of terms or phrases which we consider may imply directly or indirectly that a product is organically produced and handled and about which we specifically request comment include: ''produced without synthetic pesticides''; ''produced without synthetic fertilizers''; ''raised without synthetic chemicals''; ''pesticide-free farm''; ''no drugs or growth hormones used''; ''raised without antibiotics''; ''raised without hormones''; ''no growth stimulants administered''; ''ecologically produced''; ''sustainably harvested''; and ''humanely raised''.

Informational Statements Prohibited—Section 205.104

We are proposing in this section to prohibit certain informational statements from being included on the principal display panel and ingredients statement of any products containing organically produced ingredients because we believe such statements might mislead consumers. Because these are the areas that consumers generally examine to obtain information about the nature of the product they are purchasing, we believe that these areas should therefore contain only terms or phrases that are familiar to consumers and are readily understood by them.

In paragraph (a) of this section, we propose to prohibit the phrase one hundred percent, stated in letters, numbers or symbols, when used as part of any phrase or sentence that includes the term organic, on the principal display panel and in the ingredients statement of a product that is sold, labeled, or represented as organic. Examples of phrases that would be prohibited by this paragraph are: our ingredients are one hundred percent organic; 100% organic whole wheat; and we only use 100 percent organic methods.

In paragraph (b) of this section, we propose to prohibit the placement of a statement of the percentage of organic ingredients on the principal display panel and in the ingredients statement of any product containing organic ingredients. Our proposal would not prohibit a statement of the percentage of organic ingredients from being used on labeling materials, market information and any panel other than the principal display panel.

The NOSB received comments from manufacturers both in favor and in opposition to allowing the inclusion of a statement of the percentage of organic ingredients on product labels. The NOSB recommended to the Secretary that a percentage statement be allowed on the principal display panel only for products containing one hundred percent organic ingredients. For all other products, the NOSB recommended that a percentage statement be restricted to the information panel.

We agree with the NOSB that a percentage statement should be permitted, and accordingly propose to allow a statement of the percentage of organic ingredients on a product label for the benefit of consumers who believe that this information is important to them as part of their purchasing decisions. However, we propose to prohibit its placement on the principal display panel and in the ingredients statement. We propose this prohibition on the placement of the percentage statement because we do not consider a percentage statement to be essential program information. Its use on the principal display panel and ingredients statement would be inconsistent with our proposed labeling scheme, as previously explained, which provides for placing only essential program information on the principal display panel and ingredients statement. We request comment on our proposal to allow a statement of the percentage of organic ingredients on a product package and on our proposal to prohibit its use on the principal display panel and in the ingredients statement.

In paragraph (c) of this section, we propose to prohibit the use of the phrase organic when available, or a term of similar meaning or intent, on the principal display panel and in the ingredients statement of products containing organic ingredients.

Agricultural Products in a Form Other Than Packages That are Sold, Labeled, or Represented as Organic or Made With Certain Organic Ingredients—Section 205.105

We propose in paragraphs (a) and (b) of this section the terms and marks that may be used on products in a form other than packages that are sold or represented as organic or made with certain organic ingredients, in order to prevent the possibility of mixing organic and nonorganic products. Products in a form other than packages are those products that either are not enclosed in a container or wrapping or are products labeled as bulk food items in containers. Products in other than package form include such products as bulk food items, unpackaged fruits and vegetables for sale in a retail store, raw agricultural products such as grains, and products in shipping containers for further processing.

We propose in paragraph (a)(1) of this section that agricultural products that contain at least 95 percent organic ingredients that are sold or represented as organic may use the term organic on a retail display label (or labeling) or display container to modify the name of the product. We propose in paragraph (a)(2) of this section that the term organic may be used in the ingredients statement to modify the name of an ingredient organically produced and handled in accordance with the Act and the regulations in this part. The proposals made in paragraphs (a)(1) and (a)(2) of this section would be applicable to organic products in other than package form at the time of retail sale and, thereby, would provide for organic products sold in retail stores in bulk or other non-package form to be identified by the same terms as we propose to be used on organic products in package form.

We propose in paragraph (a)(3) of this section that shipping containers for organic products in other than package form may bear a clearly recognizable organic identification mark(s) or term(s) in plain view on the shipping container. The mark(s) or term(s) are proposed to be chosen from the following: the term organic used to modify the name of the product; the USDA seal; a seal representing an approved State organic program; and the certifying agent's name, seal, logo, or other identification representing certification of the operation that produced or handled the product. We believe that this provision would assist those handlers who handle both organically produced and non-organically produced products to readily identify and separate the products and prevent their commingling, as required in proposed section 205.19.

We propose in paragraph (b) of this section the labeling requirements for agricultural products in other than package form that are sold or represented as made with certain organic ingredients. We believe that agricultural products in a form other than packages that are sold or represented as made with certain organic ingredients need to meet specific labeling requirements that are similar to the requirements proposed for agricultural products in other than package form that are sold, labeled, or represented as organic. These labeling requirements are needed to ensure that these products can be readily identified and to assist handlers in preventing the possibility of commingling products sold, labeled, or represented as made with certain organic ingredients with non-organically produced products. Accordingly, we propose in paragraph (b)(1) of this section that agricultural products that are sold or represented as made with certain organic ingredients

that are described in section 205.16(b) shall use the statement made with certain organic ingredients on a retail display label (or labeling) or display container to modify the name of the product. We propose in paragraph (b)(2) of this section that the term organic be used in the ingredients statement to modify the name of an ingredient organically produced and handled in accordance with the Act and the regulations in this part. Finally, we propose in paragraph (b)(3) of this section that agricultural products in a form other than packages would use the statement made with certain organic ingredients located in plain view on the shipping container, which may be accompanied by the certifying agent's name, seal, logo, or other identification. The rationale for the provisions proposed in paragraph (b) of this section are discussed in the supplementary information for paragraph (a) of this section regarding organic products in a form other than packages.

Agricultural Products Produced on an Exempt Farm or Handling Operation—Section 205.106

Section 2106(d) of the OFPA (7 U.S.C. 6505(d)) provides an exemption from the compliance requirements of section 2106(a)(1) of the OFPA (7 U.S.C. 6505(a)(1)), which does not permit a person to sell or label an agricultural product as organically produced unless it has been produced and handled in accordance with the Act. This exemption applies to a person who sells no more that $5,000 annually in value of agricultural products, unless such person voluntarily chooses to be certified. In § 205.202(a)(1) of subpart D, we propose that a farm, handling operation, or wild crop harvesting operation that produces, handles or harvests agricultural products, but which annually sells no more than $5,000 in value of agricultural products, would be exempt from the certification requirements of the Act and the regulations set forth in subpart D of this part. Consistent with section 2107(a)(11) of the OFPA (7 U.S.C. 6506(a)(11)), however, which allows the Secretary to require such other terms and conditions determined to be necessary, we propose in paragraphs (a) and (b) of this section certain labeling requirements for agricultural products that are produced on these exempt operations that have not been certified. We propose these labeling prohibitions in order to help ensure that consumers are not misled when they purchase agricultural products from them, and in order to assure that products and ingredients sold, labeled, or represented as meeting the requirements of the OFPA in fact have been produced and handled in accordance with the Act.

In paragraph (a) of this section, we propose to prohibit the displaying of the USDA seal or any certifying agent's name, seal, logo, or other identification of certification referring to the requirements of the Act and the regulations of this part. The purpose of this provision would be to ensure that only agricultural products that meet the proposed requirements for organic production and certification in part 205 could have a label or other market information that incorporated the USDA seal or certification identification, either of which would indicate compliance with the Act and the regulations in this part. Additionally, the provision proposed in paragraph (a) of this section would assist consumers in distinguishing between an organic product from an exempt operation and an organic product from an operation certified to national or State program requirements.

In paragraph (b) of this section, we propose that an agricultural product that is produced or processed on an exempt farm or handling operation that annually sells no more than $5,000 in value of agricultural products and which has not been certified could not be identified as an organic ingredient in a product produced or processed on a farm or handling operation that annually sells more than $5,000 in value of agricultural products. We propose this prohibition for the purpose of prohibiting organic agricultural products that originate from exempt uncertified operations from being commingled with organic agricultural products that originate from operations that are certified to national or State program requirements. This provision as proposed would help promote clarity for consumers in identifying when an agricultural product was produced and handled in accordance with the Act and the regulations in this part.

The USDA Seal—Section 205.107

Section 2106(a)(2) of the OFPA (7 U.S.C. 6505(a)(2)) allows labels affixed to, or market information provided for, domestic agricultural products that meet the USDA standards for organic production to incorporate the USDA seal. In accordance with this section of the OFPA, we propose in paragraph (a) of this section that the USDA seal could be used only on those agricultural products (raw or processed) labeled as organic (i.e., products that contain at least 95 percent organic ingredients), as described in § 205.16(a), that are produced in the U.S. and are produced and handled on a certified operation. This provision as proposed would permit a product produced in the U.S. which contained imported organic ingredients obtained from a program determined by the Secretary to be equivalent to the national program to display the USDA seal.

In paragraphs (b) and (c) of this section, we propose the form and design of the USDA seal. We propose to require the reproduction of the mark in a dark color on a light background, or in a light color on a dark background, or in a standard four color label. We propose that the USDA seal consist of an interior globe with continents displayed and a diagonal line across the globe (continents) with the word organic on the diagonal. The globe with continents would be surrounded by concentric circles with arrows containing the words meets USDA requirements. A triangle would enclose the globe and the concentric circles.

The use of the globe with continents is intended to represent the principles of organic production upon which the national organic program is founded. These principles are oriented toward the nurturing of a healthy agroecosystem as part of the biosphere, represented by the globe. The concentric circles with arrows represent the basic practice of recycling nutrients and materials which is essential to a system of organic farming. The triangle represents the stability of a healthy agroecosystem based upon the stewardship of soil, water and air as its components.

We believe that this seal, which may be used at the option of the producer or handler in accordance with the provisions of subpart C of this part, would allow consumers to readily identify that the organic product met the requirements of the National Organic Program as proposed in the regulations of this part. We request comment on the design of the USDA seal and its use as proposed in this subpart as to whether the proposed design will readily identify an organic product as one that meets the requirements of the National Organic Program.

In particular, we would like to receive examples of alternative designs for the USDA seal that would be effective in allowing consumers to readily identify that an organic product meets the requirements of the organic program. We would appreciate it if any alternative designs submitted are accompanied by an explanation about how the alternative design suggested would more effectively make organic products readily identifiable as being produced under the National Organic Program than the proposed design for

the USDA seal. In addition, we would like comments from all interested persons as to whether the proposed design for the USDA seal would create any burdens for its use.

We have provided a chart of what is required to be reflected on the labels and labeling of various types of organic products, as well as what is required to be reflected on certain types of market information provided about organic products. The chart also indicates where required information is to be placed on labels, on labeling, and on certain types of market information. Additionally, the chart indicates what type of information may, but is not required, to be placed on labels, on labeling, and on certain types of market information for various types of organic products. Further, the chart indicates what type of information may not be placed on the labels, labeling, and market information of various types of organic products, and where it is prohibited from being placed.

SUBPART C—LABELS, LABELING, AND MARKET INFORMATION

Required	Discretionary	Prohibited
Agricultural products in packages sold, labeled or represented as organic		
Principal display panel:		
• None	• The term organic to modify the name of the product. • USDA seal • State seal	• Certifying agent's name, seal, logo, or other identification. • One hundred percent stated in letters, numbers, or symbols, used with any phrase or sentence that includes the term organic. • Statement of the percentage of organically produced ingredients contained in a product. • Phrase: organic when available (or term of similar meaning or intent).
Ingredients Statement:		
• None	• The term organic to modify the name of an ingredient organically produced and handled.	• One hundred percent stated in letters, numbers, or symbols, used with any phrase or sentence that includes the term organic. • Statement of the percentage of organically produced ingredients contained in a product. • Phrase: organic when available (or term of similar meaning or intent).
Information panel:		
• None	• Organic with product name • USDA seal. • State seal. • Certifying agent's name, seal, logo, or other identification.	• None.
Agricultural products in packages sold, labeled, or represented as made with certain organic ingredients		
Principal display panel:		
• Statement: made with certain organic ingredients.	• None	• One hundred percent stated in letters, numbers, or symbols, used with any phrase or sentence that includes the term organic. • Statement of the percentage of organically produced ingredients contained in a product. • Phrase: organic when available (or term of similar meaning or intent). • USDA seal. • State seal. • Certifying agent's name, seal, logo, or other identification
ingredients statement:		
• The term organic to modify the name of an ingredient organically produced and handled..	• None	• One hundred percent stated in letters, numbers, or symbols, used with any phrase or sentence that includes the term organic. • Statement of the percentage of organically produced ingredients contained in a product. • Phrase: organic when available (or term of similar meaning or intent).
Information panel:		
• None	• Statement: made with certain organic ingredients. • Certifying agent's name, seal, logo, or other identification.	• USDA seal. • State seal.
Multi-ingredient agricultural products that are not produced by certified operations and that only represent the organic nature of such ingredients in the ingredient statement and which are not sold, labeled, or represented as organic or made with certain organic ingredients		
Principal display panel:		
• None	• None	• The term organic to modify the name of the product. • Statement: made with certain organic ingredients. • USDA seal. • State seal.

SUBPART C—LABELS, LABELING, AND MARKET INFORMATION—Continued

Required	Discretionary	Prohibited
		• Certifying agent's name, seal, logo, or other identification. • One hundred percent stated in letters, numbers, or symbols, used with any phrase or sentence that includes the term organic. • Statement of the percentage of organically produced ingredients contained in a product. • Phrase: organic when available (or term of similar meaning or intent).
Ingredients statement:		
• None	• Organic to modify the name of an ingredient that is organically produced and handled.	• One hundred percent stated in letters, numbers, or symbols, used with any phrase or sentence that includes the term organic. • Statement of the percentage of organically produced ingredients contained in a product. • Phrase: organic when available (or term of similar meaning or intent).
Information panel:		
• None	• None	• The term organic to modify the name of the product. • Statement: made with certain organic ingredients. • USDA seal. • State seal. • Certifying agent's name, seal, logo, or other identification.
Agricultural products in other than package form that are sold, labeled or represented as organic or made with certain organic ingredients.		
Retail display label or display container:		
For organic products:	• For organic products:	
• None	• The term organic to modify the name of the product. • USDA seal. • State seal. • Certifying agent's name, seal, logo, or other identification..	• None.
For made with certain organic ingredients products:	For made with certain organic ingredients products:	
• Statement: made with certain organic ingredients.	• Certifying agent's name, seal, logo, or other identification.	None
Ingredients statement:		
For organic products:	For organic products:	
• None.	• The term organic to modify the name of an ingredient organically produced and handled..	• None.
For made with certain organic ingredients products:	For made with certain organic ingredients products:	
• The term organic to modify the name of an ingredient organically produced and handled.	• None	• None.
Shipping container:		
For organic products:	For organic products, one or more of the following:	
• None	• The term organic to modify the name of the product; or • USDA seal; or. • State seal; or. • Certifying agent's name, seal, logo, or other identification..	• None.
For made with certain organic ingredients products:	For made with certain organic ingredients products:	
• Statement: made with certain organic ingredients.	• Certifying agent's name, seal, logo, or other identification.	• None.

Subpart D—Certification

Section 2104(a) of the OFPA (7 U.S.C. 6503(a)) requires that the Secretary establish an organic certification program for producers and handlers of agricultural products that have been produced using organic methods, and that this program be implemented through certifying agents. Section 2107(a) of the OFPA (7 U.S.C. 6506(a)) requires that all agricultural products sold or labeled as organically produced be produced on a farm and handled through a handling operation that has been certified, and delineates a number of other provisions that must be included in a certification program established under the Act. The Act,

however, provides for certain exemptions from certification. In this subpart we propose the certification provisions of the National Organic Program, which includes the requirements that must be met by farm, wild crop harvesting, and handling operations that want to be certified, and the procedures that must be followed by certifying agents in evaluating and making determinations concerning operations seeking certification. Subpart E of this part delineates our proposed accreditation program for organic certifying agents, as required by section 2115(a) of the OFPA (7 U.S.C. 6514(a)), including the requirement that a certifying agent must conduct certification activities in accordance with the procedures proposed in subpart D of this part to maintain its accredited status.

The certification process is needed to ensure that products labeled as organic and made with certain organic ingredients are produced and handled in accordance with the requirements proposed in subpart B of this part. Numerous private organizations and States already have developed experience and expertise in organic certification procedures. In developing this proposal, we have consulted with and examined the programs developed by existing private and State certifying agencies, considered the NOSB's recommendations, and considered comments received from the public. We also have reviewed the guidelines for the certification or registration of quality systems and for the assessment or accreditation of certifying bodies, as promulgated by the International Organization for Standardization. Other information we have reviewed includes guidelines for inspection, certification and accreditation established by other countries, international organic interest groups, and standards setting organizations, such as the International Federation of Organic Agricultural Movements.

This proposal is consistent with the provisions of the Act and incorporates, to the extent possible, the current practices of the organic certification community. We have designed the proposed regulations to minimize the burdens placed on organic producers and handlers, ensure that decisions made by certifying agents are well founded and fair, and provide sufficient guidance and oversight to protect the integrity of the organic label. We also have developed this proposal to utilize the expertise that exists in the organic community, which encompasses a broad range of producers, handlers and geographic locales, and to allow for differences in size, scope and organizational style represented by existing and anticipated private and State certification programs.

Synopsis of Proposed Certification Program

The provisions of sections 205.201 through 205.206, and sections 205.216 through 205.217(a), address the certification of farm, wild crop harvesting and handling operations that produce agricultural products, including livestock, that are, or are intended to be, sold, labeled or represented as organic or as made with certain organic ingredients. These proposed sections delineate the types of operations that must be certified; the types of operations that would be exempt or excluded from the certification requirement; the general requirements that must be met to obtain and maintain certification; and the information that must be submitted when applying for certification, including the provisions of an organic plan. Certification applicants would have to submit a statement agreeing to comply with the proposed production and handling requirements and would have to allow access to their facilities and records by a certifying agent, representatives of the Secretary, and the applicable governing State official in the case of operations located in a State that operates an approved State program. An operation whose request for certification was approved would have to operate in compliance with the requirements proposed in Subpart B, maintain records of its operations to show that it was complying with those requirements, and submit updated information annually.

Sections 205.207 through 205.215, and sections 205.217(b) through 205.220, propose the procedures that a certifying agent must follow in determining the certification status of a certification applicant or a certified operation, including the procedure for conducting on-site inspections; the basis for approving an application for certification; the procedure for notifying an operation of, along with an opportunity to correct, non-compliance with the Act and the regulations; and the procedure for recommending that the certification of an operation or a portion of an operation be denied or terminated by the Administrator, after providing notice and an opportunity to be heard. The final section of this subpart proposes the notifications that a certifying agent would have to provide to the Administrator concerning operations that it certified.

It should be noted that, in a State that establishes an approved State program, as provided for and discussed in sections 205.401 through 205.403 of subpart F, the certifying agent also would have to provide these notifications to the applicable governing State official. Additionally, the certifying agent would be required to verify that an applicant for certification in a State that establishes an approved state program was complying with any additional requirements provided under the State program. Proceedings to deny or terminate certification, and an opportunity to appeal such actions, would be initiated and conducted in accordance with the approved State program regulations.

What Has to be Certified—Section 205.201

Section 2106(a)(1) of the OFPA (7 U.S.C. 6505(a)(1)) requires that agricultural products that are sold or labeled as organically produced, including products for which other market information is provided that directly or indirectly implies that the products have been produced and handled using organic methods, must comply with the requirements of the Act. Therefore, we propose that, except as discussed below in proposed section 205.202, any farming, wild crop harvesting, or handling operation, or portion of any of these operations, that intends to sell, label or represent an agricultural product as organic, or as made with certain organic ingredients, would have to comply with all the applicable production and handling requirements set forth in subpart B of this part and be certified in accordance with the regulations of this subpart.

We further propose in section 205.201(a) that any operation that provides handling services to fewer than 3 certified entities that produce or handle agricultural products that are, or that are intended to be, sold, labeled or represented as organic or made with certain organic ingredients, would not be required to be separately certified apart from the operations for which it provides such services. This provision is proposed because, as is sometimes the case in existing certification programs we have examined, a certified operation may comprise facilities owned by different entities that it contracts with to provide handling services, such as washing and packing fresh produce, freezing multi-ingredient products, or warehousing. In such cases, the facilities that provide these services would be included in the certification obtained by the contracting operation, and therefore considered certified with respect to the handling of any products to be sold, labeled or represented as

organic or made with certain organic ingredients. Such a facility would, for the purposes of this proposal, also be considered to be a distinct portion of the operation for which it provides the handling services. However, as proposed in this section, if such a facility were to provide handling services under contract to three or more certified handling operations, it would then have to obtain a separate certification. For example, a facility that provided washing and packing services to one or two organic produce growers could be included in the growers' certifications as a portion of each of their operations, but if it were to then provide packing services for a third organic produce grower it would have to obtain its own separate certification. Comment is invited concerning the potential impact of this proposed requirement on handling operations that currently contract for handling services or that currently provide such services.

Section 2106(c) of the OFPA (7 U.S.C. 6505(c)) exempts products that contain at least 50 percent (but less than 95 percent) organic ingredients from complying with the requirements of the Act, but allows the Secretary, in consultation with the NOSB and the Secretary of HHS, to permit such products to be labeled on the principal display panel as containing certain organically produced ingredients. In section 205.101 of subpart C, we propose that such products could be labeled as made with certain organic ingredients on the principal display panel. In section 205.201(b) we propose that a handling operation, or portion of a handling operation, that handles only agricultural products that are, or that are intended to be, sold, labeled or represented as made with certain organic ingredients would have to be certified but would be exempt from complying with the requirement proposed in section 205.3(b)(2) of Subpart B, which requires that a commercially available non-synthetic substance be selected in preference to an allowed synthetic substance.

Products labeled as made with certain organic ingredients would not, in accordance with section 2106(c) of the OFPA (7 U.S.C. 6505(c)), have to be handled by a certified organic handling operation. However, the organically produced ingredients contained in such products would not be exempt from the Act's certification requirement. Therefore, because the preponderance of the ingredients in such a product would be organically produced, we believe that the level of oversight provided by the certification process is needed in order to safeguard the integrity of the organically produced ingredients and to assure consumers that these ingredients comply with consistent national standards. Because this type of product would be able to use the word organic on its principal display panel within the statement made with certain organic ingredients, we believe that consumers will generally expect that such products are in compliance with the Act and the regulations in this part. However, because the product itself is not represented as an organic product, we are proposing that such products need not comply with the requirement to select non-synthetic substances in preference to allowed synthetic substances. Such products would still have to comply with all other applicable provisions, including selecting only non-agricultural ingredients that are included on the National List.

Exemptions and Exclusions—Section 205.202

In accordance with section 2106(d) of the OFPA (7 U.S.C. 6505(d)), paragraph (a)(1) of this section would exempt producers and handlers that produce, handle or harvest agricultural products who sell no more than $5,000 annually in value of agricultural products from complying with the certification requirements set forth in this subpart. However, we propose in subpart C to prohibit the products produced on these exempt operations from being represented as originating from a certified operation, displaying the USDA seal, or being identified as an organic ingredient in a product processed or produced on an operation that sells more than $5,000 in value of agricultural products. These prohibitions are necessary to ensure that the organically produced ingredients contained in products that originate from certified operations are accurately represented. These prohibitions would not apply to an otherwise exempt operation that voluntarily chose to become certified under the Act and the regulations.

As indicated above, the exemption from certification proposed in the regulations for producers and handlers who sell no more than $5,000 annually of agricultural products is what is provided for in section 2106(d) of the OFPA (7 U.S.C. 6505(d)). During the course of public input given at NOSB meetings, various commenters suggested that the exemption from certification should include producers and handlers who annually sell no more than $10,000 of agricultural products, as opposed to $5,000. In order to provide for such an exemption in our regulations, we would need to have the OFPA amended. We would appreciate comments as to whether the current statutory limitation of $5,000 for exemption from certification should be raised to $10,000, or to another amount, and why such an increased monetary limitation for exemption from certification is appropriate. In addition, we would like data as to the number of operations that may be exempt under the current $5,000 limitation for exemption, and the number of operations that may be exempt under any new monetary amount suggested.

In paragraph (a)(2) of this section, we propose to exempt retail operations, or portions of such operations, that handle organically produced agricultural products but do not process them. This is consistent with the definition of handling operation as set forth in section 2103(10) of the OFPA (7 U.S.C. 6502(10)). An exclusion for certain retail operations that do process organic agricultural products is proposed in paragraph (b)(3) of this section.

Section 2106(c) of the OFPA (7 U.S.C. 6505(c)) states that the provisions of section 2106(a) (7 U.S.C. 6505(a)) regarding compliance with the requirements of the Act do not apply to two types of processed agricultural products that contain less than 95 percent organic ingredients. This section of the Act exempts products that contain less than 50 percent organically produced ingredients from compliance with the regulations proposed in this part, and we have accordingly proposed, in paragraph (a)(3) of this section, to exempt any handling operation, or portion of a handling operation, that handles only agricultural products that contain less than 50 percent organic ingredients from all the requirements proposed in this part except the applicable labeling provisions proposed in subpart C and the provisions proposed in section 205.19 of subpart B for the prevention of commingling and contact of organic products by prohibited substances with regard to any organically produced ingredients used in this type of product. We believe that these requirements are necessary for a handler of this type of product in order to safeguard the integrity of the organic ingredients used in any such product, and to ensure that any use of the word organic in the ingredient listing is in accordance with our proposed labeling provisions.

In section 205.202(b), we propose that certain types of operations or portions of operations be excluded from compliance with the certification requirements in subpart D. After careful consideration of the NOSB recommendations, public input, and

information received from representatives of various types of handling and retail operations, we believe that it would be burdensome to require certification of the types of handling operations addressed in this section and, furthermore, that such a requirement is unnecessary because it would not contribute to assuring the integrity of an organically produced product. Accordingly, we propose that three types of handling operations, or portions of operations, not be required to be certified.

In section 205.202(b)(1) we propose that a handling operation, or portion of a handling operation, would be excluded from compliance with the proposed regulations in this part, except for the requirements for the prevention of commingling and contact by an organic product with prohibited substances in section 205.19 of subpart B, if it handles only products labeled as organic or as made with certain organic ingredients that meet two criteria. These two criteria are that the products are packaged or otherwise enclosed in a container prior to being received by the operation, and that the products remain in the same package or container and are not processed while in the control of the operation. This exclusion would avoid creating an unnecessary barrier for handlers who distribute non-organic products and who want to include a selection of organic products in their offerings. However, in order to protect the integrity of the organically produced products, we do not propose to exempt this type of handling operation from the requirements set forth in section 205.19 of subpart B regarding the prevention of commingling and contact with prohibited substances with respect to any organically produced products.

In section 205.202(b)(2) we propose to exclude restaurants and other food-service type establishments that process ready-to-eat organic agricultural products but which do not enclose the food in a container labeled or represented to the consumer as organic or made with certain organic ingredients. As further explained below in paragraph (b)(3) of this section, we are not proposing to require certification of operations that process food as part of their normal retail operations if they do not repackage the food in containers that are labeled or represented by the operation as organic or as made with certain organic ingredients. We consider the act of preparing ready-to-eat food by restaurants to be part of their normal retail operations.

We propose in section 205.202(b)(3) to exclude a retail operation, or portion of a retail operation, that processes products labeled as organic or as made with certain organic ingredients in the course of its normal retail operations, but does not repackage products under its own organic label. A retail operation, or portion of a retail operation, excluded under this proposal in paragraph (b)(3) of this section would have to satisfy two requirements. First, the operation would have to process only products that were previously labeled as organic or made with certain organic ingredients before being acquired by the retailer. Second, the products would have to be processed by the operation in the course of its normal retail business solely for the purpose of presenting or offering the product to a consumer. These requirements mean that the product offered to the consumer by the retail operation could not be one that was created by the retailer by combining two or more ingredients into a single product that is then labeled or represented by the retail operation as organic or as made with certain organic ingredients, and it could not be a product that is repackaged by the operation and newly labeled or represented as organic or made with certain organic ingredients. We do not consider either creating a new product from two or more ingredients, or repackaging and relabeling a product, to be normal retail business practices for retail operations solely for the purpose of presenting or offering a product to a consumer. It should be noted that a weight label is not included within our proposed definition of label as set forth in section 205.2 of subpart A; therefore, we would not consider a retail operation applying a weight label to a product repackaged from a bulk container or sliced from a larger quantity to be a repackaging activity that would require certification because applying weight labels is an activity that we consider to be within normal retail business practices for retail operations.

Examples of retailer processing activities that would be excluded and which therefore would not require that the retail operation be certified are washing and sorting fresh produce for display in bulk; cutting cheese from a bulk wheel and placing weight labels on the cheese packages; repackaging two pound bags of organic brown rice from a 50 pound sack and placing weight labels on the two pound bags; and allowing consumers to package their own bags of organic grain from a bulk container. Examples of retailer processing activities that would not be excluded and which therefore would require that the retail operation be certified are baking organic bread; preparing an organic pasta salad for sale at the deli counter; repackaging a series of products such as grains or pastas under the retailer's own label that identifies the products as organic; and preparing a private label pizza labeled as made with certain organic ingredients for customers to purchase from a refrigerated display case for baking at home. We invite further comment concerning the exclusions proposed in this section.

In section 205.202(c) we propose that farm or handling operations that are either exempt from certification under section 205.202(a), or excluded from certification under section 205.202(b), would still be required to maintain certain records and to make those records available to authorized representatives of the Secretary and the applicable governing State official. Small operations that are exempt pursuant to paragraph (a)(1) of this section would have to keep records for no less than one calendar year to substantiate that the operation did not sell more than $5,000 in agricultural products in the previous calendar year, and therefore met the requirements for exemption of small operations provided by section 2106(d) of the OFPA (7 U.S.C. 6505(d)).

Handlers of products that contain less than 50 percent organic ingredients who are exempt under section 205.202(a)(3), or handlers who are excluded under section 205.202(b)(1), would have to maintain records for no less than one year from the date of receiving a product labeled as organic or made with certain organic ingredients, that are adequate to verify the source and quantity of the product and that the product or ingredient was handled in accordance with section 205.19 to prevent commingling and contact with prohibited substances. Records also would have to be maintained for no less than one year from the date of shipping a product that contains organic ingredients so as to verify the destination and quantity of the product shipped. The recordkeeping requirements proposed in paragraph (c)(2) of this section are necessary to assist in enforcement of the national organic program and to verify that the operation is adequately safeguarding the integrity of organically produced products and organically produced ingredients.

We would like comments on the various exemptions from certification we have proposed, as well as on any other exemptions from certification that should be proposed, keeping in mind that legislative changes may have to be

sought to provide additional exemptions from certification.

General Requirements for Certification—Section 205.203

This section of our proposal delineates the six general requirements with which an organic farm, wild crop harvesting, or handling operation must comply in order to receive and maintain certification. These proposed provisions summarize the requirements provided in the Act and various sections of the regulations proposed in this part, so that a person seeking organic certification can determine all the requirements which must be met by the operation to be certified.

The first requirement, proposed in paragraph (a) of this section, is to comply with the applicable organic production and handling requirements of the Act and the regulations in this part. Paragraph (b) of this section would require that the operation establish and implement an organic plan that is submitted to an accredited certifying agent, as required by section 2107(a)(2) of the OFPA (7 U.S.C. 6506(a)(2)), and updated annually. The provisions that must be in the organic plan are proposed in section 205.205. The third requirement, proposed in paragraph (c) of this section in accordance with section 2107(a)(5) of the OFPA (7 U.S.C. 6506(a)(5)) is that an annual on-site inspection by the certifying agent must be permitted. In paragraph (d) of this section we propose that a certified operation must maintain all records applicable to the organic operation for a period of not less than five years from the date of creation of the record, and allow the Secretary, the applicable governing State official if the operation is in a State where there is an approved State program, and the certifying agent, access to such records, as proposed in section 205.216. This provision is proposed because we believe it is necessary in order to determine the operation's compliance with the Act and the regulations in this part for the purpose of providing adequate enforcement procedures, as required in section 2107(a)(7) of the OFPA (7 U.S.C. 6506(a)(7)). Section 205.203(e) of this proposal requires that a certified operation submit the required fees to the certifying agent, as proposed in section 205.422 of subpart F in accordance with section 2107(a)(10) of the OFPA (7 U.S.C. 6506(a)(10)).

In section 205.203(f) we propose that a certified operation must immediately notify the certifying agent about any application of a prohibited substance to any field, farm unit, site, facility, livestock, or product that is part of the certified operation, and about any other change in a certified operation, or any portion of the operation, that may affect its compliance with the Act and the regulations in this part. This provision is necessary in order to ensure that an operation that is approved for certification would notify the certifying agent in the event that anything occurs that would change the operation's compliance with the requirements proposed in subpart B. This provision therefore would require notification of the certifying agent if an operation was subject to a Federal or State emergency pest or disease treatment program as described in proposed section 205.432 of subpart F and provided for in section 2107(b)(2) of the OFPA (7 U.S.C. 6506(b)(2)).

Applying for Certification—Section 205.204

As proposed in this section, a certification applicant would have to submit an organic plan, as proposed in section 205.205, and a statement agreeing to comply with the Act and the regulations, as proposed in section 205.206, to an accredited certifying agent. An applicant also would need to submit basic contact information, such as phone and fax numbers, for the operation for which certification is sought. In paragraph (c) of this section, we further propose that the applicant submit the name or names of any organic certifying agent to which any application for certification previously has been made, including the year or years of the application and the outcome of each application. It should be noted that, if the certification applicant previously had applied to a different certifying agent who issued a notification of non-compliance as proposed in section 205.215(a), the applicant also would have to submit documentation that shows that the defects in compliance identified in that notice had been corrected, in accordance with proposed section 205.215(b). Knowledge of previous certifications or applications for certification is needed in order to determine if information about implementation of an organic plan or other updated information, as proposed in section 205.217(a), should be provided. It also would enable a certifying agent to verify whether any new applicant for certification was previously issued a notification of non-compliance by another certifying agent.

Organic Plan—Section 205.205

Section 2114 of the OFPA (7 U.S.C. 6513) requires a producer or handler who wants certification to submit an organic plan to the certifying agent, and provides for certain provisions that should be in the plan to foster the production and handling of agricultural products in accordance with the Act. Section 2103(13) of the OFPA (7 U.S.C. 6502(13)) defines an organic plan as a plan of management of an organic farming or handling operation that has been agreed to by the producer or handler and the certifying agent and that includes written plans concerning all aspects of agricultural production or handling, including crop rotation and other practices required under the Act and the regulations in this part. The specific organic crop production and wild crop harvesting practices required by sections 2114(b) and (f) of the OFPA (7 U.S.C. 6513(b) and (f)) are addressed in this proposal in section 205.6 (crop rotation), section 205.7 (soil fertility and crop nutrient management), and section 205.11 (wild crop harvesting). The required provisions of the organic plan proposed here are consistent with the OFPA definition, and would enable a certifying agent to determine whether the applicant's management methods meet the requirements of the Act and the regulations of this part. We also believe that the establishment of an organic plan, as proposed here, would be a means by which organic producers and handlers could evaluate their operations and develop strategies to help them maintain compliance with the relevant organic production or handling requirements.

Section 205.205 of this proposal would require a certification applicant to submit an organic plan to the certifying agent. In a State with an approved State program, as proposed and discussed in section 205.402 of subpart F, the applicant also would have to submit the organic plan to the applicable governing State official. The organic plan would have to identify, as applicable to the operation for which certification is requested, a description of the practices and activities previously implemented, and intended to be implemented and maintained, to establish a system of organic farming and handling that complies with the applicable crop, livestock, wild crop harvesting, and handling requirements proposed in Subpart B. Details of any multi-year planning necessary in order to comply with all applicable requirements would have to be included in the organic plan. For example, a rotation plan or a description of other methods for ensuring adequate pest management, such as introduction of diverse species into areas planted with perennial crops, would have to be

provided for each field or farm parcel, as provided for in section 205.6 of subpart B. The organic plan also would have to describe practices implemented and intended to be implemented to comply with proposed section 205.3(b) of subpart B, which proposes that any practices used not result in measurable degradation of soil and water quality and that non-synthetic substances be chosen in preference to synthetic substances, to the extent possible. For example, a farmer might describe practices implemented to ensure that soil quality is not measurably degraded by tillage practices or that contamination of water by nitrates does not occur when manure is applied. The organic plan also would have to describe activities to evaluate the effects of practices for which more specific restrictions are proposed. For example, a farmer who is using a composted waste material that contains a non-active residue of a substance, as proposed in section 205.7(b)(4), would include information in the organic plan to demonstrate that the level of non-active residues that may be present in the composted waste material was not increasing in the soil to which it is applied.

The information delineated in sections 205.205(b) through 205.205(e) would have to be submitted as it was applicable to the operation for which certification is sought. These proposed paragraphs would require sufficient information about the farm, wild crop harvesting or handling operation for which certification is sought to evaluate whether an applicant is complying with or is able to comply with the Act and our proposed organic production and handling requirements in sections 205.3 through 205.28 of subpart B. It also is needed to aid the certifying agent in determining which areas of the operation should be observed in the course of the on-site inspection.

Section 205.205(b) proposes the information that would have to be submitted with respect to a farm operation. This information includes a description of the farm's crops, livestock, and on-farm processing activities, total acreage, and a map or maps showing all fields or farm parcels for which certification is requested. The map(s) are required to show field and farm parcel boundaries, sizes, locations, and any significant identifying features. They must also show any adjoining land, that is not part of the operation to be certified, to which a prohibited substance may be applied, and the location of any facility used for livestock housing, storage, or post-harvest handling. Information also would be required that provides a history of the crops grown and fertilizers or other production inputs applied to each field or farm to be certified for the three year period immediately preceding the date of the request for certification. The information would have to include the crops intended to be planted or managed on each field in the coming crop year, and a list of agricultural products to be sold as organic or as made with certain organic ingredients.

A farm operation also would have to submit information about the intended use of certain categories of production inputs. First, information would have to be submitted that listed all substances intended to be used as production inputs in the crop year. This list would have to indicate each substance intended to be applied to land or crops, its source, the anticipated quantity of it to be used, and where it would be applied. We also propose to request a list of all the seeds or planting stock intended to be purchased that would indicate for each of these its source (e.g. nursery or seed company), the approximate quantity to be used, and whether it was organically produced, treated, or untreated.

We propose that a livestock producer submit a list of all animals or livestock management units (such as flocks of poultry or colonies of bees) to be maintained on the operation and to be purchased in the following year for use as organic livestock or for the production of organic livestock products. The list also would have to indicate the source of the livestock (e.g., born on the farm, or name of the hatchery), estimated number of each type of livestock to be used and purchased in the certification year, the intended use of the livestock (such as slaughter stock, milk, wool, or breeding), and whether the livestock were purchased from a certified operation. Other information required to be submitted would indicate the livestock feed and feed supplements intended to be purchased in the certification year, and their source (e.g., local feed mill, or neighboring farm) and estimated quantity. Additionally, information as to what portion, if any, of the purchased feed was not organically produced would need to be provided. The livestock operation also would have to submit the name of the veterinarian from whom the producer obtains animal drugs or prescriptions for animal drugs, and a list of any animal drug expected to be used in the certification year, including its source, estimated amount to be used, and the types of livestock to which it might be administered. Finally, a farm operation would have to describe the post-harvest handling or processing methods and facilities to be used. Examples of post-harvest handling facilities would include fresh produce washing and packing facilities, grain cleaners, milk bottling, herb drying, and slaughtering facilities, whether the facilities are part of the farm operation to be certified or located elsewhere.

It should be noted that, in cases where the regulation provides for the use of a particular substance or production input only when other applicable proposed methods or production inputs are not effective or are not commercially available, such as botanical pesticides (section 205.9), treated seeds (section 205.8), or non-organically produced livestock feed (section 205.13), a description of the reasons for using a restricted substance or production input would have to be included in the organic plan. For example, a farmer might describe why botanical pesticides, rather than measures that did not involve the use of a substance, were used to control particular pests on particular crops. Similarly, a livestock producer would describe the reasons for feeding non-organic feed, such as an unanticipated expansion of a dairy herd. Annual updates to the plan also would describe the conditions that necessitated any allowed emergency or unanticipated use of a particular production input. For example, if treated seed were used to replant a corn crop lost to flooding, the farmer would provide this information as part of the next annual update to the organic plan.

Paragraph (c) of this section would require that an applicant requesting certification of a split operation (a farm or facility using both organic and non-organic practices in different field units or aspects of the operation) submit certain additional information. This information would include: anticipated quantities and locations of any crop, livestock or livestock product intended to be grown or raised both organically and non-organically in the coming crop year; each prohibited substance that was applied on the farm in the three years prior to the request for certification; each prohibited substance or practice that may be used in the certification year on a non-organic portion of the farm; and a description of the measures that will be used to prevent commingling of organic and non-organic products, and contact of organic field units or products with prohibited substances. This information is needed to determine whether there is any potential for organically managed portions of the operation to come into

contact with synthetic pesticides or other substances that are prohibited for use in organic farming and handling under the Act.

In paragraph (d) of this section we propose that a certification applicant be required to submit the following information regarding a wild crop harvesting operation: a map showing each area from which wild crops will be harvested in the certification year; the ownership of the area and evidence of permission to harvest in this area; a history of this area that demonstrates that no prohibited substance has been applied within three years prior to the initial harvest of a wild crop to be sold or represented as organic; each species of plant to be harvested, as well as its botanical name, the part of the plant to be taken (such as leaves, roots, flowers, fruits, or the whole plant), and the quantities of the plant expected to be harvested in the coming crop year; the dates of the harvest season; other information that the certifying agent might need to assess the impacts of the harvest operation on the environment and sustained growth and production of the wild crop; each type of wild product expected to be sold or represented as organic or made with certain organic ingredients, and the quantity of each type of product to be sold or represented (such as dried flowers in bulk, fresh roots and potpourri mixes); and a list of all post-harvest handling or processing methods and facilities to be used by the applicant.

As proposed in paragraph (e) of this section for handling operations, a handling operation applying for certification must submit: a brief, general description of the type of handling operation and the processing, manufacturing or other handling procedures it will use (such as grain cleaning and milling, meat or produce packing, dairy processing, or frozen food manufacturing); a description of the structural pest management methods used and intended to be used in each facility; and a list of each product intended to be handled and sold or represented in the certification year as organic or made with certain organic ingredients. A handling operation that produces both organic and non-organic products also would have to provide a list of each non-organically produced product or type of product to be sold in the certification year, and a description of the measures to be used to prevent the commingling of organic and non-organic products and ingredients, and the contact of organic products, and packaging and storage areas used for organic products, with prohibited substances. Finally, the handling operation would have to submit a list of each ingredient, incidental additive, and type of packaging material to be used for organic products in the certification year, and specify for each, as applicable, whether it is an organic agricultural product, a non-organic agricultural product, or a non-agricultural ingredient; the estimated quantity to be used; its source or manufacturer (e.g., name of the farm(s), flavor company, or packaging manufacturer from which it is purchased); and the country of origin for each imported organic agricultural product to be used. The source of any water to be used as an ingredient in an organic product would have to be identified in order to determine that the water meets the Safe Drinking Water Act (42 U.S.C. 300(f) *et seq.*) requirements. This determination needs to be made because section 2111(a)(7) of the OFPA (7 U.S.C. 6510(a)(7)) prohibits handling operations from using water that does not meet all the Safe Drinking Water Act requirements.

We would like to point out that we believe that the information we are requiring be submitted to certifying agents when an application for certification is made could result in many positive benefits for the organic program. We believe that the submitted information will significantly decrease the amount of time it will take to conduct inspections of operations seeking certification. If this occurs, then the costs incurred by operations applying for certification will be reduced.

We also believe that the information submitted at the time an application for certification is made will also lessen the burdens that could be incurred by certifying agents in making their own certification decisions, and in responding to requests for information from other certifying agents. This could occur because certifying agents will not have to continually re-contact certification applicants or certified operations when carrying out their responsibilities.

Additionally, we believe that information that is immediately available will help ensure that timely decisions are made. For example, the marketing of multi-ingredient products that may require multiple certifications should be able to occur in a timely and efficient manner because accredited certifying agents will be able to readily exchange the information needed to assure that these multiple certifications occur. Additionally, the easy accessibility to information that documents what is to occur in a certified operation will provide both certifying agents and the Administrator with the ability to help ensure that violations of the organic program that occur can promptly be substantiated, thus helping to ensure the integrity of representations made about the organic nature of a product.

However, an alternative scheme for having the necessary records available for certification decisions might be a scheme in which information needed for certification decisions would be required to be created by an applicant and made available for review and copying at an applicant's sites of operation, but would not be required to be submitted to certifying agents at the time an application for certification is made. In this scheme, these records would be reviewed by inspectors acting on behalf of certifying agents when an inspection is carried out as part of the process of determining whether an applicant should be certified. If records are needed at any other time, they could either be submitted to the certifying agent or made available for review at a farm or handling operation.

We would like comments from the public in regard to our proposed scheme, and the possible alternative to it discussed above. In particular, we would like information regarding the following:

(1) Whether the suggested alternative scheme which would require the creation and availability, but not the submission, of needed records would provide certifying agents with the records they need to make certification decisions in a timely and efficient manner;

(2) Whether the suggested alternative scheme would be less, or alternatively, more burdensome economically, or in any other manner, than the proposed scheme for submission of records for anyone participating in the organic certification program, including certifying agents, inspectors, farming operations, and handling operations, and if so, how and why it would be less or more burdensome; and

(3) Whether any records we are proposing to be submitted as part of the certification application, which in our alternative scheme would be maintained at the sites of operation, are not needed to make appropriate certification decisions or to ensure the integrity of the organic program. For example, we would like comments as to whether certifying agents need to know the anticipated quantities of non-organic agricultural products intended to be grown or harvested in order to make certification decisions for split operations. We also would like comments in this area regarding our requirement that split operations submit

information that indicates the expected quantity and location of each substance prohibited for use under the OFPA that may be used on a non-certified portion of the split operation.

Statement of Compliance—Section 205.206

We propose in this section, in accordance with section 2107(a)(4) of the OFPA (7 U.S.C. 6506(a)(4)), that an applicant for certification also submit a statement agreeing to comply with the Act and the regulations in this part, including the requirements for receiving and maintaining certification proposed in section 205.203, to the Secretary and the certifying agent. This statement of compliance would be submitted along with the certification application, and annually thereafter.

Preliminary Evaluation of an Application for Certification—Section 205.207

Section 205.207 would require a certifying agent to make a preliminary evaluation to determine whether the applicant may be in compliance with the applicable production and handling requirements before conducting an inspection. This preliminary evaluation, which would be based on an examination of the application materials received, would avoid the necessity of conducting an inspection of an applicant who clearly could not be in compliance with the applicable organic requirements, thus preventing unnecessary burdens on both the certifying agent and the applicant.

This section also would require that the certifying agent verify that an applicant who had previously applied to another certifying agent and received a notification of non-compliance, as proposed in section 205.215(a), had submitted documentation to support the correction of any deficiencies identified in the notification of non-compliance. This provision would assist a certifying agent to identify corrections made in response to deficiencies in compliance that previously had been noted by another certifier. Once the preliminary evaluation was completed and the information indicated that the operation may be in compliance with the Act and the regulations, the certifying agent would then arrange to conduct an on-site inspection of the operation.

Arranging for Inspections—Section 205.208

Section 2107(a)(5) of the OFPA (7 U.S.C. 6506(a)(5)) requires that an annual on-site inspection be performed by the certifying agent of each farm and handling operation that has applied for certification or that is certified. In section 205.208(a), we propose that a certifying agent arrange to conduct an initial on-site inspection of each farm, facility, and site that is included in an operation for which certification is requested, for the purpose of determining whether to approve the request for certification. Another on-site inspection would be conducted each year thereafter, to determine if the certification should be continued. Paragraph (b) of this section would require that such initial inspection be conducted within a reasonable time following a favorable preliminary evaluation of an application for certification, as proposed in section 205.207. While the Act does not specify that on-site inspections be performed prior to granting certification, performing at least one inspection prior to certification is the customary and required procedure for all existing certification programs of which we are aware, and we believe that it should be required in our proposal in order to verify that the information provided in an application for certification accurately reflects the practices used by the operation requesting certification. We have not specified a time period within which an inspection must be conducted because this will vary depending on when an application is submitted and the type of operation to be inspected.

In paragraph (c) of this section, we propose that an inspection be scheduled at a time when the inspector can observe land, facilities, and activities that demonstrate the operation's compliance with, or capacity to comply with, the organic production and handling requirements proposed in subpart B. Inspections also would have to be arranged so that the applicant or an authorized representative of the applicant who is knowledgeable about the operation will be present during the inspection. This requirement is necessary so that information pertinent to whether an applicant is complying or can comply with the Act and the regulations, can be obtained or clarified through discussion with personnel knowledgeable about the operation being certified.

Verification of Information—Section 205.210

Section 2105(3) of the OFPA (7 U.S.C. 6504(3)) requires that an agricultural product to be sold or labeled as an organically produced agricultural product must be produced and handled in compliance with an organic plan agreed to by the producer and handler of the product and the certifying agent. In section 205.210 we propose the means by which a certifying agent, through the use of an inspector, would verify that the information provided in the application for certification and in the organic plan, as proposed in sections 205.204 and 205.205, or in any annual update to this information, as provided in section 205.217, accurately represents that the applicant is complying or has the ability to comply with the Act and the regulations. When an inspection is conducted to evaluate continuation of certification, its purposes also would include verification that the provisions of the organic plan are being implemented.

The inspector should be able to determine from his or her observations whether the facilities and equipment used by an applicant for certification would enable the operation to be in full compliance with all the applicable requirements. For example, the inspector might verify that a produce operation that was preparing to plant annual vegetable seedlings had already obtained or produced seedlings that comply with section 205.8. If non-organically produced seedlings were being used, the inspector also would examine the operation's records that demonstrate that comparable organically produced seedlings were not commercially available.

In order to verify that the information submitted to the certifying agent is accurate and that practices used by the applicant are in compliance with the applicable provisions of the Act and the regulations, an inspection might include an examination of the applicant's fields, buildings, storage areas, production inputs, equipment, and other facilities, including any off-site facilities used by the operation for organic production or handling. In addition, all supplies and inventories of products that are, or that are intended to be, sold, labeled or represented as organic or as made with certain organic ingredients might be examined to observe whether they are stored and handled in a manner that creates any possibility of their being commingled with non-organic products. Labels, labeling, and other market information might also be examined to determine if such material was in compliance with the requirements of Subpart C. The inspector also might observe boundaries, buffer zones, and other critical control points where prohibited substances could contact organic crops, livestock, or other agricultural products, equipment or production areas used in organic production or handling, and places where commingling with nonorganic products might occur, especially in split

operations. Observations of the overall general health and condition of the soil, livestock, crops and other biological elements, such as hedgerows and waterways, as appropriate, also might be made. Additionally, the inspector might examine the operation's records and recordkeeping system, as needed to determine the applicant's compliance, or ability to comply with, the recordkeeping requirements proposed in section 205.216. Additionally, the inspector might need to collect samples of materials or substances for laboratory analysis that may serve as evidence of compliance, as proposed in sections 205.430 and 205.431 of subpart F, when instructed to do so by the certifying agent, or when the inspector observed a situation, such as herbicide damage to plants, which could indicate that any crop, field, livestock, product or facility within the operation has come into contact with a prohibited substance.

Post-inspection Conference—Section 205.211

In section 205.211 we propose to require that the inspector conduct a post-inspection conference with the certification applicant or an authorized representative of the inspected operation. During this conference, the inspector would discuss specific observations made concerning the applicant's compliance, or ability to comply, with the Act and the regulations, such as the adequacy of buffer areas observed to prevent contact with organically managed fields by prohibited substances, or the adequacy of the segregation of organic products from non-organic products in storage areas. We have proposed this requirement because such discussions are routinely included in procedures currently used by most existing certification programs, and we believe that permitting an applicant to clarify any information that is to be reported by the inspector to the certifying agent would help ensure the accuracy of the information. For example, if a crop being grown in a particular field is different from the crop indicated in the applicant information, the applicant could explain why the alternative crop had been substituted. This discussion also would assist the applicant in preparing future revisions to the organic plan and in making other changes to the operation, such as implementing practices that reduce the need to use pest control substances or animal drugs.

Reporting to the Certifying Agent—Section 205.212

In section 205.212, we propose that the certifying agent would require that the inspector prepare and submit to the certifying agent, within thirty days of completing an inspection, a written report that describes the inspector's observations and assessments of the inspected operation's compliance, or ability to comply, with the Act and the regulations. The inspection report is a key document that will be used by the certifying agent to verify an applicant's compliance, or ability to comply, with the regulations of the National Organic Program.

In accordance with section 2105(3) of the OFPA (7 U.S.C. 6504(3)) which requires that organic products be produced and handled in compliance with an organic plan agreed to by both the producer or handler and the certifying agent, we believe that sufficiently detailed information must be contained in an inspection report in order for the certifying agent to determine whether to approve the organic plan or require that it be revised, and also to determine whether a certified operation is complying with the organic plan as previously approved. Therefore, it is critical that the report include a complete, detailed description of the observations and assessments made by the inspector pursuant to section 205.210.

Additional Inspections—Section 205.213

In paragraph (a) of this section, we propose that, in addition to the annual on-site inspection required in section 205.208(a), a certifying agent could conduct an inspection of any farm, facility, or site used by a certified operation or an applicant for certification when necessary to determine compliance with the Act and the regulations in this part. In paragraph (b) of this section, we propose that the Secretary also may require that additional inspections be performed for the purpose of determining compliance with the Act and the regulations in this part. In a State in which there was an approved State program, the governing State official also would be able to require additional inspections. A certifying agent thus could decide to conduct additional inspections of certification applicants or certified operations as necessary to obtain information that was needed by the certifying agent to determine or verify the certification of the operation.

We believe that the requirements and procedures proposed in sections 205.208 through 205.213 to be followed by a certifying agent in conducting an inspection of an applicant for organic certification or a certified operation represent a key provision of our proposed certification program. The inspection process is critical for maintaining the integrity of the national organic certification program and must be undertaken in a reliable, thorough and consistent manner. Clear, consistent criteria for performing inspections are essential because of the diversity of private and State certifying agents who will be conducting inspections and evaluating inspection reports under this program.

Approval of Certification—Section 205.214

In this section we propose the basis for a certifying agent to approve an application for certification, and the procedure to be used by the certifying agent in notifying the applicant of the approval. Paragraph (a) of this section would require that the certifying agent review the information submitted by the applicant, including the organic plan, and the report submitted by the inspector, and request that the certification applicant submit any additional information and documentation that may be needed to determine if the certification applicant is complying, or is able to comply, with the Act and the regulations. For example, this might include information about changes in crops actually planted in certain fields, additional livestock added to the operation, or new sources for ingredients in a processed product, that occurred since the inspection took place.

Based on a review of all the information submitted by the certification applicant and the inspector, including any additional information the applicant has provided pursuant to paragraph (a) of this section, paragraph (b) of this section would require the certifying agent to approve an application for certification after determining that the applicant's operation satisfies four criteria. First, the certifying agent would need to determine that the practices and substances used, or intended to be used, by the operation are consistent with a system of organic farming and handling, as defined in section 205.2, and comply with the applicable production and handling requirements in this proposal. The second criterion that must be met is that the applicant satisfies the general requirements for certification, as proposed in section 205.203. Third, the certifying agent would have to determine that the applicant's organic plan satisfies the applicable requirements of the Act and the production and handling regulations in subpart B, including the provisions for the use of substances proposed in the

National List. The fourth criterion that must be met is that the applicant's records and recordkeeping system satisfy the applicable requirements proposed in section 205.216.

After the certifying agent determines that an application for certification should be approved, paragraph (c) of this section would require that the certifying agent send the applicant a written notification, and to state in the notice any restrictions or requirements that are being imposed as a condition of certification. For example, if the inspector noted that information about persons who had applied substances to certain farm parcels was missing from the applicant's records, the notice would require that such information be submitted by a certain time.

Along with the notification of approval, the certifying agent would provide a certificate which the operation could use as proof of certification. In paragraph (d) of this section, we propose that the certificate include the name of the certified operation, the effective date of the certification, and the category(ies) and type(s) of products and crop year, if applicable, covered by the certification.

Denial of Certification—Section 205.215

In this section we propose the procedure to be followed if the certifying agent has reason to believe, based on a review of the information specified in section 205.214(a), that an applicant for certification is not able to comply, or is not in compliance, with the requirements of the Act and the regulations in this part. When this occurs, the certifying agent would be required to provide a written notification of non-compliance to the applicant, as proposed in section 205.218(a). This notification would be sent by certified mail to the certification applicant, and would contain a description of each deficiency in the applicant's ability to comply with the Act and the regulations in this part that the certifying agent has reason to believe has occurred, the evidence on which the notification is based, and the date by which the operation must correct each deficiency in compliance identified in the notification.

Following the correction of deficiencies identified in the notification of non-compliance, section 205.215(b) would permit the applicant to submit a new application for certification to any accredited certifying agent. A new application would include documentation of actions taken by the applicant to correct the deficiencies in compliance identified in the notification of non-compliance sent pursuant to paragraph (a) of this section. If a new application is submitted to a different certifying agent, the certification applicant would be required to simultaneously inform the certifying agent who issued the notification of non-compliance that a new application has been submitted and the name of the certifying agent to whom it was submitted. It should be noted that an applicant for certification must provide information to a certifying agent about previous applications for certification and their outcome, as proposed in section 205.204(d) (applicant information). A certifying agent thus would be able to determine whether a new applicant previously had received a notification of non-compliance from a different accredited certifying agent and would be required to include with the application for certification documentation that deficiencies in compliance identified in the previous notification had been corrected.

Finally, in paragraph (c) of this section, we propose that if a certification applicant who receives a notification of non-compliance does not correct the deficiencies or does not notify the certifying agent that it has submitted a new application within the time specified in the notice of non-compliance, the certifying agent would submit to the Administrator a notice of its recommendation to deny certification to the applicant. The Administrator then could institute proceedings to deny certification pursuant to the Rules of Practice, 7 CFR 1.130, *et seq.* The Rules of Practice provide for the formal filing of a complaint by the Secretary, an opportunity for the certification applicant to answer the complaint, a procedure for holding a hearing, and a procedure for further appealing an adverse decision following any hearing that is held. A final determination to deny certification would not be made until the applicant had received notice and an opportunity to be heard.

Recordkeeping—Section 205.216

Section 2112(d) of the OFPA (7 U.S.C. 6511(d)) requires that producers who operate a certified organic farm or handling operation maintain certain records for five years concerning the production or handling of agricultural products that are sold or labeled as organically produced. We accordingly propose in section 205.216 that a certified operation maintain records concerning the production, harvesting, and handling of agricultural products that are, or that are intended to be, sold, labeled or represented as organic or made with certain organic ingredients sufficient to demonstrate compliance with the Act and the regulations, for a period of five years. These records would have to be made available to authorized representatives of the Secretary, the applicable governing State official in a State with an approved State program, as proposed and discussed in section 205.402 of subpart F, and the certifying agent, for the purpose of verifying the operation's compliance with the Act and the regulations in this part and the provisions of the applicable State program. Records maintained in accordance with this provision could include written, electronic, or graphic documentation, such as maps or plant diagrams, that serve to support and substantiate any information provided to the certifying agent concerning the operation's production and handling methods.

In paragraph (b) of this section we propose that certain specific records would have to be maintained by a certified operation. Other records, in addition to those indicated, also may be maintained as considered appropriate by the operation to support information provided to the certifying agent. In paragraphs (b)(1) and (b)(2) of this section it is proposed, in accordance with sections 2105(2) and 2112(d) of the OFPA (7 U.S.C. 6504(2) and 6511(d)), that the operation would have to maintain a list of all substances applied to fields or land that are part of the certified operation for a period of no less than three years preceding the intended or actual time of harvest of an organic crop from such fields or land, along with the name and address of any person who applies or has applied any substance to any part of the farm, the name of the substance, and the date(s), location(s), rate(s) and method(s) of application. Section 2110(f)(2) of the OFPA (7 U.S.C. 6509(f)(2)) requires that certain records be kept with respect to livestock maintained under organic management. Accordingly, we propose in section 205.216(b)(3) that, for each animal (or livestock management unit, such as a poultry flock or bee colony) that is, or whose products are, intended to be sold or represented as organic in accordance with the livestock production requirements proposed in sections 205.12 through 205.15 of subpart B, the producer would have to keep records of: the source of the animal or livestock management unit and the date it entered the certified operation; the amounts and sources of all animal drugs administered to it; all feeds and feed supplements fed to it; and the location of the field, farm unit, or

facility where it is maintained, as applicable. These records all are necessary in order to maintain a detailed, verifiable audit trail so that each animal (or livestock unit) can be traced back to the farm, as required by section 2110(f)(1) of the OFPA (7 U.S.C. 6509(f)(1)).

A fourth category of records we propose would have to be maintained includes any information submitted to a certifying agent as part of an application for certification or as part of continuation of certification, as proposed in sections 204.204 and 205.217.

We are also proposing that the records would have to be adequate to establish an audit trail. An audit trail is defined as the ability to follow, through documentation, the transfer of ownership and the transportation of any agricultural product labeled as organic or made with certain organic ingredients. This information would include, as applicable, the source, production and handling methods, transfer of ownership, and transportation of any agricultural product labeled as organic or made with certain organic ingredients that is received by or shipped from the certified operation. Although section 2110(f)(1) of the OFPA (7 U.S.C. 6509(f)(1)) imposes a verifiable audit trail requirement only on livestock operations, our proposal to establish a verifiable audit trail for all organically produced products is needed in order to adequately enforce the provisions of the Act. It also is consistent with the recordkeeping requirements of most existing certification programs we have reviewed, and consistent with the recommendations provided by the NOSB.

Paragraph (c) of this section reiterates that any operation that is exempt or excluded from certification under section 205.202 (a) or (b) must maintain records in accordance with proposed section 205.202(c).

Continuation of Certification—Section 205.217

Section 2107(a)(4) of the OFPA (7 U.S.C. 6506(a)(4)) requires that a certified operation certify on an annual basis that it is producing agricultural products that are sold, labeled, or represented as organic in compliance with the Act and the regulations. Additionally, section 2107(a)(5) of the OFPA (7 U.S.C. 6506(a)(5)) requires an annual on-site inspection of each certified operation. The annual submission of updated information proposed in paragraph (a) of this section would provide a certifying agent with information about changes that may have been made in an operation during the preceding year which is needed by the certifying agent to properly prepare for the annual inspection. Although nearly all the existing certification programs we reviewed require an annual renewal of certification, we are proposing in section 205.217 that a certified operation needs to submit only updated information to the certifying agent on an annual basis. As proposed here, an approved certification status would continue in effect until the operation voluntarily ceased to be certified or was terminated, as proposed in section 205.219.

As proposed in paragraph (a) of this section, a certified operation would submit to the certifying agent any additions or changes to each item of information contained in the previous year's application and any amendments to the organic plan, including a description of activities undertaken in the previous year, and intended to be undertaken in the coming year, to implement the provisions of the organic plan, as proposed in sections 205.204 and 205.205. For example, if a farm had expanded its acreage in organic production or the number of livestock included in its operation had decreased, this information would have to be included in the update. The certifying agent would have the previous application information on file, or would be able to obtain it from the certifying agent who had previously certified the operation, so that the applicable information specified in section 205.204 and 205.205 would be available when preparing for the on-site inspection.

The application materials also would have to include a statement that the certified operation will remain in compliance with the Act and the regulations in this part, as well as any other information that may be requested by the certifying agent. In section 205.217 (b) and (c) we propose that after receiving the updated information as specified in paragraph (a) of this section, the certifying agent would arrange to conduct an on-site inspection of the certified operation pursuant to sections 205.208 through 205.211. After conducting an on-site inspection of the certified operation pursuant to section 205.212, if a certifying agent has reason to believe that a certified operation is not complying with the requirements of the Act and the regulations, the certifying agent would provide a written notification of non-compliance to the operation, as proposed in section 205.218(a).

Notification of Non-compliance With Certification Requirements—Section 205.218

Section 2107(a)(7) of the OFPA (7 U.S.C. 6506(a)(7)) requires that a certification program established under the Act provide for appropriate and adequate enforcement measures. In section 205.218 we propose the procedure by which a certifying agent would identify any problems that may occur in the compliance with, or possible violations of, the Act or the regulations in this part by a certified operation, or a certification applicant, and then provide an opportunity for the operation to correct any defects in its compliance.

In paragraph (a) of this section we propose that a certifying agent would send a written notification of non-compliance by certified mail sent to the place of business of the certification applicant or the certified operation. The notification would have to contain the following information: a description of each deficiency in compliance and each possible violation of the Act and the regulations that the certifying agent has reason to believe has occurred; the evidence on which the notification is based; and the date by which the operation must correct each deficiency in compliance and each possible violation delineated in the notification, and submit documentation to the certifying agent to support such corrections.

In paragraph (b) of this section we propose the procedure to be followed after a certifying agent sends a notification of non-compliance to an operation it has certified. If the documentation to support corrections received by the certifying agent from an operation it has certified is not adequate to demonstrate that each deficiency in compliance and each possible violation has been corrected, we propose that the certifying agent would conduct an additional inspection, if one is necessary, to determine whether the operation is complying with, or has violated, the Act or the regulations. After conducting an additional inspection, if one is necessary, or without conducting an additional inspection, if one is not necessary, the certifying agent would review the status of the certified operation to determine whether the operation or any portion of the operation has ceased to comply with, or has violated, the Act and the regulations.

Paragraph (b)(3) of this section proposes the procedure to be followed after the certifying agent has reviewed the certified operation's status, pursuant

to paragraph (b)(2) of this section. Following a review of a certified operations's status, if a certifying agent determines that the operation is in compliance with the Act and the regulations, the certifying agent would be required to notify the certified operation in writing of its determination of compliance. If the outcome of the review gives the certifying agent reason to believe that the certified operation or any portion of the operation is not in compliance with the Act and the regulations, the certifying agent would submit to the Administrator a notice of its recommendation to terminate the certification of the certified operation or any portion of the certified operation that the certifying agent believes to have ceased to comply with the Act and the regulations. It should be noted that a recommendation could be made to terminate the certification of only a portion of an operation: for example, when a prohibited substance is applied to only one field that is part of a certified farm operation, but all other fields remain in compliance with the Act and the regulations.

Termination of Certification—Section 205.219

In section 205.219 we propose the procedure to be followed to terminate the certification of an operation or a portion of an operation that a certifying agent believes has ceased to comply with the Act and the regulations. In paragraph (a) of this section we propose that a certifying agent would send the certified operation a notification of non-compliance and follow the other procedures proposed in section 205.218 if the certifying agent has reason to believe that a certified operation or a person responsibly connected with a farm, wild crop harvesting, or handling operation it has certified has: violated the purposes of the national organic certification program; made a false statement; or attempted to have a label indicating that an agricultural product is organically produced affixed to such product when such product was not organically produced in accordance with the Act and the regulations.

In section 205.219(b) we propose that if a certifying agent has reason to believe that a certified operation or a person responsibly connected with an operation certified by the certifying agent has wilfully violated the Act and the regulations, the certifying agent would not send a notification of non-compliance pursuant to section 205.218. Instead, the certifying agent would submit to the Administrator a notice of its recommendation to terminate the certification of the certified operation or any portion of the certified operation that the certifying agent believes to have ceased to comply with the Act and the regulations. The names of any persons the certifying agent believes to have willfully violated the Act and the regulations would have to be listed in the recommendation to terminate certification submitted to the Administrator.

In section 205.219(c) we propose that the Administrator could institute the proceedings to terminate certification (pursuant to the Rules of Practice 7 CFR 1.130, *et seq.*) following the Administrator's receipt from a certifying agent of a notification of a recommendation to terminate the certification of an operation or any portion of an operation. The Rules of Practice provide for the formal filing of a complaint by the Secretary, an opportunity for the person(s) named in the complaint to answer the complaint, a procedure for holding a hearing, and a procedure for further appealing an adverse decision following any hearing that is held. A final determination to terminate the certification would not be made, therefore, until the person(s) believed to have violated the Act and the regulations had received notice and an opportunity to be heard. A notification of a certifying agent's recommendation to terminate certification could be submitted either in accordance with paragraph (b) of this section, or in accordance with section 205.218(b)(3)(ii) following a review of the status of a certified operation.

Section 2120(c) of the OFPA (7 U.S.C. 6519(c)) requires that, after notice and an opportunity to be heard, a person who is determined to have violated the Act and the regulations; made a false statement; or attempted to have a label indicating that an agricultural product is organically produced affixed to such product that such person knows, or should have reason to know, was not organically produced, shall not be eligible to receive certification for five years from the occurrence of such violation. Section 205.219(d)(1) is proposed in accordance with the Act's requirement, with the period of ineligibility to begin when a determination is made subsequent to the proceedings to terminate certification as proposed in paragraph (c) of this section. This section of the Act also permits the Secretary to waive or reduce the period of ineligibility if it is in the best interests of the certification program established under the Act, and we accordingly propose in paragraph (d)(2) of this section that the Secretary may waive ineligibility for certification if it is in the best interests of the certification program established under subpart D.

Notification of Certification Status—Section 205.220

In section 205.220 we propose that a certifying agent would be required to submit to the Administrator a copy of any notification of non-compliance, sent pursuant to section 205.218, simultaneously with its issuance to the certification applicant or the certified operation, and also to submit to the Administrator on a quarterly calendar basis the name of each operation whose application for certification has been approved. This information is needed in order for the Administrator to maintain current information concerning the status of certified farm, wild crop harvesting and handling operations, and therefore provide adequate enforcement measures. Information about any operation that has received a notification of non-compliance, pursuant to section 205.218(a), is needed in order to ensure that information about possible violations of the Act and the regulations is provided to the Administrator in a timely manner. This provision also would enable a certifying agent to determine whether a new certification applicant had previously received a notification of non-compliance from a different certifying agent, and was therefore required to document that any defects in compliance had been corrected.

SUBPART D—WHAT HAS TO BE CERTIFIED

Entity	Needs to be certified	Records required for organic ingredients and organic products
ORGANIC OPERATION SELLING or HANDLING NO MORE THAN $5,000 annually in agricultural products § 205.202(a)(1).	NO	*SALES RECORDS § 205.202(c)(1). *Sales records for all agricultural products.

SUBPART D—WHAT HAS TO BE CERTIFIED—Continued

Entity	Needs to be certified	Records required for organic ingredients and organic products
ORGANIC OPERATION SELLING or HANDLING MORE THAN $5,000 in agricultural products or a HANDLING OPERATION (i.e., co-packer, etc.) that provides handling services to THREE (3) OR MORE operations that produce or handle agricultural products sold, labeled, or represented as organic or as made with certain organic ingredients § 205.201(a).	YES	ALL RECORDS § 205.216.
HANDLER of made with certain organic ingredients product §§ 205.201(a) and (b)	YES	ALL RECORDS § 205.216.
HANDLER of products that contain less than 50% organic ingredients § 205.202(a)(3).	NO	SOURCE/QUANTITY RECEIVED—§ 205.202(c)(3)(i). COMMINGLING/CONTACT—§ 205.202(c)(3)(i). DESTINATION/QUANTITY SHIPPED—§ 205.202(c)(3)(ii)).
HANDLER (distributor, warehouser, etc.) of packaged or otherwise enclosed products that remain in the same packages § 205.202(b)(1).	NO	SOURCE/QUANTITY RECEIVED—§ 205.202(c)(3)(i). COMMINGLING/CONTACT—§ 205.202(c)(3)(i). DESTINATION/QUANTITY SHIPPED—§ 205.202(c)(3)(ii)).
RETAIL OPERATION that does not process organic products § 205.202(a)(2)	NO	
RETAIL OPERATION that processes in the course of normal retail activity solely for the purpose of offering the product to the consumer § 205.202(b)(3).	NO	
RETAIL OPERATION that processes other than in the course of normal retail activity, i.e., combines into a single product products previously labeled organic and represents for sale under a new label § 205.201(a).	YES	ALL RECORDS—§ 205.216.
RESTAURANTS and FOOD SERVICE ESTABLISHMENTS that process ready-to-eat food but do not package and label the food § 205.202(b)(2).	NO	

Subpart E—Accreditation of Certifying Agents

Section 2115(a) of the OFPA (7 U.S.C. 6514(a)) requires that the Secretary establish and implement a program to accredit a governing State official, and any private person, who meets the requirements of the Act, as a certifying agent for the purpose of certifying a farm or handling operation as a certified organic farm or certified organic handling operation. Section 2104 of the OFPA (7 U.S.C. 6503) provides for the establishment of an organic certification program, which we have proposed in subpart D of this proposal, and section 2104(d) of the OFPA (7 U.S.C. 6503(d)) requires that the Secretary implement the certification program through certifying agents. We accordingly have proposed the provisions contained in this subpart to establish a program to accredit certifying agents to implement the certification program that is proposed in subpart D. We have developed this subpart following an extensive review of information about, and consultation with representatives of, existing organic certification programs and existing accreditation programs. We also have reviewed recommendations provided by the NOSB and public input submitted to the NOSB and the USDA.

This subpart delineates the procedure which a governing State official or a private person must follow in order to apply for and maintain accreditation as a certifying agent. A governing State official is defined by the Act as the chief executive official of a State or, in the case of a State that provides for the Statewide election of an official to be responsible solely for the administration of agricultural operations of the State, such official, who administers an organic certification program under the Act. A person is defined as an individual, group of individuals, corporation, association, organization, cooperative, or other entity. Over 33 private certification organizations currently exist, including some that are organized for profit and others that are non-profit membership organizations. Some of these organizations cover a broad geographic scope and certify a wide range of operations producing diverse agricultural products. Others are small and cover limited geographical areas or types of operations. This proposal has been developed to provide enough flexibility to allow for diversity of organizational types, while ensuring that the requirements of the Act are met. We anticipate that new private certifying agents will be organized when certification becomes mandatory for the marketing of agricultural products that are represented as organically produced. Eleven States currently certify organic producers in accordance with State laws, and additional States have expressed interest in establishing organic certification programs in their States.

Additionally, a governing State official may establish an approved State program, as proposed and discussed in section 205.402 of subpart F, in accordance with section 2108 of the OFPA (7 U.S.C. 6507). A State could elect to operate the certification component of an approved State program by utilizing accredited certifying agents who are private persons; the State would not need to apply for and receive accreditation as a certifying agent as a condition of its State program being approved by the Secretary. Conversely, a governing State official could apply for and receive accreditation as a State certifying agent without having to establish an approved State program.

Synopsis of Proposed Accreditation Program

This subpart delineates the requirements that must be met for a private person or a governing State official to receive and maintain accreditation as a certifying agent. These requirements include those that are provided under sections 2115 and 2116 of the OFPA (7 U.S.C. 6514 and 6515) which include having sufficient expertise in organic farming and handling techniques. They also include other requirements that we believe are necessary in order to perform the certification functions we have

proposed in subpart D, such as having an annual internal review conducted of the accredited certifying agent's operations.

Subpart E also provides a procedure for applying for accreditation, including the information that an applicant must submit. The application material includes basic information about the applicant's operation, information that provides evidence of its expertise in organic farming and handling techniques, evidence of the applicant's ability to implement the organic certification program required under the Act, and an agreement to comply with the Act and the regulations, as well as certain other terms and conditions. A private person would have to agree to certain additional terms, including agreeing to hold the Secretary harmless for any failure on its part, and to furnish reasonable security to protect the rights of participants in the certification program in the event the applicant ceases its operations.

This subpart then delineates the procedures by which the Administrator either would approve or deny an application for accreditation. The procedure for denial of accreditation would not be initiated until the applicant had been notified of defects in its ability to comply with the requirements and given an opportunity to correct them. This proposal would require an initial on-site evaluation of an accredited certifying agent's operations within a reasonable time after approving an application for accreditation, and a subsequent review by a peer review panel, as provided under section 2117 of the OFPA (7 U.S.C. 6516). The Administrator then would review the site evaluation report and the recommendations provided by each peer reviewer to determine whether to confirm or deny confirmation of the agent's accredited status. Following confirmation of accreditation, this proposal would require a certifying agent to submit fees and reports annually, and to request renewal of accreditation every 5 years. Each USDA review of a certifier's request for renewal of accreditation would include an on-site evaluation of a certifying agent's operations and a subsequent review by a peer review panel. This proposal also would permit the Administrator to conduct site evaluations whenever needed, including prior to approving accreditation, in order to verify the accuracy of information submitted and ensure compliance with the Act and the regulations.

This proposal further provides for certain enforcement actions to be taken if a certifying agent is not complying with or has violated the Act or the regulations in this part. A notification would be sent to a certifying agent if the Administrator has reason to believe that the certifying agent is not complying with the Act and the regulations. The basis for initiating the procedure for suspending or terminating an accreditation, which would be initiated after the certifying agent had an opportunity to correct deficiencies in compliance, is then proposed. A private person or a governing State official whose accreditation was suspended could reapply for accreditation after taking corrective actions to bring its activities into compliance with the Act and the regulations. A private person whose accreditation was terminated would be ineligible to receive accreditation for no less than three years, as provided by section 2120(e)(2) of the OFPA (7 U.S.C. 6519(e)(2)).

Distinctions Between Certifying Agents

The OFPA provides that a governing State official and any private person can become an accredited certifying agent if it successfully can demonstrate that it meets the requirements for accreditation established by the Secretary. All organic certifying agents, whether new or existing, or a private person or a governing State official, generally will have to meet the same qualifications, demonstrate the same capabilities, and undergo the same accreditation process. There are, however, certain requirements stated in the OFPA that pertain only to private certifying agents. Section 2116(e) of the OFPA (7 U.S.C. 6515(e)) requires only private certifying agents to furnish reasonable security, in an amount determined by the Secretary, to protect the rights of participants in the organic certification program. This section of the Act also requires only a private certifying agent to agree to hold the Secretary harmless for any failure on its part to carry out the Act's provisions.

Another difference between private and State certifying agents concerns the termination of accreditation. Section 2120(e) of the OFPA (7 U.S.C. 6519(e)) provides for the loss of accreditation only for a private certifying agent who violates the provisions of the Act and the regulations or who negligently certifies an operation, and also requires that the private certifying agent be ineligible for accreditation for a period of at least three years. Section 2116(j)(1) of the OFPA (7 U.S.C. 6515(j)(1)) provides for the suspension of accreditation for any certifying agent who is not properly adhering to the provisions of the OFPA and does not require a minimum period of ineligibility. These provisions of the Act are reflected in our proposed section 205.316 (termination of accreditation).

Areas of Accreditation—Section 205.300

As provided by section 2115(a) of the OFPA (7 U.S.C. 6514(a)), this section proposes that the Secretary shall accredit a qualified accreditation applicant in the areas of crops, livestock, wild crops, or handling, or any combination thereof, to certify a farm, wild crop harvesting operation, or handling operation as a certified organic farm, a certified organic wild crop harvesting operation, or a certified organic handling operation. This proposal would allow certifying agents who may have limited areas of expertise to become accredited to conduct certifications only of those types of operations for which they have expertise. Thus, certifying agents would not be required to have expertise in areas for which they are not requesting accreditation, in order to obtain accreditation in the areas for which they request it. For example, a certifying agent that only wanted to be accredited to certify mushroom farming operations would not have to have expertise in the raising of organic livestock in order to become accredited to certify mushroom operations. Additionally, a number of the existing non-profit certification programs we have reviewed certify only farms, since their personnel are not knowledgeable enough about manufacturing and processing procedures to certify those types of operations. Under this proposal, these organizations would not have to acquire the capability to certify other types of operations in order to be accredited to certify only farms.

General Requirements for Accreditation—Section 205.301

Sections 2115 and 2116 of the OFPA (7 U.S.C. 6514 and 6515) delineate certain requirements that accredited certifying agents must meet in carrying out the organic certification program mandated by the Act. This section of our proposal delineates those general requirements that are provided in these sections of the Act, as well as certain additional requirements that we have determined to be necessary to ensure the integrity of the program. These additional requirements are authorized by section 2107(a)(11) of the OFPA (7 U.S.C. 6506(a)(11)) which permits a program established under the Act to require other necessary terms and conditions, as determined by the Secretary.

All of the requirements proposed in paragraph (a) of this section would apply equally to both State and private certifying agents. The first two require that an accredited certifying agent have sufficient expertise in organic farming and handling techniques, and demonstrate the ability to fully comply with the requirements for accreditation to implement the certification program under the Act and the regulations, as provided respectively in sections 2115(b)(2) and 2116(a) of the OFPA (7 U.S.C. 6514(b)(2) and 6515(a)).

The third requirement we propose in section 205.301(a) is that a certifying agent carry out the provisions of the Act and the regulations in this part, which would include sections 205.207 through 205.214 of subpart D that describe certifying agent responsibilities and section 205.430 of subpart F, concerning compliance testing. The fourth requirement proposed in paragraph (a) of this section is consistent with section 2116(b) of the OFPA (7 U.S.C. 6515(b)), which requires a certifying agent to use a sufficient number of inspectors to implement the applicable organic certification program. Our proposal also would include in this requirement personnel other than inspectors, such as those who review applicants for certification. After reviewing information from existing certification programs, we have concluded that sufficient qualified personnel in addition to inspectors are essential for a certifying agent to have the expertise necessary to implement the certification program as proposed in subpart D of this part. Paragraph (a)(4) of this section additionally would require that the personnel be adequately trained to implement the organic certification program established under the Act and the regulations.

In section 205.301(a)(5) we propose that a certifying agent be required to conduct an annual performance review for each inspector used and to implement measures to correct any possible defects in compliance with the Act and the regulations identified in each such review. The quality and consistency of the performance of inspections is critical to the integrity of the certification program we have developed and proposed in subpart D. In order to ensure that all inspections are conducted in a manner that adequately scrutinizes certified operations, we believe that a certifying agent must annually evaluate the performance of each inspector it uses during the year. Paragraph (a)(6) of this section similarly would require that an annual internal evaluation review be conducted of the certifying agent's own certification activities, and that measures to correct any possible defects in compliance with the Act and the regulations be implemented, as identified in each such review. We propose this requirement in order to safeguard further the integrity of the certification process, and also to provide an additional means of evaluating the adequacy of a certifying agent's performance and compliance with the Act and the regulations. Such a procedure is consistent with accepted quality management methods and would assist the certifying agent in helping to ensure that its operations continue to comply with the requirements of the Act and the regulations. The requirements proposed in paragraphs (a)(5) and (a)(6) of this section would help ensure that a certifying agent possesses the requisite expertise to conduct certification activities, as required by section 2115(b)(2) of the OFPA (7 U.S.C. 6514(b)(2)), and maintains the administrative capability to fully implement the proposed program, as required by section 2116(a) of the OFPA (7 U.S.C. 6515(a)).

In section 205.301(a)(7) we propose the requirement that a certifying agent provide sufficient information to persons seeking certification to enable an applicant for certification to comply with the applicable requirements of the Act and the regulations. This would require that a certifying agent provide applicable information, such as information about the National Organic Program's requirements for: the production and handling of agricultural products; wild crop harvesting; certification; labeling; inspection; appeals of adverse actions; fees and expenses; approved State program requirements; and any other information that is needed for a person to be able to apply for certification and comply with all the relevant requirements.

Section 2116(c) of the OFPA (7 U.S.C. 6515(c)) requires that a certifying agent maintain records of its activities under the Act for not less than 10 years, and that it allow only representatives of the Secretary and the governing State official access to these records. Paragraph (a)(8) of this section reflects those requirements. Section 2116(g) of the OFPA (7 U.S.C. 6515(g)) requires that a certifying agent maintain strict confidentiality with respect to its clients under the applicable organic certification program and not disclose any business related information of its clients to third parties, with the exception of the Secretary or the applicable governing State official. Paragraph (a)(9) of this section reflects this provision, and also allows for certain exceptions, as proposed and discussed in section 205.304(b)(5) of this subpart.

The requirements provided in section 2116(h) of the OFPA (7 U.S.C. 6515(h)) address the prevention of conflicts of interest by certifying agents, and paragraph (a)(10) of this section is proposed to be consistent with those provisions. We have found it necessary in some cases to add certain clarifications to the language contained in the Act in order to establish requirements that are both feasible for the diverse range of certifying agents and adequate to prevent conflicts of interest. The first provision proposed in paragraph (a)(10) of this section is that a certifying agent could not certify an operation in which the agent, or a responsibly connected party of the agent, has held a commercial interest, including the provision of consultancy services, within 12 months prior to the application for certification. This provision also would require that a certifying agent not certify an operation through the use of any employee that has or has held a commercial interest in the operation, including the provision of consultancy services, within the 12 month period prior to the application for certification. This proposal therefore would permit a certifying agent to certify the operation of an employee provided that the employee was not used in certifying that operation. This clarification is consistent with the intent of the Act, and would permit the use by certifying agents of peer reviewers, as is the practice in many of the current organic certification programs we have examined. While the Act does not mention responsibly connected parties, which we have defined as any person who is a partner, officer, director, holder, manager, or owner of 10 per centum or more of the voting stock of an applicant or a recipient of certification or accreditation, we believe that any such person should be limited in the same way as the agent itself. Section 2116(h)(1) of the OFPA (7 U.S.C. 6515(h)(1)) also does not specify a time limit for previous commercial relationships in its conflict of interest provisions; however, we are proposing here that the prohibition of commercial relationships extend only to the previous 12 months. We believe that extending this period indefinitely into the past would prevent certifying agents from hiring qualified personnel who at some time had a financial interest in an operation certified by the agent. An indefinite extension would have the effect of severely curtailing most

certifying agents' ability to comply with the Act's requirement of employing people with sufficient expertise to implement the applicable certification program. We believe that 12 months is a sufficient period to ensure that any previous commercial interest would not create a conflict of interest situation, since this time period is consistent with similar provisions governing conflict of interest for government employees.

The second provision proposed in paragraph (a)(10) of this section would similarly prohibit a certifying agent from assigning an inspector to perform an inspection of an operation in which the inspector has or has held a commercial relationship within the 12 months prior to conducting the inspection. We propose this because of the fact that many existing organic certification programs use inspectors who are neither employees nor responsibly connected parties, but who instead are independent contractors who work for multiple certifying agents. As proposed here, such inspectors would be appropriately prevented from performing inspections in which they had any conflict of interest.

In accordance with section 2116(h)(2) of the OFPA (7 U.S.C. 6515(h)(2)), the third provision proposed in paragraph (a)(10) of this section would prohibit a certifying agent and any employee, inspector, or other personnel involved in certification activities to accept payment, gifts, or favors of any kind, other than prescribed fees, from any business inspected. We would not consider a volunteer who performs services for a not-for-profit certifying agent as providing favors to any particular individual in that agency and, therefore, would not consider the certifying agent as being in a conflict of interest situation by accepting such services from volunteers. The final provision of paragraph (a)(10) of this section, proposed in accordance with section 2116(h)(3) of the OFPA (7 U.S.C. 6515(h)(3)), would prohibit a certifying agent from providing advice concerning organic practices or techniques to any certification applicant for a fee other than as part of the fees established for its accredited certification program.

Section 205.301(a)(11) would require that a certifying agent accept the certification decisions made by another USDA accredited certifying agent as equivalent to its own. We believe this provision is necessary so as to prevent certifying agents from requiring handlers to purchase only organic products originating from operations certified by the particular certifying agent, under the premise that products originating from operations certified by other certifying agents are not equivalent. Such a situation would conflict with the purposes of the Act to establish national standards for organically produced products and to facilitate interstate commerce for organically produced agricultural products.

Section 205.301(12) would require a certifying agent to refrain from making false or misleading claims about its accreditation status, the USDA accreditation program, or the nature or qualities of products labeled as organically produced. For example, a certifying agent could describe its procedure for certifying organic production methods, but it could not claim that its certification procedure offers a guarantee of product quality. We believe that this provision is needed to prevent the dissemination of inaccurate or misleading information to consumers about organically produced products, which is consistent with the purpose of the Act to assure consumers that organically produced products meet a consistent standard.

Section 205.301(a)(13) would require that a certifying agent charge only such fees to applicants for certification and operations it certifies that the Secretary determines are reasonable. This provision is consistent with section 2107(a)(10) of the OFPA (7 U.S.C. 6506(a)(10)), which requires the certification program established under the Act to provide for the collection of reasonable fees from producers and handlers who participate in such program. AMS will review the fees charged by the certifying agents when they apply for accreditation and when they submit annual reports to ensure that the fees are reasonable and that small businesses are not unduly burdened. Section 205.301(a)(14) would require a certifying agent to pay and submit fees to AMS in accordance with sections 205.421 and 205.422(b) of subpart F, in which we propose that certifying agents would be required to pay certain fees to become accredited and to maintain accreditation, and also would be required to collect National Organic Program fees from farmers and handlers to be submitted to AMS.

In section 205.301(a)(15) we propose that a certifying agent would have to comply with and implement such other terms and conditions deemed necessary by the Secretary. This provision is made in accordance with section 2116(d) of the OFPA (7 U.S.C. 6515(d)).

Paragraph (b) of this section would permit a certifying agent to establish a seal, logo or other identifying mark that could be used by farm, wild crop harvesting, and handling operations that it certifies for the purpose of denoting affiliation with that certifying agent. This provision, authorized by section 2107(a)(11) of the OFPA (7 U.S.C. 6506(a)(11)), is proposed in consideration of public input provided by many organic producers and handlers expressing their desire to identify their operations with a particular certification program. Some existing certification programs also stated that they have made a considerable investment in developing consumer recognition for their names or logos. Although we also received comments stating that the use of certifying agent seals or logos should be prohibited, we have determined that a prohibition of seals and logos is not necessary. We believe that the use of certifying agent identification to indicate affiliation with a certifying agent would provide information of value to some consumers and would not be in conflict with the purpose stated in section 2102(2) of the OFPA (7 U.S.C. 6501(2)) of assuring consumers that organically produced products meet a consistent national standard.

This proposal would require that the use of any such seal or logo not be required as a condition for receiving certification, and, thereby, its use would be optional on the part of the farmer or handler. In order to ensure that any use of a certifying agent's logo does not conflict with the purposes of the Act, proposed section 205.301(b)(2) also specifies that the agent could not require, as a condition for use of its identification mark, compliance with any farming or handling requirements in addition to those provided for in the Act and the regulations in this part. Some public input has been received suggesting that certifying agents be allowed to use their logo or seal to recognize ''additional achievements'' on the part of farmers and handlers that exceed the requirements proposed in the national organic standards. This position was not recommended by the NOSB, which instead adopted a recommendation as a policy matter that was consistent with the provisions of this section of our proposal. Our proposal would not prohibit a certifying agent from verifying that a producer or handler it certifies is meeting contractual specifications that include requirements in addition to those of the Act and the regulations. It would prohibit the use of the certifying agent's logo or seal on a label, labeling material or other market information to represent compliance with farming or handling requirements in addition to those

provided under the Act and the regulations in this part.

In accordance with section 2116(e) of the OFPA (7 U.S.C. 6515(e)), section 205.301(c) proposes three additional requirements for a certifying agent who is a private person. These requirements are that a private certifying agent must: hold the Secretary harmless for any failure on the part of the certifying agent to carry out the provisions of the Act and the regulations; furnish reasonable security, in an amount and according to terms as may be prescribed by regulation by the Secretary, for the purpose of protecting the rights of farms and handling operations certified by certifying agents under the Act and the regulations in this part; and transfer to the Secretary and make available to the applicable governing State official all records or copies of records concerning the person's certification activities in the event that the certifying agent dissolves or loses its accreditation. The amount and the type of reasonable security that must be furnished by a private certifying agent for the purpose of protecting the rights of operations certified by the agent will be the subject of future rule making by the Department.

Applying for Accreditation—Section 205.302

As provided under section 2115(b)(1) of the OFPA (7 U.S.C. 6514(b)(1)), this section instructs a private person or a governing State official who wishes to become accredited under this proposal to submit applicable documents and information, as delineated in proposed sections 205.303 through 205.305, and the fees required in section 205.421(a) of subpart F to the Program Manager of the National Organic Program. The Administrator then would determine whether the applicant demonstrates sufficient expertise and ability to fully implement the organic certification program proposed in subpart D of this part.

Information to be Submitted by an Accreditation Applicant—Section 205.303

In order to evaluate an applicant for accreditation, it is necessary to identify who the applicant is, how it may be contacted, who is responsible for conducting its operations, if it is a private person, and the extent of the certification activities it intends to conduct under the Act and the regulations. Accordingly, in this section we propose that a person seeking accreditation as a certifying agent provide certain descriptive information about its organization and intended certification activities. This includes the name of the applicant, location of its offices, and its contact numbers (telephone, fax number, and Internet address). A private person also would have to identify the individual responsible for its day-to-day operations, as required by section 2116(i) of the OFPA (7 U.S.C. 6515(i)), and its taxpayer identification number. Paragraph (b) of this section requires the applicant to submit a list of any organization units, such as chapters or subsidiary offices, including the names of contact persons, office addresses and other contact information. This information is needed in order to determine whether multiple sites are used to conduct certification activities and, if so, to evaluate whether these activities are conducted in compliance with the Act and the regulations.

In paragraph (c) of this section, we propose that the accreditation applicant specify the intended scope of its certification activities, and estimate the numbers of producers or handlers in each type of operation, such as crops, wild crops, livestock, or handling, that it expects to certify each year. This information is needed so that the Administrator may determine the types of certifications a certifying agent is qualified to conduct. This proposed provision would require an applicant that was limited in scope, such as one that intends to certify producers of only one commodity, to demonstrate only that it had sufficient capability and expertise to conduct the types and numbers of certifications that fell within its requested scope of accreditation.

Paragraph (d) of this section requests an accreditation applicant to indicate the type of entity it is (i.e., for profit private, non-profit private, or State), and to provide documentation pertaining to its legal status and organizational structure. An applicant who is a governing State official would have to submit a copy of the official's statutory or regulatory authority to conduct certification activities in that State, and a private person would have to submit information about its status and organizational purpose, such as articles of incorporation, by-laws, ownership or membership provisions, and the date of establishment. This type of documentation is generally maintained on file by an organization, and would be required to assist the Administrator in verifying that the purposes of the organization are consistent with its intended activities under the Act and the regulations in this part.

Paragraph (e) of this section would require an applicant to submit a list of all the States where it currently conducts and intends to conduct certification activities. This information would be required so that the Administrator could determine whether a certifying agent who conducts or intends to conduct certifications in more than one State is knowledgeable of any additional requirements of an approved State program, if applicable, as provided under section 2108(b) of the OFPA (7 U.S.C. 6507(b)).

Evidence of Expertise and Ability to be Submitted by an Accreditation Applicant—Section 205.304

Sections 2115(b)(2) and 2116(a) of the OFPA (7 U.S.C. 6514(b)(2) and 6515(a)) require that a private person or a governing State official seeking accreditation as a certifying agent have sufficient expertise in organic farming and handling techniques and be able to fully implement the applicable organic certification program established under the Act. This section accordingly requests that an applicant for accreditation submit information and documents that demonstrate such expertise and ability. Paragraph (a) of this section requests information concerning personnel used by the applicant to conduct certification activities. The first item requested in this proposed paragraph is a description of the applicant's policies and procedures for training, supervising, and evaluating personnel. This information is needed for the Administrator to determine whether the applicant is providing sufficient oversight over personnel involved in certification activities to ensure compliance with the Act and the regulations in this part. The second item requested in this paragraph is the names and functions of all personnel intended to be used in the certification operation, including all parties responsibly connected to the applicant, administrative staff, certification inspectors, and members of certification review and internal evaluation committees. This information may include the job title or position of each person and a description of the organic certification functions they will perform. This information would enable the Administrator to determine that the applicant has sufficient personnel to perform the certification activities for which it seeks accreditation, and whether it has a sufficient number of inspectors to implement the certification program, as required under section 2116(b) of the OFPA (7 U.S.C. 6515(b)).

The third item in proposed paragraph (a) of this section requests the submission of more descriptive

information about the qualifications, such as past experience, training, and education in organic farming and handling, of each of the applicant's inspectors and persons designated to review or evaluate certification applicants. This proposal would provide the Administrator with the information needed to evaluate the qualifications of inspectors and review personnel when determining whether the applicant possesses the requisite expertise in organic farming and handling techniques.

Although inspector qualifications would receive careful scrutiny by the Secretary, we have not proposed the specific types of training and experience a certification inspector must possess. We have determined through consultation with experienced organic inspectors that such provisions would not be feasible because of the variability of expertise needed for the types of operations to be inspected. Furthermore, current organic inspectors differ widely in terms of their background, training and experience, as well as in their relationship to existing certification programs. For example, current organic inspectors may be seasonal employees of a private certifying agent, full-time State employees who conduct inspections for several State regulatory agencies, or independent contractors used by several certifying agents, and the expertise required in each case would differ significantly. We also are aware of at least one existing association that accredits independent professional organic inspectors according to criteria consistent with the requirements of our proposed certification program; we would consider an inspector's receipt of such accreditation when we evaluate the inspector's qualifications.

The final item in paragraph (a) of this section would request a description of any training measures the accreditation applicant has provided or intends to provide to its personnel in organic farming and handling and in the skills needed to ensure compliance with the Act and the regulations in this part. This information would enable us to determine whether the applicant would take measures to ensure that its personnel maintain adequate levels of expertise and are able to fully implement the certification program.

Paragraph (b) of proposed section 205.304 delineates the information that we propose an applicant for accreditation must submit concerning its administrative policies and procedures. We have determined that this information is needed to evaluate whether the applicant is able to fully implement the proposed certification program and to meet the general responsibilities and requirements proposed in section 205.301. The first item in this paragraph would request a description of the procedure to be used by the applicant to evaluate certification applicants and issue certificates. This information might, for example, include copies of any forms to be used to record inspection visit results and other information about certification applicants. This information would be used by the Administrator to determine that an accreditation applicant has adequate procedures in place to properly evaluate the eligibility of a farmer or handler to receive certification for their operations.

The second item in this paragraph requests information about the applicant's procedures for reviewing whether operations that it will certify are in compliance with the Act and the regulations in this part and for reporting violations to the Secretary and the applicable governing State official. Sections 2112(a) through (c) of the OFPA (7 U.S.C. 6511(a) through (c)) require certain testing to be done to assist in enforcement of the Act. We have addressed and discussed these provisions in sections 205.430 through 205.432 of subpart F. The information requested in paragraph (b)(2) of this section would help the Administrator determine whether an applicant would be able to comply with these requirements. This information also would assist in determining whether the applicant would be able to comply with the requirement in section 2120(d) of the OFPA (7 U.S.C. 6519(d)) that a certifying agent immediately report any violations of the Act to the Secretary or the governing State official, if applicable.

The third and fourth items proposed in paragraph 205.304(b) request a description of procedures the applicant would use to comply with the recordkeeping and confidentiality provisions proposed in sections 205.301(a)(8) and (9), in accordance with sections 2116(c) and (g) of the OFPA (7 U.S.C. 6515(c) and (g)). This information would be used to evaluate an applicant's ability to maintain records of its activities under the Act for 10 years, maintain strict confidentiality of its records with respect to its clients' business information, and allow representatives of the Secretary and the governing State official access to these records, as required under the Act.

Section 2107(a)(9) of the OFPA (7 U.S.C. 6506(a)(9)) requires that a certification program provide for public access to certification documents and laboratory analyses that pertain to certification. The fifth item proposed in section 205.304(b) accordingly requests that an accreditation applicant submit a description of its procedures for making certain information available to the public upon request. This information includes a list of all the operations it has certified, effective dates of certification, organic products produced by each certified operation, and the results of laboratory analyses for residues of pesticides and other prohibited substances. This information would have to be made available for certifications conducted up to ten years prior to receipt of the request. As proposed here, the policies and procedures described also would provide for public access to other non-confidential business information as permitted by the producer or handler and approved by the Secretary. This provision would permit a certifying agent to disclose to the public other non-confidential information about its clients' production practices if permitted to do so by the client and approved by the Secretary.

Paragraph (c) of proposed section 205.304 requests a description of the applicant's policies and procedures for the collection and disbursement of funds, and documents that identify anticipated sources of income, including all fees to be collected from producers and handlers in accordance with the requirements proposed in section 205.301(a)(15) of this subpart and section 205.422(a) of subpart F. This information is needed to determine whether the applicant is charging reasonable fees to its clients, and whether it has sufficient income to submit the required fees proposed in section 205.421. This information also would help the Administrator determine that certification decisions were not influenced by the concern for their financial impact on the certifying agent and to review an applicant's anticipated revenue sources for other potential conflicts of interest, such as fees charged on the basis of the sale of organic products by certified operations.

Paragraph (d) of section 205.304 requests information about policies and procedures to be implemented by the applicant to prevent conflicts of interest. Conflict of interest requirements are proposed in section 205.301(a)(10) in accordance with section 2116(h) of the OFPA (7 U.S.C. 6515(h)). This proposal would request information concerning any food and agriculture-related business interests of the applicant's personnel, as well as the business interests of immediate family members, so that the Administrator may

determine whether conflicts of interest may exist.

Some accreditation applicants currently may be conducting organic certification activities under State laws or private programs. Paragraph (e) of this section accordingly provides for the optional submission of information about certification activities currently conducted by these applicants. This information could include a list of all farms and handling operations currently certified by the applicant, and copies of inspection reports and certification documents for representative farms or handling operations certified by the applicant during the previous year. An accreditation applicant who previously has undergone a process of accreditation or evaluation of its organic certification activities, such as might be performed by a private accreditation body, also could submit any information concerning such a process conducted within the previous year. We believe that documentation of a previously conducted independent evaluation of the applicant's expertise and organizational capability would be helpful in determining whether the certifying agent is qualified and prepared to comply with the Act and the regulations. Although we would not expect an applicant for accreditation to have been complying with the requirements of the Act and the regulations in this part prior to becoming accredited, these documents would be valuable as an indication of the applicant's prior experience in evaluating organic farming and handling operations and of its ability to implement the proposed certification program. Finally, because we recognize that an applicant may possess other information that is relevant to the Secretary's decision whether to approve an accreditation, we propose in paragraph (f) of this section that an applicant for accreditation could submit any other information the applicant believes may support the Secretary's evaluation of its request for accreditation.

As previously discussed, an applicant for accreditation may be a newly formed organization that intends to begin conducting certifications after it is accredited, or it may be a certification organization that currently exists. Based on a review of currently existing certification programs, we believe that all the information requested in sections 205.303 and 205.304 should be readily available to any person or governing State official who is eligible for accreditation under the Act and the regulations in this part and is applicable to both existing and newly formed organizations preparing to perform certification activities under the National Organic Program or an approved State program. We also believe that all of the information we are proposing to require in sections 205.303 and 205.304 is essential to enable the Administrator to make a determination concerning approval of an application for accreditation.

Statement of Agreement To Be Submitted by an Accreditation Applicant—Section 205.305

In this section we propose that an applicant for accreditation would have to submit a statement of agreement along with the information and documents delineated in sections 205.303 and 205.304. Paragraph (a) of this section delineates seven provisions to which a private person or governing State official seeking accreditation must agree. Two provisions of this agreement would be to carry out the provisions of the Act and the regulations in this part and to implement and carry out any other terms and conditions that the Secretary determines appropriate, both of which are required by section 2116(d) of the OFPA (7 U.S.C. 6515(d)). It should be noted that this agreement would encompass all the general requirements proposed under section 205.301, including the provision repeated here that a certifying agent accept a certification decision made by another USDA accredited certifying agent as equivalent to its own.

The remaining four provisions to which an accreditation applicant would have to agree would state the requirements proposed in sections 205.301(a)(5), (a)(6), (a)(12), and (a)(13). These provisions are that the applicant agrees to: refrain from making false or misleading claims about its accreditation status, the USDA accreditation program for certifying agents, or the nature or qualities of products labeled as organically produced; conduct an annual performance review for each inspector to be used and implement measures to correct any possible defects in compliance with the Act and the regulations in this part identified in each review conducted; have an annual internal evaluation review conducted of its certification activities and implement measures to correct any possible defects in compliance with the Act and the regulations in this part identified in each review conducted; and pay and submit fees to AMS in accordance with sections 205.421 and 205.422(b) of subpart F of this part.

Paragraph (b) of this section provides for certain agreements that would apply only to certifying agents who are private persons, as provided for in section 2116(e) of the OFPA (7 U.S.C. 6515(e)), and as proposed in section 205.301(c) as general requirements for accreditation. These provisions are that a private certifying agent must agree to hold the Secretary harmless for any failure on the part of the certifying agent to carry out the provisions of the Act, and also must furnish reasonable security for the purpose of protecting the rights of participants in the applicable organic certification program. We also have proposed, in accordance with section 2116(c)(3) of the OFPA (7 U.S.C. 6515(c)(3)), that a private certifying agent agree to transfer to the Secretary and make available to the applicable governing State official all records or copies of records concerning the person's certification activities in the event that the certifying agent dissolves or loses its accreditation.

Approval of Accreditation—Section 205.306

In this section we propose that if the Administrator determines that an applicant has submitted all of the information and the statement of agreement proposed in sections 205.303 through 205.305, has paid the required fee as proposed in section 205.421(c) of Subpart F, and meets or is capable of meeting the general requirements for accreditation as proposed in section 205.301, the Administrator would notify the applicant in writing that its request for accreditation has been approved. We also provide for the Administrator to consider information obtained from a site evaluation visit, as proposed in section 205.309, in making this determination. The written notice of approval of accreditation would state the area(s) for which accreditation was given and the effective date of the accreditation. A private person also would be notified of the amount and type of security determined by the Administrator that would be needed to protect the rights of farming and handling operations certified by such certifying agent, in accordance with section 2116(e)(2) of the OFPA (7 U.S.C. 6515(e)(2)).

We have received public input expressing concerns about granting accreditation to applicants prior to conducting a site evaluation and a peer review process. However, we believe that the procedure proposed here is appropriate for several reasons. First, we believe that the document review process proposed here is sufficiently rigorous to permit a well-founded assessment of the applicant's capabilities and qualifications. In cases

where the application documentation reveals possible concerns about the applicant's expertise and ability to implement the proposed certification program, our proposed section 205.309 would authorize us to conduct a preliminary site evaluation visit. Our proposal would allow all eligible certifying agents, both existing and newly formed, to receive accreditation in a timely manner and would avoid conferring an advantage on those certifying agents for whom we complete the initial site evaluation and peer review process before those of competing certifying agents. We further believe that conducting a site evaluation of a newly established certifying agent before it had begun any certification activities might not contribute information that would be useful for our evaluation. Previously existing certifying agents also would need time to make adjustments in their operations to comply with the National Organic Program regulations.

Finally, section 2107(a)(1)(A) of the OFPA (7 U.S.C. 6506(a)(1)(A)) requires that any product sold as organic be produced and handled by a certified operation; this provision of the Act cannot be implemented until certifying agents have been accredited by AMS. We have received considerable public input that the OFPA should be implemented as quickly as possible. A proposal that would require full site evaluations and peer reviews to be conducted prior to granting accreditation would further delay implementation of the Act.

Denial of Accreditation—Section 205.307

In section 205.307 we propose the procedure for denying an application for accreditation. Paragraph (a) provides that, if there was reason to believe, based on a review of the information specified in sections 205.303 through 205.305, that an applicant for accreditation is not able to comply, or is not in compliance, with the requirements of the Act and the regulations in Part 205, including the general requirements proposed in section 205.301, the Administrator would provide a written notification of non-compliance to the applicant, as proposed in section 205.315(a). The notification would be sent by certified mail to the accreditation applicant, and would state any deficiencies in the ability of the applicant to comply with the Act and the regulations that the Administrator believes exist, the evidence on which the notification is based, and a date by which the deficiencies must be corrected.

In section 205.307(b) we propose that, following the correction of deficiencies identified in the notification issued in accordance with paragraph (a) of this section, the applicant could submit a new application for accreditation to the Administrator. The new application would have to include documentation of actions taken by the applicant to correct the deficiencies delineated in the notification of non-compliance.

If an accreditation applicant who receives a notification pursuant to paragraph (a) of this section does not correct the deficiencies identified within the time specified in the notice of non-compliance, paragraph (c) of this section would require that the Administrator institute proceedings to deny accreditation.

Maintaining Accreditation—Section 205.308

This section proposes that, in order to maintain its accreditation, a certifying agent must continue to satisfy the general requirements of section 205.301 of this subpart throughout the duration of its accredited status, and must pay the required fees in accordance with the provisions proposed in sections 205.421 and 205.422(b) of subpart F.

Site Evaluations—Section 205.309

This section of our proposal would require AMS to conduct a site evaluation of each certifying agent's operation initially, and at least once every 5 years thereafter, to examine its operations in order to evaluate the agent's compliance with the Act and the regulations. A site evaluation to determine compliance may include an examination of the certifying agent's facilities, records, procedures and activities conducted under the Act and the regulations set forth in Part 205. Although the Act does not specifically require that site evaluations be conducted, we concur with the recommendations made by the NOSB that such a process is necessary for the Secretary to maintain adequate oversight of the activities of accredited certifying agents under the Act and the regulations in this part. This procedure is integral to other accreditation programs that we reviewed, and is analogous to the annual on-site inspection that is required of all operations that are certified under the Act, as provided for in section 2107(a)(5) of the OFPA (7 U.S.C. 6506(a)(5)).

This proposal provides that the Administrator would arrange and conduct the site evaluations to verify compliance with the Act and the regulations in this part. In order to verify the certifying agents's compliance, the Administrator might conduct visits to selected farm, wild crop harvesting, and handling operations that have been certified by the agent. We anticipate that the operations to be visited might be chosen in consultation with the agent and as might be determined necessary by the Administrator to verify the agent's compliance with the regulations. A site evaluation report would be prepared which described the observations made about the certifying agent's compliance with the Act and the regulations in this part, including its performance of certification activities.

We have received some public input suggesting that we use peer reviewers, as provided for in section 2117 of the OFPA (7 U.S.C. 6516), in the site evaluation process. We have not provided for peer reviewers to participate in site evaluations. We believe that the use of peer reviewers to conduct site evaluations is unnecessary and could pose an excessive burden on the certifying agents, because the use of persons other than a single AMS evaluator would increase the costs of conducting site evaluations, due to additional travel and per diem expenses, and could delay site evaluations due to the need to accommodate the peer reviewers' scheduling constraints. Furthermore, AMS personnel will be sufficiently qualified and prepared to perform the site evaluations.

Paragraph (a) of this section also provides for a site evaluation of a newly accredited certifying agent to be conducted within a reasonable time after the date on which the certifying agent's notice of approval of accreditation is issued, provided that the agent has conducted sufficient certification activities under the Act and the regulations upon which the Administrator may base an evaluation. We expect to confer closely with newly established certifying agents prior to scheduling an initial site evaluation to determine that they have performed enough certifications on which to base the evaluation.

We proposed in paragraph (b) of this section that a site evaluation of an accreditation applicant or a certifying agent's operation and performance may be conducted by the Administrator at any time to determine compliance under the Act and the regulations in this part. For instance, site evaluations of the operations of a certifying agent requesting renewal of accreditation would be conducted under this proposal as part of the renewal process, which we propose in section 205.314(b) to occur

every five years. However, as proposed in section 205.309(b), site evaluations could be conducted whenever the Administrator determined that one was necessary to evaluate whether the certifying agent's operations and performance are in compliance with the Act and the regulations. Thus, although accreditation would have to be renewed every five years, a site evaluation could occur more often than every five years. We believe that the frequency of site evaluations needed to properly oversee the activities of certifying agents would likely be higher than once every five years in the initial few years after implementation, but that a five year period may be a reasonable interval of time for conducting site evaluations of established accredited certifying agents. This proposal would give us the flexibility to conduct site evaluations based on an assessment of the previous performance of the certifying agent and the need to oversee the agent's certification activities. Comments as to the impacts of this proposed provision on certifying agent operations are invited.

Additionally, this section would give the Administrator the authority to conduct an additional site evaluation prior to the approval of accreditation, as needed to verify whether an accreditation applicant can comply with the general requirements of section 205.301. We also believe it is essential to be able to conduct a site evaluation at any time that circumstances warrant a site visit to ensure the integrity of the organic certification program. For example, a site visit may be necessary if we receive a significant number of substantiated complaints from clients or the public about the performance of a certifying agent.

Peer Review Panel—Section 205.311

Section 2117 of the OFPA (7 U.S.C. 6516) provides for the establishment of a peer review panel to assist the Secretary in evaluating applicants for accreditation. This section of our proposal accordingly delineates the function, composition, duties, and the meeting and reporting procedures for the peer review panel. In section 205.311(a) we are proposing that a peer review panel be required to review the accreditation status of a certifying agent after AMS has conducted a site evaluation for confirmation or renewal of accreditation, as proposed in sections 205.309(a) and 205.314(b) of subpart E, respectively. This section would require the Administrator to consider the reports received from each individual member of a peer review panel when making a determination whether to confirm the accreditation of a certifying agent, pursuant to section 205.312, or when making a determination whether to renew the accreditation of a certifying agent, pursuant to section 205.314(b). We are also proposing that the Administrator could choose to convene a peer review panel at any time for the purpose of evaluating a certifying agent's activities under the Act and the regulations. This provision would provide flexibility for the Administrator to seek recommendations from peer reviewers at other times when it may be necessary to evaluate a certifying agent's compliance with the Act and the regulations.

In paragraph (b) of this section we propose that the Administrator establish a pool of peer review panel members to perform a review of any certifying agent for which an initial or renewal site evaluation has been conducted, pursuant to proposed section 205.309. We anticipate that a notice calling for candidates for the peer review panel pool would be published in the **Federal Register** shortly after publication of the final rule. Candidates would be requested to submit a letter to the Program Manager of the National Organic Program requesting appointment to the peer review panel pool, stating in the letter their name and address, qualifications, and a disclosure of any association with any person who is or who may become an accredited certifying agent, which may constitute a conflict of interest, such as being a responsibly connected party of a certified operation. Candidates accepted for this pool would be notified by the Administrator and could continue to serve until otherwise notified. As the need arose for additional members of the pool, the Administrator would publish an announcement to that effect in the **Federal Register**.

Section 2117(b) of the OFPA (7 U.S.C. 6516(b)) provides for the peer review panel to consist of no less than three persons who have expertise in organic farming and handling methods, and for at least two of the panelists to be other than USDA or approved State program personnel. This proposal is consistent with these requirements. Section 205.311(b) of this proposal calls for the Administrator to convene a three to five member panel from the pool of peer reviewers. Each panel would include one member from AMS as a permanent member, who would be responsible for presiding over any proceedings to ensure that they are conducted in accordance with AMS policy. Under the scheme proposed here, personnel from an approved State program could be included as an additional panel member on a panel that consisted of at least four members. Our proposal would keep the panel to a minimum size so as to minimize costs, but would permit sufficient numbers of persons with organic production and certification expertise to participate in the accreditation process.

In paragraph (b)(2) of this section we propose that each convened peer review panel include no less than one member who possesses sufficient expertise, as determined by the Administrator, in the areas of accreditation delineated in the notice of approval of accreditation, as proposed in section 205.306(a), for each certifying agent whose operations and performance are to be reviewed. This approach would allow for the selection of panelists whose expertise matches the characteristics of the particular certifying agents under review. For example, a panelist with a background in organic processing and manufacturing practices, but who was unfamiliar with organic mushroom production, would not be used to review a certifying agent whose scope of certification included only mushroom producers.

We propose in paragraph (b)(3) of this section to prohibit the selection of a peer reviewer who was associated with a certifying agent being reviewed in a manner that would constitute a known or perceived conflict of interest, as determined by the Administrator. We believe that to ensure the integrity of our proposed program we must take measures to ensure that any recommendations provided by peer reviewers are not influenced by the possibility of a financial interest in the outcome of the Administrator's determination.

Some public input we received suggested that we include representatives of consumer, environmental and other public interest groups as members of the peer review panel as a means of having broader public involvement in the oversight of certifying agents. The Act requires that persons who possess the necessary technical expertise in organic production and handling practices evaluate the performance of certifying agents. Persons representing consumer, environmental, or other similar groups who possess the necessary expertise could be eligible to participate in the peer review panel if they file a letter with the Administrator, and are determined to meet the criteria established to become a peer review panel member.

We propose in section 205.311(c) that each peer review panel member would individually review the site evaluation

report prepared by the Administrator and any other information that may be provided by the Administrator relevant to confirming or renewing the accreditation status of a certifying agent. Each peer review panel member would provide an individual report to the Administrator regarding the certifying agent's ability to conduct and perform certification activities under the regulations. We also propose in this section that each peer reviewer would have to agree to treat the information received for review as confidential, and could not release, copy, quote, or otherwise use material from the information received, other than in the report required to be submitted. This provision is needed in order to protect the confidentiality of business information received by USDA concerning the operations of certifying agents, as well as any information about operations certified by those agents.

In section 205.311(d) we propose that the Administrator could decide to convene a meeting or conference call of a peer review panel, if necessary, for evaluating the accreditation status of a certifying agent, or if it is requested by at least one peer review panel member. This section also would permit the Administrator to include in this meeting or conference call the certifying agent being evaluated, or a representative of the agent, for the purpose of providing additional information. This provision is proposed so that members of the peer review panel may have the opportunity to request clarification of any aspect of the agent's activities described in the site evaluation report. However, any meeting or conference call would have to be conducted in a manner that will ensure that the actions of panel members are carried out on an individual basis with any opinions and recommendations by a member being individually made.

Section 205.311(d) would additionally permit copies of peer review panel reports to be provided to the certifying agent, who could then submit a written response for consideration by the Administrator. This provision would permit a certifying agent to submit clarifications or additional information bearing on its activities under the Act and the regulations, whether or not a meeting or conference call of the peer review panel was conducted.

In the final paragraph of this section we propose that each peer review panelist would individually provide a written report to the Administrator. This report would contain the panelist's recommendations concerning confirmation or renewal of accreditation for each certifying agent reviewed, and a description of the basis for each recommendation. These recommendations might, for example, include conditions that the reviewer believes should be included in the notice of confirmation of accreditation, as proposed in section 205.312, or the notice of renewal of accreditation, as proposed in section 205.314(c).

We are soliciting comments on our proposed accreditation provisions, including whether alternative provisions should be promulgated. In particular, we would like comments on whether the peer review process for accreditation should occur when the initial application for accreditation is made, as opposed to when accreditation is confirmed after a site visit.

Confirmation of Accreditation—Section 205.312

In this section we propose that the Administrator would make a determination whether or not to confirm the accreditation of a certifying agent. This determination would occur following review of a site evaluation report and the reports from the peer reviewers. If the Administrator determined that the certifying agent was in compliance with the Act and the regulations, including the general requirements proposed in section 205.301, the Administrator would issue the agent a written notice of confirmation of accreditation status. Confirmation notices, therefore, would not be issued to any certifying agent who was not complying with the Act and the regulations, which would include payment to AMS of all fees owed by the certifying agent and the furnishing of reasonable security by a private certifying agent. The confirmation notice would include any terms or conditions that must be addressed by the certifying agent before the certifying agent submits a request for renewal of its accreditation. After confirmation, a certifying agent's accreditation would be effective until such time that the certifying agent fails to renew accreditation in accordance with section 205.314, or the accreditation was suspended or terminated pursuant to section 205.316, or the certifying agent voluntarily ceased its certification operations.

Denial of Confirmation—Section 205.313

In section 205.313 we propose the procedure to be followed to deny confirmation of accreditation to a certifying agent. Paragraph (a) of this section provides that, if the Administrator has reason to believe, based on a review of the information specified in sections 205.303 through 205.305, and the results of a site evaluation and reports submitted by the peer review panel, pursuant to sections 205.309 and 205.311(e), respectively, that the certifying agent is not complying with the requirements of the Act and the regulations in this part, including the general requirements for accreditation proposed in section 205.301, the Administrator would provide a written notification of non-compliance to the applicant in accordance with section 205.315(a) of this subpart.

In paragraph (b) of this section we propose that if a certifying agent who receives a notification pursuant to paragraph (a) of this section corrects the deficiencies identified within the time specified in the notice of non-compliance, and submits documentation supporting actions taken by the certifying agent to correct the deficiencies, as proposed in section 205.315(a)(3), the Administrator would issue a notice of confirmation of accreditation to the certifying agent, pursuant to section 205.312(a). Paragraph (c) of this section would permit the Administrator to institute proceedings to deny confirmation of accreditation if the certifying agent does not correct the deficiencies identified in the notice of non-compliance.

Continued Accreditation—Section 205.314

We propose in paragraph (a) that an accredited certifying agent shall submit certain information annually to the Administrator on or before the anniversary date of the issuance of the notice of confirmation of accreditation. This information would be reviewed by the Administrator to determine whether the certifying agent was maintaining its accreditation status in accordance with proposed section 205.308 of subpart E and to assess the need to conduct a site evaluation visit. We believe that an annual process of reviewing information submitted by certifying agents is necessary so that the Administrator can be informed of any changes in the procedures and personnel used by certifying agents, who also must annually review the certification of producers and handlers, in accordance with section 2107(a)(4) of the OFPA (7 U.S.C. 6506(a)(4)).

We propose that the accredited certifying agent annually submit four kinds of information in addition to the proposed fees required in section 205.421(a) of subpart F. First, the agent would have to update the general information and evidence of expertise

and ability submitted in the previous year, pursuant to sections 205.303 and 205.304 of subpart E. Second, if an agent is requesting any changes in its areas of accreditation, as delineated in section 205.300, the additional information needed to support the request for a change in the certifying agent's scope of certification activities would be submitted. Third, we propose that the certifying agent submit a report that describes the measures the agent has implemented in the previous year, and any measures it plans to implement in the coming year, to address the conditions delineated by the Administrator in the most recent notice of confirmation of accreditation or renewal of accreditation. The certifying agent also would be required to describe the corrective actions implemented and intended to be implemented by the certifying agent in response to the most recent inspector performance reviews and the required internal evaluation review of the agent's operations.

Section 2115(c) of the OFPA (7 U.S.C. 6514(c)) provides for accreditation to be granted for a period not to exceed five years. Section 205.314(b) would accordingly require that an accredited certifying agent request renewal of accreditation on or before the fifth anniversary of the issuance of the notice of confirmation of accreditation, and of each subsequent renewal of accreditation. The Administrator would then review the information contained in the annual reports submitted in accordance with paragraph (a) of this section, along with the results of the site evaluation(s) performed in accordance with section 205.309 and peer review panel reports submitted in accordance with section 205.311(e), in order to determine whether the certifying agent was still in compliance with the Act and the regulations.

Because section 2115(c) of the OFPA (7 U.S.C. 6514(c)) stipulates that accreditation may be granted for a period of time ''not to exceed'' 5 years, we considered proposing a period of time less than 5 years before a certifying agent would be required to renew its accreditation. Our intent in considering a lesser period of time for renewal of accreditation would be to establish an adequate level of oversight activity to ensure that the certifying agent is in compliance with the Act and the regulations. However, we believe that an adequate level of oversight necessary to ensure compliance with the Act and the regulations would be provided by the requirement proposed in section 205.314(a) that certifying agents submit annual updates to the Administrator. Additionally, as proposed in sections 205.309(b) and 205.311(a)(2) of this subpart, the Administrator could decide to conduct an additional site evaluation and peer review of a certifying agent's activities at any time. We also believe that a requirement that accreditation be formally renewed more frequently than every five years might pose an undue burden on certifying agents. Comment concerning the length of time for which accreditation should be granted is invited.

We propose in section 205.314(c) that the Administrator would issue a notice of renewal of accreditation after having made the determination that the certifying agent continues to comply with the Act and the regulations in this part. The notice of renewal, as in the case of the notice of confirmation of accreditation, would specify any terms and conditions that would have to be addressed by the certifying agent, and the time within which the terms and conditions must be satisfied. In paragraph (d) of this section, we propose that if the Administrator determines that there is reason to believe that the certifying agent is not in compliance with the Act and the regulations, the Administrator would issue a notification of non-compliance to the certifying agent, as proposed in section 205.315.

Notification of Non-Compliance With Accreditation Requirements—Section 205.315

In section 205.315 we propose the procedure for the Administrator to notify an accredited certifying agent, or an applicant for accreditation, of deficiencies in its compliance, or ability to comply, with the Act and the regulations, including the general requirements proposed in section 205.301, and provide an opportunity to correct any deficiencies identified. In paragraph (a) of this section we propose that a written notification of non-compliance would be sent by certified mail to the place of business of the accreditation applicant or the certifying agent, as applicable. The notification would contain the following information: a description of each deficiency in compliance and each violation of the Act and the regulations in this part that the Administrator has reason to believe has occurred; the evidence on which the notification is based; and the date by which the accreditation applicant or the certifying agent, as applicable, must correct each deficiency and each violation delineated in the notification, and submit documentation to the Administrator to support such corrections.

In paragraph (b) of this section we propose the procedure to be followed if an accredited certifying agent does not provide documentation to the Administrator, pursuant to paragraph (a)(3) of this section, that is adequate to demonstrate that each deficiency in compliance and each violation has been corrected by the date indicated in the written notification. This paragraph would permit the Administrator to conduct an additional site evaluation, as provided for in section 205.309, to determine whether the certifying agent is complying with, or has violated, the Act or the regulations, including the general requirements proposed in section 205.301.

In section 205.315(c)(1) we propose that the Administrator would notify the certifying agent in writing of a determination that the agent was complying with the Act and the regulations, if, following receipt of a notification of non-compliance as proposed in paragraph (a) of this section, the certifying agent submitted the requisite documentation of corrective actions taken, and if, following any additional site evaluation conducted pursuant to paragraph (b) of this section, the Administrator determined that the certifying agent was fully complying with the Act and the regulations. This paragraph further provides in paragraph (c)(2) of this section that, if the Administrator has reason to believe that the certifying agent is not in compliance with the Act and the regulations in this part, the Administrator may institute a proceeding to suspend or terminate the certifying agent's accreditation.

Termination of Accreditation—Section 205.316

Section 2116(j)(1) of the OFPA (7 U.S.C. 6515(j)(1)) provides for the suspension of a certifying agent's accreditation if the Secretary determines that the certifying agent is not properly adhering to the provisions of the Act and the regulations. This provision of the OFPA would permit the Secretary to suspend the accreditation of either a governing State official or a private certifying agent. Section 2120(e) of the OFPA (7 U.S.C. 6519(e)) provides for the loss of accreditation by a private certifying agent if the certifying agent violates the provisions of the Act and the regulations, or if the agent falsely or negligently certifies any farming or handling operation that does not meet the requirements for a certified operation under the certification program established by the Act. In section 205.316 we accordingly propose that the accreditation of any certifying

agent could be suspended, but that only a private certifying agent could have its accreditation terminated.

In section 205.316(a) we propose that if the Administrator has reason to believe that an accredited certifying agent or a person responsibly connected with an accredited certifying agent has ceased to comply with or has violated the Act or the regulations, including the general requirements proposed in section 205.301, then the Administrator would initiate the process proposed in section 205.315 by issuing a notification of non-compliance. However, as proposed in paragraph (b) of this section, if the Administrator has reason to believe that an accredited certifying agent or a person responsibly connected with an accredited certifying agent has wilfully violated the Act and the regulations in this part, including the general requirements proposed in section 205.301, the Administrator may institute a proceeding to suspend or terminate the accreditation of the certifying agent pursuant to the Rules of Practice 7 CFR 1.130, *et seq.* The Rules of Practice provide for the formal filing of a complaint by the Secretary, an opportunity for the certifying agent to answer the complaint, a procedure for holding a hearing, and a procedure for further appealing an adverse decision following any hearing that is held. A final determination to suspend the accreditation would not be made, therefore, until the certifying agent had received notice and an opportunity to be heard.

In section 205.316(c) we propose that a private person or a governing State official whose accreditation as a certifying agent is suspended or terminated would have to cease any certification activity in each area of accreditation and in each State for which its accreditation is suspended, or in the case of a private person whose accreditation is terminated, cease all certification activities conducted under the Act and the regulations. The person or governing State official whose accreditation was either suspended or terminated would have to transfer to the Secretary, and make available to the applicable governing State official, all records concerning its certification activities that were suspended or terminated. This would enable the Secretary to promptly determine whether farms or handling operations certified by such certifying agent may retain their organic certification. This provision is consistent with section 2116(j)(2) of the OFPA (7 U.S.C. 6515(j)(2)), which requires the Secretary to promptly determine whether farms or handling operations certified by a certifying agent who has lost accreditation may retain their organic certification.

As proposed, a certifying agent who was determined to be in compliance with all the requirements for certifying certain types of operations, such as farms, but no longer had the requisite expertise to certify other types of operations, such as handling operations, could have its accreditation suspended only in the area of handling operations. Additionally, if a certifying agent was determined not to be complying with the additional requirements of an approved State program, but was otherwise complying with the Act and the regulations, this proposal would permit its accreditation to be suspended only in that state.

The Act provides for the Secretary or a governing State official to suspend the accreditation of a private certifying agent. However, we have not included a provision for the governing State official to suspend accreditation in this proposal because the Act only provides for the Secretary, not the governing State official, to grant (or reinstate) accreditation. Therefore, we believe that the authority to remove an accredited status must remain with the Secretary. In the event that a private certifying agent was to cease complying with, or to violate, the provisions of an approved State program, we would expect the applicable governing State official to present this information to the Secretary for appropriate action.

In section 205.316(d) we propose that a private person or a governing State official whose accreditation as a certifying agent is suspended by the Secretary under this section could at any time submit a new request for accreditation, pursuant to section 205.302. The new request for accreditation would have to be accompanied by documentation that demonstrates that appropriate corrective actions to comply with and remain in compliance with the Act and the regulations, including the general requirements proposed in section 205.301, have been taken. This might, for example, entail payment of outstanding accreditation fees or evidence that sufficient funds have been provided for the required reasonable security to protect the rights of certified farms and handling operations.

In accordance with section 2120(e)(2) of the OFPA (7 U.S.C. 6519(e)(2)), we propose in section 205.316(e) that a private person whose accreditation as a certifying agent is terminated would be ineligible to be accredited as a certifying agent under the Act and the regulations for a period of not less than three years following the date of such determination.

Subpart F—Additional Regulatory Functions

State Programs

Section 2104(a) of the OFPA (7 U.S.C. 6503(a)) requires the Secretary to establish an organic certification program for producers and handlers of agricultural products. Section 2104(b) of the OFPA (7 U.S.C. 6503(b)) requires that the Secretary permit each State to implement a State organic certification program for producers and handlers of organic products that have been produced using organic practices as provided for in the OFPA. Section 2108(b) of the OFPA (7 U.S.C. 6507(b)) provides for State programs under certain circumstances to contain more restrictive requirements, than in the program established by the Secretary, for the production or handling of agricultural products sold or labeled as organically produced in such State and for the certification of farms and handling operations. Section 2103(20) of the OFPA (7 U.S.C. 6502(20)) defines a State organic certification program as one that meets the general requirements for an organic program set forth in section 2107 of the OFPA (7 U.S.C. 6506), is approved by the Secretary, and is designed to ensure that a product that is sold or labeled as organically produced is produced and handled using organic methods. Under a State program, an accredited State official and/or private certifying agent would perform certification activities for producers and handlers according to the procedures and requirements established in subpart D; such agents are discussed in subpart E (Accreditation) of this proposal. As discussed in subpart E, it is not necessary for a State to have a State program to be accredited as a certifying agent, and vice versa.

In order for a State program to be approved as meeting the general requirements set forth in section 2107 of the OFPA (7 U.S.C. 6506), the program must have regulatory provisions that meet the following requirements: (1) provide that an agricultural product to be sold or labeled as organically produced must be produced only on certified organic farms and handled only through certified organic handling operations in accordance with the requirements of the Act; and be produced and handled in accordance with such program; (2) require that producers and handlers desiring to participate under such program establish an organic plan as provided for in section 2114 of the OFPA (7 U.S.C.

6513); (3) provide for procedures that allow producers and handlers to appeal an adverse administrative determination under the Act; (4) require each certified organic farm, certified organic wild crop harvesting operation, and each certified organic handling operation to certify to the governing State official, on an annual basis, that such farmer or handler has not produced or handled any agricultural product sold or labeled as organically produced except in accordance with this title; (5) provide for annual on-site inspection by the certifying agent of each farm, wild crop harvesting, and handling operation that has been certified under this title; (6) require periodic residue testing by certifying agents of agricultural products that have been produced on certified organic farm and handled through certified organic handling operations to determine whether such products contain any pesticide or other nonorganic residue or natural toxicants and to require certifying agents, to the extent that such agents are aware of a violation of applicable laws relating to food safety, to report such violation to the appropriate health agencies; (7) provide for appropriate and adequate enforcement procedures; (8) protect against conflict-of-interest as specified under section 2116(h) of the OFPA (7 U.S.C. 6515(h)); (9) provide for public access to certification documents and laboratory analyses that pertain to certification; (10) provide for the collection of reasonable fees from producers, certifying agents and handlers who participate in the program; and (11) require such other terms and conditions as may be determined by the Secretary to be necessary.

Once a State program is approved, farm, wild crop harvesting, and handling operations in that State that wish to sell, label, or represent their product as organically produced would have to be approved as a certified operation under the State program. The determination as to whether or not a farm, wild crop harvesting, or handling operation meets a State's certification requirements would be made by a certifying agent accredited by the USDA under the National Organic Program. The accredited certifying agent who would make this determination either would be a private person who has been accredited by the USDA, or a governing State official who has been accredited by the USDA.

In order to be certified under the State program, an operation would have to meet all of the State certification requirements. However, these certification requirements, as discussed previously, must reflect the requirements of the National Organic Program. Certified operations in States that have their own program would be producing products that are represented as organically produced in accordance with the requirements of the National Organic Program, which will have been included in the State program in accordance with section 2107 of the OFPA (7 U.S.C. 6506). Therefore, the provisions set forth in our proposal in part 205 would be applicable to operations that are located in States that have their own programs since these provisions would be included in programs that are approved by the Secretary. It is important that all interested persons provide comments on the provisions of our proposed rule since these are the provisions that would be required to be included in a State program in accordance with section 2108 of the OFPA (7 U.S.C. 6507). If an operation is located in a State that does not have an approved State program, that operation would carry out its operations only under the requirements of the National Organic Program.

States may have requirements that are in addition to those of the National Organic Program if they are approved by the Secretary and meet the statutory criteria for approval. This means that if a State has received approval from the Secretary for requirements in its program that are in addition to those of the National Organic Program, all certified farm, wild crop harvesting, and handling operations that operate in that State would have to comply with these additional requirements that have been approved. However, one State would not be allowed to require farm, wild crop harvesting, and handling operations in another State to comply with any additional requirements that have been approved by the Secretary for the former State.

Requirements of State Programs—Section 205.401

As required in section 2104(b) of the OFPA (7 U.S.C. 6503(b)), we propose in section 205.401(a) to permit a State to establish a State program for producers and handlers of agricultural products within the State that have been produced and handled using organic methods as provided by the OFPA and its implementing regulations.

The accreditation of a governing State official to conduct certification activities of farms and handling operations is specifically authorized in section 2115(a) of the OFPA (7 U.S.C. 6514(a)) and is set forth in subpart E of our proposal. As reflected in our proposal, the approval by the Secretary of a State organic program would be a separate decision from the determination of whether a governing State official who applies to be a certifying agent should be accredited. Although the Act provides for the accreditation of a governing State official as a certifying agent, it does not require that the certification of producers and handlers operating in a State that has an approved program be performed solely by the State certifying agent. Rather, the required certification of producers and handlers operating under an approved State program can be conducted by either the State certifying agent or a private certifying agent. Producers and handlers of organic products operating in a State that chooses to implement a State program, but which does not obtain accreditation for a governing State official, would be certified by private certifying agents.

In accordance with section 2108(a) of the OFPA (7 U.S.C. 6507(a)), we would require in section 205.401(b) that a State program meet the requirements of the regulations in part 205 and the Act, including the general requirements for an organic program listed in section 2107(a) of the OFPA (7 U.S.C. 6506 (a)). These requirements would require: that an agricultural product that is to be sold or labeled as organically produced be produced and handled only on certified operations in accordance with the Act and the regulations in part 205; that participating producers and handlers establish an organic plan; that an annual on-site inspection by the certifying agent of each certified farm and handling operation be done; that reasonable fees be collected from producers, certifying agents and handlers who participate in such program; that public access to certification documents and laboratory analyses that pertain to certification be established; that procedures that allow producers and handlers to appeal an adverse administrative determination be established; that appropriate and adequate enforcement procedures and conflict-of-interest provisions be established; and that periodic residue testing by certifying agents of agricultural products that have been produced on certified organic farms and handled through certified organic handling operations be done.

As provided for in section 2108(b)(1) of the OFPA (7 U.S.C. 6507(b)(1)), we propose in section 205.401(c) that a State program that meets the requirements of regulations in part 205 and the Act also could contain more restrictive requirements governing the certification of organic farming and

handling operations and the production and handling of organic agricultural products than those in USDA's National Organic Program. However, in accordance with section 2108(b)(2) of the OFPA (7 U.S.C. 6507(b)(2)), we propose that any additional requirements must further the purposes of the Act and the regulations in part 205; not be inconsistent with the Act and the regulations in part 205; not be discriminatory towards agricultural commodities organically produced in other States in accordance with the Act and the regulations in part 205; and not become effective until approved by the Secretary.

One concern expressed by private certification organizations in response to the NOSB draft recommendations was that a State that had its own program also might implement its own accreditation program for certifying agents, and require that a certifying agent be accredited by the State, as well as by the USDA. In this regard, section 2115(a) of the OFPA (7 U.S.C. 6514(a)) requires that both a governing State official and a private person be accredited solely by the Secretary and, thus, provides for the Secretary alone to establish and implement an accreditation program for existing and new certifying agents. Accordingly, a State cannot implement an accreditation program for certifying agents.

Another concern expressed by private certification organizations was that a State might attempt to prevent them from certifying farm and handling operations in that State by charging a high, unreasonable fee to them for registering with the State as a certifying agent or for purchasing a business operating license. As part of the approval process for a State organic certification program, we would review any fees established by States with respect to the requirements in section 2107(a)(10) of the OFPA (7 U.S.C. 6506(a)(10)) for the collection of reasonable fees from certifying agents and in section 2108(b)(2)(A) of the OFPA (7 U.S.C. 6507(b)(2)(A)) that additional State program requirements further the purposes of the Act. In order for the State program to be approved, the fees established would have to be determined to be reasonable.

We know that some current requirements in existing State organic programs vary from our proposed regulations. We also expect State program proposals to include requirements we have not considered. Therefore, in section 205.401(c) of the proposed regulation we do not include a list of additional requirements which might be determined to be in compliance with the Act's criteria for approval of additional requirements. Rather, each State program's proposal would be reviewed to ensure that it complies with the provisions of section 205.401(c) (1) through (4) which are the Act's criteria for approval of additional requirements.

Approval of State Programs and Program Amendments—Section 205.402

In section 205.402(a), we propose that a governing State official must submit to the Secretary any proposed State program, or proposed substantive amendments to a State program, and must obtain the Secretary's approval prior to implementation of the program and any amendments to it. In section 205.402(b), we propose that the Secretary would notify the governing State official within six months after receipt of the program or any proposed change to the program as to whether the program or substantive amendment is approved or disapproved. This is consistent with the provisions of section 2108(c) of the OFPA (7 U.S.C. 6507(c)). After receipt of the notice disapproving a State program, the governing State official may reapply at any time.

Review of Approved Programs—Section 205.403

In section 205.403, we propose that the Secretary would review a State program not less than once every five years from the date of initial approval of the State program. This is consistent with section 2108(c)(1) of the OFPA (7 U.S.C. 6507(c)(1)), which requires this be done. The State program would be notified within six months after initiation of the review, whether the program is approved or disapproved, and if disapproved, the reasons for the disapproval.

Fees

Section 2107(a)(10) of the OFPA (7 U.S.C. 6506(a)(10)) authorizes the collection of reasonable fees from farmers, handlers, and certifying agents who participate in the national organic certification program. In sections 205.421 through 205.424 we propose the fees we intend to charge to reflect the cost of the services provided by the USDA. The statute provides that the fees collected be deposited into the general fund of the U.S. Treasury. Accordingly, the agency must obtain appropriated funds to operate this program.

In our efforts to assemble the economic and demographic information needed to develop the details for assessing and collecting reasonable fees, we consulted extensively with both State and private certifying agencies. We received assistance from the USDA Economic Research Service, as well as from other programs within AMS, in identifying various options for the assessment of fees in this program. Additionally, we determined the number of certifying agents and their chapters that are currently operating in the United States and conducted an analysis to determine the number of organic farms and handling operations that were operated in the United States for 1994 (Dunn, Julie Anton. 1995. ''Organic Food and Fiber: An Analysis of 1994 Certified Production in the United States.'' U.S. Department of Agriculture, Agricultural). We also examined an analysis of data collected by the California Department of Food and Agriculture concerning registered organic farms and handling operations in that state (California Department of Health Services. 1995. ''Report on the Registration of California Organic Processed Food Firms.'' Sacramento: State of California Marketing Service). Based on these analyses, we estimate that 44 certifying agents may apply for accreditation and that 30 chapters or subsidiary offices would be included in their applications. We further estimate that 4,000 farmers and 600 handlers would be eligible for certification.

We estimate that it will cost approximately $1,000,000 in the first full year of operation to operate our program when it is implemented. These costs include approximately $644,000 for the salaries and benefits of 12 staff members, which would be comprised of a program manager, 8 marketing specialists, and 3 support staff personnel, and approximately $356,000 for general administrative overhead and operating costs, such as printing, training, travel, NOSB meetings, equipment, supplies, rent, heat, and communications. A description of the services that would be provided to program participants by the NOP staff is presented in the applicable supplementary information sections on fees that follow.

Based on 1994 workload data, we estimate that $500,000 of this $1,000,000 will be collected from farms, handling operations, and wild crop harvesting operations, $389,000 from applicants for accreditation and accredited certifying agents, and $112,000 from private foreign certification programs, for a total of $1 million. Note, actual billing may be somewhat greater due to inflation since 1994. We have included a chart at the end of the fee discussion that illustrates the fees that will be charged. The fees in this rule are based upon estimates of the cost to AMS of providing each of the

services described, and may be adjusted in future years based upon program experience and projected or actual changes in the cost of operations (e.g. inflation).

We again would like to point out that, in addition to the fees that certified operations would be required to submit to USDA, farm, wild crop harvesting, and handling operations that want to be certified under the Act, and those that have been so certified, also would need to pay certifying agents, whether State or private, for the certification services provided by them. These certification services would include review of an initial application for certification, annual review of updated information, review of an organic plan and updates to the organic plan, and conducting annual inspections both before and after certification is granted. As part of the accreditation process for certifying agents that we propose in subpart E, USDA would require certifying agents to submit for approval the fees they intend to charge to operations for which they are going to conduct certification activities. If the intended fees submitted are deemed reasonable, as required in section 2107(a)(10) of the OFPA (7 U.S.C. 6506(a)(10), USDA will approve the fees schedule submitted.

The AMS, as set forth in section 205.423 of this proposal, also would be charging fees to foreign organic certification programs, other than those operated by a foreign country itself. These fees would cover the costs AMS will incur in determining whether these programs have requirements equivalent to those of the AMS program. These fees are authorized under the Independent Offices Appropriations Act (31 U.S.C. 9701 *et seq.*).

Fees for Accreditation Applicants and Accredited Certifying Agents—Section 205.421

Section 2107(a)(10) of the OFPA (7 U.S.C. 6506(a)(10)) provides for the collection of reasonable fees from certifying agents who participate in the program. This section discusses the fees proposed to be paid by applicants who are initially applying for accreditation and fees to be paid by accredited certifying agents.

In section 205.421(a)(1) we propose that each applicant for accreditation, and each accredited certifying agent submitting an annual report, would be required to submit to the Administrator a non-refundable fee of $640. This fee would cover the AMS cost to review and evaluate the material required to be submitted to become accredited or to continue accreditation. We believe it is appropriate to establish a fee structure to recover the cost of this service.

We estimate that it will take an average of 16 hours to review each application for accreditation, or each annual report, for certifying agencies that do not have chapters or subsidiary offices. Our estimation is based upon knowledge gained from examining current accreditation programs as well as our general experience and knowledge gained from other AMS programs that involve the submission and review of applications. We estimate that the hourly cost for AMS personnel to handle and review the applications and annual reports will be $40 per hour. This is the average hourly cost for AMS to conduct a program of this nature. Based on an hourly fee of $40 per hour and an estimated time of 16 hours for handling and review, we estimate the cost to evaluate accreditation applications and annual reports to be $640 per applicant or accredited certifying agent, as applicable. Therefore, we are proposing that each applicant of this type (i.e., single, non-multi-unit organization) seeking accreditation or submitting an annual report pay a $640 non-refundable fee at the time of submission of application for accreditation or an annual report.

Assessing a uniform fee for accreditation application and submission of an annual report is based on our knowledge gained from other AMS programs and current accreditation programs being operated. We are not proposing a fee for this activity based on the size and complexity of the certifying agent because we believe that differences in the size and complexity of the certifiers would result in an insignificant difference in the amount of time needed to review applications and annual reports.

We further propose in section 205.421(a)(2) that an additional application or annual report review fee of $160 be charged for each chapter or subsidiary office of an accreditation entity. This additional fee of $160 is the cost we estimate AMS will incur for the additional 4 hours we estimate will be necessary to review the additional information required to be submitted for each part of a multi-unit organization. We estimate the hourly cost will be $40, the same average hourly cost we propose for reviewing application information and annual reports submitted by applicants and accredited certifying agents. Based on our estimate that 44 certifying agents with 30 chapters or subsidiary offices may apply for accreditation, we estimate that we may collect $32,960 annually from fees associated with reviewing accreditation applications and annual reports.

In paragraph (b) of section 205.421, we are proposing the fees that certifiers would be assessed for a site evaluation visit conducted by AMS. The fees that would be assessed for a site evaluation visit would be any travel and per diem expenses incurred as a result of the conduct of site evaluations, as well as the hourly costs to conduct the site evaluation. Site evaluations are proposed in section 205.309(a) of subpart E to be performed by AMS within a reasonable time after issuance of a notice of approval of accreditation to verify compliance of the certifying agent with the Act and the regulations. In section 205.309(b), we propose that a site evaluation also may be conducted at any time to determine an applicant's or certifying agent's compliance with, or quality of performance under, the Act and the regulations. Additionally, we propose in section 205.314(b) that a site evaluation would occur every 5 years as part of the process of renewal of accreditation for an accredited certifying agent.

We estimate that the hourly cost of performing site evaluations will be $40, calculated to the nearest fifteen minute period, for each AMS evaluator conducting the site evaluation visit, including travel time to and from the evaluator's duty station. This is the average cost for AMS to conduct evaluations of this nature. We anticipate that the time necessary for AMS to conduct a site evaluation, and therefore the total cost to be assessed a certifying agent for a site evaluation, will vary between certifying agents due to differences in their size, complexity, and other similar factors. The fee we propose in paragraph (b) of this section would be a direct assessment on applicants and accredited certifying agents for the hourly costs and travel and per diem expenses associated with conducting our site evaluations. As proposed, an applicant or accredited certifying agent would be required to pay these fees within 30 days following the date the bill is issued. As proposed in section 205.424 of this subpart, the fees submitted as payment for the costs of the site evaluation would be required to be submitted by certified check or money order made payable to AMS and sent to the address specified on the bill.

AMS estimates that an average site evaluation would require 5 days and would cost a certifying agent $3,500. The $3,500 expense would result from the hourly costs for staff time necessary to prepare for and conduct the site evaluation, and the related travel and per diem expenses, such as air fare, car

rental, lodging, meals, and incidental expenses. We estimate that of the $3,500 cost, approximately $1,100 would result from related travel and per diem expenses and approximately $2,400 would result from the time (hourly costs) necessary to prepare for and conduct the site evaluation. We anticipate that of this $2,400 hourly cost, $1,600 would result from the time spent by one AMS evaluator being on site for 5 days (40 hours) at $40 per hour, and $800 would result from the 20 hours we estimate will be needed to prepare for the evaluation, write an evaluation report, and communicate the results of the evaluation process to the certifying agent. As previously noted, the actual cost for each site evaluation will vary based on the length of the evaluation, due to such factors as the certifying agent's location, size and complexity.

Based on our estimate that 44 certifying agents with 30 subsidiary offices or chapters may be accredited, we expect to receive $259,000 annually from fees associated with site evaluations. We note that under our scheme for site evaluations proposed in section 205.309 of subpart E, a site evaluation visit may not be performed each year for every certifying agent and every subsidiary office or chapter. However, also under our scheme, a site evaluation may be performed more than once each year for a certifying agent or its subsidiary office or chapter, when determined necessary by the Administrator to determine the certifier's compliance or evaluate its performance. For the purpose of estimating fees to be collected annually from certifying agents, we assumed that for the intital year that site visits are performed, a site visit would be performed for each certifying agent and each subsidiary office or chapter. Thereafter, a site visit of a certifying agent, subsidiary office, or chapter may be performed more or less often than annually. The previously discussed number of 12 NOP staff members estimated to be needed to conduct program activities would be adjusted accordingly with an increase or decrease in workload.

A different model which we considered for the site evaluation fee, but which we are not proposing, was based on categorizing certifiers according to their size and assessing them a fee for a site evaluation based solely on this factor. In such a scenario, for example, a certifying agent who certified less than 50 clients might be assessed a fee equivalent to 3 days of work while a certifying agent that certified more than 500 clients would be assessed a fee equivalent to 30 days of work. We decided not to propose this model after determining that site evaluation costs would depend on factors other than the size of the certifying agent's operation, such as the complexity of the certification activities conducted by the certifier, the location of the certifier's facilities, and the certifier's organizational structure.

In paragraph (c) of this section, we propose that an administrative fee of $2,000 be paid by a certifying agent upon the initial granting of accreditation, upon the granting of confirmation of accreditation, and upon the submission of each subsequent annual report. Under the regulatory scheme we are proposing, a person who wants to be an accredited certifying agent first would have to apply for and be granted accreditation, then would have to have this accreditation confirmed, and then would have to submit annual reports to provide current information.

Our $2,000 fee is based upon the yearly cost we estimate we would incur for providing various administrative services to accredited agents which would cover the administrative costs discussed below. Since we expect that confirmation of accreditation would occur approximately 12 months after the granting of initial accreditation, and that submission of an annual report would occur subsequently one year later, we propose to assess a $2,000 fee for each of these yearly periods so that the fees charged will reflect the cost of the services provided. We also are proposing that, upon the granting of initial accreditation, upon the granting of confirmation of accreditation, and upon the submission of an annual report, a certifying agent would pay an additional fee of $300 for each chapter or subsidiary of the agent's organization. Our fees here are based on knowledge gained from the review of currently existing accreditation programs such as the International Organization for Standardization program and the International Federation of Organic Agricultural Movements program.

Our administrative fees would cover costs for the operation of our accreditation program that are not covered by paragraphs (a) and (b) of section 205.421. The $2,000 fee would cover day-to-day program activities and operational and overhead costs for single-site accreditation entities. Examples of operational and overhead costs are utilities, rent, supplies, printing, equipment purchases, and communication. Program activities include: develop and provide guidance on the NOP production, handling and certification requirements; compile, copy, and mail site evaluation reports; conduct peer review panel meetings or conference calls; and enforce the program. The $300 fee for each additional chapter or subsidiary would cover the additional time for program activities, and additional overhead and operating expenses, we believe can be attributed to, and which are necessary for, our providing the previously identified services to chapters and subsidiary offices. Based on our estimate that 44 certifying agents with 30 subsidiary offices or chapters may be accredited, we expect to receive $97,000 annually from administrative fees.

Payment of the non-refundable fees would be required 30 days from the date of issuance of a notification of approval of accreditation and notification of confirmation of accreditation, and with the submission of each annual report.

An alternative model for the administrative fee that we considered would be to base the administrative fee on the types of certifications performed by certifiers. For example, certifying agents who certify farmers and handlers trading in international markets, or who certify processors producing multi-ingredient products, would pay a higher administrative fee. The underlying assumption is that certifying agents who provide more complex services to farmers and handlers utilize more program resources and derive greater benefit from the National Organic Program than other certifiers. In evaluating this alternative, we considered that the AMS costs to administer this model would be considerably higher than the costs associated with the uniform administrative fee model we are proposing.

Fees for Certified Operations—Section 205.422

In order for AMS to carry out the OFPA, and in turn fulfill the mission of AMS, certain program activities must be undertaken. We used the time required to accomplish these program activities as the basis for determining the amount of fees charged to each certified farm or handling operation. Program activities that would have to be carried out include: financial and staff support for the NOSB; compliance and enforcement; provision to the public of information about the program; attendance at meetings, conferences and trade fairs conducted both inside and outside the United States to convey information about the program; and other general and administrative functions. To accomplish these activities, we would need to pay various

fixed costs, including costs for overhead (utilities, rent and communications), equipment costs for computers and copying machines, and staff expenses, which would include salaries, benefits and travel costs.

In this section, we propose the fees to be collected from certified farmers, wild crop harvesters, and handlers. The total cost for the program activities which we estimate that AMS will provide for farm, wild crop harvesting, and handling operations certified under the National Organic Program is $500,000, one half of the annual projected program cost of $1,000,000. We estimate that approximately 40 percent of the $500,000, or $200,000, would be needed to carry out program activities concerned with the issues of certified farms and wild crop harvesting operations, and that approximately 60 percent of the $500,000, or $300,000, would be needed to carry out activities concerned with the issues of certified handling operations.

The fee we propose is based upon dividing our estimated cost for program activities for farmers and harvesters, and handlers, respectively, among the estimated 4,000 farmers and 600 handlers we believe will participate in our program. Accordingly, we propose that each farmer and wild crop harvester would pay $50 annually, or $200,000 divided by 4,000 farmers. We propose that each handler would pay $500 annually, or $300,000 divided by 600 handlers. We used this manner to determine the fee that will be charged each farmer, each wild crop harvester, and each handler because almost all of the activities that would be carried out for each group, i.e., for the certified farmers and wild crop harvesters, and for the certifier handlers, will be equally applicable to each farmer and harvester, and each handler. It would not be practical to apply any of the possible small portion of activities that remain to individual farmers, wild crop harvesters, and handlers separate and apart from the overall costs to each group. We request any additional information that would improve the estimates of farmer, wild crop harvesting, and handler participation, so that a more accurate estimate of these fees can be developed.

In our consideration of farmer, harvester, and handler fees, we determined that the allocation of a higher percentage of costs to handlers' issues (60 percent), as opposed to farmer/harvester issues (40 percent), would be appropriate. We anticipate that handling issues, especially such issues as enforcement; record keeping and auditing; labeling, including use of the USDA seal and State seals on different product lines; equivalency of imported organically produced ingredients; and maintenance of the National List of non-agricultural ingredients, will require greater program staff time and operating expenses than farming and harvesting issues.

In developing our proposed fee structure, we considered proposing a fee structure that did not include a fee collected directly from producers and handlers, but that instead assessed fees on certifying agents to cover the total $1,000,000 cost of the National Organic Program. We considered this alternative because we recognize that any fee charged to a certifying agent ultimately will be incorporated into the fee that the certifying agent charges the producer and handler for certification services. However, we did not propose this alternative because we consider our proposal that would directly assess producers, handlers and certifying agents for services we provide to them to better represent an appropriate and practical method of providing transparency and distributing overall program costs among the universe of potential participants and beneficiaries.

We also considered developing a sliding scale of fees to be charged to producers and handlers, based on the size and complexity of their operations. For example, a farmer or handler who sells $5,000 annually of agricultural products would be charged proportionately less than a farmer or handler whose sales exceed $5,000. However, we are proposing fees that are related directly to the costs of services provided by AMS, rather than to such factors as a participant's sales volume or income from the sale of organically produced products, because we estimate that a scheme for charging fees based on factors such as sales volume or income is a more complex scheme and would require additional recordkeeping burden and administrative costs for producers and certifiers.

As discussed previously, we have made a distinction between services provided to farmers/harvesters as a group and handlers as a group. However, we have not made a distinction within each group for assessing fees to farms and harvesting operations, and handling operations, based on their size, complexity, or other similar factor. Because we are concerned about the impact of our proposed uniform fee structure on smaller farms and smaller handling operations, we are requesting public comment on the impact of our proposed structure on smaller operations. Additionally, we are request public comment on alternative methods for calculating fees, including, but not limited to (1) the actual cost of providing services to each individual or operation, and (2) the size of the operation or value of the product(s) for which service is being provided.

Fees for Import Programs—Section 205.423

We are proposing in section 205.423(a) that foreign organic certification programs, other than those operated by a foreign country itself, pay a fee of $40 per hour plus any travel and per diem costs that might be incurred to establish the equivalency of the program. This is the average hourly cost for AMS to conduct a program of this nature. Before equivalency is final and effective for foreign certification programs for which payment for determination of equivalency is required, payment must be made to AMS.

In section 205.423(c) we are proposing that the fees must be submitted by certified funds made payable to AMS and paid within 30 days following the date of notification of AMS of its intent to approve the program subject to receipt of the fees. Fees should be submitted according to the instructions provided by AMS. As indicated in the proposal, no program would be approved until all required fees are paid.

Payment of Fees and Other Charges—Section 205.424

In section 205.424(a) we propose that all fees be submitted in the form of a certified check or money order made payable to AMS and sent to the address identified in the bill issued for these fees. We also propose, in accordance with section 3717 of the Debt Collection Act of 1982 as amended (31 U.S.C. 3717), that all fees required to be submitted would incur interest, penalties, and other costs in the case of late payment of the fees due. In addition, failure to submit payment, or a late payment, of a bill owed to AMS may result in the loss of, or failure to obtain, certification, accreditation, or equivalency status.

Fees for application for accreditation or for the review of an annual report must be included with the application or with the annual report. Without payment of the fee, AMS will not act on the application. Fees for site evaluations and administrative fees that are not paid or that are received late may cause AMS to refrain from issuing, confirming, or continuing accreditation. Certification of farm, wild crop harvesting and handling operations is dependent upon

the payment of the fees. Import programs, other than those operated by a foreign country itself, would not be acknowledged as being equivalent until payment is made to cover the AMS cost for the establishment of equivalency.

ESTIMATED NATIONAL ORGANIC PROGRAM FEES

[Based on 1994 data]

Description	Certification agents (est. 44)	Subsidiary offices or chapters (est. 30)	Handlers (est. 600)	Farmers (est. 4,000)	Private foreign certification programs (est. 16)
Application or Annual Report Fee	$640/Annually	$160/Annually	$0	$0	$0
Administrative Fee	2,000/Annually	300/Annually	500/Annually	50/Annually	0
Site Evaluations	3,500*	3,500*	0	0	0
Equivalency Review	0	0	0	0	7,000
Total Estimated Fees**	270,160	118,800	300,000	200,000	112,000

* The $3,500 estimated cost is based on a 5 day site evaluation computed at $40 per hour plus travel and per diem costs. The actual cost will vary based on the length of the evaluation. Initial site evaluations would be performed approximately 12 months after initial granting of accreditation, after which site evaluations will be conducted at least once every 5 years and as necessary to determine compliance. The $40 per hour rate, which is used in many of the National Organic Program fees, is based upon the average hourly cost for AMS to conduct a program of the nature.

** The estimated numbers of farmers, handlers and certifiers are based on data collected in 1994; therefore, the total estimated fees may not represent the number of farmers, handlers and certifiers who might participate in the National Organic Program after implementation. We also estimated the number of equivalency reviews conducted for private foreign certification programs to be approximately 16 per year. An equivalency review may cost more than accreditation of a certification agent because it would include an analysis of the following: production standards, criteria for allowing certain substances to be used, certification requirements, enforcement measures and accreditation process, and may include a site visit to the foreign program headquarters. We request information that would improve the estimates of farmer, handler, certifier and private foreign program participation so a more accurate estimate of these fees can be developed.

Compliance Review and Other Testing

Sections 205.430 through 205.433 contain our proposed provisions for compliance review, preharvest tissue testing, application of a prohibited substance due to emergency pest or disease treatment, and the reporting of the application of a prohibited substance. Section 2107(a)(6) of the OFPA (7 U.S.C. 6506(a)(6)) requires the establishment of a program under which certifying agents would conduct periodic residue testing of agricultural products from certified farms and handling operations and report any violations of food safety laws which they are aware of to the appropriate health agencies. Section 2112 of the OFPA (7 U.S.C. 6511)) requirements in regard to preharvest tissue testing and testing of products sold or labeled as organically produced also are addressed in the proposal. Additionally, the proposal addresses the provisions of section 2107(b)(2) of the OFPA (7 U.S.C. 6506(b)(2)) regarding the application of prohibited substances on certified organic farms that occur as the result of a Federal or State emergency pest or disease treatment program.

Compliance Review—Section 205.430

This proposed section would implement the residue testing requirements of sections 2107(a)(6) of the OFPA (7 U.S.C. 6506(a)(6)) and 2112(a) and (b) of the OFPA (7 U.S.C. 6511(a) and (b)). Section 2107(a)(6) of the OFPA (7 U.S.C. 6506(a)(6)) requires a certifying agent to undertake periodic residue testing of products from certified farms and handling operations to determine if such products contain a detectable residue level of a pesticide or other prohibited substance and to report violations of food safety laws, if found, to the appropriate health agencies. Section 2112(a) of the OFPA (7 U.S.C. 6511(a)) requires the Secretary, the applicable governing State official or the certifying agent to utilize a system of residue testing to test products sold or labeled as organically produced to assist in enforcement of this title. Section 2112(c) of the OFPA (7 U.S.C. 6511(c)) further requires the Secretary, applicable governing State official and the certifying agent to conduct an investigation of a certified farm or handling operation when the residue test of a product from the certified farm or operation shows a detectable residue level of a pesticide or other prohibited substance, to determine if the organic certification program has been violated, and may require the producer or handler of such product to prove that any prohibited substance was not applied to such product.

In paragraph (a) of this section we propose that a certifying agent would arrange with inspectors to conduct periodic sampling for the purpose of testing organically produced agricultural products from farm, wild crop harvesting, and handling operations certified by that agent to enforce the Act and the regulations set forth in this part. Certifying agents would instruct inspectors when to sample organically produced products on certified farm, wild crop harvesting, and handling operations. We do not propose that this sampling would be performed at each annual inspection. We believe that the frequency of sampling should be adequate to monitor compliance with the section 2105(2) of the OFPA (7 U.S.C. 6504(2)) provision that prohibits the sale or labeling of agricultural products as organic that are produced on land to which any prohibited substances, including synthetic chemicals, have been applied during the 3 years immediately preceding the harvest of the agricultural products, but yet not so frequent as to be unnecessary or burdensome to the certified operations. We have proposed testing not less frequently than every 5 years. However, we specifically request comment on whether this period of time is appropriate. As required by the Act, we also propose to require certifying agents, to the extent that such agents are aware of a violation of applicable laws relating to food safety, to report such violation to the appropriate health agencies (Federal, State, and local).

In paragraph (b) of this section, which addresses the compliance provisions of section 2112(a) of the OFPA (7 U.S.C. 6511(a)), we propose that the Secretary or governing State official would arrange for sampling and residue testing of organically produced products at any point of production or distribution, and may require the certifying agent to conduct sampling and residue testing of organically produced products originating from operations certified by that agent. These product samples could be taken from any point in the

distribution chain, from the farm to the retail store. We believe that taking samples from any point in the distribution chain would assist in maintaining the integrity of organically produced agricultural products after they leave the certified operation and would provide consumers with added assurance that no pesticide or other prohibited substance was used in producing or handling the products.

The results from all sampling and testing would be used to determine if an agricultural product contains any detectable residue level of a pesticide or other prohibited substance. We define the detectable residue level in proposed section 205.2 of subpart A as being the level that is 5 percent or greater of the established EPA tolerance level for the product that was tested, provided that if there is no tolerance level established, but an action level has been established, the detectable residue level will be the action level established by FDA for the product tested. The EPA tolerance levels, expressed in terms of parts of a pesticide residue per million parts of the food (ppm), refer to the amount of a pesticide residue that may legally be present in or on a raw agricultural commodity, as set forth in section 408(a) of the Federal Food, Drug and Cosmetic Act (FFDCA) (21 U.S.C. 346(a)), or present in processed food or feed under the terms of the food additive regulation as set forth in section 409 of the FFDCA (21 U.S.C. 348). Tolerance levels for raw agricultural commodities are published in 40 CFR Part 180; for processed foods, in 40 CFR Part 185; and for processed feed, in 40 CFR Part 186. The FDA action levels, which are based on recommendations received from the EPA, also are expressed in terms of parts of a pesticide residue per million parts of the food and are used to regulate the occurrence of very low levels of pesticide residues that result from pesticides that are persistent in the environment and for which EPA does not establish a tolerance level. The FDA action levels are published in FDA's Compliance Policy Guide (CPG), Chapter 5 (Foods), subchapter 575, section 575.100. We have based our compliance testing proposals on the EPA tolerances and the FDA action levels because they represent the best data available on what are appropriate and safe residue levels.

In our proposal, we have determined that the detectable residue level for a prohibited substance would be at 5 percent of the EPA tolerance for the product tested, or at the actual FDA action level for the product tested, as applicable, so as to establish a practical benchmark for determining when to conduct an investigation pursuant to section 2112(c)(1) of the OFPA (7 U.S.C. 6511(c)(1)). A practical benchmark must be low enough to provide adequate protection against the use of pesticides or other prohibited substances and yet high enough not to burden a producer or handler, and the national or applicable State program, with an investigation unless a reasonable question of non-compliance exists. Our proposed levels of 5 percent of the EPA tolerance, or at the actual FDA action level, as indicators of a detectable residue level are based upon the historical use of 5 or 10 percent of the EPA tolerance, or the actual FDA action level, by States and other certifying agents in the organic industry.

The NOSB recommended that the USDA enter into an arrangement with the Department of Health and Human Services to conduct sampling and testing of raw organic agricultural products as a part of the FDA's regulatory monitoring program of all agricultural products for pesticide residues. The NOSB suggested a similar arrangement with States that conduct their own pesticide residue monitoring programs. After implementation, we will consider these possibilities and similar arrangements with other existing pesticide residue testing programs to fulfill the proposed sampling provision set forth in paragraph (b) of this section.

In paragraph (c) in this section, we propose to require each product sample collected by an inspector representing the Secretary, a certifying agent, or applicable governing State official, as part of the compliance review, to be submitted to a laboratory facility accredited to test the commodity sampled. (Laboratory accreditation is not a part of the USDA accreditation program and is currently administered through private and independent third parties.) Each product sampled would be collected in accordance with instructions provided in subchapter 400 of the FDA Investigations Operations Manual (IOM). We have chosen the IOM because it serves as the FDA's primary guide to field investigators and inspectors on investigational policies and procedures, and thus provides for consistency in periodic and random sample collection. The analytical methods used to test each product sample to determine if an agricultural product contains a detectable residue level of a pesticide or other prohibited substance would be selected as appropriate from the FDA's Pesticide Analytical Manual (PAM) Volumes I and II, the Official Methods of Analysis of the Association of Official Analytical Chemists, or the Food Safety Inspection Service (FSIS) Residue Chemical Guidebook. We have adopted the analytical methods contained or referenced in these publications because they serve as the standard analytical methods used by the FDA, FSIS, and other laboratories to examine food and animal feed for pesticide residues for regulatory purposes. The results of such tests would be reported to the certifying agent or governing State official, as applicable, and to the Secretary.

Our proposed paragraph (c)(3) of this section would require that the Secretary, the governing State official, or the certifying agent, as applicable, inform the appropriate regulatory agency in the event a residue test level exceeded either the EPA tolerance level or the FDA action level, as applicable, for that substance. This proposal is consistent with section 2107(a)(6) of the OFPA (7 U.S.C. 6506(a)(6)), which requires reporting of violations related to food safety to the appropriate health agencies.

Paragraphs (d)(1) and (2) of this section propose the actions that would be undertaken by the Secretary after the receipt of a residue test result that indicated a detectable residue level of a prohibited substance. Our proposed paragraph (d)(1) of this section would require the Secretary, applicable governing State official, or certifying agent to conduct an investigation to determine the cause of a detectable residue level of a prohibited substance in the sample, as provided for under section 2112(c)(1) of the OFPA (7 U.S.C. 6511(c)(1)). The investigation may include a visit to the certified operation to determine whether the detectable residue level exceeds the unavoidable residual environmental contamination level for the prohibited substance at the specific certified operation.

Proposed paragraph (d)(2) of this section would implement the provision of section 2112(c)(2) of the OFPA (7 U.S.C. 6511(c)(2)) which prohibits organically produced agricultural products from being sold or labeled as organically produced if the investigation into the cause of a detectable residue level in a sample determines that the residue was the result of an intentional application of a prohibited substance or was at a level greater than the unavoidable residual environmental contamination level for the prohibited substance. The NOSB recommended that the unavoidable residual environmental contamination level be at the actual FDA action level, or not to exceed 5 percent of the EPA tolerance, as applicable. We propose instead that the unavoidable residual environmental contamination be established for each

specific site only after a product produced on that site is found to contain a detectable residue level of 5 percent of the EPA tolerance, or at the actual FDA action level, as applicable. We believe that unavoidable residual levels of contaminants in the environment vary so greatly by region, State, and site so as to render impractical the use of a uniform level. The certification eligibility of certified operations also would be better evaluated by our proposal to establish a site-specific unavoidable residual level during the investigation, rather than applying a pre-determined level. Proposed paragraph (d)(2) of this section would authorize the Administrator to institute proceedings to terminate the certification of an operation, or portion of an operation, after an investigation determined that the residue resulted from an intentional application of a prohibited substance or that the residue level exceeded the unavoidable residual environmental contamination level. The termination procedure is more fully described in section 205.219 of subpart D.

Preharvest Tissue Testing—Section 205.431

Section 2112(b) of the OFPA (7 U.S.C. 6511(b)) authorizes the Secretary, the governing State official, or the certifying agent to conduct preharvest tissue testing of any crop grown on soil suspected of harboring contaminants. We accordingly propose in paragraph (a) of this section that such a test may be conducted when the soil is suspected by the Secretary, the governing State official or the certifying agent of containing contaminants. We have defined contaminant in section 205.2 of subpart A to be a residue of a prohibited substance that persists in the environment. This pre-harvest tissue test would be conducted to determine whether the crop to be harvested contained levels of any contaminant greater than either the actual FDA action level, or EPA tolerance, as applicable, for that contaminant.

We also believe a pre-harvest tissue test could assist producers of organically grown crops raised on soil to which certain highly persistent prohibited substances were applied more than three years prior to the harvest of an organic crop to be knowledgeable of the residue levels contained in their crops. For example, any soil could potentially harbor sufficient amounts of prohibited substances, such as chlorinated hydrocarbons, that are known to causes certain types of crops, such as squash or cucumbers, to absorb enough of these contaminants to exceed established FDA action levels or EPA tolerances.

In paragraph (b) of this section, we propose that preharvest tissue samples be collected by an inspector representing the certifying agent or applicable governing State official and submitted in accordance with subchapter 400 of the FDA Investigations Operations Manual (IOM). The analytical methods used for determining if preharvest tissue samples contain a detectable residue of a pesticide or prohibited substance are identified among the methods contained or referenced in the FDA's Pesticide Analytical Manual Volume I and II or the Official Methods of Analysis of the Association of Official Analytical Chemists. This parallels the procedure for compliance testing and sampling as proposed in section 205.430(c).

Paragraph (c) of this section would require the certifying agent or the governing State official to report the results of each preharvest tissue test to the Secretary and to the appropriate health agencies if a pre-harvest tissue test result indicated that the residue level of a contaminant exceeds the EPA tolerance or the FDA action level, as applicable, for that contaminant.

The NOSB submitted recommendations addressing instances of drift of prohibited substances upon organically produced crops. The NOSB defined drift as the physical movement of prohibited pesticides or fertilizers from the intended target site onto a certified organic field or farm, or portion thereof, caused by a person who is not the certified organic producer or a person working under the direction of the certified organic producer. They recommended that agricultural products exposed to drift should not be sold or labeled as organically produced or fed to livestock on certified operations and that pre-harvest tissue tests be required to verify which crops were not drifted upon.

We have not provided in our proposal for instances of drift, or for the use of pre-harvest testing to verify portions of fields that receive drift. Although drift may be commonplace, especially in those agricultural regions where pesticide use on non-organic lands is routine and heavy, exposure to drift does not constitute use of a prohibited substance and does not affect the integrity of organically produced crops because the amount of prohibited substance to which the crops are exposed is negligible. We believe our provisions proposed in sections 205.430 and 205.431 for the testing of organically produced agricultural products, both before and subsequent to harvest, to determine residue levels and, if necessary, to conduct an investigation as to the cause of a detectable residue level, are adequate to protect the integrity of agricultural products sold or labeled as organically produced.

Emergency Pest or Disease Treatment—Section 205.432

This proposed section would address situations where certified organic farms are subject to Federal or State emergency pest or disease programs. It would, pursuant to the discretionary requirements of 2107(b)(2) of the OFPA (7 U.S.C. 6506(b)(2)), provide that a farm subject to such treatment program would not have its certification status affected, so long as certain prohibitions in the proposed regulations are complied with.

The NOSB recommended, and we agree, that land that is subject to an emergency treatment program with a prohibited substance should not be required to be withheld from production of organically produced products for a period of three years. Therefore, we are proposing that a certified farm that is otherwise in compliance with the regulations would not have its certification status affected as a result of a Federal or State emergency pest or disease treatment program, provided that the conditions stated in paragraphs (a) and (b) of this section, as applicable, are satisfied.

Paragraph (a) of this section would prohibit the sale or labeling of any crop harvested from a treated farm as organically produced if the harvested crop, or plant part to be harvested, had come in contact with a prohibited substance applied as part of the emergency program. Field observations by the producer, combined with the reporting requirements of proposed section 205.433 and the testing and sampling provisions of sections 205.430 and 205.431 would be used to determine which crops had come in contact with the prohibited substance and to monitor that they were not being sold or labeled as organically produced.

We propose in paragraph (b) of this section that any livestock that were treated with a prohibited substance as part of a Federal or State emergency pest or disease treatment program, or product derived from such livestock, could not be sold as organically produced. However, exceptions to the prohibition on the sale of treated livestock and their products as organically produced are proposed in paragraphs (b)(1) and (b)(2) of this section. In accordance with section 2110(e)(2) of the OFPA (7 U.S.C. 6509(e)(2)), we propose in paragraph

(b)(1) of this section that milk and milk products from a treated dairy animal could be sold as organically produced beginning no less than twelve months following the last treatment with the prohibited substance. Additionally, in accordance with section 2110(b) of the OFPA (7 U.S.C. 6509(b), we propose in (b)(2) of this section that offspring from breeder stock that was not in the last third of its gestation at the time of the last application of a prohibited substance could be considered as organic at the time of birth.

Reporting the Application of a Prohibited Substance—Section 205.433

Section 205.433 provides a general requirement that producers or handlers immediately notify the certifying agent of any instance of an application of a prohibited substance on their certified operations. This requirement would ensure that the certifying agent was made aware of any incident of this type, that occurs on an operation certified by them, which might affect the integrity and status of an agricultural product sold as organically produced by the operation or the status of the operation from which an agricultural product is harvested. Failure to notify the certifying agent may result in termination of certification, as provided for in section 205.219 of subpart D.

Appeals

General—Section 205.452

Section 2121(a) of the OFPA (7 U.S.C. 6520(a)) requires the Secretary to establish an administrative appeals procedure under which persons may appeal an action of the Secretary or a certifying agent that adversely affects such person or that is inconsistent with the applicable organic certification program. We accordingly propose in this section that any person subject to the OFPA who believes that he or she is adversely affected by a decision of a member of the National Organic Program staff or by a certifying official may appeal such decision to the Administrator of the Agricultural Marketing Service.

Equivalency of Imported Organic Products

Section 2106(b) of the OFPA (7 U.S.C. 6505(b)) provides that agricultural products imported into the United States may be sold or labeled as organically produced only if the Secretary determines that the products have been produced and handled under an organic certification program that provides safeguards and guidelines that are at least equivalent to the requirements of the Act. We are proposing provisions concerning equivalency and the process for establishing equivalency in accordance with this requirement.

Eligibility of Agricultural Products for Importation Into the United States—Section 205.480

Section 205.480 requires that imported agricultural products, or ingredients in products, that are to be sold or labeled as organic must have been produced and handled under an organic certification program that the Secretary has determined has safeguards and guidelines equivalent to those in the Act and our proposed regulations.

Determination of the Equivalency of Foreign Programs—Section 205.481

To provide for the importation of organic agricultural products, we propose in section 205.481 that an evaluation of a foreign organic certification program would include a review of its: standards for production and handling of agricultural products; lists of substances allowed and prohibited for use and the criteria used to establish the lists; inspection and certification requirements for farm and handling operations and oversight of certification provisions; enforcement provisions; the accreditation process and requirements for an accredited status; and any additional information deemed necessary by the Secretary to use to determine equivalency. Examples of other information that may be required to be submitted are a list of products certified by the program and copies of inspection reports used in determining certification status.

It is necessary to evaluate these elements in order to satisfy the provisions of the OFPA that foreign programs provide safeguards and guidelines at least equivalent to the requirements of the OFPA and its implementing regulations. These equivalent safeguards and guidelines should include: standards for organic farming and handling, including substances allowed and prohibited for use in the production and handling of organic products; provisions for certification of farming and handling operations; and oversight of persons and organizations who will be responsible for the certification of farm and handling operations. In addition, there should be equivalent measures provided for enforcement of any program requirements.

One example of an element that may be examined in determining equivalency is whether the program's standards for farm and handling operations incorporate, as does the Act and our proposed regulations, the principle of prevention, i.e., prevention of disease in animals, pest infestation in crops, and commingling of non-organic products with organic products in a food handling operation.

We note that farms and handling operations certified by agents operating under a foreign organic certification program that is determined to be equivalent with the USDA National Organic Program would be able to import products into the United States without the certified farm or handling operation itself having to apply for approval for importation from the USDA.

We recognize that not all organic products produced in foreign countries are produced in countries that would have established their own equivalent foreign organic certification programs. We intend that the determination of equivalency of any other type of foreign organic certification program, such as one conducted by a certifying agent that operates in a country that has not been determined to have an equivalent program, also be based on an evaluation and determination of the components set forth in section 205.481. We also are aware that the accreditation of some foreign organic certification programs may be conducted by an agency other than an agency of the government.

Process for Establishing Equivalency of Foreign Programs—Section 205.482.

In this section, we propose the process by which a foreign organic certification program may apply for a determination of the equivalency of its program with the National Organic Program, and in turn, the procedure for notification of a determination of equivalency or nonequivalency. In paragraph (a) of this section, a foreign organic certification program that wants to establish the equivalency of its organic program with the National Organic Program would submit to the Secretary a complete and accurate description of its program, including any of the laws and applicable requirements upon which the program is based and any other information requested by the Secretary.

In paragraph (b) of this section, we propose that the Secretary would make a determination of equivalency or nonequivalency and notify the foreign organic certification program of the decision. If the Secretary determines that a foreign organic certification program is equivalent to the USDA National Organic Program, we propose that the Secretary provide the foreign organic certification program written

notification of the date upon which organically produced agricultural products produced and handled under the program may be imported into the United States and labeled or sold as organic. If a foreign organic certification program has been determined by the Secretary not to be equivalent, we propose that the Secretary provide the foreign organic certification program written notification and state the basis for such determination. After receipt of such notice, the foreign organic certification program may reapply at any time.

We propose in paragraph (c) of this section that, if at any time the Secretary determines that a foreign program is not equivalent, the Secretary may withdraw the equivalency status. Termination of the equivalency status will be effective upon receipt by the foreign organic program of the notice.

Maintenance of Eligibility for Importation—Section 205.483

In order to determine if a foreign organic certification program continues to be eligible to import agricultural products into the United States that are to be sold or labeled as organic, we propose in section 205.483 that reviews of the foreign organic certification program be conducted periodically to reevaluate whether the program continues to be equivalent. The Secretary will review, as a part of the reevaluation, documents and other information related to the conduct of the foreign organic certification program, including any amendments made to the program requirements since its last evaluation. Continuance of the eligibility for importation of products produced and handled under a program would depend on the results of these reviews and the timely submissions of all documents and other information needed for the review.

List of Subjects in 7 CFR Part 205

Administrative practice and procedure, Agriculture, Animals, Archives and records, Foods, Imports, Labeling, Organically produced products, Plants, Reporting and recordkeeping requirements, Seals and insignia, Soil conservation.

For the reasons set forth in the preamble, it is proposed that Title 7, Chapter I of the Code of Federal Regulations be amended as follows:

1. Parts 205 through 209, which are currently reserved in subchapter K (Federal Seed Act), are removed.

2. A new subchapter M consisting of parts 205 through 209 is added to read as follows:

SUBCHAPTER M—ORGANIC FOODS PRODUCTION ACT PROVISIONS

PART 205—NATIONAL ORGANIC PROGRAM

Subpart A—Definitions

Sec.

Subpart B—Organic Crop and Livestock Production and Handling Requirements

Organic Crop Production Requirements

Organic Livestock Production Requirements

Organic Handling Requirements

The Use of Active Synthetic Substances, Non-synthetic Substances, Non-Agricultural (Non-organic) Substances and Non-organically Produced Ingredients in Organic Farming and Handling Operations, Including the National List of Allowed and Prohibited Substances

The National List of Allowed and Prohibited Substances

Subpart C—Labels, Labeling, and Market Information

Subpart D—Certification

Subpart E—Accreditation of Certifying Agents

Authority: 7 U.S.C. 6501–6522.

PART 205—NATIONAL ORGANIC PROGRAM

Subpart A—Definitions

§ 205.1 Meaning of words.

For the purpose of the regulations in this subpart, words in the singular form shall be deemed to impart the plural and vice versa, as the case may demand.

§ 205.2 Terms defined.

Accreditation. A determination made by the Secretary that authorizes a governing State official or private person to conduct certification activities as a certifying agent under this part.

Act. The Organic Foods Production Act of 1990, as amended (7 U.S.C. 6501 *et seq.*).

Active ingredient in any input other than pesticide formulations. Any substance, that when used in a system of organic farming or handling, becomes a chemically functional part of that system; is a labeled ingredient or food additive; or is a substance that is otherwise of significant consequence to the production, handling and integrity of an organically produced agricultural product.

Active ingredient in pesticide formulations. Any substance (or group of structurally similar substances) as specified by the EPA in 40 CFR 152.3(b), that will prevent, destroy, repel or mitigate any pest, or that functions as a plant regulator, desiccant, or defoliant, within the meaning of section 2(a) of the Federal Insecticide, Fungicide, and Rodenticide Act, as amended (7 U.S.C. 136(a)).

Administrator. The Administrator for the Agricultural Marketing Service (AMS), United States Departure of Agriculture, or the representative to whom authority has been delegated to act in the stead of the Administrator.

Agricultural product. Any agricultural commodity or product, whether raw or processed, including any commodity or product derived from livestock that is marketed in the United States for human or livestock consumption.

Agroecosystem. A system consisting of the functions, interactions, and balances of biological, hydrological, geological, and other environmental elements that are found within a given farm operation.

Allowed synthetic. A substance that is included on the National List of synthetic substances allowed for use in organic farming.

Animal drug. Any drug as defined in Section 201 of the Federal Food, Drug and Cosmetic Act, as amended (21 U.S.C. 321) that is intended for use in livestock, including any drug intended for use in livestock feed, but not including such livestock feed.

Annual seedling. A plant grown from seed that will complete its life cycle or produce a harvestable yield within the same crop year or season in which it was planted.

Area of operations. The types of operations: crops, livestock, wild crop harvesting, handling, or any combination thereof, that a certifying agent may be accredited to certify under this part.

Audit trail. Documentation that is sufficient to determine the source, transfer of ownership and transportation of any agricultural product labeled as organic or made with certain organic ingredients, or of any agricultural product identified as organic in an ingredients statement.

Biodegradable. Subject to biological decomposition into simpler biochemical or chemical components.

Biologics. All viruses, serums, toxins, and analogous products of natural or synthetic origin, such as diagnostics, antitoxins, vaccines, live microorganisms, killed microorganisms and the antigenic or immunizing components of microorganisms intended for use in the diagnosis, treatment or prevention of diseases of animals.

Botanical pesticides. Natural (non-synthetic) pesticides derived from plants.

Breeding. Selection of plants or animals to reproduce desired characteristics in succeeding generations.

Buffer area. An area located between a certified farm or portion of a farm, and an adjacent land area that is not maintained under organic management. A buffer area must be sufficient in size or other features (e.g., windbreaks or a diversion ditch) to prevent the possibility of unintended contact by prohibited substances applied to adjacent land areas with an area that is part of a certified operation.

Cation balancing agent. A mineral substance applied to the soil to adjust the ratio among positively charged (cation) nutrients on soil colloids. The major cation nutrients are calcium (Ca), magnesium (Mg), and potassium (K), and the cation micronutrients include iron (Fe), zinc (Zn), copper (Cu) and manganese (Mn).

Certification or certified. A determination made by a certifying agent that a farm, wild crop harvesting, or handling operation is in compliance with the Act and the regulations in this part, which is documented by a certificate that identifies the entity certified, the effective date of certification, and the types of agricultural products for which certification is granted.

Certification activities. Activities conducted by a certifying agent in regard to certification applicants or certified farms, handling operations and wild crop harvesting operations.

Certification applicant. A producer or handler of agricultural products who applies to a certifying agent for certification.

Certified facility. A processing, manufacturing, livestock housing or other site or structure maintained or operated to grow, raise or handle organically produced agricultural products that is part of a certified organic farm, a certified organic wild crop harvesting operation, or a certified organic handling operation.

Certified organic farm. A farm, or portion of a farm, or site, where agricultural products or livestock are

produced, that is certified by the certifying agent under the Act as utilizing a system of organic farming as described by the Act and regulations in this part.

Certified organic handling operation. An operation, or portion of a handling operation, that is certified by a certifying agent as utilizing a system of organic handling as described under the Act and the regulations in this part.

Certified organic wild crop harvesting operation. An operation, or portion of an operation, that is certified by a certifying agent as harvesting wild crops in compliance with the Act and the regulations in this part.

Certifying agent. The chief executive officer of a State or, in the case of a State that provides for the Statewide election of an official to be responsible solely for the administration of the agricultural operations of the State, such official, and any person (including private entities) who is accredited by the Secretary as a certifying agent for the purpose of certifying a farm, wild crop harvesting operation, or handling operation as a certified organic farm, wild crop harvesting, or handling operation.

Certifying agent's operation. All sites, facilities, personnel and records used by a certifying agent to conduct certification activities under the Act and the regulations in this part.

Chapter. A subsidiary organizational unit of a certifying agent that conducts certification activities in a manner consistent with relevant policies and procedures developed by the certifying agent in accordance with the Act and the regulations of this part.

Commercially available. The ability to obtain a production input in an appropriate form, quality, and quantity to be feasibly and economically used to fulfill an essential function in a system of organic farming and handling.

Commingling. Physical contact between unpackaged organically produced and non-organically produced agricultural products during production, transportation, storage or handling, other than during the manufacture of a multi-ingredient product containing both types of ingredients.

Compost. A process that creates conditions that facilitate the controlled decomposition of organic matter into a more stable and easily handled soil amendment or fertilizer, usually by piling, aerating and moistening; or the product of such a process.

Confirmation of accreditation. A determination made by the Secretary following the receipt of an AMS site evaluation report and peer review panel reports that a certifying agent is operating in compliance with the Act and regulations in this part.

Contaminant. A residue of a prohibited substance that persists in the environment.

Control. Any method that reduces or limits damage by, or populations of, pests, weeds or diseases to levels that do not significantly reduce productivity.

Critical control point. Any point, step or procedure in a certified production or handling operation where loss of control may result in a loss of an organic product's integrity, such as the commingling of organic products with non-organic products or contact of organic products with prohibited substances.

Crop. A plant or part of a plant intended to be marketed as an agricultural product or fed to livestock.

Crop residues. The plant parts remaining in a field after the harvest of a crop, which include stalks, stems, leaves, roots and weeds.

Crop rotation. The practice of alternating the annual crops grown on a specific field in a planned pattern or sequence in successive crop years, so that crops of the same species or family are not grown repeatedly without interruption on the same field during two or more crop years.

Crop year. That normal growing season for a crop as determined by the Secretary.

Cultivation. Digging up or cutting the soil to prepare a seed bed, control weeds, aerate the soil or work organic matter, crop residues or fertilizers into the soil.

Cultural. Methods used to enhance crop and livestock health and prevent weed, pest or disease problems without the use of substances; examples include the selection of appropriate varieties and planting sites; selection of appropriate breeds of livestock; providing livestock facilities designed to meet requirements of species or type of livestock; proper timing and density of plantings; irrigation; and extending a growing season by manipulating the microclimate with green houses, cold frames, or wind breaks.

Cytotoxic mode of action. Having a toxic effect by means of interference with normal cell functions.

Degradation. Measurable evidence of damage or adverse effects over the course of two or more crop years, as determined by monitoring one or more indicators of soil or water quality.

Detectable residue level. The level of a pesticide or other prohibited substance that is 5 percent or greater of the established EPA tolerance level, as set forth in 40 CFR Parts 180, 185, and 186, for the product that was tested, provided that if there is no tolerance level established, but an action level has been established, the detectable residue level will be the action level established by FDA for the product tested.

Disease vectors. Plants or animals that harbor and carry disease organisms which may attack crops or livestock.

Emergency pest or disease treatment program. A mandatory program authorized by a State, federal or local agency for the purpose of controlling or eradicating a pest or disease.

Employee. Any person who will be involved in certification decisions.

Extract. The action of producing a substance by a process of dissolving the soluble fractions of a plant, animal or mineral in water or another solvent; or the product thereof.

Farm. An agricultural operation maintained for the purpose of producing agricultural products.

Fertilizer. A single or blended substance applied to the soil to supply any of the three primary plant nutrients, nitrogen (N), phosphorus (P) and potassium (K), needed for the growth of plants.

Field. An area of land identified as a discrete unit within a farm operation.

Foliar nutrient. Any liquid substance applied directly to the foliage of a growing plant for the purpose of delivering essential nutrient(s) in an immediately available form.

Formulated product. A commercial product composed of more than one substance.

Fungicide. Any substance that kills fungi or molds.

Generic name. The general or scientific name of a substance that is not a trade name.

Genetic engineering. Genetic modification of organisms by recombinant DNA techniques.

Governing State official. The chief executive official of a State or, in the case of a State that provides for the Statewide election of an official to be responsible solely for the administration of the agricultural operations of the State, such official, who administers an organic certification program under the Act.

Handle. To sell, process, or package agricultural products.

Handler. Any person engaged in the business of handling agricultural products, except such term shall not include final retailers of agricultural products that do not process agricultural products.

Handling operation. Any operation or portion of an operation (except final retailers of agricultural products that do not process agricultural products) that receives or otherwise acquires

agricultural products and processes, packages, or stores such products.

Incidental additive. An additive present in agricultural products at an insignificant level that does not have any technical or functional effect in the product and is therefore not an active ingredient.

Inert ingredient in any input other than pesticide formulations. Any substance other than an active ingredient intentionally included in any product used in organic crop production.

Inert ingredient in pesticide formulations. Any substance (or group of structurally similar substances if designated by the EPA) other than an active ingredient which is intentionally included in a pesticide product (40 CFR 152.3(m)).

Information panel. That part of the label of a packaged product that is immediately contiguous and to the right of the principal display panel as observed by an individual facing the principal display panel, unless another section of the label is designated as the information panel because of package size or other package limitations.

Ingredients statement. The listing of the ingredients contained in a product listed by their common and usual names in the descending order of predominance.

Inspector. Any person retained or used by a certifying agent who is qualified to conduct inspections of certification applicants or certified farms, handling operations or wild crop harvesting operations.

Intentionally applied. The deliberate use of a substance on a certified organic farm or handling operation.

Label. Any display of written, printed, or graphic material on the immediate container of an agricultural product, or any such material affixed to any agricultural product or affixed to a bulk container containing an agricultural product, except for a display of written, printed, or graphic material which contains only information about the weight of the product.

Labeling. All written, printed, or graphic material accompanying an agricultural product at any time, or written, printed, or graphic material about the agricultural product displayed at retail stores for the product.

Livestock. Any cattle, sheep, goats, swine, poultry, equine animals used for food or in the production of food, fish used for food, wild or domesticated game, or other nonplant life.

Made with certain organic ingredients. An agricultural product wherein organic agricultural products used as ingredients comprise at least 50 percent, but less than 95 percent, of the total weight of the finished product, excluding water and salt; additionally, the percentage of the total weight of the finished product, excluding water and salt, that is not comprised of organic agricultural products is some combination of non-agricultural ingredients and/or non-organically produced agricultural products included on the National List.

Market information. Any written, printed, audio-visual or graphic information, including advertising, pamphlets, flyers, catalogues, posters and signs, that are used to assist in the sale or promotion of a product.

Mating disrupter. A biochemical substance that serves to prevent pest insects from reproducing by interfering with their ability to locate a suitable mate.

Micronutrient. A soil or crop mineral nutrient required in very small quantities.

Mulch. Any material, such as wood chips, leaves, straw, paper or plastic that serves to suppress weed growth, moderate soil temperature or conserve soil moisture.

National list. A list of allowed and prohibited substances as provided for in section 2118 of the OFPA (7 U.S.C. 6517).

National organic program. The program authorized by the Act for the purpose of implementing its provisions.

National Organic Standards Board. A Board established by the Secretary under 7 U.S.C. 6518 to assist in the development of standards for substances to be used in organic production and to advise the Secretary on any other aspects of the implementation of the National Organic Program.

Non-active residues. Any synthetic substance that does not appear on the National List of synthetic substances allowed for use, any non-synthetic substance that appears on the National List of non-synthetic substances prohibited for use, or any non-synthetic (natural) poison (such as arsenic or lead salts) that has long-term effects and persists in the environment, and which occurs in a very small quantity as a non-active substance in a production input or water.

Non-agricultural ingredient. A substance that is not a product of agriculture, such as a mineral or a bacterial culture, that is used as an ingredient in an agricultural product. For the purposes of this part, a non-agricultural ingredient also includes any substance, such as gums, citric acid or pectin, that is extracted, isolated from, or is a fraction of an agricultural product, so that the identity of the agricultural product is unrecognizable in the extract, isolate or fraction.

Non-organic agricultural ingredient or product. An agricultural ingredient or product that has not been produced or handled in accordance with the Act and the regulations in this part.

Non-synthetic (natural). A substance that is derived from mineral, plant or animal matter and does not undergo a synthetic process as defined in section 2103(21) of the OFPA (7 U.S.C. 6502(21)). For the purposes of this part, non-synthetic is used as a synonym for natural as the term is used in the Act.

Non-toxic. Not known to cause any adverse physiological effects in animals, plants, humans or the environment.

Organic. A term that refers to a raw agricultural product produced in accordance with the Act and the regulations in this part; or, to an agricultural product wherein organic agricultural products used as ingredients comprise between 95 percent and 100 percent of the total weight of the finished product, excluding water and salt; additionally, the percentage of the total weight of the finished product, excluding water and salt, that is not comprised of organic agricultural products is some combination of non-agricultural ingredients and/or non-organically produced agricultural products included on the National List.

Organic matter. The remains, residues or waste products of any living organism.

Organic plan. A plan of management of an organic farming or handling operation that has been agreed to by the producer or handler and the certifying agent and that includes written plans concerning all aspects of agricultural production or handling described in the Act and the regulations in subpart B of this part, including crop rotation and other practices as required under the Act.

Package. A container or wrapping that bears a label and which encloses an agricultural product, except for agricultural products in bulk containers, shipping containers, or shipping cartons.

Packaging. Material used to wrap, cover, or contain an agricultural product, including wax applied directly to an edible surface of an agricultural product.

Peer review panel. A panel of individuals who have expertise in organic farming and handling methods and certification procedures, and who are appointed by the Administrator to assist in evaluating the performance of a certifying agent.

Person. An individual, group of individuals, corporation, association, organization, cooperative, or other entity.

Pesticide. Any substance which alone, in chemical combination, or in any formulation with one or more substances, is defined as a pesticide in section 2(u) of the Federal Insecticide, Fungicide, and Rodenticide Act (7 U.S.C. 136(u) *et seq.*).

Petition. A request to amend the National List that is submitted by any person in accordance with this part.

Planting stock. Any plant or plant tissue, including rhizomes, shoots, leaf or stem cuttings, roots or tubers used in plant production or propagation.

Preliminary evaluation. A determination made by a certifying agent, prior to an initial inspection of the operation to be certified, as to whether a person seeking certification of an operation may be in compliance with the regulations in this part.

Principal display panel. That part of a label that is most likely to be displayed, presented, shown, or examined under customary conditions of display for sale.

Processing. Cooking, baking, heating, drying, mixing, grinding, churning, separating, extracting, cutting, fermenting, eviscerating, preserving, dehydrating, freezing, or otherwise manufacturing, and includes the packaging, canning, jarring, or otherwise enclosing food in a container.

Processing methods. Mechanical, biological and chemical procedures used in the preparation of an agricultural product for market.

Producer. A person who engages in the business of growing or producing food or feed.

Production aid. A substance, material, structure, or device, but not an organism, which may or may not be an active ingredient and may or may not be a synthetic substance, used to significantly aid a producer or handler to produce, handle, or maintain the integrity of, an agricultural product during, production, handling and marketing.

Production input. A substance or agricultural product that is used to produce or handle an agricultural product.

Prohibited substance. A substance whose use in any aspect of organic production or handling is prohibited or not provided for in the Act or the regulations in subpart B of this part.

Proper manuring. Any use or application of plant or animal materials, including green manure crops, so as to improve soil fertility, especially its organic content, including the use of compost and other recycled organic wastes whether or not they contain livestock manure.

Putrefaction. Partial anaerobic decomposition of organic matter so that it releases noxious oxidation products and gases, attracts vermin, or harbors pathogens.

Records. Any information in written, visual, or electronic form that documents the activities undertaken by a producer, handler, or certifying agent to comply with the Act and regulations in this part. Records include questionnaires, affidavits, inspection reports, field or production logs, maps or facility diagrams, receipts, invoices, billing statements, bills of lading, inventory control documents, laboratory analysis reports, minutes of meetings, personnel files, correspondence, photographs and other materials.

Responsibly connected. Any person who is a partner, officer, director, holder, manager, or owner of 10 per centum or more of the voting stock of an applicant or a recipient of certification or accreditation.

Routine use of parasiticide. Administering a parasiticide to an animal without cause.

Secretary. The Secretary of Agriculture or a representative to whom authority has been delegated to act in the Secretary's stead.

Site evaluation. An examination of a certifying agent's operations and records at its places of business for the purpose of determining, reviewing or evaluating accreditation status under these regulations.

Slaughter stock. Any animal that is intended to be slaughtered for human consumption.

Soil amendment. Substance or material applied to the soil as a production input to improve its physical qualities or biological activity, complement or increase soil organic matter content, or complement or adjust a soil nutrient level.

Soil quality. Observable indicators of the physical, chemical or biological condition of soil.

Split operation. An organic farming operation that also produces crops or livestock that are not organically produced in accordance with the Act and the regulations of this part.

State. Any State, Territory, the District of Columbia, or the Commonwealth of Puerto Rico.

State organic certification program. A program that meets the requirements of section 2107 of the OFPA (7 U.S.C. 6506), is approved by the Secretary, and is designed to ensure that an agricultural product that is sold or labeled as organically produced under the Act is produced and handled using organic methods.

Subtherapeutic. Administration of an animal drug, at levels that are below the levels used to treat clinically sick animals, for the purpose of increasing weight gain or improving feed efficiency.

Suspension of accreditation. An action taken by the Secretary that results in a certifying agent losing its authority to carry out certification activities.

Synergist. A substance that is an active ingredient which enhances the activity or efficiency of another substance, thereby reducing the amount of other active ingredients needed to achieve the desired function or result.

Synthetic. A substance that is formulated or manufactured by a chemical process or by a process that chemically changes a substance extracted from naturally occurring plant, animal, or mineral sources, except that such term shall not apply to substances created by naturally occurring biological processes.

Synthetic volatile solvent. A synthetic substance used as a solvent, which evaporates readily, such as hexane or isopropyl alcohol.

System of organic farming and handling. A system that is designed to produce agricultural products by the use of methods and substances that maintain the integrity of organic agricultural products until they reach the consumer. This is accomplished by using, where possible, cultural, biological and mechanical methods, as opposed to using substances, to fulfill any specific function within the system so as to: maintain long-term soil fertility; increase soil biological activity; ensure effective pest management; recycle wastes to return nutrients to the land; provide attentive care for farm animals; and handle the agricultural products without the use of extraneous synthetic additives or processing in accordance with the Act and regulations in this part.

Transplant. An annual seedling grown on a certified organic farm and transplanted to a field on the same farm operation to raise an organically produced crop.

Treated. A seed, plant propagation material or other material purchased for use as a production input in an organic farming or handling operation that has been treated or combined with a synthetic pesticidal substance (that does not appear on the National List) prior to having been purchased.

Unavoidable residual environmental contamination. The residue level of a prohibited substance, as determined by the Secretary in consultation with the

applicable governing State official and the appropriate environmental regulatory agencies, that could be expected to exist in the soil at, or in a product originating from, a specific production site to which the prohibited substance had not been applied for a minimum of three years.

Untreated seeds. Seeds that have not been treated with a prohibited substance.

USDA Seal. The logo described in § 205.107 of subpart C of this part.

Weed. Any plant that directly competes or interferes with the growth or harvest of a crop.

Wild crop. Any plant or portion of a plant that is collected or harvested from an area of land that is not maintained under cultivation or other agricultural management.

Subpart B—Organic Crop and Livestock Production and Handling Requirements

§ 205.3 Applicability.

(a) Any agricultural product that is sold, labeled, or represented as organic shall be:

(1) Produced in accordance with the requirements specified in § 205.3 and §§ 205.5 through 205.9, or §§ 205.12 through 205.15, and all other applicable requirements of part 205 on a certified organic farm; or

(2) Harvested, if a wild crop, in accordance with the requirements specified in § 205.11 and all other applicable requirements of part 205; and

(3) Handled in accordance with the requirements specified in § 205.3 and §§ 205.16 through 205.19 and all other applicable requirements of part 205 in a certified organic handling operation.

(b) A method or substance that is used in accordance with this subpart shall be used in accordance with all applicable requirements of part 205 and shall be selected and used such that:

(1) Use or application of the practice or substance does not result in measurable degradation of soil or water quality; and

(2) A commercially available non-synthetic (natural) substance is selected in preference to an allowed synthetic substance if the two substances are equally suitable for the intended purpose and there is no discernable difference between the two substances in terms of their effects on soil or water quality.

§ 205.4 [Reserved]

Organic Crop Production Requirements

§ 205.5 Land requirements.

(a) Any field or farm parcel from which organically produced crops are intended to be harvested shall:

(1) Have had no prohibited substances, as delineated in the categories of substances prohibited for use in organic farming and handling set forth in § 205.21, applied to it for a period of three years immediately preceding harvest of the crop; and

(2) Have clearly defined and identifiable boundaries.

(b) If organically managed land adjoins any area that is not under organic management, a producer shall implement, or include in the organic plan a proposal to implement, physical barriers, diversion of runoff, buffer areas or other means to prevent the possibility of unintended application of a prohibited substance to the land or contact of a prohibited substance with the land on which organically produced crops are grown.

§ 205.6 Crop rotation.

A crop rotation or other means of ensuring soil fertility and effective pest management in any field or farm parcel shall be established.

§ 205.7 Soil fertility and crop nutrient management.

(a) *Tillage and cultivation.* Tillage and cultivation implements and practices shall be selected and used in a manner that does not result in measurable degradation of soil quality.

(b) *Proper manuring.* Composted or uncomposted plant or animal materials used to replenish soil organic matter content and essential crop nutrients shall be selected according to the following order of preference, and used in a manner that does not significantly contribute to water contamination by nitrates and bacteria, including human pathogens, or result in other measurable degradation of soil or water quality:

(1) Any composted materials, except those materials provided for in paragraphs (b)(4) and (5) of this section;

(2) Any uncomposted materials of plant or animal origin, including aged, fully decomposed animal manure, that are not known to have a high soluble nutrient content or that are not prone to putrefaction.

(3) Any materials of plant or animal origin that are known to have a high soluble nutrient content or that are prone to putrefaction.

(4) Plant or animal waste materials that contain non-active residues of substances may be applied, *Provided, That* the plant or animal material is composted prior to application, and *Provided, Further That* levels of any non-active residues detected in the raw plant or animal waste materials do not increase in the soil.

(5) Chemically altered plant and animal waste materials may be applied, *Provided, That* such material appears on the National list of active synthetic substances allowed for use in organic crop production provided for in § 205.22, and *Provided, Further That* levels of any non-active synthetic residues or heavy metals detected in the plant or animal waste materials do not increase in the soil.

(c) *Providing mineral nutrients.* A substance used as a source of major nutrients or micronutrients shall be selected from the following:

(1) A non-synthetic substance of low solubility may be added to soil, including:

(i) A non-synthetic mineral having a low solubility and salt index;

(ii) A substance extracted from a plant or animal substance or from a mined mineral; and

(iii) Ash obtained from the burning of a plant or animal material, except as prohibited in paragraphs (d) (2) or (3) of this section, *Provided, That* the material burned has not been treated or combined with a prohibited substance, or the ash is not included on the National List of non-synthetic substances prohibited for use in organic crop production.

(2) A highly soluble or synthetic substance may be added to soil to correct a known nutrient deficiency, *Provided, That* its use does not result in measurable degradation of soil or water quality. Highly soluble or synthetic substances include:

(i) A synthetic substance included on the National List of active synthetic substances allowed for use in organic crop production applied as a source of micronutrients, *Provided, That* the substance is not applied in a manner intended to be herbicidal;

(ii) A non-synthetic mineral that is highly soluble and has a high salt index; or

(iii) A cation balancing agent, *Provided, That* the specific cation balancing agent appears on the National List of active synthetic substances allowed for use in organic crop production if it is synthetic or of unknown origin.

(d) *Prohibited.* The following methods or substances are prohibited for use in soil fertility and crop nutrient management:

(1) The use of any fertilizer or commercially blended fertilizer that

contains an active synthetic substance not allowed for use in crop production as provided for in § 205.22, or that contains an active prohibited substance;

(2) The use of ash obtained from the disposal of manure by burning; and

(3) The burning of manure or crop residues produced on the farm as a means of disposal.

§ 205.8 Selection and use of seeds, seedlings and planting stock.

(a) Organically produced seeds and planting stock, including annual seedlings and transplants, shall be used, except that non-organically produced seeds and planting stock may be used to produce an organic crop when an equivalent organically produced variety is not commercially available, and *Provided, That:*

(1) Treated seeds are used only when untreated seeds of the same variety are not commercially available or unanticipated or emergency circumstances make it infeasible to obtain untreated seeds; and

(2) Untreated planting stock is selected in preference to treated planting stock whenever there is a choice.

(b) Non-organically produced planting stock to be used as planting stock to produce a perennial crop may be sold, labeled or represented as organically produced only after the planting stock has been maintained under a system of organic management on a certified organic farm for a period of no less than one crop year.

(c) Prohibited. Transplants that have been treated with a prohibited substance are prohibited for use as planting stock.

§ 205.9 Prevention and control of crop pests, weeds, and diseases.

(a) Pests, weeds, and diseases in crops shall be prevented by practices including, but not limited to:

(1) Crop rotation or other means provided for in § 205.6;

(2) Replenishment and maintenance of soil fertility in accordance with § 205.7;

(3) Sanitation measures to remove disease vectors, weed seeds and habitat for pest organisms; and

(4) Cultural practices that enhance crop health, including selection of plant species and varieties with regard to suitability to site-specific conditions and resistance to prevalent pests, weeds and diseases.

(b) If pest prevention measures provided for in paragraph (a) of this section are not effective, pest problems shall be controlled through:

(1) Augmentation or introduction of predators or parasites of the pest species;

(2) Mechanical or physical controls; or

(3) Non-synthetic, non-toxic controls such as lures and repellents.

(c) If weed prevention measures provided for in paragraph (a) of this section are not effective, weeds shall be controlled through:

(1) Mulching with fully biodegradable materials;

(2) Livestock grazing;

(3) Mechanical, heat or electrical means; or

(4) Plastic or other synthetic mulches, *Provided, That* they are removed from the field at the end of the growing or harvest season.

(d) If disease prevention measures provided for in paragraph (a) of this section are not effective, plant diseases shall be controlled through practices that suppress the spread of disease organisms, including, but not limited to, steam sterilization of growing media.

(e) If the practices provided for in paragraphs (a) through (d) of this section are not effective to prevent or control crop pests, weeds and diseases, the following substances may be used *Provided, That* its use does not result in measurable degradation of soil or water quality:

(1) Any non-synthetic biological or botanical substance, or synthetic substance that is included on the National List of active synthetic substances allowed for use in crop production, may be applied to prevent, suppress or control pests, weeds or diseases.

(2) A synthetic substance that is included on the National List of active synthetic substances allowed for use in crop production may be used to defoliate cotton.

(f) Prohibited. A synthetic carbon-based substance that functions through a cytotoxic mode of action shall not be applied for any prevention or control purpose.

§ 205.10 [Reserved]

§ 205.11 Wild crop harvesting.

(a) Any land from which a wild crop intended to be sold, labeled or represented as organic is harvested shall have had no prohibited substance, as delineated in the categories of substances prohibited for use in organic farming and handling set forth in § 205.21, applied to it for a period of three years immediately preceding the harvest of the wild crop and at any time thereafter.

(b) A wild crop shall be harvested in a manner that assures that such harvesting or gathering will not be destructive to the environment and will sustain the growth and production of the wild crop.

Organic Livestock Production Requirements

§ 205.12 Origin of livestock.

(a) *Origin of livestock.* Livestock on a certified organic farm that themselves or their products are to be sold, labeled, or represented as organically produced shall have been under organic management from birth or hatching, or shall be the offspring of parents who have been under organic management, except that:

(1) *Breeder stock.* Livestock may be designated as breeder stock for offspring that are to be raised as organic livestock upon entry onto a certified facility, *Provided, That,* if such livestock is a gestating mammal, she must be brought onto the certified facility prior to the last third of pregnancy;

(2) *Dairy livestock.* Livestock may be designated as organic dairy livestock from which milk or milk products obtained therefrom can be sold, labeled or represented as organically produced, *Provided, That* she is brought onto a certified facility beginning no later than 12 months prior to the production of the milk or milk products that are to be sold, labeled or represented as organic;

(3) *Poultry.* Poultry may be designated as organic poultry from which meat or eggs obtained therefrom can be sold, labeled or represented as organically produced, *Provided, That* they are brought onto a certified facility beginning no later than the second day of life;

(4) *Livestock used for the production of non-edible livestock products.* Livestock may be designated as livestock from which skin, fur, feathers, fibers and all non-edible products obtained therefrom can be sold, labeled or represented as organically produced, *Provided, That* such livestock are brought onto a certified facility in accordance with one of the subparagraphs of paragraph (a) of this section and, *Provided, Further That* any livestock not raised under organic management from birth or hatching shall have been under organic management no less than 90 days prior to harvest of the non-edible product intended to be sold, labeled, or represented as organic; and

(5) *Other livestock.* Livestock, other than those described in paragraphs (a)(1) through (4) of this section, may be designated as organic livestock from which edible products obtained therefrom, can be sold, labeled, or represented as organically produced, if brought onto a certified facility:

(i) At any stage of life for bees;

(ii) If necessary, no later than the 15th day of life for mammalian livestock of non-organic origin to be designated as organic slaughter stock for the production of meat; or

(iii) No later than the earliest commercially available stage of life for livestock types other than bees, or mammalian livestock designated as slaughter stock.

(b) *Prohibited.* The following practices are prohibited:

(1) The switching of livestock or facilities between organic and non-organic management methods for the purpose of circumventing any provision of this part; and

(2) The use of hormones for breeding purposes.

§ 205.13 Livestock feed.

(a) *Feeding of livestock.* (1) Agricultural products, including pasture and forage, that are organically produced and, if applicable, organically handled in accordance with the Act and the regulations in subpart B of this part shall comprise the total feed ration of livestock under organic management, *Provided, However, That* if necessary:

(i) Livestock, other than as provided for in paragraphs (a)(1)(ii) through (iv) of this section, may receive a maximum of 20 percent of the total feed ration in a given year that is not organically produced;

(ii) The Administrator may authorize the use of non-organic feed in addition to the amount provided for in paragraph (a)(1)(i) of this section in an emergency situation determined by the Administrator to affect the commercial availability of organic feed;

(iii) An entire distinct herd of dairy livestock that is converted to organic management for the first time may be provided with non-organic feed until 90 days prior to the production of milk or milk products to be sold, labeled, or represented as organic; and

(iv) Bees from which organic honey and other products are harvested shall have access to forage organically produced in accordance with the requirements specified in §§ 205.3 through 205.11 so as to comprise the predominant portion of their forage needs.

(2) Non-agricultural products provided as vitamin or mineral supplements may be used to satisfy the health requirements of livestock under organic management, *Provided, That* a synthetic supplement is included on the list of synthetic substances permitted for use in livestock production provided for in § 205.24.

(3) Synthetic amino acid additives that appear on the list of synthetic substances permitted for use in livestock production as set forth in § 205.24 may be fed to livestock under organic management only as necessary for the purpose of fulfilling the nutritional requirements of the livestock.

(b) *Prohibited.* The following substances or methods for the feeding of livestock are prohibited:

(1) The use of hormones or growth promoters whether implanted, injected, or administered orally;

(2) The use of the following for the purpose of stimulating the growth or production of the livestock:

(i) Antibiotics or other animal drugs;

(ii) Synthetic amino acid additives or synthetic trace elements fed above levels needed for adequate nutrition; and

(3) The feeding of plastic pellets for roughage, feed formulas containing urea, or the refeeding of manure.

§ 205.14 Livestock health care.

(a) The health of livestock under organic management shall be maintained by the implementation of preventive measures, including, but not limited to:

(1) Providing diverse feedstuffs;

(2) Establishing appropriate housing, pasture conditions and sanitation practices so as to minimize the occurrence and spread of diseases and parasites;

(3) Administering veterinary biologics, vitamins and minerals; and

(4) Selecting species and types of livestock with regard to suitability for site-specific conditions and resistance to prevalent diseases and parasites.

(b) If the preventive measures provided for in paragraph (a) of this section are not effective in maintaining livestock health, an animal drug may be administered to any animal at any time of life, except as prohibited by paragraph (d) of this section, and *Provided, That*:

(1) Animal drugs, other than animal drugs administered topically or parasiticides, may be administered to mammals intended as organic slaughter stock only within the first 21 days of life; and

(2) Animal drugs, other than animal drugs administered topically or parasiticides, may be administered to livestock intended as organic slaughter stock, other than mammals, only within the first 7 days after arrival onto a certified facility.

(c) A product from organic livestock to which an animal drug has been administered shall be obtained and thereafter sold, labeled, or represented as organic only after the producer has determined that the animal has fully recovered from the condition(s) being treated, but in no case shall that time be less than the withdrawal period specified on the label or labeling of the animal drug or as required by the veterinarian.

(d) Prohibited. The following livestock health care methods are prohibited:

(1) Administering any animal drug, other than vaccinations, in the absence of illness;

(2) The routine use of synthetic internal parasiticides; and

(3) The subtherapeutic use of antibiotics.

§ 205.15 Livestock living conditions and manure management.

(a) The following living conditions shall be adequately provided, as appropriate to the species, to promote livestock health:

(1) Protection from the elements;

(2) Space for movement;

(3) Clean and dry living conditions;

(4) Access to outside; and

(5) Access to food and clean water.

(b) If necessary, livestock may be maintained under conditions that restrict the available space for movement or their access to the outside, *Provided, That* the other living conditions specified in paragraph (a) of this section are adequate to maintain their health without the use of animal drugs, except as provided in § 205.14(b).

(c) Manure management practices used to maintain any area in which livestock are housed, pastured or penned shall be implemented in a manner that:

(1) Does not result in measurable degradation of soil quality;

(2) Does not significantly contribute to contamination of water by nitrates and bacteria, including human pathogens;

(3) Optimizes recycling of nutrients; and

(4) Does not include burning or any practice inconsistent with the provisions of § 205.14(a)(2).

Organic Handling Requirements

§ 205.16 Product composition.

(a) For an agricultural product, including a raw agricultural product, sold, labeled, or represented as organic:

(1) Organically produced agricultural products shall comprise 100 percent of the total weight of the finished product, excluding water and salt, except that not more than five percent of the total weight of the finished product, excluding water and salt, may consist of one or more of the following ingredients that are included on the National List:

(i) Non-agricultural substances allowed as ingredients in or on processed products sold, labeled, or represented as organic or made with certain organic ingredients, provided for in § 205.26; and

(ii) Non-organically produced agricultural products allowed as ingredients in or on processed products sold, labeled, or represented as organic or made with certain organic ingredients, provided for in § 205.27.

(2) An ingredient intended to be used in a processed product sold, labeled, or represented as organic shall be selected according to the following order of preference:

(i) An organically produced agricultural product, if commercially available, shall be selected for use as an ingredient in preference to a non-organically produced agricultural product or a non-agricultural ingredient included on the National List;

(ii) A non-organically produced agricultural product, if commercially available, shall be selected for use as an ingredient in preference to a non-agricultural ingredient allowed on the National List; and

(iii) A non-organically produced agricultural product or a non-agricultural ingredient included on the National List that is extracted without the use of a synthetic volatile solvent or which does not contain propylene glycol as a carrier, if commercially available, shall be selected in preference to a product or ingredient that is extracted with a synthetic volatile solvent or which contains propylene glycol as a carrier.

(b) For an agricultural product sold, labeled, or represented as made with certain organic ingredients on the principal display panel:

(1) Organically produced agricultural products shall comprise at least 50 percent, but less than 95 percent, of the total weight of the finished product, excluding water and salt;

(2) The percentage of the total weight of the finished product, excluding water and salt, that is not comprised of organically produced agricultural products shall consist of one or more of the following ingredients:

(i) Non-agricultural substances allowed as ingredients in or on processed products sold, labeled, or represented as organic or made with certain organic ingredients, provided for in § 205.26; and

(ii) Non-organically produced agricultural products allowed as ingredients in or on processed products sold, labeled, or represented as organic or made with certain organic ingredients, provided for in § 205.27; and

(3) The finished product shall have been produced in compliance with §§ 205.16 through 205.19 of this subpart, except that the provisions set forth in §§ 205.16 (a) and (c) shall not apply.

(c) Multi-ingredient agricultural products that only represent the organic nature of such ingredients in the ingredients statement and which themselves are not sold, labeled or represented as organic or made with certain organic ingredients shall not be subject to the provisions of this subpart, except for the provisions for prevention of commingling and contact of organic products by prohibited substances, as set forth in § 205.19, with respect to any organically produced ingredients.

(d) Organic and non-organic forms of the same agricultural ingredient shall not be combined in a product sold, labeled, or represented as organic or made with certain organic ingredients if the ingredient is represented as organic in the ingredient statement.

(e) The addition of the following substances to any agricultural product intended to be sold, labeled, or represented as organic or made with certain organic ingredients is prohibited:

(1) Any sulfites, nitrates, or nitrites; or

(2) Water that does not meet the requirements of the Safe Drinking Water Act. (42 U.S.C. 300(f) *et seq.*).

§ 205.17 Processing practices.

(a) Mechanical or biological methods, including cooking, baking, heating, drying, mixing, grinding, churning, separating, extracting, cutting, fermenting, eviscerating, preserving, dehydrating, freezing or chilling shall be used to process an agricultural product intended to be sold, labeled, or represented as organic or made with certain organic ingredients for the purpose of retarding spoilage or otherwise preparing the agricultural product for market; *Provided, However, That* if necessary an incidental additive, except for volatile synthetic solvents prohibited in paragraph (b)(3) of this section, may be used to process such agricultural product.

(b) Prohibited. The following methods and substances are prohibited for use in the processing and preparation of a raw agricultural product, and on a finished agricultural product, intended to be sold, labeled, or represented as organic or made with certain organic ingredients:

(1) Storing, coating or packaging in a storage container or bin, including packages or packaging materials, that contain a synthetic fungicide, preservative, or fumigant;

(2) The use or reuse of any bag or container that had previously been in contact with any substance in such a manner as to compromise the organic integrity of any products; and

(3) The use of a volatile synthetic solvent.

§ 205.18 Prevention and control of facility pests.

(a) Pest occurrence in a certified organic handling facility shall be prevented by methods including, but not limited to:

(1) Measures to remove potential habitat of, or access to handling facilities by, pest organisms; and

(2) Management of environmental factors, such as temperature, light, humidity, atmosphere and air circulation to prevent pest reproduction.

(b) If pest prevention measures provided in paragraph (a) of this section are not effective, facility pest problems shall be controlled through:

(1) Augmentation or introduction of predators or parasites for the pest species;

(2) Mechanical or physical controls including, but not limited to, traps, light or sound; or

(3) Non-toxic, non-synthetic controls, such as lures and repellants.

(c) If pest prevention or control measures provided for in paragraphs (a) and (b) of this section are not effective, any substance may be used to control pests, *Provided, That:*

(1) The substance is approved for its intended use by the appropriate regulatory authority; and

(2) The substance is applied in a manner that prevents such substance from contacting any ingredient or finished product intended to be sold, labeled, or represented as organic or made with certain organic ingredients.

§ 205.19 Prevention of commingling and contact with prohibited substances.

A certified handling operation, and a handling operation that is exempt or excluded from certification in accordance with § 205.202(a)(3) or § 205.202(b) of subpart D, shall establish, as appropriate, adequate safeguards during the handling, storage and transportation of organically produced products in order to:

(a) Prevent the commingling of organic and non-organic products; and

(b) Assure that organic products and certified facilities are protected from contact with prohibited substances.

The Use of Active Synthetic Substances, Non-Synthetic Substances, Non-Agricultural (Non-Organic) Substances and Non-Organically Produced Ingredients in Organic Farming and Handling Operations, Including the National List of Allowed and Prohibited Substances

§ 205.20 General rules for categories of substances and ingredients permitted for use in organic farming and handling.

(a) Any active synthetic substance or ingredient on the National List, as set forth in §§ 205.22, 205.24, 205.26 and 205.27, is permitted for use in a certified organic farming or handling operation in accordance with the Act and the regulations in part 205.

(b) Any other non-prohibited substance or ingredient may be used in a certified organic farming or handling operation if used in accordance with the Act and all other applicable provisions of part 205. These substances or ingredients are:

(1) A non-synthetic substance that is not included on the National List as a prohibited non-synthetic substance in either § 205.23 or § 205.25;

(2) A synthetic substance or device that does not function as an active ingredient or substance in a system of organic farming and handling, or as an active ingredient in a processed product; and

(3) A formulated product containing inert ingredients (substances) that is used in a certified organic farming operation, *Provided, That* the formulated product does not contain:

(i) Any active ingredient prohibited under § 205.21; and

(ii) Any synthetic inert ingredient classified by EPA as an inert of toxicological concern.

§ 205.21 General rules for categories of substances and ingredients prohibited for use in organic farming and handling.

The following synthetic and non-synthetic substances and ingredients are prohibited for use in a certified organic farming or handling operation:

(a) An active synthetic substance that is not included on the National List as an allowed synthetic substance in either § 205.22 or § 205.24, including any synthetic carbon-based substance that functions through a cytotoxic mode of action;

(b) A non-agricultural substance, used as an ingredient in or on a processed product labeled as organic or made with certain organic ingredients, that is not included on the National List as a non-agricultural substance in § 205.26;

(c) A non-synthetic substance that is included on the National List as a prohibited non-synthetic substance, in either § 205.23 or § 205.25;

(d) A formulated product that contains any synthetic inert ingredient classified by EPA as an inert of toxicological concern; and

(e) A fertilizer or commercially blended fertilizer that contains an active synthetic substance not allowed for use in crop production as provided for in § 205.22, or that contains an active prohibited substance.

The National List of Allowed and Prohibited Substances

Crop Production Substances

§ 205.22 Active synthetic substances allowed for use in organic crop production.

The following may be used in accordance with any restrictions specified in this section and §§ 205.3 through 205.10 of subpart B:

(a) Horticultural oils may be used as insect pest smothering or suffocating agents. Horticultural oils include:

(1) Dormant oils;

(2) Suffocating oils; and

(3) Summer oils.

(b) Soaps may be used as insecticides, algicides, de-mossers, large animal repellants, and herbicides.

(c) Production aids may be used as follows:

(1) Acetic acid may be used as a pesticide;

(2) Pheromones may be used as insect mating disruptors;

(3) Vitamins may be used as growth promoters and rooting facilitators;

(4) Vitamin D3 may be used as a rodenticide;

(5) Amino acids may be used as growth promoters;

(6) Antibiotics may be used as pesticides;

(7) Magnesium sulfate may be used as a cation balancing agent;

(8) Newspaper and other recycled paper products may be used as mulch and compost feedstocks;

(9) Piperonyl butoxide may be used as a synergist;

(10) Potassium sulfate may be used as a cation balancing agent; and

(11) Boric Acid may be used as a pesticide.

(d) Toxins, derived from genetically engineered bacteria (or other microorganisms) that are not released live into the agroecosystem, may be used as pesticides.

(e) Copper and sulfur compounds as follows may be used as pesticides:

(1) Bordeaux mixes;

(2) Copper, including fixed coppers exempt from tolerance by EPA: hydroxides, basic sulfates, oxychlorides, and oxides;

(3) Lime sulfur, including calcium polysulphide, and

(4) Sulfur dioxide.

(f) Micronutrient minerals as follows may be used:

(1) Chelated micronutrients;

(2) Soluble boron products; and

(3) Sulfates, carbonates, oxides, or silicates of zinc, iron, manganese, molybdenum, selenium, cobalt or copper.

(g) Minerals as follows may be used as defoliants in organic fiber production:

(1) Calcium chloride;

(2) Magnesium chloride;

(3) Sodium chlorate; and

(4) Sodium chloride.

§ 205.23 Non-synthetic substances prohibited for use in organic crop production.

None.

Livestock Production Substances

§ 205.24 Active synthetic substances allowed for use in organic livestock production.

Any substance in the following categories may be used in organic livestock production in accordance with any restrictions specified in this section and §§ 205.3, and 205.12 through 205.15 of subpart B:

(a) Trace minerals;

(b) Nutrients and dietary supplements;

(c) Feed additives, *Provided, That* they are also included in § 205.26;

(d) Animal drugs and other animal health care substances;

(e) Vaccines and biologics; and

(f) Pest control substances, *Provided, That* they are also included in § 205.22.

§ 205.25 Non-synthetic substances prohibited for use in organic livestock production.

None.

Processed Product Substances

§ 205.26 Non-agricultural (non-organic) substances allowed as ingredients in or on processed products labeled as organic or made with certain organic ingredients.

The following non-agricultural ingredients may be used only in accordance with any restrictions specified in §§ 205.3, and 205.16 through 205.19 of subpart B:

Non-agricultural Substances Allowed as Ingredients in or on Processed Products Labeled as Organic or Made With Certain Organic Ingredients

Agar-agar
Alginates
Alginic Acid
Aluminum-free baking powder
Ammonium bicarbonate

Ammonium carbonate
Ascorbic acid
Beeswax
Calcium carbonate
Calcium chloride
Calcium citrate
Calcium sulfate
Calcium hydroxide
Calcium phosphates (mono, di and tribasic)
Candelilla wax
Carbon dioxide
Carnauba wax
Carrageenan
Chymosin
Citric acid
Colors, non-synthetic
Cultures, dairy, non-synthetic
Dipotassium phosphate
Enzymes, non-synthetic
Glycerin
Gums
Lactic acid
Lecithin, unbleached or bleached
Magnesium chloride
Magnesium carbonate
Magnesium stearate
Magnesium sulfate
Mono and diglycerides
Natural flavoring agents, non-synthetic
Nutrient supplements
Pectin, low-methoxy and native (high-methoxy)
Potassium acid tartrate
Potassium carbonate
Potassium chloride
Potassium citrate
Potassium phosphate
Silicon dioxide
Sodium bicarbonate
Sodium carbonate
Sodium citrate
Sodium phosphates (mono, di and tribasic)
Sulfur dioxide (not to exceed 100 ppm when used in wine)
Tartaric acid
Tocopherols
Whey and its fractions
Wood rosin
Xanthan gum
Yeast autolysate, non-synthetic
Yeast, bakers, non-synthetic
Yeast, brewers, non-synthetic
Yeast, nutritional, non-synthetic
Yeast, smoked, non-synthetic

§ 205.27 Non-organically produced agricultural products allowed as ingredients in or on processed products labeled as organic or made with certain organic ingredients.

Any non-organically produced agricultural product may be used in accordance with any restrictions specified in § 205.16.

§ 205.28 Amending the National List.

(a) Purpose of petition process. Any person may petition the NOSB for the purpose of having a substance evaluated for recommendation to the Secretary for inclusion on the National List.

(b) A petition may be submitted to: Program Manager, USDA/AMS/TM/NOP, Room 2945 South Building, P.O. Box 96456, Washington, D.C. 20090–6456.

(c) Categories of substances. A substance may be added to the National List only in the following categories:

(1) Active synthetic substances allowed for use in organic crop or livestock production;

(2) Non-synthetic substances prohibited for use in organic crop or livestock production; or

(3) Non-agricultural substances allowed for use as ingredients in or on processed products labeled as organic or made with certain organic ingredients.

(d) Content of the petition. A person should include in the petition as much of the following information as is available to the person for each specific substance:

(1) Background information about the following:

(i) Substance name (generic or common name);

(ii) Manufacturer's name, address, and telephone number, if different from the petitioner's;

(iii) Area of intended or current use (crops, livestock, or handling);

(iv) Current or intended use of the substance;

(v) Sources from which the substance is derived;

(vi) Description of the manufacturing or processing procedures for the substance; and

(vii) Summary of previous reviews of the substance by State or private organic certification programs or other organizations that review materials.

(2) Regulatory Information (as applicable) including, but not limited to:

(i) EPA registration (include the registration number);

(ii) Food and Drug Administration registration;

(iii) State regulatory authority registration (include State registration number);

(iv) Chemical Abstract Service (CAS) number or other product number; and

(v) Labels of products that contain the petitioned substance.

(3) Research, characteristics, and safety information:

(i) Detailed findings relevant to the following characteristics of the substance:

(A) Detrimental chemical interactions with other materials used in organic production;

(B) Toxicity and persistence in the environment;

(C) Environmental contamination resulting from its use and manufacture;

(D) Effects on human health; and

(E) Effects on soil organisms, crops and livestock;

(ii) Bibliographies of pertinent research on the substance;

(iii) Material Safety Data Sheet (MSDS);

(iv) Information on the substance obtained from the National Institute of Environmental Health Studies; and

(v) Information on whether all or part of any submission is believed to be confidential commercial information, and if so, what parts, and the basis for the belief that it is confidential commercial information and should not be released to the public.

(4) Statements of justification for placement on the National List, as follows:

(i) If petitioning for approval of an active synthetic substance or non-agricultural ingredient, state the reasons why the substance is necessary to the production or handling of the organic product;

(ii) If petitioning for prohibition of a non-synthetic substance, state the reasons why the use of the non-synthetic substance should not be permitted in organic farming or handling; or

(iii) Describe alternative substances or alternative cultural methods that could be utilized in place of the substance, summarize effects on the environment, human health, and the agroecosystem, and describe its compatibility with a system of sustainable agriculture.

(e) The Secretary or the NOSB may request additional information from the petitioner following receipt of the initial petition if necessary to evaluate the substance.

§§ 205.29 through 205.99 [Reserved]

Subpart C—Labels, Labeling, and Market Information

§ 205.100 Agricultural products in packages sold, labeled, or represented as organic.

(a) Agricultural products in packages described in § 205.16(a) of subpart B that are sold, labeled, or represented as organic may use the terms as described below:

(1) The term organic on the principal display panel to modify the name of the product;

(2) The term organic in the ingredients statement to modify the name of an ingredient organically produced and handled in accordance with the Act and the regulations in this part;

(3) On the principal display panel, the following terms or marks:

(i) The USDA seal described in § 205.107; and

(ii) A seal representing a State organic program approved by the Secretary, as

provided for in § 205.402 of subpart F; and

(4) On the information panel, the following terms or marks:

(i) The term organic used to modify the name of the product;

(ii) The USDA seal described in § 205.107;

(iii) A seal representing a State organic program approved by the Secretary, as provided for in § 205.402 of subpart F; and

(iv) A certifying agent's name, seal, logo, or other identification which represents that the farm, wild crop harvesting, or handling operation that produced or handled the finished product is a certified operation.

(5) On other panels of the label, labeling and market information: Any term or mark identified in paragraph (a)(4) of this section may be used on package panels of labels not covered by paragraph (a)(3) of this section as well as on any labeling or market information.

(b) [Reserved]

§ 205.101 Agricultural products in packages sold, labeled, or represented as made with certain organic ingredients.

(a) Agricultural products in packages described in § 205.16(b) of subpart B that are sold, labeled, or represented as made with certain organic ingredients shall use the terms and marks as described below:

(1) The statement made with certain organic ingredients on the principal display panel; and

(2) The term organic in an ingredients statement to modify the name of an ingredient organically produced and handled in accordance with the Act and the regulations in this part.

(b) Agricultural products in packages described in § 205.16(b) of subpart B that are sold, labeled or represented as made with certain organic ingredients may use the terms and marks as described below:

(1) On the information panel, the following terms or marks:

(i) The statement made with certain organic ingredients; and

(ii) A certifying agent's name, seal, logo, or other identification which represents that the farm, wild crop harvesting, or handling operation that produced or handled the finished product is a certified operation.

(2) On other panels of the label, labeling and market information: Any term or mark identified in paragraph (b)(1) of this section may be used on package panels of labels not covered by paragraphs (a) or (b)(1) of this section, as well as on labeling or market information.

§ 205.102 Multi-ingredient agricultural products that only represent the organic nature of such ingredients in the ingredients statement.

Any agricultural product composed of more than one ingredient, no matter the percentage organic ingredients it contains, that only represents in an ingredients statement the organic nature of its ingredients, may use the term organic in the ingredients statement of a label, labeling, or market information, to modify the name of an ingredient that is organically produced and handled in accordance with the Act and the regulations in this part, without the finished product having to comply with the certification requirements set forth in subpart D of this part, *Provided, That* the record keeping requirements of § 205.202(c) of subpart D are satisfied, and *Provided, Further That* the product itself is not sold, labeled, or represented as organic or made with certain organic ingredients.

§ 205.103 Use of terms or statements that directly or indirectly imply that a product is organically produced and handled.

Any label, labeling or market information that implies directly or indirectly that a product, including an ingredient, is organically produced and handled may be used only for an agricultural product, including an ingredient, that has been produced and handled in accordance with the Act and the regulations in this part.

§ 205.104 Informational statements prohibited.

The use of the following informational statements on the principal display panel and the ingredients statement of products sold, labeled, or represented as organic or made with certain organic ingredients, or products described in § 205.102 that contain organic ingredients, is prohibited:

(a) The phrase one hundred percent, stated in letters, numbers or symbols, used as part of any phrase or sentence that includes the term organic;

(b) A statement of the percentage of organic ingredients contained in a product; and

(c) The phrase organic when available or a term of similar meaning or intent.

§ 205.105 Agricultural products in a form other than packages that are sold, labeled or represented as organic or made with certain organic ingredients.

(a) Agricultural products described in § 205.16(a) of subpart B, in a form other than packages, that are sold or represented as organic at the time of retail sale may use the terms and marks as described below:

(1) The term organic on the retail display label, labeling or display container to modify the name of the product;

(2) The term organic in the ingredients statement to modify the name of an ingredient organically produced and handled in accordance with the Act and the regulations in this part; and

(3) A clearly recognizable organic identification mark(s) or term(s), selected from the following, located in plain view on the shipping container:

(i) The term organic used to modify the name of the product;

(ii) The USDA seal as described in § 205.107;

(iii) A seal representing a State organic program approved by the Secretary as provided for in § 205.402 of subpart F; or

(iv) The certifying agent's name, seal, logo, or other identification which represents that the farm, wild crop harvesting, or handling operation that produced or handled the finished product is a certified operation.

(b) Agricultural products described in § 205.16(b) of subpart B, in a form other than packages, that are sold, labeled, or represented as made with certain organic ingredients shall use the terms and marks as described below:

(1) The statement made with certain organic ingredients on the retail display label, labeling or display container;

(2) The term organic in the ingredients statement to modify the name of an ingredient organically produced and handled in accordance with the Act and the regulations in this part; and

(3) The statement made with certain organic ingredients, which may be accompanied by the certifying agent's name, seal, logo, or other identification, located in plain view on the shipping container.

§ 205.106 Agricultural products produced on an exempt farm or handling operation.

An agricultural product produced or processed on a farm, wild crop harvesting, or handling operation that annually sells no more than $5,000 in value of agricultural products and which has not been certified, shall not:

(a) Display the USDA seal, or any certifying agent's name, seal, logo, or other identification which represents that the farm, wild crop harvesting, or handling operation that produced or handled the product is a certified operation; or

(b) Be identified as an organic ingredient in a product produced or processed on a farm or handling operation that annually sells more than $5,000 in value of agricultural products.

§ 205.107 USDA seal.

(a) The USDA seal described in paragraphs (b) and (c) of this section shall be used in accordance with the provisions of this subpart and shall be used only on agricultural products (raw or processed) described in § 205.16(a) of subpart B that are sold, labeled, or represented as organic and which are produced and handled on certified operations.

(b) The USDA seal used on a label, labeling, or market information of an agricultural product shall replicate the form and design of the example in figure 1.

Figure 1

(c) Except as otherwise authorized by the Secretary, the USDA seal shall be:

(1) Printed on a light background with the wording and design in a dark color or on a dark background with the wording in a light color, *Provided, That* such design is legible and conspicuous on the material upon which it is printed; or

(2) Printed in a standard four color label as follows: concentric circles with arrows and diagonal on a light background with black letters; interior globe cyan blue with green continents; interior triangular sections green; exterior triangle (border) yellow; and both interior and exterior of triangular border edged with black.

§§ 205.108 through 205.200 [Reserved]

Subpart D—Certification

§ 205.201 What has to be certified.

(a) Each farm, wild crop harvesting operation, or handling operation that produces or handles crops, livestock, livestock products, or other agricultural products that are, or that are intended to be, sold, labeled or represented as organic or made with certain organic ingredients must be certified according to the provisions of subpart D of this part, and must meet all other applicable requirements of this part, *Provided, That* any handling operation that provides handling services to fewer than three certified entities that produce or handle agricultural products that are, or that are intended to be, sold, labeled or represented as organic or made with certain organic ingredients, would not be required to be separately certified apart from the operations for which it provides such services, and *Provided, Further That* none of the operations set forth in paragraph (a) of this section must be certified if exempt or excluded in § 205.202 of this subpart.

(b) A handling operation, or portion of a handling operation, that handles only agricultural products that are, or that are intended to be, sold, labeled or represented as made with certain organic ingredients is exempt from the requirement to select a commercially available non-synthetic substance in preference to an allowed synthetic substance, as set forth in § 205.3(b)(2) of subpart B.

§ 205.202 Exemptions and exclusions from certification.

(a) *Exemptions.* (1) A farm, wild crop harvesting, or handling operation that sells agricultural products as organic or made with certain organic ingredients, but which annually sells no more than $5,000 in value of agricultural products, is exempt from complying with the requirements in this part, except for the applicable recordkeeping provisions delineated in paragraph (c)(1) of this section and the applicable labeling provisions set forth in subpart C of this part.

(2) A retail operation, or portion of a retail operation, that only handles organically produced agricultural products but does not process them is exempt from the requirements in this part.

(3) A handling operation, or portion of a handling operation, that handles only agricultural products that contain less than 50 percent organic ingredients by total weight of the finished product, excluding water and salt, is exempt from the requirements in this part, except:

(i) The provisions for prevention of commingling and contact of organic products by prohibited substances set forth in § 205.19 of subpart B with respect to any organically produced ingredients used in an agricultural product; and

(ii) The applicable provisions for labeling set forth in subpart C of this part.

(b) *Exclusions.* (1) A handling operation, or portion of a handling operation, is excluded from the requirements of this part, except for the requirements for the prevention of commingling and contact with prohibited substances as set forth in § 205.19 of subpart B with respect to any organically produced products, if such operation, or portion of the operation, sells only agricultural products labeled as organic or made with certain organic ingredients that:

(i) Are packaged or otherwise enclosed in a container prior to being received or acquired by the operation; and

(ii) Remain in the same package or container and are not otherwise processed while in the control of the handling operation.

(2) A restaurant or other similar food-service type establishment that processes ready-to-eat food from organic agricultural products and which does not enclose the food in a package or container labeled or represented to the consumer as organic or as made with certain organic ingredients is excluded from the requirements of this part.

(3) A retail operation, or portion of a retail operation, that processes only agricultural products that are previously labeled as organic or made with certain organic ingredients before receipt or acquisition by the retail operation, is excluded from the requirements in this part, *Provided, That* the operation meets both of the following requirements:

(i) The agricultural product is processed by the retail operation, or portion of the retail operation, in the course of normal retail business practice solely for the purpose of offering the product to a consumer; and

(ii) The agricultural product offered to the consumer:

(A) Has not been created by the retail operation by combining two or more ingredients into a single product that is then labeled or represented by the retail operation as organic or as made with certain organic ingredients; and

(B) Has not been repackaged by the retail operation so as to provide a new label or labeling for the repackaged product which represents it as organic or made with certain organic ingredients.

(c) *Records to be maintained by exempt or excluded operations.* Any operation that is exempt or excluded from certification, as specified in paragraphs (a) or (b) of this section, shall maintain records as follows and shall allow representatives of the Secretary and the applicable governing State official access to these records to determine compliance with the applicable regulations set forth in this part:

(1) *Small farm or handling operations.* An operation that is exempt from certification pursuant to paragraph (a)(1) of this section shall maintain records for no less than one calendar year to substantiate that the operation did not

sell agricultural products in excess of $5,000 in value during the previous calendar year;

(2) *Handling operations exempt or excluded from certification.* A handling operation that is exempt from certification pursuant to (a)(3) of this section, or excluded from certification pursuant to (b)(1) of this section, shall maintain records as follows:

(i) Documentation as sufficient to verify the source and quantity of organic products received and that all organic products and ingredients have been handled in accordance with § 205.19 to prevent commingling and contact with prohibited substances shall be maintained for no less than one year from the date of receipt by the operation of a product, including ingredients, labeled as organic or made with certain organic ingredients; and

(ii) Documentation as sufficient to verify the destination and quantity of a product shipped from the operation shall be maintained for no less than one year from the date of shipping a product labeled as organic or as made with certain organic ingredients, or which contains any organic ingredients.

§ 205.203 General requirements for certification.

In order to receive and maintain organic certification under the Act and the regulations in this part, a farm, wild crop harvesting or handling operation shall:

(a) Comply with the applicable organic production and handling requirements of the Act and the regulations in this part;

(b) Establish, implement, and update annually an organic plan that is submitted to an accredited certifying agent as provided for in § 205.205;

(c) Permit an annual on-site inspection by the certifying agent, as provided for in § 205.208 through 205.211;

(d) Maintain all records applicable to the organic operation for a period of not less than five years from the date of creation of the record, and allow authorized representatives of the Secretary, the applicable governing State official, and the certifying agent access to such records to determine compliance with the Act and the regulations in this part, as provided for in § 205.216;

(e) Submit the applicable fees to the certifying agent, as provided for in § 205.422 of subpart F; and

(f) Immediately notify the certifying agent concerning:

(1) Any application of a prohibited substance to any field, farm unit, site, facility, livestock, or product that is part of a certified operation; and

(2) Any change in a certified operation or any portion of a certified operation that may affect its compliance with the Act and the regulations in this part

§ 205.204 Applying for certification.

A person seeking certification of a farm, wild crop harvesting, or handling operation under this subpart shall submit a request for certification to the certifying agent. The request shall include the following information:

(a) An organic plan, as required in § 205.205;

(b) A statement of compliance, as required in § 205.206;

(c) The applicant's business name, address, phone and fax numbers, and, in addition, the names of personnel responsible for maintaining compliance with the Act and the regulations in this part; and

(d) The name(s) of any organic certifying agent(s) to which application has previously been made, the year(s) of application, and the outcome of the application(s) submission.

§ 205.205 Organic plan.

A certification applicant shall submit to the certifying agent an organic plan that identifies, as applicable to its operation:

(a) *General.* Practices previously implemented, and intended to be implemented and maintained, to establish a system of organic farming and handling that complies with the applicable crop, livestock, wild crop harvesting, and handling requirements, provided in §§ 205.3, 205.5 through 205.9, and 205.11 through 205.28 of subpart B.

(b) *Farm operations.* The following information shall be submitted concerning a farm operation:

(1) The total acreage of the operation, the types of crops grown and livestock raised, and any on-farm processing activities;

(2) Map(s) of each field and farm parcel for which certification is requested, showing, for each parcel: A list of crops intended to be planted and/or managed; identification name or number; size; location; boundaries; any significant features that may assist the certifying agent to identify the field or parcel; identification of any adjoining land to which a prohibited substance may be applied; and the location of any facility used for livestock housing, storage, or post-harvest handling;

(3) A history of the crops grown and production inputs used for each field or farm parcel for which certification is requested, which covers the three year period immediately preceding the date of the request for certification;

(4) A list of each type of agricultural product produced on the farm that is intended to be sold, labeled or represented as organic or made with certain organic ingredients;

(5) A list of each substance intended to be used as a production input, indicating: its source, anticipated quantity to be used, and location(s) where it will be used;

(6) A list of any seeds or planting stock intended to be purchased, indicating: its source, approximate quantity to be used and whether it is treated, untreated, or organically produced;

(7) A list of all livestock to be maintained by the operation and to be purchased in the certification year for the production of agricultural products to be sold, labeled or represented as organic, or as made with certain organic ingredients, indicating: their source, the estimated number to be maintained and purchased, their intended use (e.g. slaughter stock, egg production), and whether the livestock originate from a certified organic livestock operation;

(8) A list of all livestock feed and feed supplements intended to be purchased, indicating: its source, estimated amount to be purchased, and what, if any, portion of the feed to be purchased will not be organically produced;

(9) The name of a veterinarian from whom animal drugs or a prescription for animal drugs are obtained, if applicable, and a list of any animal drugs that may be used, including their sources, estimated amount of each animal drug to be used, and the types of livestock (such as hogs, fish, or chickens) to which such drugs are to be administered; and

(10) A list of all post-harvest handling or processing methods and facilities to be used by the applicant.

(c) *Split operations.* The following information shall be submitted, as applicable, concerning a farm or wild crop harvesting operation that produces both organic and non-organic products:

(1) A list and anticipated quantities of livestock and any other agricultural product intended to be grown, raised or harvested both organically and non-organically;

(2) A list, indicating expected quantity and location, of each substance or practice prohibited for organic production under the Act and the regulations in this part that may be used on a non-certified portion of the farm; and

(3) A list of the measures used and that will be used to prevent