.

In addition, we intend to establish levels of unavoidable residual environmental contamination (UREC) for crop-and site-specific agricultural commodities to be sold, labeled, or represented as "100 percent organic," "organic," or "made with..." These levels will represent limits at which USDA may take compliance action to suspend the use of a contaminated area for organic agricultural production. Currently, USDA is seeking scientifically sound principles and measures by which it can establish UREC levels to most effectively address issues of unavoidable residual environmental contamination with respect to this rule. However, in the interim, UREC will be defined as the Food and Drug Administration's (FDA) action levels for poisonous or deleterious substances in human food or animal feed. UREC levels will be initially set for persistent prohibited substances (aldrin, dieldrin, chlordane, DDE, etc.) in the environment. They may become more inclusive of prohibited residues as additional information becomes available. Unavoidable

residual environmental contamination levels will be based on the unavoidability of the chemical substances and do not represent permissible levels of contamination where it is avoidable.

Analyses and test results will be available for public access unless the residue testing is part of an ongoing compliance investigation. Information relative to an ongoing compliance investigation will be confidential and restricted to the public.

### **Detection of Prohibited Substances or Products Derived from Excluded Methods**

In the case of residue testing and the detection of prohibited substances in or on agricultural products to be sold, labeled, or represented as "100 percent organic," "organic," or "made with....," products with detectable residues of prohibited substances that exceed 5 percent of the EPA tolerance for the specific residue or UREC cannot be sold or labeled as organically produced. When such an agricultural crop is in violation of these requirements, the certification of that crop will be suspended for the period that the crop is in production. Certifying agents must follow the requirements specified in sections 205.662 and 205.663 of subpart G, Compliance.

The "5 percent of EPA tolerance" standard is considered a level above which an agricultural product cannot be sold as organic, regardless of how the product may have come into contact with a potential prohibited substance. This standard has been established to: (1) satisfy consumer expectations that organic agricultural products will contain minimal chemical residues and (2) respond to the organic industry's request to implement a standard comparable to current industry practices. However, the "5 percent of EPA tolerance" standard cannot be used to automatically qualify agricultural products as organically produced, even if the level of chemical residues detected on an agricultural product is below 5 percent of the EPA tolerance for the respective prohibited substance. This final rule is a comprehensive set of standards and regulations that determines whether a product can or cannot be considered to carry the specified organic labeling terms in subpart D, Labeling. Therefore, in addition to this section of subpart G, Administrative, all other requirements of this part must be met by certified organic operations to have an agricultural product considered "organically produced."

When residue testing detects the presence of any prohibited substance, whether above or below 5 percent of the EPA tolerance for the specific pesticide or UREC, the SOP's governing State official or certifying agent may conduct an investigation of the certified organic operation to determine the cause of the prohibited substance or product in or on the agricultural product to be sold or labeled as organically produced. The same shall occur if testing detects a product produced using excluded methods. If the investigation reveals that the presence of the prohibited substance or product produced using excluded methods in or on an agricultural product intended to be sold as organically produced is the result of an intentional application of a prohibited substance or use of excluded methods, the certified organic operation shall be subject to suspension or revocation of its organic certification. In addition, any person who knowingly sells, labels, or represents an agricultural product as organically produced in violation of the Act or these regulations shall be subject to a civil penalty of not more than \$10,000 per violation.

### **Emergency Pest or Disease Treatment Programs**

When a prohibited substance is applied to an organic production or handling operation due to a Federal or State emergency pest or disease treatment program and the organic handling or production operation otherwise meets the requirements of this final rule, the certification status of the operation shall not be affected as a result of the application of the prohibited substance, except that: (1) any harvested crop or plant part to be harvested that has contact with a prohibited substance applied as the result of a Federal or State emergency pest or disease treatment program cannot be sold, labeled, or represented as "100 percent organic," "organic," or "made with..." and (2) any livestock that are treated with a prohibited substance applied as the result of a



Federal or State emergency pest or disease treatment program or product derived from such treated livestock cannot be sold, labeled, or represented as "100 percent organic," "organic," or "made with..."

However, milk or milk products may be labeled or sold as organically produced beginning 12 months following the last date that the dairy animal was treated with the prohibited substance. Additionally, the offspring of gestating mammalian breeder stock treated with a prohibited substance may be considered organic if the breeder stock was not in the last third of gestation on the date that the breeder stock was treated with the prohibited substance.

### **Residue Testing - Changes Based on Comments**

This portion of subpart G differs from our proposal in several respects as follows:

(1) Reporting Requirements. Commenters were not satisfied with the language in section 205.670(d)(1) that required results of all analyses and tests performed under section 205.670 to be provided to the Administrator promptly upon receipt. They asked that the paragraph be amended to include that: (1) results of all analyses and tests performed under section 205.670 be provided by the Administrator to the appropriate SOP's governing State official and (2) test results be made immediately available to the owner of the material sampled. They stated that since State organic certification programs are responsible for enforcement within their State, results of residue tests conducted by certifying agents must be provided to the SOP's governing State official for routine monitoring and for investigating possible violations of the Act.

We agree with the commenters and have responded to their concerns accordingly. To ensure that SOP's receive results of all tests and analyses conducted under the inspection and testing requirements of subpart G, section 205.670(d) has been amended to include that the results of all analyses and residue tests must be provided to the Administrator promptly upon receipt; Except: That where an SOP exists, all test results and analyses should be provided to the SOP's governing State official.

In regard to the commenters' request that certified organic operations be provided with a copy of test results from samples taken by an inspector, an additional paragraph, section 205.403(e)(2), has been added to subpart E, Certification, that assures that such information is provided to the owners of certified organic operations by the certifying agents.

(2) Integrity Of Organic Samples. We have modified language in section 205.670(c) to clarify our intent regarding the maintenance of sample integrity. The proposed rule stated that "sample integrity must be maintained in transit, and residue testing must be performed in an accredited laboratory." During the final rulemaking process, we did not believe that our intent was clear on this subject. Our intent is to ensure that sample integrity is maintained throughout the entire chain of custody during the residue testing process. Proposed language only suggests that sample integrity be maintained in transit. Therefore, the we have changed the second sentence in section 205.670(c) to state that "sample integrity must be maintained throughout the chain of custody, and residue testing must be performed in an accredited laboratory."

(3) Reporting Residue and Other Food Safety Violations to Appropriate Health Agencies. In the proposed rule, section 205.671(b) under Exclusion from Organic Sale states, "If test results indicate a specific agricultural product contains pesticide residues or environmental contaminants that exceed the FDA's or the EPA's regulatory tolerances, the data must be reported promptly to the appropriate public health agencies." During the final rulemaking process, a group of commenters suggested that we move section 205.671(b) into section 205.670 as paragraph (e). They recommended that we move section 205.671(b) because it does not specifically address the sale of organically produced products, as indicated by the section heading. They

recommended that section 205.671(b) be placed under section 205.670 as paragraph (e) because it dealt with the reporting of residues that exceed Federal regulatory tolerances. The commenters further stated that, while section 205.671(b) creates a duty to report, it is not specific as to who must report.

We have accepted the suggestions of the commenters and have responded accordingly. We have removed section 205.671(b) and relocated it under section 205.670 as paragraph (e). We have also modified the regulatory text of paragraph (e) to include language that instructs certifying agents to report, when residue testing indicates that an agricultural product contains pesticide residues or environmental contaminants that exceed either the EPA tolerance level or FDA action level, as applicable, data revealing such information to the Federal agency whose regulatory tolerance or action level has been exceeded.

(4) Exclusion from Organic Sale. We have reviewed section 205.671(a), removed the requirement to implement the Pesticide Data Program (pdp) estimated national mean as a compliance tool in monitoring for the presence of unacceptable levels of prohibited substances in agricultural products intended to be sold as organic, and added the "5 percent of EPA tolerance" standard.

Commenters voiced the opinion that the estimated national mean would be a difficult standard in organic agricultural production for several reasons. Some stated that the estimated national mean was a new concept that would confuse producers and handlers because they would not know the exact definition of "estimated national mean" and how it would be determined. Others stated that the PDP was too limited in scope to employ an estimated national mean for all commodity/pesticide combinations. Commenters reasoned that PDP data were limited in terms of the agricultural commodities that are sampled and tested.

Another group of commenters stated that PDP data would be unfair to use in the NOP's residue testing plan. They argued PDP data should not be used to set maximum residue levels for organic agricultural products because PDP samples its products as close to the point of consumption as possible. As a result, commenters believe that PDP data may not be totally reflective of residue levels of agricultural products at the farmgate level. Since most residue testing in organic agricultural production takes place at the farmgate, these commenters argued that it would be an inappropriate standard for organic agricultural production.

As a result, a large number of commenters suggested that we reconsider using the estimated national mean as a standard for the maximum allowable residues on organically produced products. Instead, commenters recommended that the NOP incorporate the National Organic Standards Board's (NOSB) recommendation and current industry practice of using 5 percent of the EPA tolerance as a maximum level of pesticide residue on organic agricultural products. Commenters argued that using 5 percent of the EPA tolerance provides a sense of confidence to the consumers of organic agricultural products.

In many respects, we agree with the commenters. We have revisited using PDP data to establish an estimated national mean for commodity/pesticide combinations and for setting a maximum level of pesticide residue that could exclude agricultural products from being sold, labeled, or represented as organic. As a result, we have concluded that such an approach may be somewhat underdeveloped to incorporate into the NOP. We have reached this conclusion based on many of the same arguments presented by commenters (i.e., limited scope of agricultural products tested under PDP, product sampling based upon market availability, testing near the point of consumption, etc.). Also, we estimated that there would be a considerable time lag between the implementation of the NOP and defining a comprehensive list of estimated national means for all commodity/pesticide combinations. Thus, we have decided not to use the estimated national mean as a tool for monitoring organic agricultural products for the presence of prohibited substances and as a standard to exclude agricultural products from being sold, labeled, or represented as organically produced.

Instead, we have decided to follow the recommendation of the commenters by replacing the estimated national mean for specific commodity/pesticide pairs with 5 percent of the EPA tolerance for the specific pesticide. Therefore, when residue testing detects prohibited substances at levels that are greater than 5 percent of the EPA tolerance for the specific pesticide detected on the particular product samples, the agricultural product must not be sold or labeled as organically produced.

We fully understand that the EPA tolerance is defined as the maximum legal level of a pesticide residue in or on a raw or processed agricultural commodity. We also acknowledge that the EPA tolerance is a health-based standard. We are not trying to employ the 5 percent standard in a manner similar to that of EPA. As mentioned in our proposal, the national organic standards, including provisions governing prohibited substances, are based on the method of production, not the content of the product. The primary purpose of the residue testing approach described in this final rule, then, is to provide an additional tool for SOP's' governing State officials and certifying agents to use in monitoring and ensuring compliance with the NOP.

(5) Unavoidable Residual Environmental Contamination. We have defined, as an interim measure, UREC as the FDA action levels for poisonous or deleterious substances in human food or animal feed.

Section 205.671 proposed the use of UREC to serve as a residue testing tool for compliance. Commenters believed UREC levels, as prescribed in section 205.671 of the proposed rule, would be problematic as a standard because they were undefined. Commenters argued that it would be impractical and very expensive to establish UREC levels for every organic crop and region in the United States. They suggested that UREC levels be managed as a practice standard or program manual issue. They also expressed the concern that inconsistent application of UREC levels could create difficulties for certifying agents and certified operations.

We agree that UREC levels should be defined. We are seeking scientifically sound principles and measures by which we can establish UREC levels to most effectively address issues of unavoidable residual contamination with respect to this rule. However, in the interim, the ability to implement an undefined standard would be difficult for certifying agents. Therefore, we have included language in the preamble that temporarily defines UREC as the FDA action levels for poisonous or deleterious substances in human food or animal feed. When residue testing detects the presence of a prohibited substance on an agricultural product greater than such levels mentioned, the agricultural product cannot be sold as organic. We have decided to use FDA action levels for UREC because they encompass many of the toxic, persistent chemicals and heavy metals that are present in the environment and may be found on food and animal feed. As mentioned earlier, the FDA action levels are being employed in this part as temporary measures for compliance. We will continue to seek scientifically sound principles and measures by which to establish UREC levels that more appropriately satisfy the purposes of this part.

### **Residue Testing - Changes Requested But Not Made**

This subpart retains from the proposed rule regulations on which we received comments as follows:

(1) Residue Testing Responsibility. Commenters petitioned that we remove the requirement in section 205.670(b) that states residue tests must be conducted by the applicable SOP's governing State official or the certifying agent at the official's or certifying agent's own expense. The commenters expressed the opinion that we were practicing "micromanagement." They also said that there was no need for the proposal to be so detailed with respect to who pays for residue testing. Based on the commenters' responses, residue analyses are reportedly paid by producers, buyers, brokers, certifiers, and government residue testing programs.

We have not adopted the suggestion of the commenters. In the proposal, we stated that conducting residue tests was considered a cost of doing business for certifying agents. Our position has not changed. Certifying agents can factor residue testing costs into certification fees. It is not our intention to "micromanage" the way that certifying agents conduct business. Section 2107(a)(6) of the Act requires that certifying agents conduct residue testing of agricultural products that have been produced on certified organic farms and handled through certified organic handling operations. OFPA also requires, under section 2112(a) through (c), that certifying agents enforce its provisions by implementing a system of residue testing to test products sold or labeled as organically produced. In addition, subpart E, Certification, authorizes certifying agents to conduct on-site inspections, which may include residue testing, of certified organic operations to verify that the operation is complying with the provisions in the Act and the regulations in this part. Certifying agents are responsible for monitoring organic operations for the presence of prohibited substances; we view residue testing as a cost of doing business. Therefore, we believe that certifying agents should factor monitoring costs associated with implementing the provisions in the Act and Rule into their certification fees.

(2) Reporting to Federal Regulatory Agencies. Commenters disagree with section 205.671(b) of the proposed rule which states that if test results indicate a specific agricultural product contains pesticide residues or environmental contaminants that exceed the FDA action level or EPA tolerance, the data must be reported promptly to appropriate public health agencies. Commenters believe that since results of all analyses and tests must be provided to the Administrator, USDA should be responsible for communicating such test results to other Federal agencies such as FDA or EPA if regulatory tolerances or action levels are exceeded. They also suggested that section 205.671(b) be removed from the national regulations. Commenters expressed the view that such a requirement is not related to organic certification.

We do not agree with the commenters. It is not our intent to create additional responsibility for the certifying agent. Section 205.671(b), redesignated as section 205.670(e), is a statutory requirement. Section 2107(a)(6) of the Organic Food Production Act of 1990 requires certifying agents, to the extent of their awareness, to report violations of applicable laws relating to food safety to appropriate health agencies such as EPA and FDA. Therefore, due to section 2107 of the Act, section 205.670(e) has been included in the national regulations.

(3) "Threshold" for Genetic Contamination. Many commenters suggested that we establish a "threshold" for the unintended or adventitious presence of products of excluded methods in organic products. Some commenters argued that a threshold is necessary because, without the mandatory labeling of biotechnology-derived products, organic operations and certifying agents could not be assured that products of excluded methods were not being used. Others argued that, without an established threshold, the regulations would constitute a "zero tolerance" for products of excluded methods, which would be impossible to achieve.

We do not believe there is sufficient consensus upon which to establish such a standard at this time. Much of the basic, baseline information about the prevalence of genetically engineered products in the conventional agricultural marketplace that would be necessary to set such a threshold-e.g., the effects of pollen drift where it may be a factor, the extent of mixing at various points throughout the marketing chain, the adventitious presence of genetically engineered seed in nonengineered seed lots-is still largely unknown. Our understanding of how the use of biotechnology in conventional agricultural production might affect organic crop production is even less well developed.

Also, as was pointed out in some comments, the testing methodology for the presence of products of excluded methods has not yet been fully validated. Testing methods for some biotechnology traits in some commodities are becoming commercially available. Without recognized methods of testing for and quantifying of all traits in a wide range of food products, however, it would be very difficult to establish a reliable numerical tolerance.

There are publicly and privately funded research projects underway that may provide useful baseline information. Efforts of Federal agencies to clarify the marketing and labeling of biotechnology- and nonbiotechnology-derived crops may also help address these concerns. FDA, for example, is developing guidance for food producers who voluntarily chose to label biotechnology- and nonbiotechnology-derived foods. USDA is also preparing a Federal Register Notice to seek public comment on the appropriate role, if any, that it can play in facilitating the marketing of agricultural products through the development of "quality assurance" type programs that help to preserve the identity of agricultural commodities. USDA, in cooperation with the technology providers, is also working to validate testing procedures and laboratories for some commodities.

All of these efforts may help to provide information on this issue. Practices for preserving product identity, including segregating genetically engineered and nongenetically engineered products, are evolving in some conventional markets. As we discussed in the preamble to the proposed rule, we anticipate that these evolving industry best practices and standards will become the standards for implementing the provisions in this regulation relating to the use of excluded methods. As was also discussed in the proposed rule, these regulations do not establish a "zero tolerance" standard. As with other substances not approved for use in organic production systems, a positive detection of a product of excluded methods would trigger an investigation by the certifying agent to determine if a violation of organic production or handling standards occurred. The presence of a detectable residue alone does not necessarily indicate use of a product of excluded methods that would constitute a violation of the standards.

(4) Certification Status After Emergency Pest or Disease Treatment. We have not modified language in section 205.672 that would affect the certification status of a certified organic operation if the operation had been subjected to a Federal or State emergency pest or disease treatment program.

Section 205.672 states that when a prohibited substance is applied to a certified operation due to a Federal or State emergency pest or disease treatment program and the certified operation otherwise meets the requirements of this part, the certification status of the operation shall not be affected as a result of the application of the prohibited substance: Provided, That, the certified operation adheres to certain requirements prescribed by the NOP. One group of commenters informed us that they did not support maintaining the organic status of an operation that has been directly treated with prohibited substances, regardless of the reason for treatment. They believe that Federal and State emergency pest or disease treatment programs should provide alternatives for organic operations whenever feasible. If no alternative measure is feasible, the organic operation should choose between voluntary surrender of their organic status on targeted parts of the operation or destruction of the crop to eliminate pest habitat. The commenters also suggested that compensation should be provided to organic producers whose crops must be destroyed to eliminate habitat. They feel that allowing the application of prohibited materials to certified organic land without affecting the certification status violates the trust consumers place in organic certification.

We disagree with the position of the commenters. Historically, residues from emergency pest or disease treatment programs have been treated as drift cases by certifiers. In these cases, the specific crop may not be sold as organic, but the organic status of future crop years are not affected. We intend to handle such cases in a similar manner. We understand that commenters would like us to remove the certification of an organic operation that has been treated with a prohibited substance, but organic certification is a production claim, not a content claim. We, along with the commenters, are concerned with consumers trusting organic certification. At the same time, we are concerned with the welfare of certified organic operations. We have tried to include language in section 205.672 that would address both issues. We believe that, if a certified organic grower has been a good steward of his/her land and has managed the production of his/her product(s) in accordance with all regulations in the Act and other requirements in this part,

the certification status of the operation should not be affected. The application of a prohibited substance as part of a Federal or State emergency pest or disease treatment program is outside the control of the certified operation. We also believe that maintaining consumer trust is important. Thus, section 205.672 states that any harvested crop or plant part to be harvested that has been treated with a prohibited substance as part of a Federal or State emergency pest or disease treatment program cannot be sold as organically produced. Therefore, the certified organic operation can retain its certification status, and the consumer can be assured that a product from a certified organic operation that has been in contact with a prohibited substance as the result of a Federal or State pest or disease treatment program will not enter the organic marketplace. Accordingly, we have not made the change to section 205.672 as proposed by the commenters.

(5) Emergency Pest or Disease Treatment Programs. Commenters suggested that the Department add a new paragraph to section 205.672 that states "the certifying agent must monitor production operations that have been subjected to a Federal or State emergency pest or disease treatment program, and may require testing of following crops, or an extended transition period for affected production sites, if residue test results indicate the presence of a prohibited substance." Commenters said the language in the proposed rule did not clearly establish that a transition period could be needed after contamination of a certified organic operation by a government-mandated spray program. They felt that there may be a need for a case-by-case determination by the certifying agent as to when it would be best for a certified organic operation to begin selling its products as organically produced after it has been subject to a government mandated spray program.

We understand that commenters would like USDA to mandate certifying agents to monitor operations that have been subject to Federal or State emergency pest or disease treatment programs; however, we do not see a need to prescribe such a provision. Based on the responsibilities of being a USDA-accredited certifier, it is our belief that certifying agents would monitor a certified organic operation that has been subjected to a Federal or State emergency pest or disease treatment program to make sure that product being produced for organic sale is actually being produced in accordance with the Act and the regulations in this part. Certifying agents have been granted the authority to conduct additional on-site inspections of certified organic operations to determine compliance with the Act and national standards under subpart E, section 205.403. Commenters requested that we include language that would allow certifying agents to recommend an extended transition period for affected production sites if residue tests indicate the presence of a prohibited substance. Again, we understand the commenters' concern, but we are not aware of comprehensive soil residue data that could guide certifying agents in determining appropriate withdrawal intervals for operations that have been subjected to emergency pest or disease treatment programs.

### **Residue Testing - Clarifications**

Clarification is given on the following issues raised by commenters as follows:

(1) Sampling and Testing. Commenters stated that the purpose of residue testing under the Act is to assure that organically produced agricultural products that are sold as organic do not contain pesticide residues or residues of other prohibited substances that exceed levels as specified by the NOP. Based on language in section 205.670(b) of the proposed rule, commenters expressed the opinion that the Agricultural Marketing Service (AMS) was, not only requiring residue testing of organic agricultural products, but also of "any" agricultural input used or agricultural product intended to be sold as "100 percent organic," "organic," or "made with..." when there is reason to believe that the agricultural input or product has come into contact with a prohibited substance. Commenters believe that organic certifying agents may be required to test many nonorganic agricultural inputs (such as seeds, compost, straw, sawdust, and plastic) and nonorganic agricultural products and ingredients used in products labeled as "made with...". They also

argued that such testing would be unnecessary, burdensome, and expensive because such materials are more likely to have come into contact with a prohibited substance. Therefore, commenters suggested that we amend section 205.670(b) by deleting "agricultural inputs" and replacing "agricultural product" with "organically produced agricultural product." They also recommended that we replace the second occurrence of "product" with "organic product." Thus section 205.670(b) would suggest that only organic agricultural products could be required to be tested by the certifying agent.

We understand the concerns of the commenters but believe that the commenters have misinterpreted the intent of section 205.670(b). It is not our intent to mandate residue testing of all inputs and ingredients used in the production of organic agricultural products. Neither is it our intent for certifying agents to abuse residue testing responsibility by conducting residue tests of certified organic operations without reason to believe that the agricultural input or product intended to be sold as organic has come into contact with prohibited substances. Our intent is to make it clear that certifying agents have the authority to test any agricultural input used or agricultural product intended to be sold as organically produced when there is reason to believe that the agricultural input or product has come into contact with a prohibited substance. Section 205.670(b) allows for testing of inputs and agricultural products, but it does not require that all inputs of a product intended to be sold as organically produced must be tested. However, certifying agents must be able to ensure that certified organic operations are operating in accordance with the Act and the regulations set forth in this part. To assure that certifying agents have established fair and effective procedures for enforcing residue testing requirements, section 205.504(b)(6) provides that they must submit to USDA a copy of the procedures to be used for sampling and residue testing pursuant to section 205.670.

(2) Chain Of Custody Training. A commenter suggested that section 205.670(c) address chain of custody training for inspectors that will be performing preharvest or postharvest tissue test sample collection on behalf of the Administrator, SOP's governing State official, or certifying agent. The commenter proposed that all inspectors should be trained to handle chain of custody samples in order to maintain the integrity of the samples.

We agree that inspectors should be appropriately trained to handle chain-of-custody samples in order to maintain the integrity of the samples taken from a certified organic operation. However, we do not believe that the language in section 205.670(c) must be modified to address such an issue. As a USDA-accredited body, a private or State entity operating as a certifying agent must ensure that its responsibly connected persons, employees, and contractors with inspection, analysis, and decision-making responsibilities have sufficient expertise in organic production or handling techniques to successfully perform the duties assigned. The certifying agent must also submit a description of the training that has been provided or intends to be provided to personnel to ensure that they comply with and implement the requirements of the Act and the regulations in this part. In addition, certifying agents must submit a copy of the procedure to be used for sampling and residue testing for approval by the Administrator. Through the accreditation process, therefore, we will be able to assess the expertise of the individuals employed by the certifying agent and provide guidance in areas where additional training is needed to comply with the requirements of the Act and the regulations in this part.

(3) Exclusion from Organic Sale. Commenters expressed that section 205.671(a) could be easily misinterpreted. They said that section 205.671(a) did not make clear that residue testing may not be used to qualify crops to be sold as organic if a direct application of prohibited materials occurred. Commenters suggested that section 205.671(a) include: "Any crop or product to which prohibited materials have been directly applied shall not be sold, labeled, or represented as organically produced."

We do not believe this additional language is necessary. Residue testing cannot be used to qualify any agricultural crop or product to which a prohibited material has been

purposefully/directly applied. The presence of any prohibited substance on an agricultural product to be sold as organic warrants an investigation as to why the detected prohibited substance is present on the agricultural product. It does not matter if the product has come into contact with a prohibited substance through means of drift or intentional application. If the outcome of the investigation reveals that the presence of the detected prohibited substance is the result of an intentional application, the certified operation will be subject to suspension or revocation of its organic certification and/or a civil penalty of not more than \$10,000 if he/she knowingly sells the product as organic. The use of prohibited substances is not allowed in the Act or this final rule. Residue testing is not a means of qualifying a crop or product as organic if a prohibited substance has been intentionally/directly applied. It is a tool for monitoring compliance with the regulations set forth in the Act and in this part.

(4) Emergency Pest or Disease Treatment Programs. Commenters requested that we make a clear distinction between crops or agricultural products that have had prohibited substances directly applied to them and those that have come into contact with prohibited substances through chemical drift. They have proposed that we amend section 205.672(a) to address this issue. Section 205.672(a) of the proposal states that any harvested crop or plant part to be harvested that has had contact with a prohibited substance applied as the result of a Federal or State emergency pest or disease treatment program cannot be sold as organically produced. Commenters did not find this language acceptable because it did not distinguish between the two types of ways that products can come into contact with prohibited substances (drift and direct/intentional application) and how each situation would be addressed with respect to the national organic standards. Commenters believed that section 205.672(a) was fairly ambiguous and open for misinterpretation. Commenters requested that we amend language in section 205.672(a) to include that "Any harvested crop or plant part to be harvested that has contact with a prohibited substance directly applied to the crop as the result of a Federal or State emergency pest or disease treatment program cannot be sold, labeled, or represented as organically produced."

We do not accept the commenters' request and believe that the commenters have misinterpreted section 205.672 of the proposed rule. Section 205.672 specifically addresses certified organic operations that have had prohibited substances applied to them due to a Federal or State pest or disease treatment program. Section 205.672 does not include those organic operations that may have been drifted upon by prohibited substances that have been applied to a neighboring farm as a result of a Federal or State emergency pest or disease treatment program. Any potential drift from a mandatory pest and disease treatment program will be treated in the same manner as drift from any other source.



## Appeals -- Preamble

### Adverse Action Appeal Process

This portion of subpart G sets forth the procedures for appealing adverse actions under the National Organic Program (NOP). These procedures will be used by: (1) producers and handlers appealing denial of certification and proposed suspension or revocation of certification decisions; and (2) certifying agents appealing denial of accreditation and proposed suspension or revocation of accreditation decisions. The Act and the Administrative Procedure Act (APA) (5 U.S.C. 553-559) provides affected persons with the right to appeal any adverse actions taken against their application for certification or accreditation or their certification or accreditation.

The Administrator will handle certification appeals from operations in States that do not have an approved State organic program (SOP). The Administrator will also handle appeals of accreditation decisions of the NOP Program Manager. The Administrator will issue decisions to sustain or deny appeals. If an appeal is denied, the Administrator will initiate a formal adjudicatory proceeding to deny, suspend, or revoke certification or accreditation. Such proceedings will be conducted pursuant to USDA's Rules of Practice Governing Formal Adjudicatory Proceedings Instituted by the Secretary Under Various Statutes, 7 CFR 1.130 through 1.151. Under these rules of practice, if the Administrative Law Judge denies the appeal, the appellant may appeal the Administrative Law Judge's decision to the Judicial Officer. If the Judicial Officer denies the appeal, the appellant may appeal the Judicial Officer's decision to the United States District Court for the district in which the appellant is located.

In States with approved SOP's, the SOP will oversee certification compliance proceedings and handle appeals from certified operations in the State. An SOP's appeal procedures and rules of procedure must be approved by the Secretary and must be equivalent to those of the NOP and USDA. The final decision on an appeal under the SOP may be appealed by the appellant to United States District Court for the district in which the appellant is located.

### Description of Regulations

These appeal procedures provide that: (1) persons, subject to the Act, who believe they are adversely affected by a noncompliance decision of the NOP's Program Manager may appeal such decision to the Administrator; (2) persons, subject to the Act, who believe they are adversely affected by a noncompliance decision of an SOP may appeal such decision to the SOP's governing State official who will initiate handling of the appeal in accordance with the appeal procedures approved by the Secretary; and (3) persons, subject to the Act, who believe they are adversely affected by a noncompliance decision of a certifying agent may appeal such decision to the Administrator unless the person is subject to an approved SOP, in which case the appeal must be made to the SOP.

All written communications between parties involved in appeal proceedings must be sent to the recipient's place of business by a delivery service which provides dated return receipts. All appeals filed under these procedures will be reviewed, heard, and decided by persons not involved with the decision being appealed.

### Certification Appeals

Applicants for certification may appeal a certifying agent's notice of denial of certification. Certified operations may appeal a notification of proposed suspension or revocation of their certification issued by their certifying agent. Such appeals will be made to the Administrator unless the person is subject to an approved SOP, in which case the appeal must be made to the SOP.

If the Administrator or SOP sustains an appeal, the applicant or certified operation will be granted certification or continued certification, as applicable to the operation's status. The act of sustaining the appeal will not be considered an adverse action and may not be appealed by the certifying agent which issued the notice of denial of certification or notification of proposed suspension or revocation of certification.

If the Administrator or SOP denies an appeal, a formal administrative proceeding will be initiated to deny, suspend, or revoke the certification. Such proceeding will be conducted in accordance with USDA's Uniform Rules of Practice or the SOP's rules of procedure.

### **Accreditation Appeals**

Applicants for accreditation may appeal the Program Manager's notification of accreditation denial. Accredited certifying agents may appeal a notification of proposed suspension or revocation of their accreditation issued by the Program Manager. Such appeals will be made to the Administrator. If the Administrator sustains an appeal, the applicant or certifying agent will be granted accreditation or continued accreditation, as applicable to the operation's status. If the Administrator denies an appeal, a formal administrative proceeding will be initiated to deny, suspend, or revoke the accreditation. Such proceeding will be conducted in accordance with USDA's Uniform Rules of Practice.

### **Filing Period**

An appeal of a noncompliance decision must be filed within the time period provided in the letter of notification or within 30 days from the date of receipt of the notification, whichever occurs later. The appeal will be considered "filed" on the date received by the Administrator or, when applicable, the SOP. Unless appealed in a timely manner, a notification to deny, suspend, or revoke a certification or accreditation will become final. The applicant, certified operation, or certifying agent that does not file an appeal in the time period provided waives the right to further appeal of the compliance proceeding.

### **Where and What to File**

Appeals to the Administrator must be filed in writing and sent to: Administrator, USDA-AMS, Room 3071-S, P.O. Box 96456, Washington, DC 20090-6456. Appeals to the SOP must be filed in writing to the address and person identified in the letter of notification. All appeals must include a copy of the adverse decision to be reviewed and a statement of the appellant's reasons for believing that the decision was not proper or made in accordance with applicable program regulations, policies, or procedures.

### **Appeals - Changes Based On Comments**

This portion of subpart G differs from the proposal in several respects as follows:

(1) To Whom an Appeal Is Made. We have amended section 205.680 to clarify to whom an appeal is made when the noncompliance decision is made by the NOP's Program Manager, an SOP, or a certifying agent. Several commenters requested that we amend section 205.680 to make it consistent with the provision providing that appeals to the Administrator are not allowed in the case of an SOP decision, because such appeals have to be made to the SOP's governing State official.

We agree that section 205.680 did not convey sufficient explanation of to whom an appeal is made. Accordingly, we have amended the language in section 205.680 to clarify through

paragraphs (a), (b), and (c) that: (1) persons, subject to the Act, who believe they are adversely affected by a noncompliance decision of the NOP's Program Manager may appeal such decision to the Administrator; (2) persons, subject to the Act, who believe they are adversely affected by a noncompliance decision of an SOP may appeal such decision to the SOP's governing State official who will initiate handling of the appeal pursuant to appeal procedures approved by the Secretary; and (3) persons, subject to the Act, who believe they are adversely affected by a noncompliance decision of a certifying agent may appeal such decision to the Administrator unless the person is subject to an approved SOP, in which case the appeal must be made to the SOP.

(2) Written Communications. We have added a new paragraph (d) to section 205.680, which provides that all written communications between parties involved in appeal proceedings must be sent to the recipient's place of business by a delivery service which provides dated return receipts. We have taken this action to further clarify the appeals process. This addition to section 205.680 implements the same requirements for appeal documents as our addition of new paragraph (d) to section 205.660 stipulates for compliance documents.

(3) Who Shall Handle Appeals. We have added a new paragraph (e) to section 205.680, which provides that all appeals must be reviewed, heard, and decided by persons not involved with the decision being appealed. This provision was added to section 205.680 to allay the fears of commenters that the person making the decision would be the person deciding the appeal. A couple of commenters recommended that an appeal be heard by persons other than those who made the decision being appealed. Specifically, they want the appeal conducted by independent hearing officers who are not responsible for implementation or administration of the NOP. They also want the final decision-making authority in the administrative review process placed in the hands of the Secretary.

Under the NOP, once the compliance procedures are completed at the certifying agent level, the certified operation may appeal the decision of the certifying agent to the Administrator or to the SOP when the certified operation is located within a State with an approved SOP. The Administrator or the SOP will review the case and render an opinion on the appeal. When the appeal is sustained, the certified operation and certifying agent are notified and the case ends. However, if the appeal is denied the certified operation and certifying agent are notified and the certified operation is given an opportunity to appeal the decision of the Administrator or SOP.

Appeals of decisions made by the Administrator will be heard by an Administrative Law Judge. If the Administrative Law Judge rules against the certified operation, the Administrative Law Judge's decision may be appealed by the certified operation to the Judicial Officer. The Judicial Officer is the USDA official delegated authority by the Secretary as the final deciding officer in adjudication proceedings. If the Judicial Officer rules against the certified operation, the Judicial Officer's decision may be appealed by the certified operation to the United States District Court for the district in which the certified operation is located. For additional information see USDA's Uniform Rules of Practice found at 7 CFR Part 1, subpart H.

Appeals of decisions made by an SOP will follow procedures comparable to those just described for an appeal of a decision made by the Administrator. As with a final decision of USDA, a final decision of the State that goes against the certified operation may be appealed to the United States District Court for the district in which the certified operation is located.

(4) Filing Period. We have amended the first sentence of section 205.681(c) by replacing "at least" with "within" and by adding the words, "whichever occurs later," to the end thereof. This amendment has been made to clarify our intent that persons affected by a noncompliance proceeding decision receive not less than 30 days in which to file their appeal of the decision.

(5) Where To File an Appeal. We have amended section 205.681(d) to clarify where appeals are to be filed. First, we have amended what is now paragraph (1) by removing the requirement that the appellant send a copy of the appeal to the certifying agent. This action shifts the responsibility of notifying the certifying agent of the appeal from the appellant to USDA or, when applicable, the SOP. Second, we have added language at paragraph (2) which clarifies that appeals to the SOP must be filed in writing to the address and person identified in the letter of notification. Finally, we have amended what is now paragraph (3) of section 205.681 by replacing "position" with "reasons for believing" to clarify the intended scope and purpose of the appellant's appeal statement. Clarification of section 205.681(d) was prompted by a commenter who stated that it is discriminatory to require clients of private certifying agents to appeal to USDA in Washington, when State program clients can appeal locally.

There are various levels of appeal within the NOP. Clients of certifying agents (State and private) are provided with an opportunity to rebut the noncompliance findings of the certifying agent. Once the certified operation has exhausted its options at the certifying agent level, the certified operation may appeal the decision of the certifying agent to the Administrator or to the SOP when the certified operation is located within a State with an approved SOP.

The Administrator will review the case and render an opinion on the appeal. This level of appeal will not require the certified operation's representative to travel to the Administrator. An appeal of a decision made by the Administrator will be heard by an Administrative Law Judge as near as possible to the certified operation's representative's place of business or residence. An appeal of a decision made by the Administrative Law Judge will be heard by the Judicial Officer. Again the certified operation's representative will not be required to travel outside of the representative's place of business or residence. If the certified operation appeals the decision of the Judicial Officer, the appeal would be heard by the United States District Court for the district in which the certified operation is located.

Appeals of decisions made by an SOP will follow procedures comparable to those just described for an appeal of a decision made by the Administrator. As with a final decision of USDA, a final decision of the State that goes against the certified operation may be appealed to the United States District Court for the district in which the certified operation is located.

(6) Appeal Reports. We will submit an annual report on appeals to the National Organic Standards Board (NOSB), which will include nonconfidential compliance information. A commenter requested that we report quarterly to the NOSB on appeals (number, outcome, kinds, and problems). We agree that it would be appropriate for the NOP to submit an appeals report to the NOSB. We will compile appeal data such as the number, outcome, kinds, and problems encountered. We will maintain this information under the compliance program to be developed within the NOP. We do not believe that it is necessary to put this type of detail or activity into the regulations. Further, we do not believe, at this time, that reporting more frequently than annually will be needed. The NOP, however, will work closely with the NOSB to provide it with the information it may need to recommend program amendments designed to address compliance and appeal issues.

(7) Availability of Appeal Information. We will develop and distribute appeal information. A commenter requested that section 205.680 be amended to require the distribution of an appeal information brochure to any applicant for accreditation or certification. We agree that the development and distribution of such information is a good idea. We do not believe, however, that it is necessary or appropriate to put this type of detail or activity into the regulations. We plan to provide program information, including appeals and related issues, on the NOP website.

## **Appeals - Changes Requested But Not Made**

This portion of subpart G retains from the proposed rule, regulations on which we received comments as follows:

(1) National Appeals Division. Several commenters recommend amending sections 205.680 and 205.681 to provide for appeals to the National Appeals Division under the provisions at 7 CFR Part 11. We disagree with the request that the NOP use the National Appeals Division Rules of Procedure. The Act and its implementing regulations are subject to the APA for rulemaking and adjudication. The provisions of the APA generally applicable to agency adjudication are not applicable to proceedings under 7 CFR Part 11, National Appeals Division Rules of Procedure. USDA uses 7 CFR Part 1, Rules of Practice Governing Formal Adjudicatory Proceedings Instituted by the Secretary Under Various Statutes, for adjudicatory proceedings involving the denial, suspension, and revocation of certification and accreditation.

### **Appeals - Clarifications**

Clarification is given on the following issues raised by commenters:

(1) Appeals. A commenter stated that appeals of certification decisions should always be taken first to the certifying agent to provide an opportunity to rectify any possible error. Another commenter requested an appeals process that includes private certifying agents.

Section 205.662(a) requires a written notification of noncompliance with opportunity to rebut or correct. When the noncompliance has been resolved due to rebuttal or correction, a written notification of noncompliance resolution is issued in accordance with section 205.662(b). When rebuttal is unsuccessful or correction of the noncompliance is not completed within the prescribed time period, a written notification of proposed suspension or revocation will be issued in accordance with section 205.662(c). This notification will advise the certified operation of its right to request mediation or file an appeal with the Administrator or, when applicable, an SOP. We believe this process of providing a notification of noncompliance with opportunity to rebut or correct, followed by a notification of proposed suspension or revocation, provides ample opportunity for the certified operation to work with its certifying agent to resolve issues of noncompliance.

(2) Timely Notification. A few commenters requested that we amend section 205.680 to include mandatory procedures for timely written notice of an adverse decision, the reasons for the decision, the person's appeal rights, and the procedures for filing an appeal. We recognize that all compliance activities need to be carried out as quickly and expeditiously as possible within the confines of due process. We believe that the commenters' concerns are addressed through various sections of these regulations. Section 205.402(a) requires review of an application upon acceptance of the application. Section 205.405, on denial of certification, requires a notification of noncompliance, followed, as applicable, by a notice of denial of certification. In accordance with section 205.405(d), the notice of denial of certification will state the reasons for denial and the applicant's right to request mediation or appeal the decision. Section 205.507 on denial of accreditation requires a notification of noncompliance, followed, as applicable, by a denial of accreditation. The notification of accreditation denial will state the reasons for denial and the applicant's right to appeal the decision. Compliance sections 205.662 for certified operations and 205.665 for certifying agents require a notification of noncompliance with an opportunity to correct or rebut the noncompliance(s). Sections 205.662 and 205.665, when applicable, require the issuance of a notification of proposed suspension or revocation. Such notice must describe the noncompliance and the entity's right to an appeal. Section 205.681 provides the procedures for filling an appeal.

## Miscellaneous -- Preamble

### Miscellaneous

Section 205.690 provisions the Office of Management and Budget control number assigned to the information collection requirements of these regulations. Sections 205.691 through 205.699 are reserved.