

DEPARTMENT OF AGRICULTURE**Agricultural Marketing Service****7 CFR Part 205****[Docket Number: TMD-00-02-PR2]****RIN 0581-AA40****National Organic Program****AGENCY:** Agricultural Marketing Service, USDA.**ACTION:** Proposed rule.

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

DATES: Comments must be submitted on or before June 12, 2000.**ADDRESSES:** Interested persons are invited to submit written comments on this proposal to: Keith Jones, Program Manager, National Organic Program, USDA-AMS-TMP-NOP, Room 2945-So., Ag Stop 0275, PO Box 96456, Washington, DC 20090-6456. Comments also may be sent by fax to (703) 365-0760 or filed via the Internet through the National Organic Program's homepage at: <http://www.ams.usda.gov/nop>. Written comments to this proposed rule submitted by regular mail and

faxed comments should be identified with docket number TMD-00-02-PR. To facilitate the timely scanning and posting of comments to the NOP homepage, multiple page comments submitted by regular mail should not be stapled or clipped. Commenters should identify the topic and section number of this proposal to which the comment refers.

It is our intention to have all comments to this proposal, whether mailed, faxed, or submitted via the Internet, available for viewing on the NOP homepage at <http://www.ams.usda.gov/nop> in a timely manner. Comments submitted in response to this proposal will be available for viewing at USDA-AMS, Transportation and Marketing, Room 2945-South Building, 14th and Independence Ave., SW, Washington, DC, from 9:00 a.m. to 12:00 p.m. and from 1:00 p.m. to 4:00 p.m., Monday through Friday (except official Federal holidays). Persons wanting to visit the USDA South Building to view comments received in response to this proposal are requested to make an appointment in advance by calling (202) 720-3252.

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

SUPPLEMENTARY INFORMATION:**Background of the National Organic Program**

To address problems created by inconsistent organic standards, the organic industry attempted to establish a national voluntary organic certification program in the late 1980's. However, that effort failed to develop a consensus on needed organic standards. Congress was then petitioned by an organic industry trade association to establish a mandatory national organic program, resulting in the Organic Foods Production Act of 1990 (the Act). Congress passed the Act to: (1) Establish national standards governing the marketing of certain agricultural products as organically produced products; (2) assure consumers that organically produced products meet a consistent standard; and (3) facilitate commerce in fresh and processed food that is organically produced. This proposal is designed to implement the Act.

To help readers better understand this proposal, we have provided answers to some frequently asked questions about

the proposed rule, including some of the issues most commonly raised in public comments.

Is this the final word on National organic standards?

No. This is only a proposed rule. It is important that you take the time to read it carefully and write to USDA to give us your recommendations, being as specific as you can. Your comments are due by June 12, 2000.

Your comments do matter. On December 16, 1997, the first proposed rule was published in the **Federal Register**, and 275,603 people wrote to us to explain why and how the rule should be rewritten, the largest public response to a proposed rule in USDA history. Then, in the October 24, 1998 **Federal Register**, we asked for public comment on issues concerning livestock confinement, medications, and the authority of certifying agents, and 10,817 people wrote to us. As you read through this document, you will get a sense of what these comments said because in each section we briefly summarize the relevant comments and provide our response to them.

We expect to publish a final rule later this year, once we know what you think about this proposal. The final rule will have, as proposed here, an implementation phase-in period so farmers and processors won't have to change overnight.

Has there been citizen input on this proposal beyond public comments?

Yes. The National Organic Standards Board (NOSB) is a 15-member citizen board that advises the Secretary on all aspects of the National Organic Program and has special responsibility for development of the National List. Established by law in 1990, the NOSB includes 3 environmental representatives, 3 consumer representatives, 4 organic farmers/ranchers, 2 organic processors, 1 retailer, 1 scientist, and 1 certifying agent. Currently, the NOSB comprises 14 members. The 15th member, an accredited certifying agent, would be appointed after certifying agents are accredited by the Secretary. Since the first NOSB was appointed in 1993, the Board has held 19 public meetings, including one public teleconference, crisscrossing the country to hear from the public before making recommendations to the Secretary on national standards. The vast majority of commenters on the first proposed rule urged the Secretary to rewrite the proposal in line with NOSB recommendations—and this is what we have done. More information on NOSB

members, meeting minutes, and a side-by-side comparison of this proposal with NOSB recommendations can be found at www.ams.nop.gov.

In addition, to be consistent with OMB Circular No. A-119, which directs agencies to use voluntary consensus standards, USDA considered adoption of the *American Organic Standards, Guidelines for the Organic Industry* as a voluntary consensus standard for use in the National Organic Program. In October 1999, the Organic Trade Association published the American Organic Standards (AOS). The AOS standards were developed over several months with two opportunities for comment from interested parties. The introduction states that the standards are written as an up-to-date compilation and codification of organic standards and certification procedures, as they are understood and applies in the United States. Organic Trade Association members are expected to follow the guidelines.

USDA has determined that it would be impractical to use the American Organic Standards in lieu of USDA developed standards for the following reasons: (1) Not all participants in the organic industry elected to participate in developing the AOS; (2) the AOS are new to the industry so there has not been sufficient time for the industry to assess their effectiveness, and (3) some certifying agents disagree with portions of the AOS.

Why do we need national standards for organic food?

National standards for organic food production are designed to bring about greater uniformity in the production, manufacture, and marketing of organic products. In the absence of a national standard, 49 State and private organizations have established individual programs and standards for certifying organic agricultural products. The lack of consistency between these standards has created problems for farmers and handlers of organic products, particularly if they want to sell their products in multiple States with different standards. Lack of a nationwide standard has also created confusion for consumers, who may be uncertain what it really means when a food product is called "organic."

With a national standard, consumers across the country can go into any store and have full confidence that any food product labeled "organic" meets a strict, consistent standard no matter where it was made. Use of the word, "organic," on the label of any product that does not meet the standard is strictly prohibited.

Consumers will have that confidence, because this proposal requires for the first time that all organic operations be certified by USDA-approved certifying agents. Up to now, certification has been optional; some farmers choose not to be certified at all, and others are certified by State or private certifiers using different standards. It can be hard for consumers to know if a product has been certified, or, if it has, to what standard. Under this proposal, all organic operations, except for the very smallest, would be certified to the same standard. And all products labeled as "organic" would have to comply with the production and handling standards in this rule.

Consumers can also look for the USDA organic seal, which can only be used on products that have been certified by USDA-approved certifying agents. This seal assures consumers that the maker of the product is part of a rigorous certification program and has been thoroughly reviewed by professional inspectors trained in organic agriculture.

National standards will also bring greater predictability for producers of organic foods. There will be no confusion about whether a product satisfies the particular standard of any State, for example, because all organic foods will meet the same standards.

Finally, a national standard for organic food will help our farmers and manufacturers sell organic products in other countries. The lack of a consistent national organic program has limited access to important markets in other countries because of the confusion created by multiple, independent standards. A strong national standard will help to ensure buyers in other countries that all U.S. organic products meet the same standards.

How can I tell how much organic food is in a product?

This proposal sets strict labeling standards based on the percentage of organic content. If a product is 100 percent organic, it can, of course, be labeled as such. A product that is at least 95 percent organic can be described as, for example, "organic cereal." If a cereal, for example, contains between 50 and 95 percent organic content, it can be described as "cereal made with organic ingredients," and up to three organic ingredients can be listed. Finally, if the food contains less than 50 percent organic content, the term, "organic," may only appear on the ingredient information panel. These four new labeling categories will provide consumers with much greater

information than they have today. [Labeling is covered in subpart D.]

What is the National List?

The National List of Allowed and Prohibited Substances (known as the National List) identifies specific substances that may or may not be used in organic production and handling operations. The National List is developed by the NOSB, through consultation with outside experts, and forwarded to the Secretary for approval. The list identifies those synthetic substances, which would otherwise be prohibited, that may be used in organic production based on the recommendations of the NOSB. Only those synthetic substances found on the National List may be used. The National List also identifies those natural substances that may not be used in organic production, as determined by the Secretary based on the NOSB recommendations.

The first proposal included some substances on the National List that were not recommended by the NOSB. This proposal contains no substances on the approved list that were not found in the NOSB recommendations.

This proposal also includes restrictions or other conditions on the use of allowed substances, also known as "annotations," as recommended by the NOSB. Such annotations have been used by existing State and private certification programs to further ensure that allowed substances are used in a manner that is consistent with organic production. (The National List is covered in subpart G, §§ 205.600 through 205.607.)

Does this proposal prohibit use of genetic engineering in organic production?

Yes. This proposal prohibits the use of genetic engineering (included in the broad definition of "excluded methods" in this proposal, based on the definition recommended by the National Organic Standards Board) in the production of all foods and ingredients that carry the organic label.

275,603 commenters on the first proposal nearly universally opposed the use of this technology in organic production systems. Based on this overwhelming public opposition, this proposal prohibits its use in the production of all organic foods even though there is no current scientific evidence that use of excluded methods presents unacceptable risks to the environment or human health. While these methods have been approved for use in general agricultural production and may offer certain benefits for the

environment and human health, consumers have made clear their strong opposition to their use in organically grown food. Since the use of excluded methods in the production of organic foods runs counter to consumer expectations, foods produced with these methods will not be permitted to carry the organic label. (Excluded methods are defined in subpart A and discussed further under Production and Handling (subpart C), Labeling (subpart D), and the National List (subpart G).)

Will genetic engineering be allowed in the production of foods that contain both organic and nonorganic ingredients?

No. For products with mostly organic content—those products where more than half of the ingredients are organic and that have the word, “organic,” on the main product label—excluded methods must not be used in the production of any ingredients. Only those products, in which fewer than half of the ingredients are organic and in which the organic ingredients are only identified on the ingredient panel, could contain nonorganic ingredients produced through excluded methods.

We believe consumers have expressed a clear expectation that these methods should not be used in the production of any ingredients contained in mostly organic products. Because prominent use of the word, “organic,” on the label of such products reinforces that expectation, we have chosen to prohibit use of excluded methods in production of both the organic and nonorganic ingredients.

We recognize that this policy will place additional burdens on organic food processors and certifying agents because the ability to meet these requirements will depend largely on practices used in conventional agricultural markets. For organic food processors, it may be harder to find sources of nonorganic ingredients that are produced without use of excluded methods. Similarly, certifying agents may face greater difficulty because they will be required to ensure that handlers have complied with this requirement. However, we believe that the need to meet strong consumer expectations outweighs these concerns. Furthermore, we anticipate that as marketplace practices or standards evolve, these practices will be the basis for implementing this provision, providing handlers and certifying agents recognize criteria with which to evaluate sources of nonorganic ingredients in products containing both organic and nonorganic ingredients.

Does this proposal prohibit use of irradiation in organic production?

Yes. This proposal prohibits the use of irradiation in the production of all foods and ingredients that carry the organic label. 275,603 commenters on the first proposal almost universally opposed the use of this technology in organic production systems. Based on this overwhelming public opposition, this proposal prohibits its use in the production of all organic foods even though there is no current scientific evidence that use of irradiation presents unacceptable risks to the environment or human health and may, in fact, offer certain benefits. Because this rule is a marketing standard and consumers have expressed a clear expectation that irradiation should not be used in the production of organic foods, foods produced with this technology will not be permitted to carry the organic label.

The prohibition on irradiation extends to nonorganic ingredients used in mostly organic ingredients—those products where more than half of the ingredients are organic and that have the word, “organic,” on the main product label. Only those products, in which fewer than half of the ingredients are organic and in which the organic ingredients are only identified on the ingredient panel, could contain irradiated nonorganic ingredients. We do not believe that this prohibition on irradiation in nonorganic ingredients will place undue burden on either handlers or certifiers because of current labeling requirements for irradiated products.

Does this proposal prohibit use of sewage sludge in organic production?

Yes. This proposal prohibits the use of sewage sludge in the production of all foods and ingredients that carry the organic label. This prohibition extends to nonorganic ingredients used in the production of mostly organic foods—those products in which more than half of the ingredients are organic and that have the word, “organic,” on the main product label. Only those products, in which fewer than half of the ingredients are organic and which the organic ingredients are only identified on the ingredient panel, could contain nonorganic ingredients produced using sewage sludge.

275,603 commenters on the first proposal almost universally opposed the use of this technology in organic production systems. Based on this overwhelming public opposition, this proposal prohibits its use in the production of all organic foods, even though there is no current scientific

evidence that use of sewage sludge in the production of foods presents unacceptable risks to the environment or human health. We believe consumers have expressed a clear expectation that sewage sludge should not be used in the production of any ingredients contained in mostly organic products. Because prominent use of the word, “organic,” on the label of such products reinforces that expectation, we have chosen to prohibit use of sewage sludge in production of both the organic and nonorganic ingredients. We recognize that this policy may place additional burdens on organic food processors and certifying agents. However, we believe that the need to meet strong consumer expectations outweighs these concerns.

Does this proposal set standards for livestock production?

Yes. The proposal sets the first comprehensive standards for production of organic animals and meat products. Under this proposal, use of antibiotics would be prohibited in organic livestock production. The standards also prohibit the routine confinement of animals and require that ruminant animals have access to outdoor land and pasture, although temporary confinement would be allowed under certain, limited circumstances. Animals under organic management must also receive 100-percent organically grown feed. (Organic livestock management issues are discussed in greater detail under subpart C, 205.236 through 205.239.)

Does this proposal prohibit “ecolabeling”?

No. This proposal only regulates use of the term, “organic,” on product labels. Other labels would be allowed as long as they are truthful and not misleading and meet general food labeling requirements. The labeling requirements of this proposal are intended to assure that the term, “organic,” and other similar terms or phrases are not used in a way that misleads consumers. Should we find that terms or phrases are being used to represent “organic” when the products are not produced to the requirements of this regulation, we would proceed to restrict their use. (Labeling is covered in subpart D.)

Are organic foods pesticide-free?

No. Organic farmers can use natural pesticides to control weeds and insects and maintain the high quality of organic products that consumers have come to expect. Use of synthetic chemical pesticides, however, is prohibited unless specifically allowed on the National List as recommended by the

National Organic Standards Board and approved by the Secretary. (The National List is covered in subpart G, sections 205.600 through 205.607.)

Who needs to be certified?

As a general rule, all organic production and handling operations must be certified. The Act and this proposal, however, do provide for some exceptions. For example, organic operations with less than \$5,000 in annual sales of organic products do not require certification. Similarly, organic operations that handle only those products with less than 50 percent organic content or that restrict labeling of organic ingredients to the ingredient information panel do not require certification. Finally, we are not requiring certification of most grocery stores and restaurants (referred to in this proposal as "retail food establishments") at this time.

Even where operations do not require certification, however, all organic food products must meet the national standards as described in this proposal. In that way, consumers can be confident that all products labeled as "organic" meet the national standards, even if they did not require certification under the NOP. (Certification is covered in subpart E; the exceptions from certification are found in subpart B.)

Will organic farmers have to pay fees?

Organic farmers and other organic operations will have to pay fees for organic certification but will not be charged any fees by USDA. Fees for certification services will be set by the private or State certifying agents. The proposal also requires that certifying agents make their schedule of fees publicly available so that organic operations can plan appropriately and so that they can make informed choices where multiple certifying agents are available. USDA will also review fees charged by certifying agents to ensure that they are reasonable and that they are being applied fairly to all organic operations. Under this proposal, USDA would only charge fees for reviewing ("accrediting") certifying agents. These fees will primarily be based on the actual costs of the accreditation work done by USDA staff so that certifying agents with smaller and less complex programs will pay lower fees. The proposal also provides for a reduction in the accreditation fees during the first 18 months of the program to provide an incentive for certifying agents to become accredited under the new national program as soon as possible. (Fees are covered in subpart G, §§ 205.640 through 205.642.)

How do I become an accredited certifying agent?

All certifying agents must be accredited by USDA. Certifying agents may apply for accreditation effective with publication of the final rule and are encouraged to apply as soon after publication of the final rule as possible. USDA will provide additional information on applying for accreditation on or about the date of publication of the final rule. This information will be available on the NOP website and by mail upon request.

Applications for accreditation will be handled on a first-come-first-served basis. Those that apply within the first 6 months following publication of the final rule and are determined by the Administrator to meet the requirements for accreditation will be notified of their status in writing on or about 12 months after publication of the final rule. This approach is being taken because of the market advantage that could be realized by accredited certifying agents if USDA did not announce the accreditations simultaneously. (Accreditation is covered in subpart F.)

What are the roles and responsibilities of certifying agents in the National Organic Program?

Certifying agents are the "front line" representatives of USDA and play a critical role in the oversight and enforcement of the national organic standards program. Once accredited by USDA, certifying agents are empowered to make key decisions regarding the status of organic operations. Certifying agents review the organic plans of organic operations and are authorized to grant certification to those operations that meet the strict national organic standards. Certifying agents are also responsible for the continuing oversight of organic operations— reviewing annual updates of organic plans, conducting residue analyses, and conducting other monitoring activities.

In cases in which a certifying agent finds that an organic operation does not meet the national standards, the agent is empowered to issue notices of noncompliance and to initiate suspension or revocation of certification. Organic operations can appeal such decisions to USDA but unless the organic operation appeals the certifying agent's decision or can correct the problems identified by the certifying agent, the agent's decision will stand. (Accreditation is covered in subpart F; Compliance is covered in subpart G, §§ 205.660 through 205.668; and Appeals are covered in subpart G, §§ 205.680 through 205.681.)

How will USDA ensure that the National standards are applied fairly and consistently by all certifying agents?

Because this proposal gives certifying agents such an important role in enforcing the national standards, USDA oversight of those certifying agents is particularly important. Under this proposal, all certifying agents, both private and in State organic programs, would have to be accredited by USDA before they could begin to certify organic operations. It is this accreditation process, in which USDA reviews all certifying agents to make sure they understand and can accurately apply the national organic standards, that is USDA's main tool to ensure that the standards are applied fairly and consistently by all certifying agents.

The accreditation process is really one of ongoing oversight by USDA.

Accreditation must be renewed every 5 years so that we can be sure certifying agents continue to meet the program standards. USDA will conduct one or more site visits of certifying agents during the period of accreditation as another mechanism of monitoring their compliance. Finally, certified operations may file complaints with USDA if they believe they have been treated unfairly or if a certifying agent is otherwise not following the program requirements. We will investigate these complaints for possible enforcement action.

Can States have organic standards that are more strict than the National standard?

Yes. Some States may have unique environmental or other concerns that they believe require extra conditions above the national standard. In those cases, States would apply to USDA to have their special State program approved by the Secretary.

However, no State would be allowed to set up a program that does not at least meet the national standard. And States would not be allowed to use their programs to keep out or otherwise discriminate against organic products made in another State. (State Programs are covered in subpart G, §§ 205.620 through 205.622.)

What is the timeframe for implementation?

The final rule in this rulemaking process will establish a procedure and a timeframe for implementing the NOP. We expect that the interim period between publication of the final rule in this rulemaking process and the effective date of the program (actual implementation of regulations) will be 18 months. The following is a

preliminary list of several administrative and program issues that must be implemented during that period. Certifying agent applications will be evaluated and accreditation granted. Certifying agents will, in turn, certify production and handling operations to the requirements of these regulations. Equivalency discussions will be held with foreign governments and foreign certifying agents. Guidelines and practice standards on production and handling practices must be finalized and distributed by the NOP. A petition process for recommending amendments to the National List must be developed and distributed. The NOSB will continue to review materials for the National List. State programs may have to make adjustments in their organic certification programs for consistency with the standards of this program. Producers should use the interim period to prepare their production operations to comply with the relevant requirements of this program. Handlers should use the interim period to prepare for necessary changes in the labeling of their products.

Prior Documents in This Proceeding

This proposed rule is issued pursuant to the Organic Food Production Act of 1990 (Act or OFPA), as amended (7 U.S.C. 6501 *et seq.*). This proposal replaces the proposed rule published in the **Federal Register** December 16, 1997. Comments to the first proposal were considered in the preparation of this proposed rule.

The following notices related to the NOSB and the development of this proposed regulation have been published in the **Federal Register**. Five notices of nominations for membership on the NOSB were published between April 1991 and June 1999 (56 FR 15323, 59 FR 43807, 60 FR 40153, 61 FR 33897, 64 FR 33240). Two notices of extension of time for submitting nominations were published on September 22, 1995, and September 23, 1996 (60 FR 49246, 61 FR 49725). Seventeen notices of meetings of the NOSB were published between March 1992 and October 1999 (57 FR 7094, 57 FR 27017, 57 FR 36974, 58 FR 85, 58 FR 105, 58 FR 171, 59 FR 58, 59 FR 26186, 59 FR 49385, 60 FR 51980, 60 FR 15532, 61 FR 43520, 63 FR 7389, 63 FR 64451, 64 FR 3675, 64 FR 28154, 64 FR 54858). One notice of public hearings on organic livestock and livestock products was published on December 30, 1993 (58 FR 69315). One notice specifying a procedure for submitting names of substances for inclusion on the National List was published on March 27, 1995 (60 FR

15744). A rule proposing the NOP was published on December 16, 1997 (62 FR 65850). An extension of the time period for submitting comments to the proposed rule was published on February 9, 1998 (63 FR 6498). One request for comments on Issue Papers was published on October 28, 1998 (63 FR 57624). A notice of a program to assess organic certifying agencies was published on June 9, 1999 (64 FR 30861).

This preamble includes a discussion of the proposed rule and supplementary information, including the Regulatory Impact Assessment, Regulatory Flexibility Act Analysis, Federalism Impact Statement, and Paperwork Reduction Act Analysis. The Civil Rights Impact Analysis is not included as an attachment but may be obtained by writing at the address provided above or via the Internet through the National Organic Program's homepage at: <http://www.ams.usda.gov/nop>.

National Organic Program Overview

Subpart A—Definitions

Proposal Description

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

We have amended terms and definitions carried over from the first proposal where necessary to make their wording consistent with the language used in this proposal. We have removed the definition for the following terms because the terms are not used in this proposal or have been determined to be unnecessary: Active ingredient in any input other than pesticide formulations, active ingredient in pesticide formulations, agroecosystem, botanical pesticides, breeding, chapter, cation balancing agent, certification activities, certification applicant, certified facility, chapter, confirmation of accreditation, contaminant, critical control point, cytotoxic mode of action, degradation, detectable residue level, extract, farm, foliar nutrient, formulated product, fungicide, generic name, incidental additive, inert ingredient in any input other than pesticide formulations, intentionally applied, made with certain organic ingredients, mating disrupter, micronutrient, nonactive residues, nonorganic agricultural ingredient or product, petition, preliminary evaluation, processing methods, production aid, production input, proper manuring, putrefaction, site evaluation, soil amendment, split operation, subtherapeutic, suspension of

accreditation, synergist, synthetic volatile solvent, treated, untreated seeds, USDA seal, and weed. We received comments on some of the definitions that have been deleted. We have not addressed these comments here because the relevant definitions have been deleted.

Definitions—Changes Based On Comments

This subpart differs from our first proposal in several respects as follows:

(1) We have amended the term, “audit trail,” by replacing the category, “organic” or “made with certain organic ingredients,” with “100 percent organic,” “organic,” or “made with organic (specified ingredients),” or agricultural product containing less than 50 percent organic ingredients identified as organic in an ingredients statement. We have taken this action to clarify the definition as requested by several commenters.

(2) We have amended the term, “buffer area,” to “buffer zone” and amended the term by replacing “a certified farm or portion of a farm” with “a certified production operation or portion of a production operation.” A few commenters suggested including a minimum size for the buffer zone and specifying that buffer zones must be uncropped vegetated areas. The appropriate size and type of a buffer zone is highly site-specific and cannot be rigidly specified for all locations without placing unreasonable burdens on some producers. Several commenters supported determination of the appropriate buffer zone size and type by the producer in consultation with the certifying agent. Additional information on this issue can be found at subpart C, Crop Production, Changes Requested But Not Made, item 1.

(3) We have amended the definition of the term, “certification or certified,” to make the language in the definition consistent with the language of this proposal. We have also removed the language concerning the information to be found on a certificate. Commenters suggested amending the definition by adding the words, “annual” and “based on an on-site inspection and comprehensive review of the operation.” Other commenters recommended deleting the reference to products on a certificate because it is the operation, not the product, that is certified. We have not made the suggested additions because the issues are adequately addressed in the regulations. We have removed the language concerning information found on a certificate because this information

is adequately addressed in the regulations.

(4) We have amended the definition of "certifying agent" to clarify that the term only applies to State-entity and private-entity certifying agents. We have taken this action because there was some confusion among commenters over whether the original definition included a State program's governing State official.

(5) We have amended the definition of "commercially available" by removing the phrase, "to be feasibly and economically used." We have taken this action because we agree with commenters that use of the phrase provides an opportunity for producers and handlers to avoid use of preferred inputs. We have also clarified that "commercially available" applies to processors by including the words, "or processing ingredient." Additional information on this issue can be found at subpart C, Production and Handling (General), Changes Requested But Not Made, item 2.

(6) We have amended the definition of "compost" by referring to compost as "the product of a carefully managed process through which microorganisms break down plant and animal materials into more available forms suitable for application to the soil." We also state that "composting" must use methods to raise the temperature of raw materials to the levels needed to stabilize nutrients and kill pathogens. Specific instructions on the production of compost for use in organic production has been referenced to the National Resources Conservation Service's (NRCS) practice standard for a composting facility (Code 317). The NRCS practice Standard provides a field tested and verifiable procedure for producing compost. We have made these changes because commenters suggested that we clarify the meaning of compost. Several commenters stated that the definition should include rules about what kinds of materials are acceptable for use in compost. Additional information on this issue can be found at subpart C, Production and Handling (General), Changes Based On Comments, item 4.

(7) We have amended the definition of "crop rotation" by adding a statement about the relationship of crop rotation to perennial crops as suggested by an industry association.

Several commenters suggested inserting references to the use of legumes and sod as essential to crop rotation. The benefits achieved through the use of legumes and sod could be fulfilled through many types of rotation plans, which could only be developed according to the site-specific climate,

soil type, and type of crops or livestock produced on a given operation. In the interest of flexibility this proposal does not specify what specific crops have to be included in a crop rotation. The issue addressed in this suggestion is addressed in the crop rotation practice standard at § 205.205. Additional information on crop rotation can be found at subpart C, Production, Changes Based On Comments, item 5.

(8) We have amended the definition of "disease vectors" by adding that disease vectors include plants and animals that transmit disease organisms or pathogens which may attack crops or livestock. A few commenters pointed out that the definition as originally proposed was technically inaccurate because it did not address the transmission of disease organisms to crops or livestock.

(9) We have rewritten the definition of "employee" to provide that an employee is any person providing paid or volunteer services for a certifying agent. A few States requested that the definition clearly reference volunteers. A trade association recommended expanding the definition to include any person who works for a certifying agent. We have included volunteers in this proposal because of their substantial use by some certifying agents. Other States suggest changing "certification decisions" to "certification activities" to include any person who is involved in the certification process. We have addressed the commenters' concern by referring to services provided by the employee for the certifying agent. A few States stated that the definition needs to clarify who is the employer of an independent inspector. An independent inspector would not be included in the definition of employee. Such persons are considered to be contractors. Some States expressed concern regarding the use of volunteers from certified production and handling operations.

Section 205.501(a)(11) requires that a certifying agent prevent conflicts of interest by not permitting any employee, inspector, contractor, or other personnel to accept payment, gifts, or favors of any kind, other than prescribed fees, from any business inspected, except that a certifying agent that is a not-for-profit organization with an Internal Revenue Code tax exemption may accept voluntary labor from certified operations. Under this exception all volunteers would be excluded from work, discussions, and decisions in all stages of the certification process and the monitoring of certified production or handling operations for all entities in which such person has or has held a commercial interest, including an immediate family interest or the

provision of consulting services, within the prior 12-month period. Additional information on conflicts of interest can be found at subpart F, Changes Based On Comments, items 4 and 5, and subpart F, Changes Requested But Not Made, items 5, 6, 7, and 8; subpart F, Additional Provisions, item 2.

(10) We have rewritten the definition of "fertilizer" to provide for the inclusion of minor nutrients and trace elements with the three primary nutrients (nitrogen, phosphorus, potassium) contained in a substance or a blended substance utilized in a soil fertility program. This is a generic definition of fertilizer. Issues concerning what substances may be present in a fertilizer for organic production are addressed in subpart C of this proposal.

(11) We have amended the definition of "handle" by providing that the term shall not include the sale, transportation, or delivery of crops or livestock by the producer thereof to a handler. This change was made because we found merit in a certifying agent's concern that farmers were turned into handlers by definition. This was not our intent.

(12) We have amended the definition of "inspector" to make terms used in the definition consistent with terms used in this proposal and to remove the phrase, "who is qualified." A State certifying agent suggested deleting the phrase, "who is qualified," because the issue of inspector qualification is more appropriately addressed in the regulations. We concur that the definition of "inspector" does not need to address the issue of qualifications, especially in light of the fact that certifying agents are required by these regulations to use qualified inspectors.

(13) We have amended the definition of "livestock" by adding reference to the production of fiber, feed, and other agricultural-based consumer products and by providing that "livestock" shall not include fish or bees for the production of food, fiber, feed, or other agricultural-based consumer products. A trade association and several States recommended adding fibers to the definition. We have added fiber, feed, and other agricultural-based consumer products to the definition to capture all types of consumer products that would be produced from livestock. We have excluded aquatic animals from the definition of livestock pending future development of detailed practice standards for specific aquatic animals. We have also excluded bees from the definition of livestock pending future National Organic Standards Board (NOSB or Board) review and recommendations on apiculture.

Additional information on this issue can be found at subpart C, Livestock Production, Changes Based On Comments, items 3 and 4.

(14) We have amended the definition of "market information." A commenter suggested that the definitions of the terms, "labeling" and "market information," were difficult to distinguish from one another and needed clarification. We have added language to make a distinction between the two terms. "Market information" now includes the phrase, "distributed, broadcasted, or made available outside of retail outlets." This phrase indicates that any information distributed, broadcasted, or made available outside of retail outlets to assist in the sale or promotion of a product falls under the "market information" category. "Labeling" includes any information displayed or made available in retail outlets on or about the product.

(15) We have amended the definition of "organic" to clarify that the term, "organic," is used as a labeling term. Commenters, including several States, stated that the definition repeated the proposed requirements for allowing the use of "organic" on a product label. They suggested amending the definition to clarify that the term, "organic," is used as a labeling term. We made the suggested change because we agree that the definition unnecessarily repeated regulatory information and that use of the term, "organic," is intended as a labeling term.

(16) We have amended the definition of "producer" to clarify that the term includes the production of fiber and other agricultural-based consumer products. Several States suggested that the definition of "producer" be amended to clarify that a producer could also be growing or producing a fiber product. We agree that this clarification is needed and have also added reference to "other agricultural-based consumer products" to further clarify that the term includes all agricultural-based consumer products produced by a producer.

(17) We have changed the definition of "routine use of parasiticide" to the definition recommended by the NOSB. Commenters suggested removing "without cause" from the definition in the first proposal and adding such phrases as "without an indication of illness from parasites," "administration with need based on the presence of a diagnosed problem with parasites," and "with or without cause." The NOSB's definition solves the problems caused by the use of the phrase, "without cause." Additional information on this issue can be found at subpart C,

Livestock Production, Changes Based On Comments, item 9.

(18) We have amended the definition of "slaughter stock" by changing "human consumption" to "consumption by humans and other animals." A few commenters recommended deleting the word, "human," to indicate that organic livestock may also be used to produce pet food. We agree that slaughter stock may be used in the production of products for consumption by humans and other animals.

(19) We have amended the term, "soil quality," and its definition by referencing "water" in the term and the definition. This change was made because of the reference to "soil and water quality" in § 205.200 of this proposal. Several State commenters stated that the definition of "soil quality" was too vague and would pose problems in enforcing a requirement that addressed the effect of various practices on soil quality. Other commenters requested expansion of the definition to include a discussion of why soil quality is important and what functions healthy soil serves in an organic production system. Another State suggested expanding the definition to include water quality, since there were several references in the regulations to effects on soil or water quality. The importance of soil quality has been addressed under subpart C of this proposal. We acknowledge that the phrase, "soil and water quality," is used in subpart C and have, therefore, expanded the term, "soil quality," to "soil and water quality" and amended the definition accordingly. We have also added a new phrase to the previous definition to acknowledge that one important criterion of soil and water quality is the control of environmental contaminants. The determination of which observable indicators to monitor and how to interpret the observations will be subject to documentation in the organic system plan and consultation between the producer and the certifying agent. Guidance will be provided to certifying agents through program manuals. Additional information on this issue can be found at subpart C, Production and Handling (General), Changes Based On Comments, item 2.

(20) We have amended the term, "governing State official," to "State program's governing State official" and retained the definition to clarify the difference between a State certifying agent and a governing State official. We have used the term, "State program's governing State official," throughout this proposal. A trade association and a State recommended removing the word,

"certification," from the definition. We have not made this change because the term is meant to identify the person responsible for administering the State's organic certification program. By "State organic certification program," we mean the law, regulations, and any policies and procedures established by the State to govern the organic certification of producers or handlers by State or private certifying agents.

(21) We have amended the definition of "unavoidable residual environmental contamination." Commenters stated that USDA should set levels rather than make case-by-case decisions regarding residual environmental contamination. They suggested that background levels could be used to determine whether land exceeds the level. Another commenter requested a clear statement of "unavoidable" and "contamination" to facilitate enforcement. Some States stated that there should be a level that is unacceptable for organic agriculture. A commenter suggested that the definition read, "The presence of a material prohibited in organic production, processing, or handling in soil, crop, or food that occurs as a result of factors beyond the control of the producer, processor, or handler." Another commenter suggested that the definition read, "Background levels of prohibited substances at a site which are clearly beyond the control of a certified organic farm operator through notices to neighbors, careful avoidance of abnormally precontaminated sites, and establishment of buffer zones." In this proposal, we have defined "unavoidable residual environmental contamination" as "background levels of naturally occurring or synthetic chemicals that are persistent in the soil or present in organically produced agricultural products that are below established tolerances."

Definitions—Changes Requested But Not Made

This subpart retains from our first proposal terms and their definitions on which we received comments as follows:

(1) A few commenters requested that the definition of "Administrator" be revised to provide that authority to administer the National Organic Program may be delegated to a State official. We have not made the recommended change because the definition of "Administrator" merely addresses the top official of the Agricultural Marketing Service (AMS) and any AMS official to whom the Administrator may delegate authority. The definition is not meant to address working relationships established

between AMS and a State or State entity.

(2) An environmental group requested that we delete the phrase, "other than during the manufacture of a multiingredient product containing both types of ingredients," from the definition of "commingling." This proposal requires that a handler prevent the commingling of organic and nonorganic products but permits use of the word, "organic," in labeling a product made with organic and nonorganic ingredients in accordance with these regulations. Therefore, it is necessary to indicate that the term, "commingling," does not apply to the manufacture of multiingredient products produced in accordance with these regulations.

(3) A farmers' association recommended that the Secretary delegate authority for determining crop year to certifying agents because crop year will vary from region to region. We have found no compelling reason to make certifying agents responsible for determining crop year and have not made the recommended change.

(4) A few commenters requested that the definition of "handling operation" be amended to exclude retailers of prepackaged agricultural products. This change is unnecessary because such retailers are excluded by the definition of "handling operation" through the phrase, "except final retailers of agricultural products that do not process agricultural products."

(5) Several commenters, including a State department of agriculture, recommended elimination of the exception for weight labels in the definition of "label." We have not made the recommended change to the definition of "label" because, as used in this proposal, "label" is intended to represent the organic nature of the product. A weight label that does not refer to the organic nature of the product would not constitute a label for the purposes of this proposal.

(6) A commenter requested that the definitions for "labeling" and "market information" be amended to refer only to products produced by the seller. We have not made this requested change because changing the definitions to only include products produced by the seller would severely restrict the application of the terms, "labeling" and "market information." As defined, "labeling" and "market information" correctly include any information that may be presented to consumers concerning all products sold whether produced by the seller, most likely a retail outlet, or produced by a production or handling

operation from which the seller acquired the products.

(7) A commenter requested that we include definitions for "manure" and "aged or rotted manure." Under this proposal it is not necessary to define either term.

(8) An environmental organization requested that a phrase be added to the definition of "mulch" to indicate that acceptable mulch materials leave no chemical or toxic residues. This proposal allows the use of composted plant and animal wastes obtained from nonorganic sources, such as commercial compost products. Uncomposted plant or animal waste material which has been treated with a substance can be as utilized as a mulch provided the substance appears on the National List or complies with the OFPA. Off-farm plant and animal wastes from food processing, municipal yard waste facilities, and other sources are used extensively in existing organic operations and generally permitted by organic certification programs. Using such organic wastes is consistent with a system of organic production and handling, which calls for recycling organic wastes to return nutrients to the land. We believe that concerns about potential contaminants in plant and animal waste materials can be addressed by the requirement in this proposal that these materials be managed in a manner that prevents such contamination. Accordingly, this change has not been made. Additional information on this issue can be found at subpart C, Crop Production, Changes Requested But Not Made, items 2 and 3.

(9) Several commenters suggested adding information to the definition of "National Organic Standards Board" to address the role of the NOSB with regard to the National List. This change is unnecessary because the role of the NOSB is adequately covered in section 6517, National List, of the Act.

(10) Numerous comments were received from consumers, environmental groups, and organic producers concerning the definition of the term, "nonagricultural ingredient." Commenters expressed the view that this term represented an attempt by USDA to circumvent the intent of the Act that synthetic ingredients not be permitted in organic processed products. We disagree with the position that the Act prohibits the use of synthetic ingredients in organic processed products. The use of synthetic ingredients in organic processed products is discussed in the preamble to the National List found in subpart G. We have changed the term, "nonagricultural ingredient," to

"nonagricultural substance" to be consistent with the language used in this proposal. The definition remains the same.

(11) Commenters stated their objection to the use of the term, "nonsynthetic (natural)," and its definition. A commenter mistakenly stated that the term, "natural," was defined in the Act. Other commenters felt that use of any term that was not included in the Act was a violation of the Act. Because the term, "natural," is so ambiguous and subject to differing interpretations, the term, "nonsynthetic," as used throughout this regulation, represents an important clarification of the intent of the Act, and we have, therefore, retained it in this proposal.

(12) A few commenters requested that the definition of "petition" be amended by adding the phrase, "to the National Organic Standards Board," immediately following the word, "submitted." We have not made the requested change for two reasons. First, the change is unnecessary. Second, petitions, whether addressed to the NOSB or National Organic Program (NOP) Staff, will be received by the NOP because the administrative functions of the NOSB are performed at the NOP office. Petitions received will be distributed by the NOP to the NOSB and appropriate technical reviewers.

(13) A producers association stated that the definition for "processing" was confusing with regard to the difference between a handler and a processor. A handling operation that performs any of the activities listed in the definition of processing becomes a processor. We have found no compelling reason to revise this comprehensive definition for processing, which comes directly from the Act. A commenter suggested that this definition be changed to include repackaging for weight. In addition to the definition being stipulated by the Act, affixing a weight label to a product is a normal retail activity that does not warrant the expense and effort necessary to certify all retailers who routinely affix weight labels to organic product.

(14) A few commenters requested that the definition of "State organic certification program" be amended by adding a statement indicating that a State program could have additional requirements. This issue is addressed in subpart G, State Organic Certification Programs, Proposal Description.

(15) A technical institute recommended including genetically engineered organisms and their products in the definition of "synthetic," and an environmental

group wanted the definition to include the combustion of minerals. We have not amended the definition as given in the Act because it already includes the combustion of minerals, which are chemically changed by the process of combustion. We also do not consider it necessary to classify genetically engineered organisms as either synthetic or nonsynthetic for the purposes of this regulation, since these organisms and their products are prohibited for use in organic production or handling regardless of whether or not they are synthetic.

(16) A commenter recommended adding the word, "synthetic," immediately preceding the word, "substances," in the second sentence of the definition of "system of organic farming and handling." We disagree with this suggestion because "substances" as used in this definition could be synthetic or nonsynthetic. A few commenters requested deletion of the word, "extraneous," as a modifier of "synthetic additives" in the definition of "system of organic farming and handling." The commenters stated that use of the word, "extraneous," implied that synthetic additives can be used in organic processed products. Synthetics may be used in processed products if the substance is included on the National List. Additionally, the word, "extraneous," modifies the word, "processing," in the definition, and we consider use of extraneous processing to be inconsistent with organic handling. For these reasons, we have not removed the word, "extraneous," from the definition. We have, however, amended the term, "system of organic farming and handling," by deleting "farming" and inserting "production." The definition for the term, "system of organic production and handling," is unchanged. We have taken this action to make the term consistent with the language of this proposal. Additional information on this issue can be found at subpart C, Production and Handling (General), Changes Requested But Not Made, item 1.

(17) Several commenters, including a State Department of Agriculture and a fishery association, requested that wild game and aquatic animals be included in the definition of "wild crop." Regarding aquatic animals, we intend to develop detailed practice standards for specific aquatic species, which will be published for comment and finalized prior to the implementation of the NOP. Given the virtual absence of recognized certification programs for aquatic operations, including aquaculture, there are no U.S. models on which to base national standards. Additional

information on this issue can be found at subpart B, Changes Requested But Not Made, item 11 and subpart C, Crop Production, Changes Requested But Not Made, item 7. Accordingly, we have not made the requested changes to the definition of "wild crop."

Definitions—Additional Provisions

Upon further review of the definitions in the first proposal, we have decided to propose the following additions and changes.

Amended Definitions

(1) We have amended the definition of "accreditation" to include foreign entities as now provided for in subpart F, Accreditation. Additional information on including foreign entities in accreditation can be found at subpart B, Additional Provisions, item 1, and subpart F, Changes Based On Comments, item 1.

(2) We have amended the definition of "allowed synthetic" by replacing "for use in organic farming" with "for use in organic production, or handling." This correction was necessary because the National List includes synthetic substances used in organic production and handling.

(3) We have amended the terms, "certified organic farm," "certified organic handling operation," and "certified organic wild-crop harvesting operation," with the term, "certified operation." The term, "certified operation," is used throughout this proposal to refer to a crop or livestock production, wild-crop harvesting, or handling operation or portion of an operation that is certified by an accredited certifying agent as utilizing a system of organic production or handling as described by the Act and regulations in this part. We have taken this action to simplify the regulatory language.

(4) We have amended the term, "cultural," to "cultural methods" and amended the definition by removing all references to livestock. We have taken this action because this proposal does not refer to cultural methods with reference to livestock health care.

(5) We have amended the definition of "field" by replacing "farm" with "production operation." This action was taken because "farm" has been replaced by "production operation" throughout this proposal.

(6) We have amended the definition of "handler" by adding the phrase, "including producers who handle crops or livestock of their own production." We have made this change to clarify that producers who handle their own production become handlers under the

regulations. Such producer/handlers must be certified as a handler.

(7) We have amended the term, "inert ingredient in pesticide formulations," to "inert ingredient." We have also amended the definition by specifying that the pesticide product is used in organic crop or livestock production and handling. These changes have been made to make the term and its definition consistent with the language used in the National List. This proposal takes a different position on inert ingredients, as explained in subpart G, National List, Changes Based On Comments, item 6, than was taken in the first proposal. Because of the increased importance of inert ingredients in this proposal, we have rejected the position of the few commenters who recommended removal of this definition.

(8) We have amended the term, "organic plan," to "organic system plan" and made editorial changes to the definition to make the term and language of the definition consistent with the language in this proposal.

(9) We have amended the definition of "peer review panel" by removing "to assist in evaluating the performance of a certifying agent" and inserting "to assist in evaluating applicants for accreditation as certifying agents." This change clarifies that the role of the peer review panel is to evaluate applicants for accreditation. Additional information on "peer review panel" can be found at subpart C, Proposal Description, Production and Handling (General).

(10) We have amended the definition of "person" by adding "contractor" to clarify that, when the regulations use "person," the meaning includes "contractors."

(11) We have amended the definition of "records" by removing the record examples. A trade association and several States recommend adding "process flow charts" to the examples of records. Another commenter, who does not want to give USDA unlimited access to personnel files, suggested the creation of a specific list of records to be maintained. We have rewritten the recordkeeping provisions, removing all references to specific records or types of records which must be maintained. We have taken this action because we believe that it is impracticable to specify in detail every class of records which may be found essential in demonstrating compliance with the Act and regulations. Different types of certified production and handling operations will, by the very nature of their business, be required to maintain different records to establish their

compliance with the Act and regulations. Additional information on the issue of listing every class of records which may be found essential in demonstrating compliance with the Act and regulations can be found at subpart B, Changes Based On Comments, item 6.

(12) We have amended the definition of "State." Addition of the term, "State entity," necessitated our amendment of the definition of "State" to clarify that State means the States of the United States of America.

(13) We have amended the term, "system of organic farming and handling," to "system of organic production and handling" and retained the original definition in this proposal. The original definition was crafted to be consistent with the requirements of the Act. We have changed "farming" to "production" to provide a more encompassing term, which may come to include such diverse activities as hydroponics, green house production, and harvesting of aquatic animals. The purpose of the original definition was to describe practices and substances consistent with systems of organic farming and organic handling as required by the Act and to provide an explicit reference point for determining which practices and substances are most consistent with these systems. Several commenters suggested that the definition include the concepts, "agroecosystem health," "ecological harmony," and "biological diversity." Commenters also suggested including definitions for "organic agriculture," "organic farming," and "transition to organic." This definition is intended to clarify regulatory provisions in this proposal and is not intended as a broad philosophical statement. The terms, "organic agriculture," "organic farming," and "transition to organic," are not used in this proposal and, therefore, are not defined.

(14) We amended the definition of transplant to prevent confusion with a related term, "seedling." While the terms, "transplant" and "seedling" are often used interchangeably, the Act treats them as distinct and establishes separate regulatory requirements. We have determined that the physical process of moving and replanting a seedling results in that seedling becoming a transplant. We have created this distinction to be able to enforce the full requirements of the Act. Additional information on "transplant" can be found at subpart C, Crop Production, Changes Based On Comments, item 4.

New Definitions

(1) We have defined "accredited laboratory." Information concerning

"accredited laboratory" can be found at subpart G, Inspection and Testing, Reporting, and Exclusion from Sale, Proposal Description.

(2) We have defined "action level." Information concerning "action level" can be found at subpart G, Inspection and Testing, Reporting, and Exclusion from Sale, Changes Based On Comments, item 2.

(3) We have defined "agricultural inputs." Information concerning "agricultural inputs" can be found at subpart G, Inspection and Testing, Reporting, and Exclusion from Sale, Changes Based On Comments, item 1.

(4) We have defined "Agricultural Marketing Service (AMS)" "because the term is used throughout this proposal.

(5) We have defined "breeder stock." We have added this definition because this proposal establishes conditions for the administration of an allowed synthetic parasiticide to livestock producing offspring for incorporation into an organic operation. We have also proposed conditions under which dairy stock, whose milk or milk products are to be sold, labeled, or represented as organically produced, may be treated with allowed synthetic parasiticides. Additional information on this issue can be found at subpart C, Livestock Production, Changes Based On Comments, item 9.

(6) We have defined "bulk." Information concerning "bulk" can be found at subpart D, Additional Provisions, item 7.

(7) We have defined "claims." Information concerning "claims" can be found at subpart D, Changes Based On Comments, item 1.

(8) We have defined "detectable residue." Information concerning "detectable residue" can be found at subpart G, Inspection and Testing, Reporting, and Exclusion from Sale, Proposal Description and at Changes Based On Comments, item 2.

(9) We have defined "drift." Information concerning "drift" can be found in subpart G, Residue Testing, changes based on comments, item 2.

(10) We have defined "estimated national mean." Information concerning "estimated national mean" can be found at subpart G, Inspection and Testing, Reporting, and Exclusion from Sale, Proposal Description and at Changes Based On Comments, item 2.

(11) We have defined "excluded methods." As a result of extensive public comment, we have revised the definition of certain methods to be excluded from organic production systems. Many commenters suggested that we use the definition for certain methods to be excluded from organic

production systems proposed by the NOSB. This proposal essentially adopts that definition. "Excluded methods" refers to a variety of methods used to genetically modify organisms or influence their growth and development by means that are not possible under natural conditions or processes and are not considered compatible with organic production. Such methods would include recombinant DNA, cell fusion, and micro-and macroencapsulation. Such methods would not include the use of traditional breeding, conjugation, fermentation, hybridization, in vitro fertilization, or tissue culture.

We recognize that the phrases, "natural conditions or processes" and "not considered compatible with organic production," may be subject to interpretation. We have proposed to use these phrases for two reasons. First, "natural conditions or processes" is used in the NOSB and American Organic Standards definitions, both of which were the result of consultation with organic industry and consumer stakeholders and, thus, accurately reflect current industry practices as well as consumer preferences. Second, we recognize that industry and consumer expectations regarding the products of these techniques in organic production systems may evolve. We believe that, taken together, these phrases allow for a degree of flexibility to ensure that our regulations continue to accurately reflect industry practices and consumer preferences. In cases where questions may arise regarding a specific technique, we anticipate that such questions would be resolved by the Administrator based on recommendations from the NOSB.

(12) We have defined "feed additive." Information concerning "feed additive" can be found at subpart C, Livestock Production, Changes Based On Comments, item 7.

(13) We have defined "feed supplement" Information concerning "feed supplement" can be found at subpart C, Livestock Production, Changes Based On Comments, item 7.

(14) We have defined "forage." Information concerning "forage" can be found at subpart C, Livestock Production, Changes Based On Comments, item 4.

(15) We have defined "immediate family." Information concerning "immediate family" can be found at subpart F, Changes Based On Comments, items 14 and 15; Changes Requested But Not Made, item 18; and Additional Provisions, item 2.

(16) We have defined "ingredient" because the term is used throughout subpart D.

(17) We have defined "inspection" because the term is used throughout subparts E and F.

(18) We have defined "lot." Information concerning "lot" can be found at subpart D, Proposal Description and at Additional Provisions, item 6.

(19) We have defined "natural resources of the operation." This definition has been added to provide greater context for evaluating the "maintain or improve" requirement for a system of organic production and handling. Information concerning "natural resources of the operation" can be found at subpart C, Production and Handling (General), Changes Based On Comments, item 2.

(20) We have defined "nonretail container." Information concerning "nonretail container" can be found at subpart D, Proposal Description and at Additional Provisions, item 6.

(21) We have defined "practice standard." Practice standards have been added to this proposal in response to commenter requests for more specific guidelines for measuring the performance of an organic system of production and handling. A practice standard is a series of specific guidelines, requirements, and operating procedures through which a production or handling operation implements a required component of its organic system plan. For example, this proposal contains a practice standard for soil fertility and crop nutrient management which describes the tillage practices, sources and handling restrictions for nutrients, and prohibited activities that a production operation must comply with. There are specific practice standards applicable to crop, livestock, and wild-crop production, and handling operations. We are also proposing to incorporate the terms of the NRCS practice standard for a composting facility into the requirements of this proposal. Additional information on "practice standards" can be found at subpart C, Production and Handling (General), Changes Based On Comments, item 4.

(22) We have defined "private entity" because the term is used throughout subpart F to differentiate between governmental (State entity) and nongovernmental (private entity) organizations providing certification services.

(23) We have defined "production lot number." Information concerning "production lot number" can be found at subpart D, Proposal Description and at Additional Provisions, item 6.

(24) We have defined "residue testing" because the term is used

throughout the inspection and Testing, Reporting, and Exclusion from Sale portion of subpart G.

(25) We have defined "retail food establishment." Information on "retail food establishment" can be found in subpart B, Applicability, Proposal Description and Additional Provisions, item 2.

(26) We have defined "sewage sludge." This term has been added and defined as synonymous with "biosolids" to incorporate the Environmental Protection Agency's regulatory language for this category of materials. Information concerning "sewage sludge" can be found at subpart C, Crop Production, Changes Based On Comments, item 1.

(27) We have defined "State entity." This proposal provides for the accreditation of domestic, tribal government, and foreign governmental subdivisions that provide certification services. We refer to such an entity in this proposal as a "State entity." Additional information on "State entity" can be found at subpart F, Changes Based On Comments, item 1.

(28) We have defined "tolerance." Information concerning "tolerance" can be found at subpart G, Inspection and Testing, Reporting, and Exclusion from Sale, Proposal Description and at Changes Based On Comments, item 2.

Subpart B—Applicability

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

Proposal Description

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

Certifying agents will begin the process of certifying organic production and handling operations to the national standards upon receipt of their accreditation from the Administrator. All production and handling operations certified by an accredited certifying agent will be considered certified to the national standards until the certified

operation's anniversary date of certification. We are providing this phase-in procedure for production and handling operations certified by newly accredited certifying agents because we believe that such certifying agents will, upon publication of the final rule, demonstrate their eligibility for accreditation by applying the national standards to the certification and renewal of certification of their clients. We are also providing this phase-in procedure to provide relief to certified operations which would otherwise have to be certified twice within a 12-month period (prior to their certifying agent's accreditation and again following their certifying agent's accreditation). This relief will only be available to those certified operations certified by a certifying agent that receives its accreditation within 18 months from the date of publication of the final rule. We anticipate that certifying agents and production and handling operations will move as quickly as possible to begin operating under the national organic standards. We are providing this substantial phase-in period because accredited certifying agents will have to schedule on-site inspections around varying growing seasons and because certifying agents and production and handling operations will need time to adapt to the new national organic standards.

Exempt and Excluded Operations.

This regulation establishes several categories of exempt or excluded operations. Exempt operations derive their exemption from the Act while excluded operations are excluded as a result of a Departmental policy decision. An exempt or excluded operation does not need to be certified. However, operations that qualify as exempt or excluded operations may elect to apply for certification. A production or handling operation that is exempt or excluded from obtaining certification still must meet other regulatory requirements contained in this rule as explained below.

Exempt Operations. (1) A production or handling operation that has \$5,000 or less in gross agricultural income from organic sales annually is exempt from certification and does not need to submit an the organic system plan to anyone for acceptance or approval. However, an exempt producer or handler must comply with the labeling requirements of § 205.309 and the organic production and handling requirements applicable to its type of operation. For example a producer of organic vegetables, that performs no handling functions, would have to comply with the labeling requirements

of § 205.309 and the applicable production requirements in §§ 205.202 through 205.207. The labeling and production and handling requirements protect the integrity of organically produced products.

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

(3) A handling operation or portion of a handling operation that handles agricultural products containing less than 50 percent organic ingredients by total weight of the finished product (excluding water and salt) is exempt from the requirements in these regulations, except the recordkeeping provisions of § 205.101(c); the provisions for prevention of contact of organic products with prohibited substances in § 205.272; and the labeling regulations in § 205.309. The recordkeeping provisions maintain an audit trail for organic products. The prevention of contact with prohibited substances and the labeling requirements protect the integrity of organically produced products.

(4) If a handling operation or portion of a handling operation that handles agricultural products containing at least 50 percent organic ingredients by weight (excluding water and salt) does not use the word, "organic," on any package panel other than the information panel, it is exempt from the requirements in these regulations, except the recordkeeping provisions of § 205.101(c); the provisions for prevention of contact of organic products with prohibited substances as provided in § 205.272; and the labeling regulations in § 205.309. The recordkeeping provisions maintain an audit trail for organic products. The prevention of contact with prohibited substances and labeling requirements protect the integrity of organically produced products.

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

compliance with the applicable regulations.

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

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

(2) A retail food establishment or portion of a retail food establishment that processes or prepares, on the premises of the retail food establishment, raw and ready-to-eat food from certified agricultural products labeled as "100 percent organic," "organic," or "made with organic (specified ingredients)" is excluded from the requirements in these regulations, except for the provisions for prevention of contact of organic products with prohibited substances as provided in § 205.272; and the labeling regulations in § 205.309. The prevention of commingling and contact with prohibited substances and labeling requirements protect the integrity of organically produced products.

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

We have excluded such retail food establishments because comments to the first proposal concerning the issue of certification of retail food establishments were completely divergent. Comments ranged from the certification of all retail food establishments to exclusion of all retail food establishments. There is clearly a great deal of public concern regarding the handling of organic products by retail food establishments. Someday retail food establishments may be subject to regulation under this NOP.

Any such regulation would be preceded by rulemaking with an opportunity for public comment. Our exclusion of retail food establishments from this proposal does not prevent a State from developing an organic retail food establishment certification program or otherwise regulating retail food establishments that prepare, package, or process organic agricultural products.

No retailer, regardless of this exclusion and the exceptions found in the definitions for "handler" or "handling operation," may sell, label, or provide market information on a product unless such product has been produced and handled in accordance with the Act and these regulations. Any retailer who knowingly sells or labels a product as organic, except in accordance with the Act and these regulations, will be subject to a civil penalty of not more than \$10,000 under this program. Such retailer may also be subject to enforcement actions and penalties under Federal statutes and their implementing regulations administered by other agencies of the Federal government.

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

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

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

Request for Comment. This proposal provides that all ingredients in a multiingredient product identified as

organic must have been produced by a production or handling operation certified by an accredited certifying agent. We are seeking comment on the following question. Should handlers be allowed to identify organically produced products produced by exempt production operations as organic ingredients? Such identification would be restricted to the ingredients list on the information panel. This may provide a wholesale outlet for organically produced agricultural products produced by producers exempted from certification because their gross agricultural income from organic sales totals \$5,000 or less annually.

Compliance with Federal Statutes and Regulations. Any agricultural product that is sold, labeled, or represented as "100 percent organic," "organic," or "made with organic (specified ingredients)" must be produced and handled in accordance with the requirements in these regulations. Organic agricultural products must be produced and handled in compliance with the Federal Meat Inspection Act, the Poultry Products Inspection Act, and the Egg Products Inspection Act, concerning meat, poultry, and egg products; the Federal Food, Drug, and Cosmetic Act; the Federal Insecticide, Fungicide, and Rodenticide Act; and any other applicable Federal statute and its implementing regulations.

Foreign Applicants. The regulations in this part, as applicable, apply equally to domestic and foreign applicants for accreditation, accredited certifying agents, domestic and foreign applicants for certification as organic production or handling operations, and certified production and handling operations unless otherwise specified.

Applicability—Changes Based on Comments

This subpart differs from our first proposal in several respects as follows:

(1) *Exception for Handlers Serving Three or Fewer Certified Operations.* We have removed the provision that would have allowed handlers providing services to fewer than three certified organic producers to operate without separate certification under the NOP (§ 205.201). Such handlers will now have to be certified unless otherwise exempted or excluded from certification under § 205.101 of these regulations. We have taken this action because we believe that the first proposal invites problems, such as making certain that the contracted handler maintains compliance with the Act and regulations, taking enforcement actions against persons violating the Act and regulations, and being equitable to all

handlers since large-volume handling operations may qualify for inclusion under the provision on the basis of few clients while small-volume handlers would be disqualified because they have three or more clients.

More than 100 comments were received, most from consumers, in opposition to the provision. Many of the commenters erroneously interpreted the provision as an exemption for handlers of product for less than three certified operations. Most of these commenters expressed the belief that it is a violation of the Act to allow handlers to operate through inclusion under another certified operation's certification rather than through separate certification under the Act and regulations. Several commenters stated that it is unacceptable to exempt handling operations providing services to fewer than three certified entities from separate certification. Several commenters stated that operations that process products from a certified producer should always be certified. Several State departments of agriculture and others stated that the exemption for handlers servicing fewer than three certified operations does not make sense. They emphasized that certified operations could produce very large quantities of organic product and a large-scale handler may contract with only a few certified producer operations. Therefore, they called for elimination of the exemption. A few commenters questioned the certified operation's ability to ensure that the contracted handler maintains compliance with the Act and regulations. They expressed their belief that the certified operation would have no authority to maintain compliance with the Act within a facility it neither owns nor manages.

We never intended to exempt handlers of fewer than three certified operations from certification. Rather, we proposed a means by which handlers of fewer than three certified operations could be covered under the certification of a certified operation for which it provides handling services.

Several of the commenters favored the provision 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. However, supporters of the concept differed in their position on the proposal. Most stated that the provision would work

only if it is made clear that a handler can provide services to only one or two separate entities and qualify for the exemption and only if included in the certifications of and inspected along with the entities for which the handler will provide the services. They further emphasized that all applicable standards must be met. A few supporters recommended that there be a contract between the handler and the certified operation and that the certified operation be responsible for any failure of the handler to adhere to these regulations. Another commenter stated that, if handlers are to be exempt from certification, the qualifying parameter for exemption should be based upon economic value similar to that for production operations.

Two commenters supported the proposal but wanted the fewer-than-three-certified-operations limitation removed. One of the commenters, a nonprofit agricultural organization, expressed the belief that the limitation needlessly restricts commercial activity, invites an excessive amount of paperwork related to certification applications, and provides no greater assurances for quality control. This commenter, referring to the definition of handling operation at section 6502(10) of the Act, interpreted "to receive or otherwise acquire" as synonymous with taking legal title to the product. This commenter stated that this interpretation creates a distinct, verifiable threshold which clearly identifies those operations needing to be certified and those that do not need to be certified. Under the commenter's suggested system, handlers who take legal title to organic products assume responsibility for their subsequent handling and are required to have their operations certified. Any handler who works on organic products without taking legal title would have his or her activities approved and monitored by the certifying agent responsible for the product when it arrived at the handler's door. The commenter believes that noncertified handlers who wanted to serve organic customers would quickly learn to provide the quality control and accountability requirements which certifying agents expect to see.

We disagree with the commenters who recommended removal of the fewer-than-three-certified-operations restriction on the grounds that the proposal to limit exemptions to handlers contracting with fewer than three certified operations needlessly restricts commercial activity, invites an excessive amount of paperwork related to certification applications, and provides no greater assurances for

quality control. The primary justification given for removal of the fewer-than-three-certified-operations restriction is the belief that any handler who works on organic products without taking legal title would have his or her activities approved and monitored by the certifying agent responsible for the product when it arrived at the handler's door. First, it is unreasonable to expect the certifying agent to be responsible for monitoring noncertified handlers even if they are providing services to an operation certified by the certifying agent. Second, we disagree with the commenter's interpretation that "to receive or otherwise acquire" is synonymous with taking legal title to the product. "To receive or otherwise acquire" involves the possession, control, or custody of a product. Such possession, control, or custody of a product may or may not involve the transfer of title to the product. In other words, a handler may have possession, control, or custody of the product under a right derived from a certified operation but not under a claim of the handler's title to the product.

(2) *Certification for a Portion of a Production or Handling Operation.* We have clarified that a portion of a production or handling operation can be certified. We have taken this action because we agree with the association commenter who suggested that the Department clarify for potential applicants for certification that a portion of their production or handling operation can be certified. The Act at section 6506(b) authorizes the certification of specific fields of a production operation or parts of a handling operation when: (1) In the case of a production operation or field, the area to be certified has distinct, defined boundaries and buffer zones separating the land being operated through the use of organic methods from land that is not being operated through the use of such methods; (2) the operators of such production or handling operation maintain records of all organic operations separate from records relating to other operations and make such records available at all times for inspection by the Secretary, the certifying agent, and the State program's governing State official; and (3) appropriate physical facilities, machinery, and management practices are established to prevent the possibility of a mixing of organic and nonorganic products or a penetration of prohibited chemicals or other substances on the certified area. This clarification is found at § 205.100 of this proposal.

(3) *Exemption for Operations with \$5000 or Less in Income.* We have

clarified at § 205.101(a)(1) that the producer and handler exemption from certification applies to production and handling operations that sell agricultural products as organic but whose gross agricultural income from organic sales totals \$5,000 or less annually. We have taken this action because of commenter confusion over whether the \$5,000 level applied to all sales of agricultural products or just sales of organic agricultural products. This action is consistent with the position of a State department of agriculture, which stated that the \$5,000 exemption should apply to organic sales, not sales of all agricultural products. The commenter believes that, as originally proposed, the regulation would limit opportunities for organic industry development, especially for small producers and other small agribusinesses.

(4) *Applicability of Regulation to Exempt Operations.* We have revised the producer and handler exemption, provided to producers and handlers with gross agricultural income from organic sales totaling \$5,000 or less annually, to provide that such operations are exempt from certification and do not need to submit an organic system plan to anyone for acceptance or approval but must comply with the requirements for organic production and handling and the labeling requirements for agricultural products produced on an exempt or excluded operation. We have taken this action because the first proposal too narrowly addressed the regulatory requirements that exempt producers must meet. Our purpose is to exempt such production and handling operations from the regulatory and financial burdens of certification but not to exempt them from the standards for organic production and handling. A fundamental concept of this regulation is to establish a label for organic. To the extent that these entities will be using the term, "organic," to describe their product, they must be truthful. If they don't comply with the other requirements of this part, they cannot truthfully describe their product as organic.

Several State commenters expressed the belief that the producer exemption would be too difficult to enforce. Some expressed the belief that exempt production operations would still require monitoring to verify compliance with organic standards. A State department of agriculture commented that some monitoring of uncertified operations would still be needed to verify compliance with standards; otherwise there would be no guarantee that standards would be met for

products being sold as organic. Another State, which expressed strong disagreement with the producer exemption, asked how complaints against such producers would be reconciled if they are exempt from the NOP and do not have to maintain records over a multiple-year period. This commenter stated its intent, under its State program, to require certification of organic production operations producing less than \$5,000 in agricultural product yearly. This same commenter acknowledged the Federal program's obligation to provide the exemption as required by section 6505(d) of the Act.

A producer raised the issue of having exempt operations provide affidavits of compliance with the Act and regulations except for certification. A certifying agent made the observation that the rule as first proposed would not permit exempt producers, whether operating under an affidavit or not, to sell any of their products to a certified operation for further processing unless they were fully certified. This certifying agent stated that it did not believe excluding exempt producers from selling any of their products to a certified operation for further processing unless they were fully certified was consistent with the intent of the Act.

We disagree with both commenters. First, we believe that an affidavit program for exempt producers, opting to exercise their right to the exemption, would impose unnecessary regulation upon entities that the Act clearly intended not to impose such regulation upon. Second, an affidavit program would create a regulatory burden on the Department and certifying agents that would not be justified by the size of such operations. We recognize, as pointed out by commenters, that some State programs currently require organic production operations that would be exempt under this national program to register with the State and to comply with requirements such as filing financial records and maintaining records of production methods and substances used.

While we believe that an affidavit program is not appropriate at the national level, we do believe that States would be authorized to regulate organic operations exempted under the NOP's \$5,000-or-less organic sales exemption under an approved State program. Under this proposal, producers and handlers exempted under the NOP's \$5,000-or-less organic sales exemption will be exempt from the certification regulations and will not have to submit an organic system plan to anyone for acceptance or approval but will be

required to comply with the requirements for organic production and handling and for labeling. States may implement a program for monitoring the activities of exempt production and handling operations and enforcing compliance with the NOP. States will be permitted to require certification of federally exempted producers and handlers under an approved State organic certification program. The Department will consider any complaint of noncompliance with these regulations by an exempt production or handling operation and take appropriate action.

(5) *Applicability of Federal Statutes.* We have added at § 205.102(c) reference to a production or handling operation's responsibility for complying with all applicable Federal statutes and their implementing regulations as those statutes may apply to the production and handling of agricultural products. We have made this addition as a means of advising producers, handlers, and the public that these regulations do not supersede or alter a producer's or handler's responsibilities under other Federal statutes and their implementing regulations.

A processors association urged the Department to advise the public in this rule that food products produced and processed under the organic standard must comply with applicable provisions of the Federal Food, Drug, and Cosmetic Act; the Federal Meat Inspection Act; the Poultry Products Inspection Act; and all other relevant statutes and their implementing regulations, in all respects, especially related to adulteration and misbranding.

(6) *Recordkeeping Provisions.* We have rewritten the recordkeeping provisions removing all references to specific records or types of records which must be maintained. In their place, we are requiring that certified operations maintain records adapted to the particular business that the certified operation is conducting. Such records must disclose all activities and transactions of the certified operation in sufficient detail as to be readily understood and audited and must be sufficient to demonstrate compliance with the Act and regulations. We have taken this action because we believe that it is impracticable to specify in detail every class of records which may be found essential in demonstrating compliance with the Act and regulations. Different types of certified production and handling operations will, by the very nature of their business, be required to maintain different records to establish their

compliance with the Act and regulations.

A certifying agent and a beekeepers association expressed support for the recordkeeping requirements in the first proposal. The beekeeping association emphasized the value of such recordkeeping in monitoring the use of substances. A marketing association and a State commented that the recordkeeping period for a list of substances applied to a certified operation should be changed from 3 to 5 years to be consistent with the requirements of section 6511(d) of the Act. A research foundation suggested removal of the requirement for identifying the name and address of the person who applies and who has applied any substance to any part of the farm and any livestock or other agricultural product. A trade association recommended the addition of a new paragraph addressing the records required to be maintained by crop production operations to establish an audit trail. Specifically, the commenter recommended that the new paragraph require that an audit trail be maintained by all organic crop production operations, which records: (1) All sources and amounts of all off-farm inputs; (2) the dates, rate, method of application, location, reason for use, and name and address of applicator for all off-farm inputs; (3) the dates, projected and actual yield, and harvest location of all crops produced by the operation, both organic and nonorganic; (4) the dates, quantities, and locations of all crops stored; (5) the transport system(s) used to distribute organic crops; and (6) the product name, date, quantity, and buyer of all products sold, both organic and nonorganic. A State commenter stated that the maintenance of records on a certified operation is important, but there must be restraint in requiring redundant or irrelevant information. Approximately 50 retail commenters, speaking on behalf of a producer handler, stated that the recordkeeping requirements were burdensome and overly complicated.

Comments indicated that there was some concern regarding what records had to be maintained by certified operations. Commenters were concerned about requiring the maintenance of the correct records for establishing an audit trail, avoiding the retention of redundant or irrelevant records, and minimizing the burden and complexity of the recordkeeping.

We agree with the commenters who stated that the recordkeeping period for a list of substances applied should be consistent with the 5-year recordkeeping requirements of the Act.

Accordingly, this proposal at § 205.103(b)(3) requires that certified operations maintain all records applicable to their organic operations for not less than 5 years beyond their creation. We disagree with those commenters who called for more specifics relative to what records need to be maintained and agree with those commenters who expressed concern regarding the magnitude of records required to be maintained. This proposal provides each production and handling operation with the opportunity to decide for itself what records are necessary to demonstrate its compliance with the Act and regulations.

(7) *Exemption from Prevention of Commingling.* We have removed the requirement that 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) that is exempt from the requirements in this part comply with the provision for the prevention of commingling. As noted in item 8 below, exempt handlers of agricultural products that contain at least 50 percent organic ingredients by weight will also be exempt from complying with the provision for the prevention of commingling. We have taken this action because the commingling of agricultural products is often a part of the processing activity. Such operations must, however, comply with all of the applicable labeling provisions of subpart D including the prohibition on the combining of organic and nonorganic forms of the same agricultural product. In other words, the handler must not, for example, combine organic and nonorganic corn if corn is to be shown on the information panel as "organic corn."

A commenter called for the removal of the requirement that an exempt handler comply with the provisions for the prevention of commingling and contact of organic products with prohibited substances. The commenter claimed that requiring exempt handlers to prevent commingling of organic and nonorganic products and contact of organic products with prohibited substances is inconsistent with the Act. We do not agree. As noted above, we have removed the prevention of commingling requirement because the commingling of agricultural products is often a part of the processing activity. We have not, however, removed the requirement for the prevention of contact of organic products with prohibited substances because the requirement is necessary to safeguard

the integrity of organic ingredients used in the products being handled.

(8) *Exemption for Handlers that Handle Product Containing at Least 50 Percent Organic Ingredients.* We have provided at § 205.101(a)(4) that any handling operation or portion of a handling operation that handles agricultural products that contain at least 50 percent organic ingredients by weight (excluding water and salt) that chooses to not use the word, "organic," on any panel other than the information panel is exempt from the requirements in these regulations, except the provisions for prevention of contact of organic products with prohibited substances as set forth in § 205.272, the labeling provisions of § 205.309, and the recordkeeping provisions of § 205.101(c).

A commenter stated that the Department is required under the Act to exempt any handling operation or portion of a handling operation that processes agricultural products that contain at least 50 percent organically produced ingredients by weight (excluding water and salt). We disagree with the commenter. Section 6505(c)(1) of the Act ties the exemption from certification to use of the word, "organic," on the principal display panel. The Secretary, in consultation with the National Organic Standards Board (NOSB) and the Secretary of Health and Human Services, may require certification of any operation that chooses to use the word, "organic," on the principal display panel. This proposal provides that handlers, processing agricultural products that contain at least 50 percent organically produced ingredients by weight (excluding water and salt), who choose to only use the word, "organic," on the information panel are exempt from certification. Handlers processing agricultural products that contain at least 50 percent organically produced ingredients by weight (excluding water and salt) who choose to use the word, "organic," on any other panel, including the principal display panel, must be certified. Use of the word, "organic," on the principal display panel carries with it connotations in the minds of consumers regarding the organic nature of the product which necessitate certification of handlers of such products. Further, requiring certification of handlers of such products is consistent with current industry practice.

Applicability—Changes Requested But Not Made

This subpart retains from our first proposal regulations on which we received comments as follows:

(1) *Exemptions for Handlers.* Commenters stated that under no circumstances should organic handling operations be exempt from certification. A few environmental organizations, a certifying agent, and an industry association commented that the first proposal exceeded statutory authority by broadening the producer exemption in section 6505(d) of the Act to apply to handlers. An agriculture research and education organization stated that, while the Act does not specifically identify handling operations under the producer exemption, including them is a reasonable and workable interpretation of the Act. The commenter stated that the Act provides an exemption to persons who sell no more than \$5,000 annually in value of agricultural products and it sees no reason why the exemption should not include handlers. This commenter also recommended that the NOP develop a new category of exemption of up to \$10,000 for on-farm processing. The commenter's recommended exemption would apply to value-added, made-on-site products, such as maple syrup, jams, and relishes, and would allow individuals to combine their production and handling exemptions.

We do not agree with those commenters who stated that the first proposal exceeded statutory authority. The title of the exemption in the Act (section 6505(d)) specifically refers to small farmers. However, the text to the exemption provides, in full, that "subpart (a)(1) shall not apply to persons who sell no more than \$5,000 annually in value of agricultural products." "Person" is defined in the Act as "an individual, group of individuals, corporation, association, organization, cooperative, or other entity." The Act defines "agricultural product" as "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. Handlers are covered by the definition of "person" and "agricultural product" and are thereby eligible for exemption.

The financial burden of certification is no less for handlers with sales of no more than \$5,000 annually than it is for producers with sales of no more than \$5,000 annually. Therefore, since the cost of certification is the primary reason for exempting production

operations with sales of no more than \$5,000 annually, it is reasonable to also exempt handling operations with sales of no more than \$5,000 annually.

This proposal exempts production and handling operations that sell agricultural products as "organic" but whose gross agricultural income from organic sales totals \$5,000 or less annually. Production and handling operations exempted on the basis of organic sales of \$5,000 or less annually are exempt from certification under Subpart E and do not need to submit an organic system plan under § 205.201 but must comply with the applicable organic production and handling requirements of subpart C and the labeling requirements of § 205.309.

Exemptions for production operations and handling operations are separate exemptions. Therefore, a production operation that is also a handling operation, due to its production and sale of processed products, must qualify for each exemption separately. The balance of this paragraph lists exemption eligibility examples. A production operation with gross agricultural income from organic sales totaling \$5,000 or less annually will be exempt from certification as an organic production operation. A handling operation with gross agricultural income from organic sales totaling \$5,000 or less annually will be exempt from certification as an organic handling operation. A production and handling operation with gross agricultural income from organic production sales totaling \$5,000 or less annually and organic handling sales totaling \$5,000 or less annually will be exempt from certification as an organic production operation and from certification as an organic handling operation. A production and handling operation with gross agricultural income from organic production sales totaling more than \$5,000 annually and organic handling sales totaling \$5,000 or less annually will be exempt from certification as an organic production operation only. A production and handling operation with gross agricultural income from organic production sales totaling more than \$5,000 annually and organic handling sales totaling \$5,000 or less annually will be exempt from certification as an organic handling operation only.

Products marketed by exempt production operations and handling operations cannot be represented as certified organic or display the U.S. Department of Agriculture (USDA) organic seal. Products from exempt operations may not be included as organic ingredients in a multiingredient product produced or processed in a

certified operation. We anticipate that this exemption will be used primarily by small market gardeners, hobbyists, and other small producers who sell produce and other agricultural products at farmers markets and roadside stands to consumers within their communities.

(2) *Exceeding \$5000 Limit for Exemption.* A few commenters, including a State, raised the concern that an organic operation might not anticipate sales over \$5,000 but could exceed its exemption due to a bumper crop or market price increases, putting the operation in violation. The Department believes that once an exempted operation reaches the \$5,000 maximum exemption level, it is compelled to seek certification, which it would have to obtain and maintain if it is to continue to sell organic products. A certified organic operation, including one which previously lost its exempt status, could switch from certified to exempt if its size or operations were changed such that it no longer sold more than \$5,000 annually in value of agricultural products.

(3) *Certification of Exempt Operations.* A producer interpreted "exempt" as meaning that operations exempted from certification could not be certified as an organic operation. This interpretation is not correct. Any production or handling operation, including an exempt operation, which makes application for certification as an organic operation and meets the requirements for organic certification may be certified.

(4) *Increasing the Statutory Limitation of \$5000 for Exemption.* In the first proposal, we asked for comments as to whether the \$5,000 level for exemption from certification should be raised to \$10,000 or to another amount and why an increased amount would be appropriate. Suggested levels ranged from \$2,000 to \$50,000. The suggested levels and justifications for such levels are not sufficiently consistent for us to recommend that Congress change the \$5,000 level.

In addition, we requested 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. Comments from the few States responding to the request for data as to the number of operations that may be exempt under the current \$5,000 limitation revealed that from one-third to one-half of organic producers in the commenting States would be exempt under the statutorily authorized \$5,000 exemption limitation.

(5) *Certification of Retail Operations.* A commenter said the first proposal ignored retail operations which contract with an organic farm to produce organic products with the store's brand on the label. The commenter said the retail operation should be certified because it is responsible if violation occurs in the organic production or handling of the branded product. The commenter is incorrect in suggesting that the retailer would be held responsible for a violation if the violation occurred at the production or handling facility. When a retail operation contracts for the production, packaging, or labeling of organic product, it is the certified production or handling operation that is responsible for meeting the applicable organic production or handling requirements under the Act and these regulations. If a violation occurs in the organic production or handling of the product, the certified production or handling operation retains responsibility for the violation even if the retailer's name is on the label.

(6) *Exemption for Products Containing Less than 50 Percent Organic Ingredients.* Several commenters representing States and organic organizations opposed the exemption of a handling operation or portion of a handling operation that handles only agricultural product containing less than 50 percent organic ingredients. They stated that handling operations creating products with organic ingredients should be certified regardless of the percentage of organic ingredients found in the products they produce. These commenters stated that exemptions from certification undermine audit trails and consumer confidence. Each of these commenters called for removal of the proposed exemption. Another commenter stated that, if a product is less than 50 percent organic, then it is not organic and should not be labeled or sold as such.

We disagree with the comments. Because such products consist of less than 50 percent organic ingredients, handlers may only use the word, "organic," on the information panel of such products to truthfully represent the organic nature of the ingredients. Such handlers must also comply with the recordkeeping provisions of § 205.101(c), the prevention of contact of organic products with prohibited substances provisions of § 205.272, and the labeling provisions of § 205.309.

(7) *Ensuring Organic Ingredients are Not Contaminated.* A commenter asked how the Department would ensure that organic ingredients are not contaminated without certification of the handling operation creating the final

product. Handling operations that handle agricultural products containing less than 50 percent organic ingredients and at least 50 percent organic ingredients that are exempt from certification must maintain records sufficient to: (1) Prove that ingredients identified as organic were organically produced and handled, and (2) verify quantities produced for such ingredients. Such operations are required at § 205.101(c) of this proposal to allow representatives of the Secretary and the applicable State program's governing State official access to these records for inspection and copying during normal business hours to determine compliance with the applicable regulations.

(8) *Exclusion for Handlers that Receive and Distribute Prepackaged Product.* Commenters raised several issues regarding the exclusion of handlers who receive and distribute prepackaged organic products. At least three certifying agents commented that all retailers should be certified unless they handle only organic product in a "final, sealed retail container," or "final impermeable containers." The commenters are apparently seeking further assurance that nothing is added to the organic product while under control of a distributor or retail operation. Because of the wide variety of organic products and the special needs of some of those products, establishing restrictions on the kind of containers used for transportation could unfairly treat some products and commodity industries. For example, some organic products may require containers which "breathe" or allow the exchange of air and outside temperatures. Nonpermeable containers could hasten spoilage of some fresh and processed organic products.

A few certifying agents proposed that distributors and trucking companies which transport agricultural products also should be certified under this part. However, such transportation operations do not carry out the functions specified in the definitions for handler and handling operations. Distributors and trucking companies have traditionally been excluded from requirements of agricultural production regulations. The Act cannot be used to regulate activities or entities beyond its regulatory authorities. In this case, it is the responsibility of producers, handlers, interim handlers, and retailers to meet the requirements of this regulation by ensuring that their contracted shippers and distributors understand, respect, and protect the integrity of the organic products they are transporting.

An organic association requested that proper notification of "good organic handling practices" be made to the transportation, trucking, and public warehousing sectors to inform them of their responsibilities. The commenter stated that the notification should include requirements for audit trail records, measures needed to prevent commingling and contamination by prohibited substances. This commenter expressed the belief that excluded handlers should preregister and provide a signed statement of acknowledgment of the requirements. Regarding enforcement of the suggested requirements, this commenter stated that enforcement of the requirements should be funded and administered by existing State and Federal inspection services.

We acknowledge the need for education regarding the requirements of this rule as well as such issues as the handling of organic products. The NOP, in cooperation with the NOSB, will provide educational material to the public regarding the requirements of this rule. Such educational material will include good organic handling practices made available to the transportation, trucking, and public warehousing sectors. However, we disagree with the suggestions calling for preregistration of exempt and excluded handlers and enforcement of the requirements by existing State and Federal inspection services. We believe the suggestions create a burden, on exempt and excluded handlers, the Department, and certifying agents, not justified by the nature of the handling performed.

(9) *Seafood Products.* A marketing institute recommended that the first proposal be revised to address seafood products in a separate seafood section and to include provisions that apply to seafood harvested in the wild. This commenter stated that wild-caught seafood should be allowed to be labeled as organic. A processors association also called for the labeling of wild-caught seafood as organic.

While the first proposal contained no standards solely for aquatic animals in an organic operation, it did contain provisions applicable to their production. The first proposal allowed fish and crustaceans, among other livestock types, to be sold, labeled, or represented as organic if such livestock had been brought into an organic operation no later than the earliest commercially available stage of life. Several commenters suggested that the management of aquatic animals differs sufficiently from mammals and poultry to require separate regulatory provisions. We concur and intend to

develop detailed practice standards for specific aquatic animals as discussed further under the production and handling subpart.

Applicability—Additional Provisions

Upon further review of the applicability provisions in the first proposal, we have decided to propose the following additions and changes.

(1) *Foreign Applicants.* We have added a new provision at § 205.104 addressing applicability of these regulations to foreign applicants. We have made this addition to clarify our intent that the regulations in this part apply equally to domestic and foreign applicants for accreditation, accredited certifying agents, domestic and foreign applicants for certification as organic production or handling operations, and certified organic production and handling operations unless otherwise specified in these regulations.

(2) *New Exclusions.* We have excluded retail food establishments that process or prepare raw and ready-to-eat food from most of the requirements in these regulations. An excluded retail food establishments must comply with the requirements for the prevention of contact with prohibited substances provisions of § 205.272 and the labeling provisions of § 205.309. We have excluded such retail food establishments because comments to the first proposal concerning the issue of certification of retail food establishments (restaurant, delicatessen, bakery, grocery store, or other retail outlet) preparing, packaging, or processing raw and ready-to-eat organic agricultural products that are previously labeled as "100 percent organic," "organic," or "made with organic (specified ingredients)" were completely divergent. The first proposal also contained an inconsistency which would have required a supermarket delicatessen to be certified but would have excluded from certification a restaurant with carry-out delicatessen products.

As the comments discussed below show, there is clearly a great deal of public concern regarding the handling of organic products by retail food establishments. Should we decide to regulate retail food establishments under the NOP, we will proceed with rulemaking and provide an opportunity for public comment.

Our exclusion of retail food establishments from this proposal does not prevent a State from developing an organic retail food establishment certification program or otherwise regulating retail food establishments that prepare, package, or process organic

agricultural products. Texas and Maryland currently have retailer certification programs.

No retailer, regardless of this exclusion and the exceptions found in the definitions for "handler" or "handling operation," may sell or label a product as organically produced and handled or fix a label to or provide other market information concerning an agricultural product if such label or information implies that such product is produced and handled using organic methods unless such product has been produced and handled in accordance with the Act and these regulations. Any retailer who knowingly sells or labels a product as organic, except in accordance with the Act and these regulations, will be subject to a civil penalty of not more than \$10,000 under this program. Such retailer may also be subject to enforcement actions and penalties under Federal statutes and their implementing regulations administered by other agencies of the Federal Government.

More than 90 commenters, including an organic association, stated that the retailer exclusion in the first proposal violates the requirement to certify all handling operations. The organic association believes that processing, as defined in the Act, includes all the normal culinary arts, food manufacturing, and packaging. All of these commenters, including some States, recommended removal of the exclusion. Several commenters, including a few States, expressed concern that exclusions from certification eliminate effective audit trails and undermine consumer confidence in organic products. One State commented that it believed retail food establishments should be certified because they are the last handler link from producer to consumer.

Several commenters stated that retailers who receive organic product have a high potential for loss of integrity of the organic product due to accidental misuse of pesticides and sanitizers during shipping or storage and to inadvertent commingling with nonorganic product. The commenters believe that, even though a retailer may only display and sell organic product, such retailer should be certified and monitored for compliance to ensure proper treatment of the product in shipment and storage. A State agency, however, cautioned against establishing another burden on the organic industry. The commenter said that if sorting from bulk and repackaging into smaller packages requires certification, then many small "natural food" retail outlets would find certification more costly

than the economic benefits of marketing organic products. The commenter said many small, natural food retail food establishments would likely stop carrying organic items.

A few commenters stated there is a high potential for fraud among retailers who have the opportunity to repackage, mislabel, and sell nonorganic product as organic. Therefore, they believe that all retailers must be subject to certification or some form of oversight to assure that they are not mislabeling product.

A commenter representing a large retail grocery store operation said that good identification procedures enable retail stores to keep organic product separated from nonorganic product during transportation, storage, and in-store displays. The commenter continued that unduly rigid requirements would be burdensome on retailers. The commenter indicated that the costs of certification and compliance may outweigh the benefits of carrying organic product.

Another commenter from a major retail food establishment suggested that retailers that wash and sort fresh organic produce for display should be required to follow "good organic handling practices" that would establish recordkeeping responsibilities and prevent commingling with nonorganic products and contamination by prohibited materials. The commenter suggested that conformance could be maintained by existing State or local health inspectors or Federal inspectors with special training in organic handling systems. However, there is no authority in the Act to require the services of State or local inspectors.

Another retailer stated that retailers will comply with regulations because consumers will hold retailers responsible for deficiencies or illegal actions through the entire production and processing chain for agricultural products.

A commenter stated that, if a restaurant serves organic foods, it should be allowed to so state. The commenter went on to say that restaurants and grocery stores have a right to state that they used organic ingredients in preparing a given dish. This commenter believes that restaurants and grocery stores selling organic products, even if they prepare them, should not have to be certified. A few commenters claimed that processing, as defined in the Act, includes all culinary arts and food manufacturing. They stated that restaurants must be certified or, at the very least, be required to keep records of organic foods prepared. A State commenter who stated that exemptions

undermine audit trails and consumer confidence suggested that restaurants serving organic foods be required to maintain records showing the origin and certification status of raw agricultural ingredients used in the restaurant's food products.

The Department routinely monitors compliance of various food producers, handlers, distributors, and retailers which are regulated under a variety of Departmental programs. The Department responds to consumer complaints and often conducts unannounced compliance investigations and audits of agricultural industry businesses. The Department understands the need for and commits Departmental resources to this organic program. In addition, oversight of these operations can be conducted by State agencies.

Subpart C—Organic Crop, Wild Crop, Livestock, and Handling Requirements

Proposal Description

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

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

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

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

The first element of the organic system plan requires a narrative or other descriptive format that identifies the practices and procedures to be performed and maintained, including the frequency with which they will be performed. Practices are tangible production and handling techniques such as the method for applying manure, the mechanical and biological methods used to prepare and combine

ingredients and package finished products, and the measures taken to exclude pests from a facility. Procedures are the protocols established for selecting appropriate practices and materials for use in the organic system plan, such as a procedure for locating commercially available organically produced seed. Procedures reflect the decision-making process used to implement the organic system plan.

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

The second element that must be included in an organic system plan is information on the application of substances to land, facilities, or agricultural products. This requirement encompasses both natural and synthetic materials allowed for use in production and handling operations. For natural materials which may be used in organic operations under specific restrictions, the organic plan must detail how the application of the materials will comply with those restrictions. For example, farmers who apply manure to their fields must document in their organic system plans how they will prevent that application from contributing to water contamination.

The third element of the organic system plan is a description of the methods used to evaluate its effectiveness. Producers and handlers are responsible for identifying measurable indicators that can be used to evaluate how well they are achieving the objectives of the operation. For example, production objectives could be measured through regular tallies of bushels or pounds of product sold from the farm or in numbers of cases sold from a handling operation. Indicators that can identify changes in quality or effectiveness of management practices could be relatively simple, such as the information contained in a standard soil test. The specific indicators used to

evaluate a given organic system plan will be determined by the producer or handler in consultation with the certifying agent. Thus, if the organic system plan calls for improvements in soil organic matter content in a particular field, it would include provisions for analyzing soil organic matter levels at periodic intervals. If herd health improvement is an objective, factors such as somatic cell count or observations about changes in reproductive patterns might be used as indicators.

The fourth element of the organic system plan is a description of the recordkeeping system used to verify and document an audit trail, as appropriate to the operation. For each crop or wild-crop harvested, the audit trail must trace the product from the field, farm parcel, or area where it is harvested through the transfer of legal title. A livestock operation must trace each animal from its entrance into through removal from the organic operation. A handling operation must trace each product that is handled and sold, labeled, or represented as organic from the receipt of its constituent ingredients to the sale of the processed product. In response to several comments received, this proposal provides information, found in subpart B, § 205.103, on the records needed to establish a verifiable audit trail.

The fifth element which must be included in an organic system plan pertains to split production or handling operations. This provision requires an operation that produces both organic and nonorganic products to describe the measures used to prevent commingling of organic and nonorganic products. This requirement addresses contact of organic products, including livestock, organic field units, storage areas, and packaging to be used for organic products, with prohibited substances. Requirements in the first proposal for information about the nonorganic portion of the operation have been removed.

We do not propose to list the specific requirements to be included in an organic system plan. We expect to publish a program manual to provide guidance on appropriate documentation for the certification process. In the meantime, the accreditation process provides an assurance that certifying agents are competent to determine the specific documentation they require to review and evaluate an operation's organic system plan. Section 205.200(a)(6) allows a certifying agent to request additional information needed to determine that an organic system plan meets the requirements of this

subpart. The site-specific nature of organic production and handling necessitates that certifying agents have the authority to determine whether specific information is needed to carry out their function.

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

A producer of an organic crop must manage soil fertility, including tillage and cultivation practices, in a manner that maintains or improves the physical, chemical, and biological condition of the soil and minimizes soil erosion. Crop nutrients must be budgeted and supplied through proper use of manure or other animal and plant materials, mined mineral substances, and other substances approved for use under these regulations. The producer must manage animal and plant waste materials to maintain or improve soil organic matter content in a manner that does not contribute to contamination of crops, soil, or water by plant nutrients, pathogenic organisms, heavy metals, or residues of prohibited substances. Raw animal manure must either be composted, applied to land used for a crop not intended for human consumption, or incorporated into the soil at least 90 days before harvesting an edible product that does not come into contact with the soil or soil particles and at least 120 days before harvesting an edible product that does come into contact with the soil or soil particles. Composted plant or animal waste materials used for soil fertility must be produced in compliance with the Natural Resources Conservation Service's (NRCS) Conservation Practice Standard for a Composting Facility (Code 317). Uncomposted plant and animal waste materials may be used to amend soil fertility. A plant or animal waste material that has been chemically altered by a manufacturing process may be used only if it is included on the National List of synthetic substances allowed for use in organic production. Mined substances of low solubility may be used as sources of crop nutrients, as may mined substances of high solubility, when justified by soil or crop tissue analysis. Ashes of untreated plant or animal materials which have not been combined with a prohibited substance and which are not included

on the National List of nonsynthetic substances prohibited for use in organic crop production may be used to produce an organic crop. Synthetic crop nutrient supplements that appear on the National List of allowed synthetic substances may be used as a source of crop nutrients when justified by soil or crop tissue analysis. The producer may not use any fertilizer that contains a synthetic substance not allowed for crop production on the National List or use sewage sludge. Burning crop residues as a means of disposal, except for trimmings of perennial crops burned to suppress the spread of disease, is prohibited.

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

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

The producer must use preventive practices to manage crop pests, weeds, and diseases, including but not limited to crop rotation, soil and crop nutrient management, sanitation measures, and cultural practices that enhance crop health. Such cultural practices include the selection of plant species and

varieties with regard to suitability to site-specific conditions and resistance to prevalent pests, weeds, and diseases. Mechanical and biological methods that do not entail application of synthetic substances may be used as needed to control pest, weed, and disease problems that may occur. Pest control practices include augmentation or introduction of pest predators or parasites; development of habitat for natural enemies; and nonsynthetic, nontoxic controls such as lures, traps, and repellents. Weed management practices include mulching with fully biodegradable materials; mowing; livestock grazing; hand weeding and mechanical cultivation; flame, heat, or electrical techniques; and plastic or other synthetic mulches, provided that they are removed from the field at the end of the growing or harvest season. Disease problems may be controlled through management practices which suppress the spread of disease organisms and the application of nonsynthetic biological, botanical, or mineral inputs. When these practices are insufficient to prevent or control crop pests, weeds, and diseases, a biological or botanical substance, or a synthetic substance that is allowed on the National List may be used provided that the producer evaluates and mitigates the effects of repetitive use of the same or similar materials on resistance and shifts in pest, weed, or disease types. The producer must use a pest, weed, or disease control substance in compliance with the Federal Insecticide, Fungicide, and Rodenticide Act. Pest control substances produced through excluded methods are prohibited.

Any wild crop that is to be sold, labeled, or represented as "100 percent organic," "organic," or "made with organic (specified ingredients)" must be harvested from land to which no prohibited substances have been applied for at least 3 years prior to harvest. The wild crop must also be harvested in a manner that ensures such harvesting or gathering will not be destructive to the environment and will sustain the growth and production of the wild crop.

Livestock Production. We propose that any livestock or edible livestock product to be sold, labeled, or represented as organic must be maintained under continuous organic management from birth or hatching, with four exceptions. Poultry or edible poultry products must be from animals that have been under continuous organic management beginning no later than the second day of life. Milk or milk products must be from animals that

have been under continuous organic management beginning no later than 1 year prior to the production of such products. A nonedible livestock product must be derived from an animal that has been under continuous organic management beginning no later than 1 year prior to the harvest of the nonedible product. Livestock used as breeder stock may be brought from a nonorganic operation into an organic operation at any time, provided that, if such livestock are gestating and the offspring are to be organically raised from birth, the breeder stock must be brought into the organic operation prior to the last third of pregnancy.

We also propose that, should an animal be brought into an organic operation pursuant to this section and subsequently moved to a nonorganic operation, neither the animal nor any products derived from it may be sold, labeled, or represented as organic. Breeder or dairy stock that has not been under continuous organic management from birth may not be sold, labeled, or represented as organic slaughter stock. No organism produced with excluded methods may be used for breeding purposes or for the production of livestock products intended to be sold, labeled, or represented as organic. The producer of an organic livestock operation must maintain records sufficient to preserve the identity of all organically managed livestock and all edible and nonedible organic livestock products produced on his or her operation.

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

The producer of an organic livestock operation must establish and maintain preventive animal health care practices. The producer must select species and types of livestock with regard to suitability for site-specific conditions and resistance to prevalent diseases and parasites. The producer must provide organic feedstuffs, as well as vitamins, minerals, and other supplements, sufficient to meet the animals' nutritional requirements. The producer must establish appropriate housing, pasture conditions, and sanitation practices to minimize the occurrence and spread of diseases and parasites. Animals in an organic livestock operation must be maintained under conditions which provide for exercise, freedom of movement, and reduction of stress appropriate to the species. Additionally, all physical alterations performed on animals in an organic livestock operation must be conducted to promote the animals' welfare and in a manner that minimizes stress and pain.

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

We propose that the producer of an organic livestock operation must not treat an animal in that operation with antibiotics, any synthetic substance not included on the National List of synthetic substances allowed for use in livestock production, or any substance that contains a nonsynthetic substance included on the National List of nonsynthetic substances prohibited for use in organic livestock production. The producer must not administer any animal drug, other than vaccinations, in the absence of illness. The use of hormones is prohibited in organic livestock production, as is the use of

synthetic parasiticides on a routine basis. The producer must not administer synthetic parasiticides to slaughter stock or administer any animal drug in violation of the Federal Food, Drug, and Cosmetic Act. The producer must not withhold medical treatment from a sick animal to maintain its organic status. All appropriate medications and treatments must be used to restore an animal to health when methods acceptable to organic production standards fail. Livestock that are treated with prohibited materials must be clearly identified and shall not be sold, labeled, or represented as organic.

Under this proposal, a livestock producer must document in his or her organic system plan the preventative measures he or she has in place to deter illness, the allowed practices he or she will employ if illness occurs, and his or her protocol for determining when a sick animal must receive a prohibited animal drug. The standards we are proposing will not allow an organic system plan that envisions an acceptable level of chronic illness or proposes to deal with disease by sending infected animals to slaughter. Neither situation can be considered consistent with the principles of organic management. The organic system plan must reflect a proactive approach to health management, drawing upon allowable practices and materials. Animals with conditions that do not respond to this approach must be treated appropriately and diverted to nonorganic markets.

The producer of an organic livestock operation must establish and maintain livestock living conditions for the animals under his or her care which accommodate the health and natural behavior of the livestock. The producer must provide access to shade, shelter, exercise areas, fresh air, and direct sunlight suitable to the species, its stage of production, the climate, and the environment. This requirement includes access to pasture for ruminant animals. The producer must also provide appropriate clean, dry bedding, and, if the bedding is typically consumed by the species, it must comply with applicable organic feed requirements. The producer must provide shelter designed to allow for the natural maintenance, comfort level, and opportunity to exercise appropriate to the species. The shelter must also provide the temperature level, ventilation, and air circulation suitable to the species and reduce the potential for livestock injury. The producer may provide temporary confinement of an animal because of inclement weather; the animal's stage of production;

conditions under which the health, safety, or well-being of the animal could be jeopardized; or risk to soil or water quality. The producer of an organic livestock operation is required to manage manure in a manner that does not contribute to contamination of crops, soil, or water by plant nutrients, heavy metals, or pathogenic organisms and optimizes nutrient recycling.

Handling. This proposal permits mechanical or biological methods to be used to process an agricultural product intended to be sold, labeled, or represented as "100 percent organic," "organic," or "made with organic (specified ingredients)" for the purpose of retarding spoilage or otherwise preparing the agricultural product for market. It permits the use of nonagricultural substances and nonorganically produced agricultural products that are included on the National List in or on a processed agricultural product intended to be sold, labeled, or represented as "organic" or "made with organic (specified ingredients)." This proposal prohibits a handler from using ionizing radiation for any purpose, an ingredient produced with excluded methods, or a volatile synthetic solvent in or on a processed agricultural product intended to be sold, labeled, or represented as "100 percent organic," "organic," or "made with organic (specified ingredients)."

The practice standard for facility pest management requires the producer or handler operating a facility to use management practices to prevent pests, including removing pest habitat, food sources, and breeding areas; preventing access to handling facilities; and controlling environmental factors, such as temperature, light, humidity, atmosphere, and air circulation to prevent pest reproduction. Permitted pest control methods include augmentation or introduction of predators or parasites for the pest species; mechanical or physical controls, including traps, light, or sound; and nontoxic, nonsynthetic controls, such as lures and repellents.

This proposal permits the use of a nonsynthetic biological or botanical substance or any synthetic substance to control facility pests if the permitted prevention and control practices are not effective. Any substance applied must be used in accordance with the label provisions as approved by the appropriate authority, such as the Environmental Protection Agency (EPA) or the Food and Drug Administration (FDA). We propose that the handler of an organic handling operation who uses any biological, botanical, or synthetic substance to control facility pests must

specify in the organic system plan all measures taken or intended to be taken to prevent contact between the substance and any ingredient or finished product intended to be sold, labeled, or represented as organic or made with organic ingredients. In addition to these restrictions, the handler must include in the organic handling plan an evaluation of the effects of repetitive use of the same or similar materials on pest resistance and shifts in pest types.

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

Temporary Variances. This subpart establishes conditions under which operations may receive temporary variances from the provisions contained in §§ 205.203 through 205.207, 205.336 through 205.239, and 205.270 through 205.272. The Administrator may establish temporary variances due to natural disasters declared by the Secretary; unavoidable business interruption caused by catastrophe such as wind, fire, hail, flooding, excessive moisture, earthquake, or drought; or to conduct research on organic production and handling techniques or inputs. A certifying agent may recommend that the Administrator establish a temporary variance for unavoidable business interruption. The Administrator will determine how long a temporary variance will be in effect at the time it is established, subject to extension as the Administrator deems necessary. Upon notification by the Administrator that a temporary variance has been established due to a natural disaster, a certifying agent must inform each production and handling operation it certifies within the affected geographical region or each individual production and handling operation affected by the temporary variance. Temporary variances may not be issued for any practice, material, or procedure which is otherwise prohibited by these regulations.

A request for issuance of a temporary variance, the justification for it, and measures to evaluate the impact of the practice on the operation's natural resources must be documented in the organic plan and approved by the certifying agent. For example, if a drought resulted in a severe shortage of organically produced hay, a dairy operation might be permitted to substitute some nonorganic hay for a portion of the herd's diet to prevent liquidation of the herd. The producer must keep records showing the source and amount of the hay and update the organic plan to describe the justification for the practice and a timeframe for restoring the total feed ration to organic sources. The certifying agent might also request that the plan include contingency measures to avoid the need to resort to nonorganic feed in case of a future shortage. A variance for experimental purposes might be issued to permit a crop producer to undertake on-farm trials of small quantities of a new (but not produced with excluded methods) crop variety that was not available as organic seed.

Production and Handling (General)—Changes Based on Comments

The subpart differs from our first proposal in several respects as follows:

(1) *Genetically Engineered Organisms.* In the first proposal, we invited public comment on the use of genetically engineered organisms (GEO's) or their products in a system of organic production and handling. Specifically, we asked whether the use of GEO's or their products should be permitted, prohibited, or allowed on a case-by-case basis in organic production or handling operations. Hundreds of thousands of public comments opposed the use of GEO's or their products in organic production or processing. In response to these comments, this proposal prohibits use of genetic engineering (included in the broad definition of "excluded methods" in this proposal, based on the definition recommended by the National Organic Standards Board (NOSB)) in all stages of organic production and handling. This proposal contains a specific prohibition on the use of seeds, annual seedlings and planting stock (§ 205.204(b)), pest control substances (§ 205.206(f)), organisms (§ 205.236 (b)(3)), and ingredients (§ 205.270(c)(2)) produced with excluded methods.

Products created with modern biotechnology techniques have been tested, approved by the appropriate regulatory agencies, and can be used safely in general agricultural production. At the same time,

consumers have made clear their opposition to use of these techniques in organic food production. This rule is a marketing standard, not a safety standard. Since use of genetic engineering in the production of organic foods runs counter to consumer expectations, foods produced through excluded methods will not be permitted to carry the organic label.

We acknowledge that the broad prohibition on use of excluded methods in organic production and handling systems may create compliance obstacles for organic operations and certifying agents. For example, many current certification programs allow vaccination of animals with synthetic compounds when such treatment is mandatory. However, while many FDA-approved vaccines are now produced using excluded methods, we are unaware of any certification program which has an enforcement mechanism to ensure that such substances are not used in organic production. We do not know to what extent, if any, organic livestock producers are currently using vaccines produced with excluded methods or how a prohibition on the use of such substances would affect development of the industry.

Similarly, the prohibition on the use of excluded methods in the production of organic foods may also present challenges to organic handlers and certifying agents. This may pose a particular problem with respect to the nonorganic ingredients of multiingredient products with 50-95 percent organic content, to which the prohibition on use of excluded methods also applies. For example, it may be harder for organic food processors, who may struggle to find sources of nonorganic ingredients that are produced without use of excluded methods and for certifying agents, who must ensure that handlers have complied with this requirement.

As with most elements of this program, compliance monitoring and enforcement will rely on the ongoing oversight of organic operations by USDA-accredited certifying agents, rather than on product testing. Certifying agents must approve organic plans that detail procedures and practices to be followed by organic operations and will review extensive records maintained by organic operations to ensure that they are complying with the approved organic plans and the regulations.

This system of compliance assurance will be particularly important with respect to the prohibition on use of excluded methods. Producers and handlers must be vigilant in the

acquisition of materials and products. Certifying agents should be aware of agricultural products produced through excluded methods and must carefully review material and product origin documentation. It will be the responsibility of certifying agents to review the sourcing specifications and other provisions of producer and handler organic plans to ensure the integrity of organic and multiingredient products. We anticipate that this system of carefully reviewed and documented organic plans, which establishes documented procedures demonstrating good faith efforts to diligently pursue and maintain the integrity of ingredients produced without use of excluded methods, could satisfy the requirements in this regulation.

With respect to the prohibition on the use of excluded methods in production of the nonorganic ingredients in multiingredient products, we recognize that the ability to meet these requirements depends primarily on practices used in conventional agricultural markets. We also recognize that practices for preserving product identity, including segregating genetically engineered and nongenetically engineered products, are evolving in some conventional markets. Currently there are no consensus industry standards for product segregation, rather contractual agreements are used to the extent possible. As the marketplace evolves toward recognized best practices or standards for product testing and segregation, we anticipate that these methods and systems will become the standards for implementing the prohibition on use of excluded methods in production of nonorganic ingredients in multiingredient products. Linking the requirements pertaining to nonorganic ingredients in this proposal to the evolving practices within the marketplace will provide certifying agents with a verifiable criterion against which to evaluate production and handling processes, as well as providing greater certainty to handlers and processors as they seek to identify acceptable sources of nonorganic ingredients.

As with other prohibited substances, a positive detection of a product of excluded methods would trigger an investigation by the certifying agent to determine if a violation of organic production or handling standards occurred and would not necessarily represent a violation on its own. The presence of a detectable residue alone does not necessarily indicate use of a product of excluded methods that

would constitute a violation of the standards.

We anticipate that these issues will be of particular interest to commenters on the proposal, and that comments may help to shed light on industry capabilities and expectations. We recognize that this policy will place additional burdens on certified operations and certifying agents, but we believe that the necessity to meet strong consumer expectations outweighs these concerns.

(2) *Measurable Degradation Standard.* We are proposing that any practice implemented in accordance with the requirements for organic production and handling must maintain or improve the soil and water quality of the operation. This provision is a modification of the requirement in the first proposal that the use or application of a practice not result in measurable degradation of soil or water quality. Some commenters stated that the concept of measurable degradation was too limiting and reduced the holistic principles behind organic production to an exercise in risk assessment. In introducing the concept of measurable degradation, we stated that its purpose was to “clarify that all methods and substances used in an organic operation shall be consistent with a system of organic farming and handling and the purposes of the OFPA.” As such, measurable degradation and the specific indicators of soil and water quality used to monitor it were designed as tools to evaluate compliance with the OFPA and not as ends in themselves.

The new provision requiring that an organic operation maintain or improve its soil and water quality retains the linkage between production and handling practices and the natural resources of the operation, which is a fundamental tenet of both organic production and the OFPA. We have introduced the “maintain or improve” provision to allow for consideration of a variety of environmental indicators that contribute to the overall performance of the operation. Both the objective of certification—establishing an organic system of production and handling—and the standard by which it is achieved—the requirements in this proposal—remain constant for all operations. The environmental indicators used to establish and monitor compliance with an approved organic system plan will depend upon the site-specific conditions of the individual operation. For example, a producer and certifying agent would consider the soil types, hydrology, other environmental conditions and the specific nature of the crops and livestock being produced to

determine which indicators would best reflect the performance of the organic system plan. Site-specific conditions—high water table, soils that are prone to erosion—combined with the operation's production practices—the use of persistent inputs such as copper or sulfur compounds, the type of tillage practices used—will dictate the selection of environmental indicators. While individual indicators, especially when signaling that significant change has occurred, remain important, the "maintain or improve" provision allows a producer or handler and his or her certifying agent to assume a broader perspective in monitoring compliance with the OFPA.

Many commenters objected to the requirement in the first proposal that certain production practices "not result in a measurable degradation of the soil." The purpose of the "measurable degradation" requirement was solely to provide producers and their certifying agents with quantifiable, verifiable tools with which to evaluate compliance with the applicable regulations. While the current proposal does not refer to "measurable degradation" in the practice standards, producers and handlers must identify and incorporate into their organic system plans specific testing and evaluation techniques to measure the environmental impact of their production practices. In many cases, this requirement could be filled with a standard soil analysis, which would indicate trends in soil organic content, nutrient composition, and physical properties. In other cases, chemical or biological analysis of stream water entering and leaving a crop or livestock operation could suffice to monitor compliance with the practice standards. There is no way to substantiate the effectiveness of the practices and materials used in an organic production system without some form of measurable verification. Analytical procedures to monitor the condition, over time, of an operation's resource base are a standard feature of efficient resource management, whether or not the operation is organically managed.

(3) *Function and Content Requirements of the Organic System Plan.* We propose significant changes in the function and content requirements of the organic system plan to solidify its role in the relationship between producer or handler and certifying agent. Public comment on the first proposal identified numerous perceived deficiencies in the provisions for an organic system plan. Some commenters, including organic certifying agents and industry associations, stated that the

proposed content requirements were a "shadow" of the plan intended by the OFPA because the regulatory text did not include the words, "management," "rotation," or "manure." Some commenters characterized the organic system plan in the first proposal as a simple list of materials to be used and practices to be followed and thought that it would not adequately address why the producer or handler made specific production choices. Echoing the recommendation adopted by the NOSB at its June 1994 meeting in Santa Fe, NM, other commenters suggested that each organic system plan should be required to include key elements of organic production, such as soil and crop management, resource conservation, crop protection, and maintenance of organic integrity through growing, harvesting, and postharvest operations. We fully agree with the principle that a comprehensive organic system plan is an integral component of a certified operation and that it provides the foundation for the working relationship between the certifying agent and the producer or handler. This proposal contains a standard that defines and characterizes an organic system of production and handling and establishes the organic system plan as the centerpiece of the relationship between producer or handler and certifying agent.

Some commenters expressed concern that the first proposal did not link the organic system plan to specific regulatory requirements such as proper tillage, crop rotation, and manuring. The first proposal did, however, require operations to document compliance with all applicable standards. The obligation to document compliance with all applicable standards was implicit in the requirement that an organic system plan contain a description of the practices to be performed and maintained to establish a system of organic farming and handling. A producer or handler intending to engage in a practice must comply with the corresponding standards and include his or her intentions for doing so in the organic system plan. This proposal contains a similar provision, found in § 205.200(a)(1), which requires a description of the practices and procedures used in the certified operation, again, without stating the specific standards with which the operation must comply.

We acknowledge that, by providing the regulatory guidance necessary to implement the OFPA, the Secretary is further empowering accredited certifying agents to determine whether an operation's organic system plan

meets the requirements of the statute. The provisions for an organic system plan in § 205.200(a)(1)–(6) outline the prerequisites for certification. Combined with the production and handling standards in §§ 205.201 through 205.207, 205.236 through 205.239, and 205.270 through 205.272, these requirements provide the criteria necessary for certifying agents to determine whether to grant certification.

For similar reasons, we propose not to include in this proposal a list of the specific requirements to be included in a particular type of organic system plan. For example, while the first proposal required that a farm operation submit the total acreage under organic management as part of its organic system plan, there is no similar requirement in this proposal. We believe that accredited certifying agents are capable of determining the specific documentation they require to review an application for certification. Certifying agents are granted authority to request the information they deem essential to the performance of their duties. Many resources are available to certifying agents for determining the information needed to make certification decisions. The Federal-State Marketing Improvement Program of the Agricultural Marketing Service (AMS) helped fund a project (#12–25–G–0202) which created an organic inspection manual and developed a whole set of organic certification form templates. Among these templates are detailed forms for organic farm, livestock, and handling system plans. AMS worked with the Independent Organic Inspectors Association and the Organic Certifiers Council on this project and supports continued movement toward standardized certification documentation. The NOSB provided recommendations, including sample questionnaires, for the information it deems necessary for inclusion in an organic system plan. Additionally, the Organic Trade Association recently released the American Organic Standards that drew upon broad industry involvement to create a detailed description of organic system plan requirements.

The organic system plan in the first proposal included requirements for split farming operations—meaning farms that engage in both organic and nonorganic production—that some commenters stated were excessive. These commenters pointed out that the OFPA does not provide for the organic system plan to include any production or handling practice not consistent with the OFPA, and that the practices on the nonorganic portion of the split-farm

would not be consistent with the Act. Based on these comments, this proposed organic production system plan will not require information about a split-farm's nonorganic operations. However, this proposal requires that a split operation, whether a production or a handling operation, describe the measures it is taking or will take to prevent commingling of organic and nonorganic product and to prevent contact of organic products, fields, or facilities with prohibited substances.

(4) *Regulatory Enforcement.* The National Organic Program (NOP) will require consistent and effective enforcement of the regulations across diverse crop, wild crop, livestock, and handling operations which are differentiated by site-specific conditions within dissimilar geographic regions. The resources and objectives of each certified operation are unique, and the OFPA, accordingly, provides certifying agents with criteria, not formulas, to determine whether the practices, procedures, and inputs described in an organic system plan constitute compliance with the OFPA. The flexibility implicit in this approach allows producers and handlers to choose from a variety of production and handling options. In addition to being flexible, a regulatory mechanism must be clear, consistent, and enforceable. For this reason, producers and handlers must document the choices they make in an organic system plan and demonstrate a good-faith effort to implement the plan. For example, the decision to use an allowed synthetic pest control substance must be based on evidence that prevention and nonsynthetic pest control measures are not adequate.

Public comment indicated that the regulatory mechanisms that were introduced in the first proposal, including orders of preference, performance standards, and provision for allowance of certain practices "if necessary," provided producers and handlers too much discretion in selecting materials and practices. These comments indicated that insufficient oversight by certifying agents could dilute the meaning of organic certification. Therefore, we are proposing significant changes in the regulatory mechanisms which govern producers, handlers, and their certifying agents in determining the materials, practices, and procedures used in an organic operation.

One regulatory mechanism used in the first proposal was an "order of preference" scheme for selecting organic practices or materials employed in production and handling. This scheme

was proposed for a number of areas: Crop rotation; manuring practices; soil fertility and nutrient management; seeds and planting stock selection; crop pest, weed, and disease prevention and management; livestock health care; selection of handling ingredients; and prevention and facility pest management. There was also a general order of preference requirement that mandated the use of nonsynthetic substances in preference to synthetic substances.

Comments from at least one industry association supported using orders of preference to assure that choices made by producers and handlers will be as consistent as possible with organic farming and handling principles. Others, including several organic certifying agents, felt that the conditions for choosing a lower order of preference were not specified clearly enough and could result in inconsistent enforcement of the standards. Some commenters thought that certifying agents would be overly burdened by having to review and approve the justification in the organic plan for choosing less preferable practices, although some stated that if the criteria for choosing a lower order of preference were clarified and documentation of the reasoning behind the choice was explicitly required, then this scheme would be workable. Some noted that ranking practices and inputs according to their suitability is analogous to the "approved, restricted, prohibited" scheme which many State and private certification programs employ. A few commenters expressed the belief that establishing provisions to issue variances would address their concerns and provide for adequate oversight and enforcement concerning practices, procedures, and inputs that are considered to be acceptable but less desirable for organic production and handling.

However, several commenters, including consumers and organic certifying agents, asserted that "preference" could be interpreted as purely based on the personal choice or convenience of the producer or handler. Some certifying agents indicated that the soil fertility order of preference was too complex and difficult to enforce. A number of consumers disliked this concept because it permitted some deviation from the most desirable standards, such as use of organically produced seeds. Another commenter speculated that this scheme could be interpreted as establishing different levels of "organicness." Although these interpretations do not reflect the intent of the first proposal, in the interest of clarity, we have removed references to

orders of preference in the current regulatory text. We also removed the general requirement for orders of preference and to simplify the scheme so that it will be less burdensome for certifying agents to enforce. Several provisions in this proposal, including the seeds and planting stock practice standard (§ 205.204) and the crop pest, weed, and disease management practice standard (§ 205.206) will allow less desirable practices or substances to be used only if the preferred alternative is either ineffective or not commercially available. As was true of the first proposal, justification for choosing a less desirable alternative, such as nonorganic seeds or planting stock, must be documented in the relevant organic system plan and approved by the certifying agent.

Several commenters, including industry and environmental associations, also took issue with the use in the first proposal of performance standards, which specify the required outcome but not the practices that must be used to achieve it. The general provision that any practice or substance used in an organic operation not contribute to measurable degradation of soil or water quality is an example of such a performance standard. Objections to the use of performance standards referred to the nature of organic production standards, which focus on the production process and not quantifiable outcomes such as pesticide residue levels. Some of these commenters asserted that such a mechanism would relegate organic standards to a risk assessment model, which is not appropriate for evaluating a system of organic management.

We agree that standards for an organic management system cannot be reduced to measurable outcomes, and this was not the intent of the proposed performance standards in the first proposal. The evaluation of measurable indicators as benchmarks of the proper functioning of a management system is compatible with the overall requirement that practices be implemented that are consistent with a system of organic farming and handling. Such indicators help to determine whether a given operation is in compliance with the regulations. For example, the crop rotation provisions in this proposal list a series of functions, including weed management, that should be provided by an appropriate rotation. While the possible types of rotation that could achieve this objective are virtually limitless and could not be specifically prescribed, recording changes in weed populations could document the

effectiveness of the rotation being implemented.

Another type of regulatory provision employed in the first proposal permitted the use of certain practices or substances only "if necessary." This was proposed for the introduction of nonorganic animals into an organic operation, for using up to 20 percent nonorganic livestock feed, for permitting restrictions on access by livestock to space for movement and access to outdoors, and for use of synthetic processing aids in producing an organic processed product. A producer or handler was required to establish his or her need to use a particular practice or substance based on site-specific circumstances. The basis for each such decision was to be stated in the organic system plan and evaluated by the certifying agent. Many commenters indicated that this provision was not appropriate because, for example, the allowance for the use of 20 percent nonorganic livestock feed, "if necessary," left a loophole that could permit an unscrupulous producer to use nonorganic feed without a valid reason that was consistent with the regulations. We concur that this allowance for practices "if necessary" is overly vague and have removed the provision from this proposal. It has been replaced by more specific regulatory restrictions, referred to as practice standards, which better reflect the recommendations of the NOSB.

We have addressed comments that requested more specific guidelines for acceptable organic practices by introducing the concept of practice standards. Practice standards are a series of specific guidelines, requirements, and operating procedures for common agricultural practices such as crop rotation, pest management, and crop nutrient management. The NOSB reviewed portions of the current NRCS practice standards for crop rotation, nutrient management, pest management, composting facilities, and cover or green manure crops at its Washington, DC, meeting in June 1999. NRCS practice standards, while not public health standards, contain rigorous, field-tested provisions which provide specific benchmarks for monitoring the performance of many required organic production techniques. A practice standard can also serve as the foundation for an even more detailed program manual.

For example, we are proposing that composted animal and plant waste materials which are used for soil fertility and crop nutrient management must be produced at a facility in compliance with the NRCS practice

standard for a Composting Facility (Code 317). This document establishes minimum acceptable requirements for the design, construction, and operation of a composting facility. A copy of this practice standard may be obtained from any NRCS field office. A copy of this practice standard may be viewed at USDA-AMS-TMD-NOP, Room 2510—South Building; 1400 Independence Ave., SW, Washington, DC 20250-0248. The NOP intends to publish additional practice standards for public comment in the **Federal Register**. We are also holding discussions with NRCS to determine whether farming operations which comply with the certification requirements of the NOP will have the added benefit of being able to participate simultaneously with NRCS cost-share programs.

Incorporating NRCS practice standards into the requirements for organic certification introduces a significantly greater degree of specificity than most organic standards have previously contained. For example, the Composting Facility practice standard includes specifications for facility size, moisture content of the compost pile, carbon-nitrogen ratio, and the interval which certain temperatures must be sustained to achieve a finished product. The practice standard also contains restrictions on source materials which may make it difficult to utilize certain categories of materials which have traditionally been allowed in organic compost production. Enforcing these additional requirements will require far greater oversight from the certifying agent, and expertise in this area will become another factor in accreditation. NRCS uses its practice standards for voluntary cost-share programs, and organic producers may find the requirements burdensome as an added, mandatory expense. Despite the many comments we received criticizing the provisions for performance standards in the first proposal, organic certification schemes have traditionally prescribed outcomes and allowed producers and handlers flexibility in selecting practices used to achieve them. However, we received many other comments stating that more rigorous, clearly defined regulatory mechanisms were needed to protect the integrity of organic certification. We have considered the use of NRCS practice standards to provide clear, consistent, and verifiable guidelines for conducting essential organic production practices. We are particularly interested in receiving specific comment on the feasibility of using NRCS practice standards for compost production and

how such practice standards may generally be used to establish organic standards.

(5) *Temporary Variances*. Section 205.201(b) of this proposal provides procedures for establishing a temporary variance from certain requirements of subpart C. The temporary variance is a mechanism for providing regulatory flexibility that did not appear in the first proposal. This mechanism is proposed in response to comments from an industry association and several certifying agents who expressed the need, in certain circumstances, to use practices that would otherwise not comply with the applicable practice standard. Similar mechanisms are used by most existing certifying agents to make exceptions in cases of compelling need, when there is minimal concern for compromising the integrity of an organic system. Temporary variances are established from specific requirements and not, unless specified, from all production standards. They are established for a determined period of time, subject to extension as deemed necessary by the Administrator. For example, the Administrator could, under appropriate circumstances, waive the requirement that a producer must provide livestock with a ration composed of 100 percent organically produced feed.

Temporary variances are created under very specific circumstances and are subject to strong oversight by the Department to prevent potential abuse. This proposal contains three situations in which the Administrator could establish a temporary variance. These situations are: natural disasters as declared by the Secretary in a specific geographical area; business interruption caused by wind, flood, fire, or other catastrophic event; or for the purpose of conducting research or trials of techniques, varieties, or ingredients used in organic production or handling. In the case of natural disaster declared by the Secretary, the Administrator will establish a temporary variance available to all organic operations within the area designated as affected. For local catastrophic events in which the Secretary does not declare a disaster, the certifying agent is responsible for making recommendations to the Administrator for establishing temporary variances. Catastrophic events must be of a sufficient magnitude and have a direct, immediate impact such that the operation could not continue to function without the temporary variance. Certifying agents are responsible for making a recommendation for a temporary variance in situations prompted by

research needs. Producers and handlers cannot appeal directly to the Administrator for a temporary variance but must make such a request through their certifying agent.

Temporary variances, as proposed here, will not extend to any practice or substance that is expressly prohibited by any provision of the OFPA, the applicable standards, these regulations, or any other Federal, State, or local laws or regulations. For example, a variance cannot be granted for use of an organism produced through excluded methods, for use of sewage sludge as a fertilizer, or for use of irradiation to process an organic product or ingredient. We expect to provide additional guidelines in a program manual to assist certifying agents in evaluating how much of an allowance is appropriate, such as how much of the ration for which animals could come from nonorganic sources under a variance.

Production and Handling (General)—Changes Requested But Not Made

This subpart retains from our first proposal regulations on which we received comments as follows:

(1) *Definition of "System of Organic Farming and Handling"*. The first proposal contained a definition of a "system of organic farming and handling" to provide an explicit reference point for determining which practices and substances were consistent with such a system. Several industry associations and certifying agents commented that the definition was helpful but lacking in key concepts, such as "ecological balance," "agroecosystem health," and "biological diversity." Several thought the definition should receive greater emphasis in the regulations as a reference point for the underlying principles of organic production and handling and that the NOSB's definition should be used. Although we considered many of the concepts discussed by commenters, only the scope and not the meaning of the original definition has been changed. The definition in this proposal is based on the one we developed in consultation with the NOSB but is limited to concepts that are incorporated into the OFPA. Measuring compliance with the component-based mandates of the OFPA, such as fostering soil fertility and preventing water contamination by manure, does not require criteria as far-reaching as "agroecosystem health" or "biological diversity." We also took into consideration the costs to comply with such open-ended requirements and determined that this could be

excessively burdensome. Synergistic benefits may be associated with organic production and handling systems, but the OFPA requires only that individual components of the system—soil, water, wild crop environment—be protected. Adherence to the conservation practices found in the individual practice standards will result in cumulative benefits to the agroecosystem, but producers and handlers would have difficulty measuring compliance at this scale. Establishing standards that address individual components of an organic farming system, such as tillage practices and manure management, will directly and beneficially impact the entire ecosystem. For the purpose of enforcement, however, we propose retaining the component-based criteria for evaluating a system of organic farming and handling.

(2) *Commercial Availability Standard*. The first proposal allowed certain materials and practices, such as nonorganic seeds and nonorganic minor ingredients in a product labeled organic, to be chosen if preferable alternatives were not "commercially available." We have retained the commercial availability principle in this proposal but have limited its use to the provisions addressing the selection of organic or untreated seeds and planting stock. A number of producers, consumers, and certifying agents expressed concern that producers or handlers not be permitted to base claims of commercial unavailability on any price difference between organic and nonorganic inputs. They argued that the term, "feasibly and economically," in the proposed definition of "commercially available" were too vague to be enforceable. Comments from an industry association supported the use of this concept but requested a more specific definition that could be used to assess the economic dimension of commercial availability. The NOSB has also cited commercial availability as a valid criterion for allowing some flexibility in the choice of inputs and stated that the term is applicable to the quantity and quality of available product as well as its cost.

Although commercial availability is not defined in the OFPA, the concept is well established within current certification programs and the commercial world in general. To be considered commercially available, a preferred input must be known and readily available in the sense that a producer or handler can locate and acquire the quantity and quality of product needed to sustain his or her operation. The producer or handler must make a good faith effort to procure

the preferred input but should not be expected to rely on an inconsistent supply of a necessary commodity. We do not provide a formula for determining when price difference alone is enough to justify purchase of the less desirable input because of the multiple factors which could affect such a decision.

By limiting the application of the commercial availability standard to the selection of organic or untreated seeds and planting stock, we are limiting its use to relatively narrow and well defined markets. A producer must justify a choice based on commercial availability when submitting an organic plan to the certifying agent, and it must be supported by evidence of a good-faith effort to obtain the preferred input. The attempt to source an input from known suppliers and an investigation to discover potential new suppliers constitute the producer's good-faith effort. Certifying agent approval of the organic plan provides sufficient protection against abuse of this provision. Although comments reflected concern that too many allowances for nonorganic inputs could dilute the integrity of certification, the organic industry has built its reputation while using the commercial availability exemption for sourcing certain materials. Certifying agent oversight can ensure that it works in the NOP as well.

Production and Handling (General)—Additional Provisions

Upon further review of the provisions in the first proposal, we have decided to propose the following additions and changes.

(1) *Dual Use of an Organic System Plan*. Section 205.201(b) allows a producer or handler to submit an organic production system plan developed to meet the requirements of another Federal, State, or local regulatory program if the plan fulfills the applicable requirements of this section. Government agencies may have programs in place that require participating agricultural producers or handlers to develop and follow a management plan. For example, the NRCS Environmental Quality Incentives Program (EQIP) requires a conservation plan. An organic production system plan could be incorporated into such a conservation plan and fully comply with the requirements proposed in § 205.201 of this proposal. This new provision could reduce the paperwork burden for an operation that participates in more than one program requiring a farm conservation plan.

Crop Production—Changes Based on Comments

This subpart differs from our first proposal in several respects as follows:

(1) *Biosolids*. The first proposal requested public comment on the possible use of biosolids as a means of enhancing soil fertility on an organic agricultural operation. Our interpretation of the term, “biosolids,” is synonymous with the definition of sewage sludge contained in 40 CFR part 503. In response to the comments we received, this proposal adds biosolids to the list in § 205.203(e)(2) of substances that are specifically prohibited for use in organic production.

The first proposal reviewed some historical information about the Federal enforcement of biosolids use and the steps taken by EPA, FDA, and the U.S. Department of Agriculture (USDA) to ensure that biosolids are safe to use on crops for human consumption. Comments were solicited as to whether biosolids should be permitted or prohibited in organic production. The first proposal noted that the NOSB recommended that biosolids should be classified as synthetic and were not appropriate for use in organic crop production. The NOSB took this position at its 1996 meeting in Indianapolis, IN, and reaffirmed it at its 1998 meeting in Ontario, CA.

We received hundreds of thousands of comments, virtually all of which strongly opposed the use of biosolids in organic agriculture. The vast majority of the commenters stated that biosolids can contain synthetic substances prohibited in organic agriculture, such as industrial waste, street runoff containing petroleum products, and household waste contaminated with cleaning products, polychlorinated biphenyls (PCB’s) and dioxins. Commenters indicated that sewage sludge should not be allowable because it may contain synthetic materials prohibited in organic production which are not restricted under EPA regulations. Many commenters stated that biosolids are not currently allowed in organic production and that permitting their use would run contrary to consumer expectations. Such an allowance would place producers at a competitive disadvantage in domestic and international markets. While sewage sludge may be safely used in conventional agriculture, allowing its use under these standards would be inconsistent with the historical understanding of organic fertility management shared by producers and consumers. Therefore, this proposal

prohibits the use of sewage sludge in organic production.

(2) *Tillage and Conservation Practices*. While no comments objected to the inclusion of tillage and cultivation practices in the first proposal, a few took issue with the requirement that these practices result in “no measurable degradation” of soil quality. In this proposal, the concept of “no measurable degradation” has been replaced with the requirement to “maintain or improve” soil quality. We agree with commenters who suggest that prevention of soil erosion is an important consideration for the selection of tillage and cultivation methods and have included a requirement that tillage and cultivation practices maintain or improve the physical, chemical, and biological condition of soil and minimize soil erosion. We have removed other references to preventing measurable degradation when using plant or animal wastes in the first proposal and replaced them with a requirement, in § 205.203(c), that the producer manage these materials to maintain or improve soil organic matter content in a manner that does not contribute to contamination of crops, soil, or water by plant nutrients, pathogenic organisms, heavy metals, or residues of prohibited substances. In accordance with several comments received, this provision frames the requirement in terms of achieving a positive outcome rather than avoiding a negative one. This proposal specifies the types of measurable degradation that could result from improper or excessive application of plant or animal waste materials, and producers, in consultation with the certifying agent, will identify potential problems and address them in the organic system plan. The organic system plan must also identify appropriate monitoring activities to ensure that the “maintain or improve” requirement is being met. For example, a producer who manages an on-farm composting facility might make regular observations of the pile to check for leaking and periodically sample a nearby stream for nitrate content.

(3) *Application of Raw Manure*. The first proposal requested public comment on appropriate guidelines to ensure that use of raw animal manure would not cause contamination of food products by pathogens that cause foodborne illness. The OFPA restricts the use of raw manure by requiring that a reasonable period of time elapse between its application to a crop intended for human consumption and the harvest of that crop. This period of time must be approved by the certifying

agent, but in no event may it be less than 60 days. The OFPA stipulates that the certifying agent determine the interval between the last application of raw manure and harvest of the crop to ensure the safety of the crop. Furthermore, the OFPA prohibits raw manure from being applied to any crop in a way that significantly contributes to water contamination by nitrates or bacteria. The first proposal contained an order of preference which favored the use of composted materials, including manure, as inputs for soil fertility but allowed raw manure applications subject to the 60-day minimum preharvest interval contained in the OFPA.

Many public comments addressed the issue of raw manure use, and some industry, producer, consumer, and environmental groups submitted substantial technical information. Many of these commenters addressed the human health risk associated with the use of manure in organic crop production. Most of these comments suggested that a determination of sufficient time to ensure the safety of a crop depends on soil and climate conditions, but that the 60-day period specified in the OFPA was not sufficient. Some commenters cited various amounts of time that might be considered safe. Other commenters stated that no interval between application and harvest could be considered safe and recommended prohibiting the application of raw manure to any crop. The NOSB had extensive deliberations on the use of raw manure in organic crop production at its June 1999 meeting in Washington, DC.

The OFPA’s requirement that raw manure be applied in a manner that ensures the safety of the crop presents a unique regulatory challenge. We have consistently maintained that the NOP is for marketing, not food safety, purposes. Organic production and handling standards, which are not based on risk assessment of public health consequences, may differ from the requirements established by agencies that are responsible for food safety regulations. The OFPA’s requirement that the application of raw manure ensures the safety of the food to which it has been applied requires the NOP to move toward establishing a public health standard. This requirement is especially challenging given that there is no Federal oversight of the application of raw manure to any kind of crop nor any public health standards to establish what constitutes safe use of raw manure. Applications of raw manure are a hazardous, threatening

pathogenic contamination of food products, notwithstanding the use of composted manure, which can carry similar hazards.

We have responded to the concerns regarding the application of raw manure to organically produced crops by proposing the standards contained in § 205.203(c)(1). We propose that raw animal manure must be composted, unless it is applied to land used for a crop not intended for human consumption, incorporated into the soil not less than 120 days prior to the harvest of a product in direct contact with the soil surface or particles, or incorporated into the soil not less than 90 days prior to the harvest of a product the edible portion of which does not have contact with the soil surface or particles. However, many site-specific variables affect the viability of pathogens in raw manure, and we cannot determine whether this standard will be sufficient under all conditions to fulfill the safe food requirement contained in the OFPA. We are requesting comment on the development of more comprehensive standards that certifying agents are capable of enforcing. We are also requesting comment on how to regulate the authority to determine the "reasonable period of time" between the last application of raw manure and harvest of a crop which the OFPA delegates to the certifying agent. Given the need for far greater scientific understanding of the spread of pathogens in raw manure, we do not consider that certifying agents should be expected to make the determination of safety.

Several comments were received which suggest that any use of raw animal manure could jeopardize human health and that the use of raw animal manure by organic farmers thereby increases the risk that organic foods may not be as safe as conventionally produced foods. We recognize that our knowledge of the risks from foodborne pathogens has advanced since the OFPA was passed a decade ago, and that safety precautions have been strengthened accordingly. Therefore, we are seeking further guidance for developing regulations that minimize the potential for contamination of crops grown for human consumption by pathogens from raw animal manure. This approach is consistent with the traditional organic certification procedures which have restricted the use of raw manure for environmental as well as health concerns. Other Federal and State regulatory programs may impose additional requirements on the use of raw manure in crop production which

could be applicable to organic operations.

The first proposal required that management practices for the application and storage of raw manure be implemented in a manner that does not significantly contribute to contamination of water by nitrates and bacteria, including human pathogens. The use of the word, "significantly," in this provision is a direct reference to the authorizing language in the OFPA (Section 2114(b)(2) (C)). However, commenters suggested that this language implies that "insignificant" contamination would be acceptable. This proposal requires that soil management practices aim at preventing, to the extent possible, any contamination of water by nitrates and pathogenic bacteria.

(4) *Use of Treated Seed.* The first proposal permitted the use of treated seeds if the same variety was not commercially available in untreated form or if unanticipated or emergency circumstances made it infeasible to obtain untreated seeds. In this context, "treated seed" refers to the application of a pesticide to a seed prior to planting and does not include the use of a disinfection treatment for a seed that is intended for sprouting and food use. A number of comments from producer and industry groups suggested that this was appropriate but that a producer should have to choose an "equivalent" untreated seed variety that was commercially available. The term, "equivalent," indicates that two seed varieties have similar performance attributes, such as resistance to drought and insects, and production traits, including yield, size, and shape of the commodity. We agree with this provision because it favors a nonsynthetic input over a synthetic one and have, therefore, included it in this proposal. We are also requiring that, when selecting a nonorganically produced seed, a producer select an untreated equivalent variety in preference to one which has been treated with an allowed synthetic treatment.

Some comments objected to any allowance for the use of treated seeds or planting stock, citing the prohibition in 2109(c)(3) of the OFPA (7 U.S.C. 6508(c)(3)) on the use of transplants that are treated with any synthetic or prohibited material. We recognize that the use of synthetic seed treatments, some of which are acutely toxic, may seem inconsistent with a system of organic production and handling, but it is an established practice in State and private certification programs and is supported by provisions of the OFPA.

We believe that retention of the commercial availability requirement, a preference for untreated, nonorganically produced seed over treated, nonorganically produced seed, and the use of temporary variances in this proposal provide an appropriate context for regulating the use of synthetic seed treatments.

The requirement from the first proposal that all seeds, annual seedlings, and planting stock be organically produced is retained in this proposal. Similarly, this proposal contains a comparable exception to the requirement so that nonorganically produced seeds and planting stock could be used to produce an organic crop when an equivalent organically produced variety is not commercially available. A producer's decision to use nonorganically produced seeds and planting stock for reasons of commercial nonavailability of equivalent organic varieties must be included in his or her organic plan and agreed to by the certifying agent. We decided to retain these provisions from the first proposal after receiving comments from producer and industry groups that acknowledged that the supplies of organic farm inputs will not be sufficient to provide for the seed and planting stock needs of all organic operations in the near future. We have added the requirement that producers select equivalent untreated seed over treated seed when commercial availability allows them to use a nonorganically produced variety. We recognize that these provisions could lead to certifying agents facing numerous decisions regarding commercial availability and equivalency in the organic system plans they review. This degree of oversight is warranted, however, to ensure that the use of synthetic materials in organic production is kept to a minimum. We are not extending the commercial availability exception to the requirement for organically produced annual seedlings because the comments indicated that the organic input suppliers are effectively meeting this demand.

In contrast to the first proposal, we propose that any synthetic seed treatment used in organic production must be included on the National List of synthetic substances allowed for use in organic production. We base this requirement on the OFPA, which identifies "treated seed" as a category of synthetic substances eligible for inclusion on the National List. We believe that including specific seed treatments on the National List will satisfy the requirement in the OFPA that a farmer shall not apply a material to or

engage in a practice on seeds or seedlings that is contrary to or inconsistent with the applicable certification program. The approach we are proposing is also consistent with current practice in the organic industry. The NOSB endorsed this approach at its 1994 meeting in Santa Fe, NM, by recommending that seed treated with synthetic fungicides appearing on the National List be allowed when nontreated varieties are commercially unavailable.

We propose that producers or handlers may request a temporary variance due to unavoidable natural disaster in order to use nonorganically produced annual seedlings. The temporary variance will be appropriate in instances in which an unexpected event such as a frost, flooding, fire, or other catastrophic event destroyed the producer's nontreated planting materials and no organically produced replacements are commercially available. This provision cannot be used to compensate for mismanagement by the producer. For example, a producer who planted seedlings prior to the recognized frost date and lost his or her crop to a freeze could not claim that this disaster was unavoidable. This provision requires that the producer make all reasonable efforts to protect his or her seeds, annual seedlings, and planting stock before being allowed to substitute with treated replacements.

Some commenters cited the prohibition in section 2109(c)(3) of the OFPA against using transplants that are treated with any synthetic or prohibited material as justification for prohibiting the use of synthetic seed treatments. However, the statute permits the use of seeds and seedlings treated with substances included on the National List of allowed synthetic substances. The seemingly inconsistent requirements for seedlings and transplants, functionally equivalent terms, have made this a difficult issue to resolve. The first proposal attempted to reconcile these differences by defining transplant as an annual seedling produced on an organic farm and transplanted to a field on the same farm operation to raise an organically produced crop. Many commenters felt that distinguishing between annual seedlings which originated on and off the operation was not a valid approach. We concur, and have removed this definition, and interpret the term, "transplant," as applying to any seedling which is transported and replanted, regardless of whether it originated on the operation or not. We interpret the prohibition on using a transplant treated with any synthetic or prohibited

material as taking effect after the seedling has been physically transplanted. Therefore, the prohibition only applies to materials applied after transplanting and not to the synthetic treatment included on the National List, which may have been applied to the seed that produced the seedling.

The application of disinfectants to seeds used for sprouting represents a unique dimension of the seed treatment issue. Raw sprouts pose a potential food safety risk because the conditions under which they are produced—growing time, temperature, water activity, pH and nutrient content—can foster the rapid growth of bacteria. In 1999, FDA issued guidance advising sprout producers and seed suppliers of measures to reduce microbial hazards common to sprout production. These measures include treating seeds with one or more approved methods such as presprout soaking with 20,000 ppm calcium hypochlorite. Based on the recommendation of the NOSB, the Secretary has included on the National List in this proposal three chlorine materials to disinfect and sanitize food contact surfaces. However, these materials carry the annotation that residual chlorine levels in water shall not exceed the maximum residual disinfectant limit under the Safe Drinking Water Act, which is well below the 20,000 ppm level that FDA currently advises sprout producers to follow.

Existing State and private certification programs have diverged in their response to the FDA guidance on chlorine treatments. While treating food products with high concentrations of chlorine has traditionally been prohibited, some certifying agents currently allow sprout treatment at the 20,000 ppm level. Producers of organic sprouts are finding it increasingly difficult to balance the FDA guidance, the expectations of consumers, and the requirements of their certifying agents. This proposal contains no specific guidance on the use of chlorine treatments on seeds used in sprout production. As synthetic compounds, chlorine materials would have to be added to the National List at specified concentrations to be used for disinfecting sprouts. Without a specific National List exemption, operations that treat sprouts at the level established in the FDA guidance could not be organically managed.

(5) *Crop Rotation*. The OFPA requires an organic crop production plan to foster soil fertility through practices that include a crop rotation. The first proposal required the establishment of a crop rotation or other "means" of

ensuring soil fertility and effective pest management but did not provide explicit restrictions concerning situations in which those means could be substituted. Producers and producer groups sent many comments stressing the importance of a proper crop rotation for successful organic crop production and objecting to the vague allowance for other methods to be used in its place. Although we have not changed the definition of crop rotation from the first proposal, the new practice standard eliminates the possibility that an organic producer will substitute some other practice for a crop rotation. This proposal does, however, allow for variances from an approved crop rotation plan due to natural disasters, including weather.

A few commenters made the point that, although the OFPA includes a provision for a crop rotation as a means of improving soil fertility, a crop rotation serves other critical functions as well. We reviewed the NRCS practice standard for crop rotation (Code 328) which addresses many of the concerns raised in public comment. Accordingly, § 205.205 of this proposal requires the producer to implement a crop rotation, including, but not limited to, cover crops, sod, green manure crops, alley crops, and catch crops. These techniques serve the following functions as applicable to the operation: maintain or improve soil organic matter content; provide for effective pest management in annual and perennial crops; manage deficient or excess plant nutrients; provide erosion control to minimize soil loss; and manage subsurface water to prevent transport of dissolved materials.

A few comments suggested requiring that rotation plans include sod or legumes, which serve to improve soil organic matter content and increase soil nitrogen supplies to meet the demands of a following crop. However, all of these functions could be fulfilled through many different types of rotation plans, which could only be developed according to the site-specific climate, soil type, and type of crops or livestock produced on a given operation. In the interest of flexibility, therefore, this proposal does not specify what crops have to be included in a crop rotation. An organic plan that meets the criteria specified in this proposal must be developed by a producer and approved by the certifying agent.

Proposed § 205.205(b) specifically applies to perennial crops. Under this provision, an orchard plan might include establishment of hedgerow areas that provide habitat for beneficial insects to assist in effective pest management. This provision was added

in response to comments stating that an organic farm plan should address the functions provided by crop rotations even in the case of perennial crops such as orchards and sod. We expect to develop program manuals containing more detailed information on different types of rotations, including methods to fulfill the prescribed functions for perennial crops, that are suitable to a wide range of types of operations and geographic conditions.

(6) *Prohibition on Cytotoxic Pest Control Substances.* In response to several comments, we have deleted the provision in the first proposal to prohibit use of a synthetic carbon-based substance having a cytotoxic mode of action for any use as a pest control substance. Some commenters interpreted this provision to mean that this single criterion would substitute for those specified in the OFPA for evaluating substances proposed for inclusion on the National List. Other commenters, including industry groups, objected to this provision because it has not previously been part of certification standards and its meaning was too ambiguous. Some substances that have historically been accepted for organic production could have cytotoxic effects when used in inappropriate concentrations. Although this provision added to and did not replace the evaluation criteria contained in the OFPA and eliminated the need for the NOSB to review clearly inappropriate substances, it has been removed from this proposal in the interest of clarity.

Crop Production—Changes Requested But Not Made

This subpart retains from our first proposal regulations on which we received comments as follows:

(1) *Buffer Zones.* Section 205.202(a)(3) of this proposal requires that any land on which organic crops are produced have distinct, defined boundaries and buffer zones, such as runoff diversions, to prevent the unintended exposure of the crop to prohibited substances from adjoining land. Several commenters suggested that the regulations should specify a minimum size for buffer zones, as is currently required by some organic certifying agents. Although specifying a size for these zones would establish a more definable requirement, it could also impose unnecessary burdens on some organic producers without offering greater protection of organic fields and crops from unintended contact with prohibited substances. Another commenter argued that buffer zones should not be required for unmanaged lands such as wilderness areas or abandoned farms. There might be no

need for a buffer zone if an organic farm were completely surrounded by wilderness or abandoned farms, which is one reason why a the size of a buffer zone should not be specified. This proposal leaves the determination of an adequate buffer zone to the organic producer and the certifying agent on a case-by-case basis. Buffer zone provisions are an important part of each organic production system plan, and we will provide guidelines for buffer zones in program manuals.

(2) *Nonorganic Plant and Animal Waste Materials.* The first proposal permitted the use of any uncomposted plant or animal wastes. It also allowed use of composted plant or animal wastes obtained from nonorganic sources, such as commercial compost products. Several consumer and environmental groups objected to permitting the use of plant or animal wastes from nonorganic sources. Such materials, they argued, could potentially contain residues of prohibited substances that could compromise the integrity of the organic farm system. However, off-farm plant and animal wastes from food processing, municipal yard waste facilities, and other sources are used extensively in existing organic operations and are generally permitted by organic certification programs. Bone meal, fish meal, and seaweed meal are also commonly used as organic farm inputs. Commercial fertilizer products that contain mixtures of such plant and animal by-products are commonly permitted for use in existing organic certification programs, subject to certifying agent review. Using such organic wastes is consistent with a system of organic production and handling, which calls for recycling organic wastes to return nutrients to the land. We believe that concerns about potential contaminants in plant and animal waste materials can be addressed by the requirement in this proposal that these materials be managed in a manner that prevents such contamination. For example, cotton gin trash that had been treated with a prohibited substance could only be used if the organic system plan specified composting the material before adding it to the soil. Composting has been shown to effectively biodegrade synthetic organic compounds, and the organic system plan could also call for the compost or soil to be monitored regularly for specific residues.

Finally, the first proposal and this proposal prohibit the use of any commercially blended fertilizer product that contains a prohibited substance, as required by the OFPA. Although a number of commenters worried that a

product containing toxic synthetic substances as inert ingredients could be used for organic production, this prohibition prevents such products from being used. For this reason, the use of any composted or uncomposted plant or animal wastes to supply soil or crop nutrient is permitted without further limitation other than preventing contamination of soil or water by pathogenic organisms, heavy metals, or residues of prohibited substances. The certifying agent will be expected to have the expertise to recognize materials that might be of concern and ensure that they are properly addressed in the organic system plan. We expect to provide additional guidelines in program manuals to help evaluate whether animal manure is fully decomposed, as well as guidelines for other types of materials to address potential soil or water quality concerns. We acknowledge the need to examine carefully commercial blended fertilizers and soil amendments to ensure that such products do not contain prohibited substances.

(3) *Chemically Altered Plant or Animal Waste Materials.* The first proposal allowed the use of a composted or uncomposted plant or animal waste material that had been chemically altered by a manufacturing process—such as leather meal, newspaper, and biosolids—if the material was included on the National List of allowed synthetics. Only newspaper was proposed for inclusion on the National List. A few commenters objected to this allowance, although newspaper is commonly permitted as a mulch material or as an ingredient in compost in existing organic certification programs and was recommended for this use by the NOSB. The National List review process offers an adequate safeguard to ensure that other waste materials that may be permitted in the future will be consistent with a system of organic production and handling, and we propose to retain this provision in § 205.203(c)(5) of this proposal.

(4) *Soil and Crop Mineral Nutrients.* This proposal includes provisions for supplying soil and crop mineral nutrients that are similar to those in the first proposal. While use of a proper crop rotation and recycled plant and animal wastes can often provide all the mineral nutrients required by crops, supplemental sources of these nutrients are sometimes needed. Section 205.203(d) of this proposal permits a producer to supply soil and crop nutrients through use of mined minerals and other nonsynthetic sources. Synthetic micronutrients are also allowed if they are included on the

National List. Ash from plant or animal materials can be used, as long as the burned material was not treated or combined with a prohibited substance and was not included on the National List of prohibited nonsynthetic substances. For example, ashes from treated wood or incinerator ash are not permitted, nor is ash from manure, which is on the National List of prohibited nonsynthetics. The prohibition of burning crop residues on the farm in the first proposal has been retained, but an exception for burning trimmings of perennial crops to control diseases has been added in response to an NOSB recommendation.

Commenters raised no objection to the proposed allowance for mineral substances of low solubility, including lime, greensand (glauconite), and rock phosphate, which have traditionally been permitted in organic certification programs. However, numerous producers and certifying agents expressed concern about the allowance for use of mined mineral substances of high solubility or salinity. These include substances such as sodium (Chilean) nitrate or potassium nitrate (niter), potassium chloride (muriate of potash), langbeinite (sulfate of potash magnesia), and potassium sulfate. Because of their potential to degrade soil quality by contributing to soil salinization, these substances, along with the synthetic micronutrients that are on the National List of allowed synthetics, were allowed only when used in cases of known nutrient deficiency. Many commenters objected to the use of sodium nitrate and potassium nitrate in organic production, and some contested the determination that nonsynthetic, mined sources of potassium nitrate are available. Some also objected to allowing potassium chloride, which has traditionally been prohibited in most organic certification programs. Several commenters argued that no highly soluble source of nitrogen, synthetic or not, should be permitted for application to soil in an organic management system. They indicated that these materials are not permitted in international organic standards, and approval could potentially harm exports of organic products. The NOSB reviewed Chilean nitrate in 1995 and recommended certain restrictions on the use of this material, which is allowed with restrictions in some existing organic certification programs and prohibited in others. In accordance with the NOSB's recommendation, this proposal permits these materials to be used according to justifications in the organic system plan.

More detailed guidance will be provided in program manuals on the appropriate justifications for the use of highly soluble nutrient sources, including plans for discontinuing their use. Soil or tissue testing will be an important aspect of justifying the need for any such supplementation. Producers concerned about requirements for export markets can request certification to the standards required by individual contracts.

(5) *Nonorganically Produced Planting Stock*. The first proposal allowed nonorganically produced planting stock used to produce a perennial crop to be sold, labeled, or represented as organically produced after the planting stock had been managed on an organic operation for a period of no less than 1 crop year. This provision is authorized by section 2107(a)(11) of the OFPA (7 U.S.C. 6506(a)(11)). Some commenters thought this provision provided a loophole for indiscriminate use of treated planting stock on an organic operation. They argued that a producer could purchase treated nursery stock and list it as organic planting stock in the organic plan after only 1 year. However, producer and industry groups supported this provision as an important stimulus to the organic input suppliers, since it allows a nursery operation to purchase planting stock from a nonorganic operation and later resell this stock as organically produced. The first proposal described an organic nursery operation which could purchase nonorganic dwarf apple rootstock and graft it with locally adapted varieties and then sell the resulting planting stock as organically produced after raising it organically for at least 1 year. We agree that the potential benefits of this provision outweigh its possible abuses, and § 205.204(d) of this proposal permits nonorganically produced planting stock to be used as planting stock to produce a perennial crop to be sold, labeled, or represented as organically produced after the planting stock has been under a system of organic management for no less than 1 crop year.

(6) *Pest, Weed, and Disease Control Practice Standard*. The OFPA sets forth practices such as the use of natural poisons that persist in the environment or plastic mulches that are prohibited or restricted in the control of pests, weeds, and diseases in organic crops. It also lists the following categories of active synthetic pest, weed, and disease control substances that may be considered for exemption if they are included on the National List: Copper and sulfur compounds; toxins derived from bacteria; pheromones; soaps;

horticultural oils; fish emulsions; treated seed; vitamins and minerals; livestock parasiticides and medications, and production aids, including netting, tree wraps and seals, insect traps, sticky barriers, row covers, and equipment cleansers. Section 205.206 of this proposal contains the practice standard to implement the provisions of the OFPA for synthetic pest control substances.

We have made a minor modification by eliminating one element of the order of preference which commenters considered too difficult to enforce. There is no distinction made in this proposal between pest prevention and control practices in terms of preferability. However, a provision in the first proposal that permitted application of a botanical or allowed synthetic pest control substance only if previously delineated methods were ineffective has been retained. This provision is supported by public comments from producers, certifying agents, and many consumers who emphasized that such substances, while sometimes necessary, should only be permitted as a last resort. This provision requires a producer to document the need for copper and sulfur fungicides, dormant oils, or similar materials in their organic system plan.

(7) *Wild-crop Harvesting*. We received few comments on the provision in the first proposal concerning wild-crop harvesting, and, therefore, this proposal retains similar requirements. Changing the term for the location from which wild crops may be harvested from "land" to "area" is the only substantive difference between the first proposal and this one. We made this change to be consistent with the language in the OFPA. One commenter stated that maps should be required as part of the certification process. A certifying agent could reasonably require such maps to assist in evaluating the organic system plan, but we have not made their inclusion a requirement.

The provisions of this section apply only to the management of wild crops. The OFPA includes "fish used for food, wild or domesticated game, or other nonplant life" in the definition of livestock, and we are considering additional standards for animals and animal products harvested from the wild. We received substantial public comment on the opportunities for developing standards for marine and freshwater aquatic animals (encompassing finfish and shellfish) and apiculture operations. Additional comments addressed the feasibility of developing production standards for harvesting wild terrestrial animals.

The certification of aquatic animals has very limited precedent among existing certifying agents and will require additional dialogue before credible standards can be developed. The FY 2000 Agriculture, Rural Development, Food and Drug Administration, and Related Agencies Appropriations Act provides funds for the NOP to convene national meetings to consider the development of organic standards for aquatic animals. Meetings will be held in Alaska, Alabama, and Rhode Island. Simultaneously, the NOP will be working with stakeholders from the aquaculture community to consider standards for the production of farm-raised aquatic animals.

The certification of apiculture operations has some precedent among certifying agents. However, due to many unique production considerations, organic certification for apiculture operations has been very limited. Public comment on the first proposal indicated that consensus on critical apiculture issues including forage area and pest management will require considerable additional dialogue. The NOSB has expressed interest in leading the discussion of the key issues pertinent to certification of apiculture operations. We will incorporate public participation and the NOSB's recommendations into future production standards for apiculture as well as for other wild harvested livestock operations as needed.

(8) *Practice Standards for Specialty Crop Operations.* Several organic certifying agents and producer associations commented that the proposed rule did not sufficiently detail prescribed practices for many specialized aspects of organic production and handling, such as mushrooms, greenhouses, and aquaculture. We concur that such details are lacking, and to a certain extent, this proposal addresses that gap through the introduction of more detailed practice standards. In some cases, more specific regulations appropriate for such specialized operations, including aquaculture, mushroom production, and greenhouse operations, will be filled in as recommendations are developed by the NOSB. Beyond this, the Department expects to address the need for greater specificity through program manuals, which will provide more detailed guidance about site-specific decisions. For example, program manuals could include examples of crop rotation plans suited to different geographic regions, soil conditions, and types of enterprises. Program manuals could also be used to provide guidance about how indicators

of the condition of the natural resource base can be qualitatively assessed using simple field observations so that the impact of site-specific practices on soil and water quality can be documented in the organic plan.

Crop Production—Additional Provisions

Upon further review of the provisions in the first proposal, we have decided to propose the following additions and changes.

(1) *Mandatory Phytosanitary Treatment of Seeds, Seedlings, and Planting Stock.* Section 205.204(e) of this proposal contains a new provision that permits the use of treated seeds, seedlings, or planting stock in cases in which Federal or State phytosanitary regulations require treatment. For example, some States require seed potatoes or strawberry crowns to be treated to prevent the spread of plant diseases. The OFPA authorizes reasonable exemptions from specific requirements for compliance with Federal or State emergency pest or disease treatment programs. This provision is also consistent with the NOSB's recommendation on the use of treated planting stock.

(2) *Restriction on the Use of a Synthetic Pest Control Substance.* The first proposal included a provision that any use of biological or botanical pest control substances or synthetic pest control substances approved for use on the National List had to be used in a manner that did not result in measurable degradation of soil or water quality. This provision has been removed, and § 205.207(e) of this proposal includes a new provision that further restricts use of these substances by requiring the producer to implement measures to evaluate and mitigate the effects of repetitive use of the same or similar materials on pest resistance and shifts in pest types. This requirement can be met by reviewing available research on pest resistance to the substance being used and observing changes in pest populations following repeated application of the substance. Public comments pointed out evidence that nonsynthetic biological and botanical pest control substances, if overused, pose concerns for inducing accelerated resistance in pest populations.

Livestock Production—Changes Based on Comments

This subpart differs from our first proposal in several respects as follows:

(1) *Minimum Period of Organic Management—Nonedible Products.* The first proposal established a 90-day

minimum period of organic management for animals from which nonedible products, such as wool, were to be harvested. Many consumers and producers said that a 90-day period was too short and that an animal should be under organic management for at least 1 year before a nonedible organic product could be obtained from it. This requirement is consistent with the provision that dairy animals receive a minimum of 1 year of continuous organic management prior to the production of the milk or milk products to be sold, labeled, or represented as organic. Therefore, this proposal has been revised to state that an animal brought into an organic operation must be under continuous organic management for 1 year prior to the harvest of nonedible products that are sold, labeled, or represented as organic.

(2) *Origin of Mammalian Slaughter Stock.* The first proposal allowed mammalian livestock from a nonorganic source for the production of organic meat if the livestock was brought into an organic operation no later than the 15th day of life, if necessary. Public comment was sought as to the specific conditions, such as commercial unavailability of organic livestock or an emergency situation, that should be a prerequisite for allowing mammalian livestock of nonorganic origin to be designated as organic slaughter stock. Thousands of commenters, along with the NOSB, strongly opposed allowing the use of cows, sheep, or other mammals as organic slaughter stock if they were not organic from birth. Most of them also rejected allowing such practices on an "if necessary" basis. Accordingly, § 205.236 requires that mammalian slaughter stock be organically raised from birth.

(3) *Standard for Aquatic Animal Production.* While the first proposal contained no standards solely for aquatic animals in an organic operation, it did contain provisions applicable to their production. The first proposal allowed fish and crustaceans, among other livestock types, to be sold, labeled, or represented as organic if such livestock had been brought into an organic operation no later than the earliest commercially available stage of life. Several commenters suggested that the management of aquatic species differs significantly from mammals and poultry and would require separate regulatory provisions. We concur and intend to develop detailed practice standards for specific aquatic species that will be published for comment and finalized prior to the implementation of the NOP. Given the virtual absence of recognized certification programs for

aquatic operations, including aquaculture, there are limited models on which to base national standards. Therefore, we must create opportunities for producers, consumers, certifying agents, and other interested parties to participate in the development of practice standards. We will hold public meetings in Alaska, Alabama, and Rhode Island to receive comment and anticipate that the NOSB will also provide recommendations.

(4) *Apiculture Standard.* The first proposal allowed bees to be brought into an organic operation at any stage of life and required that the predominant portion of their forage be organically produced. Several commenters, including producer and industry groups, pointed out that bees differ significantly from other livestock types and that the first proposal lacked sufficient details to guide honey producers. Many consumers stated that the provisions proposed for bee forage, which required only that a predominant portion of the bees' forage be organic, were too vague and lenient. Recognizing that the provisions in the first proposal for certifying beekeeping operations were inadequate, we removed them entirely from this proposal. We will review the detailed production and handling standards for beekeeping operations that several certifying agents have developed and assess the feasibility of developing a practice standard. The NOSB has agreed to review and recommend an apiculture practice standard for organic honey production and hive care, including the origin of organic bees.

(5) *Organic Feed Requirement.* The first proposal allowed a producer to feed livestock up to 20 percent of the total feed ration in a given year that was not organically produced. Furthermore, in an emergency situation, the first proposal allowed the Administrator to increase the amount of nonorganic feed that could be provided. Thousands of comments were received opposing any allowance for nonorganic livestock feed, and many thought that no conditions justified providing any nonorganic feed to organic animals. Most producer groups, organic certifying agents, and industry groups, however, recognized that eliminating all flexibility in this regard could seriously inhibit growth of the organic livestock industry and reduce the availability organic livestock products. Several existing certification programs allow some use of nonorganic feed in emergencies, in one case specifying that up to 10 percent of the livestock ration may be nonorganic. Commenters made it clear that the commercial availability of certified

organic livestock feed has increased enough to eliminate exemptions based on availability, even in regions such as the Northeast where supplies were previously difficult to obtain. The NOSB also recommended providing an allowance for livestock to receive nonorganic feed in emergency situations, with strict requirements for documentation in the organic system plan.

Based on the public comment received and the recommendations of the NOSB, we agree that allowances for providing nonorganic feed to organically managed livestock should be limited to emergencies, such as fire, drought, flood, and other natural disasters. Accordingly, we have removed the provision from the first proposal that a producer may provide up to 20 percent nonorganically raised feed "as necessary." Exemptions for emergency use of nonorganic feed must be authorized by the Administrator through the procedures for establishing a temporary variance. Producers will work with their certifying agents to determine the minimum percentage of nonorganic feed needed to supply the nutritional requirements of the livestock until the 100 percent organic ration can be restored.

(6) *New Dairy Herd exemption.* The first proposal included an exemption to allow an entire, distinct dairy herd—converted to organic management for the first time—to be fed nonorganic feed up to 90 days prior to the production of milk or milk products labeled as organic. A few producer groups supported this allowance for a one-time, whole-herd exemption to make it feasible for existing conventional dairy farmers to convert to organic management without incurring the costs of 100 percent organic feed for 12 months prior to certification. However, in light of the strong opposition to any nonorganic feed allowance by consumers and its inconsistency with NOSB recommendations, we have eliminated this provision.

(7) *Synthetic Feed Additives.* The first proposal prohibited the feeding of substances containing synthetic amino acid additives and synthetic trace elements to stimulate the growth or production of livestock. In § 205.237(c)(2), the term, "synthetic amino acids," is replaced with the term, "additives," which includes nutritional substances other than amino acids. Some commenters stated that the term, "additives," more precisely reflects the intent of the OFPA, which prohibits the use of growth stimulants. The provision in the first proposal to permit use of synthetic amino acid additives to fulfill

the normal nutritional needs of livestock is retained in § 205.237(a).

(8) *Prohibition on Antibiotics.* The OFPA prohibits producers from using subtherapeutic doses of antibiotics. While this suggests that treatment with antibiotics at therapeutic levels is allowed, the OFPA does not contain affirmative conditions for their use. In developing provisions in the first proposal for treating livestock with antibiotics, we reviewed the NOSB recommendations, public input received at NOSB meetings, testimony presented at livestock hearings, and existing State and private standards. We found that innovative production practices and consumer expectations had increasingly diminished the use of antibiotics in organic livestock since passage of the OFPA. At its 1994 meeting in Santa Fe, NM, the NOSB recommended prohibiting the use of antibiotics in the production of organic slaughter stock but allowing their use with extended withdrawal intervals for dairy and breeder stock. By its Ontario, CA, meeting in 1998, the NOSB recommended prohibiting all antibiotic use after animals were brought into an organic operation. Other comments we reviewed favored allowing the use of antibiotics because organic livestock might benefit from receiving such treatments. Other commenters requested that organic producers be prohibited from withholding treatment from sick animals for economic reasons.

The first proposal permitted mammals raised as organic slaughter stock to receive antibiotics in the first 21 days of life and other species to be given antibiotics in the first 7 days of life. The rationale for allowing antibiotic use was based on concerns about the vulnerability of newly born or hatched livestock brought into an organic operation from a nonorganic source. The first proposal permitted organic slaughter stock to originate from nonorganic sources if it was brought under organic management at an early stage of life. Allowing the use of animal drugs could be an appropriate safety net for young organic livestock during their first week of organic management. We requested public comment on the use of animal drugs in the production of organic livestock, including organic slaughter stock. We also published an issue paper in October 1998 entitled "The Use of Antibiotics and Parasiticides in Organic Livestock Production," requesting additional public comment on this subject.

We received thousands of comments from consumers, producers, and industry groups objecting to any allowance for antibiotic use in

organically produced livestock. Many of these comments supported a comprehensive prohibition on the use of antibiotics, regardless of the animal's age or the type of products produced from it. Based on these public comments and the availability of alternative production practices, this proposal prohibits selling, labeling, or representing as organic any animal that has been treated with an antibiotic at any dosage.

(9) *Parasiticide Use.* The first proposal permitted livestock in an organic operation to receive parasiticides topically at any time of life, provided that the producer complied with the prohibition against routine use of a synthetic internal parasiticide. We concluded that, while some earlier public comment favored prohibiting the use of internal parasiticides and the NOSB recommended restricting their use, many producers had indicated that parasiticides were essential to their operations. These producers stated that parasites can threaten animal health at any stage of life and that the use of parasiticides is unavoidable in certain regions of the country. Even under highly controlled situations, some parasites endemic to certain regions can be carried by wild birds, water, or feed. Concerns for the overall health of an animal warranted that parasiticides be used as soon as possible after determining the presence of parasites at a level affecting the health of the infected livestock.

In responding to the first proposal, a large number of commenters stated that synthetic parasiticides should be prohibited in organic production, especially for slaughter stock. The NOSB also recommended prohibiting the use of parasiticides in slaughter animals. For other livestock, the Board recommended that, in certain climates, in certain stages of production, and for certain animals, the use of synthetic parasiticides might be necessary. The Board stated that breeding stock, for example, could receive parasiticides up to certain stages of gestation specific to the type of livestock. Such use of synthetic parasiticides would be highly restricted and include a lengthy period of elapsed time before the animal's offspring would be eligible for use in a certified operation. The Board proposed developing practice standards to address specific instances in which parasiticides could be allowed.

This proposal allows the use of synthetic parasiticides included on the National List for use in organic production on breeder and dairy stock provided that preventative practices and veterinary biologics are inadequate to

prevent infestation. This proposal prohibits administering synthetic parasiticides to livestock sold for slaughter. These provisions reflect an attempt to balance the conflicting positions taken by consumers and producers in response to the first proposal and the subsequent issue paper on livestock medications. We recognize that the goal of organic production is to use management practices and natural substances to eliminate, when possible, reliance on synthetic materials. However, we do not believe that a comprehensive prohibition on synthetic parasiticides is feasible for all species and for all regions of the country at this time. Additionally, the new requirements for access to the outdoors for organically managed livestock contained in this proposal may exacerbate exposure to parasites for animals in systems which previously used greater degrees of confinement. These provisions are also consistent with the position of the NOSB, which recommended at its October 1999 meeting to allow a synthetic parasiticide for use on organically raised breeder and dairy stock with the same restrictions incorporated in this proposal.

The OFPA prohibits the use of synthetic internal parasiticides on a routine basis. In the first proposal, the word, "routine," was defined as administering an animal drug "without cause." Many commenters objected to that definition, pointing out that producers would not administer a parasiticide unless they perceived a justifiable cause. Commenters fear that this might lead to dependence on parasiticides rather than a management system to reduce the number of parasites. Therefore, this proposal adopts the NOSB-recommended definition for "routine" as use of a synthetic parasiticide on a regular, planned, or periodic basis. The prohibition on using synthetic treatments on a routine basis is retained in § 205.238(c)(4).

(10) *Temporary Confinement.* The first proposal provided that, if necessary, animals could be maintained under conditions that restrict the available space for movement or access to outdoors if other living conditions were adequate to maintain the animals' health without the use of permitted animal drugs. This provision considered the effects of climate, geographical location, and physical surroundings on the ability of animals to have access to the outdoors. We explained that a system of organic production is soil based and that animals should be allowed, as appropriate, access to the

soil. This understanding was considered in balance with animal health issues, such as the need to keep animals indoors during extended periods of inclement weather. The determination of necessity was to be based on site-specific conditions described by the producer in an organic system plan or updates to an organic plan, which required approval from the certifying agent. We requested public comment as to the conditions under which animals may be maintained to restrict the available space for movement or access to the outdoors. We also released an issue paper in October 1998 entitled "Livestock Confinement in Organic Production Systems" to solicit further public participation in preparing this proposal.

Many commenters stated that, while confinement is appropriate under certain conditions, access to the outdoors is a fundamental tenet of organic livestock production. Commenters cited the widespread prohibition on confinement systems, such as raising poultry in battery cages, contained in domestic and international standards. Producers of organic livestock have incorporated access to the outdoors into viable production systems for all major commercial species, and consumers clearly identify these practices as a distinguishing characteristic of organic products. Some commenters stated that production standards containing broad allowances for confinement would weaken their incentive for purchasing organic products. Some producers pointed out that providing animals access to the outdoors can reduce stress and diminish the risk of transmitting disease. The vast majority of commenters strongly indicated that protection of an animal's welfare or the soil and water resources of the operation were the only appropriate conditions for restricting access to the outdoors. Furthermore, many commenters stated that the condition and properties of the outdoor area to which an animal receives access, such as the nutritional content of pasture, must be important considerations in developing livestock production standards.

Section 205.239(b) of this proposal specifies the circumstances under which animals may be temporarily confined. This new requirement proposes temporary confinement during periods of inclement weather; certain stages of production such as when dairy animals are very young; when the animal's health, safety, or well-being are jeopardized; or when there is risk to soil and water quality. The NOSB specified that the stage of an animal's production

is not intended to include the lactation cycle of dairy animals in which only dry cows would be allowed access to the outside and pasture. The NOSB recommended and we propose that when there is a risk to soil or water quality, livestock should be temporarily confined. Practice standards addressing when and how individual species may be temporarily confined will be developed and published in program manuals. We are also incorporating the NOSB recommendation that ruminants receive access to pasture during the periods they are not temporarily confined.

(11) *Physical Alterations*. This proposal contains a requirement in § 205.238(a)(5) that the producer of an organic livestock operation must perform, as needed, physical alterations on livestock to promote the animal's welfare and in a manner that minimizes pain and stress. Physical alterations include castration and other practices, such as wing clipping, intended to modify or affect the animal's behavior in confinement. We received comments on the first proposal which stated that the performance of physical alterations is integral to a system of organic livestock production which must be addressed in the standards. Subsequently, some commenters on the confinement issue paper drew a connection between certain physical alterations, such as debeaking in poultry, and the conditions for space and mobility under which livestock are raised. We anticipate that this subject will be a significant consideration when the NOP engages in equivalency discussions under the Codex Alimentarius guidelines.

While many certification programs have production standards for conducting physical alterations on animals, we cannot identify general consensus on which practices should be approved or prohibited. Many production variables, including breed, the number and concentration of animals raised, and the available natural resource base, influence the selection of production practices. Operations which raise the same species of livestock could, due to differences in production practices, require different approaches to whether and how to conduct physical alterations. We do not have sufficient information at this time to propose species-specific guidelines but anticipate working with producers, consumers, and certifying agents to develop a better understanding on which to act. By including the requirement for conducting physical alterations in a manner which promotes an animal's welfare and minimizes pain and stress in this proposal, we are

acknowledging two points. One, physical alterations have an appropriate and at times necessary role in livestock production, and, two, consideration for animal welfare and comfort is an integral component of organic livestock production.

In order to use an animal's welfare and comfort as a condition for establishing standards, we are requesting comment on techniques to measure animal stress. Certifying agents will need objective, verifiable methods to determine whether a producer is fulfilling the livestock management conditions established in the organic system plan. Such methods may include physiological or behavioral approaches to measuring stress and may be directed at individual animals or larger groups such as herds or flocks. The many comments addressing the well-being of animals under organic management indicate that this issue is central to the differentiation of organic production standards from nonorganic practices. We need consistent, verifiable enforcement techniques to ensure that organic producers are capable of attaining and documenting such standards.

(12) *Treatment of Sick or Injured Animals*. In this proposal, any animal that is to be sold, labeled, or represented as organic may not be treated with a prohibited animal drug, including antibiotics, synthetic substances that are not allowed, or nonsynthetic substances that are prohibited. Any substance used as an animal drug in organic livestock production must be approved by FDA or registered by EPA and must be administered in compliance with the Federal Food, Drug, and Cosmetic Act. This proposal simultaneously requires that sick or injured animals must be treated with the appropriate animal medicine regardless of whether organic status is lost as a result of doing so. This requirement has been added in response to an NOSB recommendation. Thousands of comments expressed concern that organic livestock would suffer unduly if producers were not required to provide treatment, especially to save the life of a critically ill animal, rather than risk the suffering or death of the animal simply to maintain its organic status. If the treatment required under this proposal includes the use of a prohibited substance, the animal and any product derived from it must be diverted to the nonorganic market.

(13) *Feeding of Animal By-Products*. Although we received thousands of comments supporting a ban on the feeding of any animal by-products to livestock under organic management, a

broad prohibition would prevent certain essential practices, such as feeding milk to young mammals. This prohibition is also inappropriate in the case of carnivorous livestock, such as many aquatic species. We believe that the comments we received were not intended to prohibit such practices but were, rather, motivated by concerns for food safety and the humane treatment of animals. This proposal prohibits the feeding of poultry and mammalian slaughter by-products to organically raised poultry or mammals. This change is based on the thousands of comments that expressed strong consumer preference against adding animal by-products into feed for the same species. There was concern that this practice could expose ruminant animals to Bovine Spongiform Encephalopathy (BSE). FDA regulates animal feed additives and uses its authority to address the human health considerations of animal refeeding. FDA continually revises its regulations to ensure the highest level of protection against known and emerging human health risks. The prohibition on feeding poultry and mammalian slaughter by-products to organically raised poultry or mammals contained in this proposal is based solely on the consumer preference expressed in public comment and is not a food safety standard. Future changes that are made to FDA regulations will be reflected in NOP standards.

(14) *Withdrawal Intervals*. The first proposal required that a producer determine that an animal was fully recovered from the condition for which an animal drug was administered before a product obtained from that animal could be sold, labeled, or represented as organic. In compliance with FDA regulations, this could not have been less than the withdrawal time specified on the label of the animal drug administered. We received comments from producer groups that favored extending the withdrawal times specified on animal drug labels. Many private certification programs applied the principle of extended withdrawal periods to the use of antibiotics in dairy and breeder stock before innovations in production led to such substances being prohibited. The NOSB has continued to include extended withdrawal period annotations with its recommendations for the use of parasiticides.

Based on consumer preference and the recommendations of the NOSB, we are proposing an extended withdrawal interval for three animal drugs (Ivermectin, Lidocaine, and Procaine) included on the National List in this proposal. FDA exercises full responsibility for determining and

enforcing the withdrawal intervals for animal drugs. No food safety arguments are used or implied to support the use of extended withdrawal periods. Rather, we determined that extended withdrawal periods are more compatible with consumer expectations of organically raised animals. In emergency situations where the need for a synthetic parasiticide or medicine is unavoidable, an extended withdrawal period would indicate that such use was neither routine nor normal. This approach is consistent with the manner in which organic certification agencies addressed antibiotic use in livestock production. Before the current prohibition on antibiotics became the industry norm, certifying agents allowed their use under restricted conditions, including extended withdrawal intervals, to demonstrate to consumers that such use was genuinely essential.

Livestock Production—Changes Requested But Not Made

This subpart retains from our first proposal regulations on which we received comments as follows:

(1) *Feed Requirements.* The first proposal required the use of preventive health care practices, including diverse feedstuffs, appropriate housing, well maintained pasture, and good sanitation practices, and this proposal contains similar provisions. It also included provisions for administering appropriate veterinary biologics, vitamins, and minerals, and on selecting species and types of livestock with regard to suitability for site-specific conditions and resistance to prevalent diseases and parasites. Preventive health care practices were generally supported by comments as being consistent with a system of organic livestock production.

Many commenters requested an explanation of the term, “diverse feedstuffs,” and some expressed concern that this provision could permit use of feed supplements which might be prohibited by other Federal, State, or local laws. All provisions proposed in this subpart must be in compliance with applicable laws and regulations, including the Federal Food, Drug, and Cosmetic Act; the OFPA; and our definition of a system of organic production and handling. Vitamins, minerals, and other synthetic or nonagricultural supplements, which appear on the National List of allowed synthetic livestock products in the first proposal are similarly permitted here, and provide a means to diversify an animal’s diet. Soybean meal and other organically produced feed concentrates also serve this purpose. We encourage the NOSB to develop and recommend

practice standards to provide additional guidance regarding the appropriate variety of feed for specific livestock species. Both the first proposal and this one defer to publications of the National Research Council’s Committee on Animal Nutrition to establish nutrient requirements for livestock. Producers and certifying agents will use these publications to ensure that animal nutrient requirements are met.

Handling—Changes Based on Comments

This subpart differs from our first proposal in several respects as follows:

(1) *Irradiation.* In the first proposal, we requested public comment on the compatibility of ionizing radiation (irradiation) with a system of organic production and handling. We also asked if there are effective alternatives to ionizing radiation, such as sanitary practices, heat pasteurization, and incidental additives, that are compatible with a system of organic production and handling, and, if so, how they are compatible. We further asked whether the use of ionizing radiation was considered an essential standard industry practice or good manufacturing practice. Although the NOSB recommended prohibiting the use of ionizing radiation for organic products, we requested this information because of increasing concern about foodborne illness and growing interest in FDA-approved ionizing radiation as a sanitation or preservation treatment for a wide range of agricultural products.

We received hundreds of thousands of comments from every segment of the organic community—producers, processors, certifying agents, consumers, environmental groups, and retailers—opposing the use of ionizing radiation. These comments indicated that ionizing radiation has been expressly prohibited in all existing organic certification standards, international as well as domestic. Allowing this practice could put domestic producers and handlers at a trade disadvantage, disrupt international markets, and undermine consumer faith in the integrity of the domestic organic label.

Comments suggested alternatives to ionizing radiation for preventing contamination by human pathogens. Alternatives include heat disinfection, refrigeration, moisture and oxygen reduction, packaging, hygienic handling, and appropriate use of disinfectant substances. Although no one suggested that any products might be unavailable if irradiation were prohibited, many commenters expressed the willingness to do without any

product that required irradiation. In response to the overwhelming consensus of public comment, this proposal prohibits any use of ionizing radiation for the handling of any organic product in § 205.270(c).

(2) *Incidental Additives.* The first proposal included a provision that permitted the use of incidental additives in processing, except those extracted with a volatile synthetic solvent, if it was necessary for the production of the product. As with previous provisions for practices that could be used only “if necessary,” the preamble to the first proposal explained that a determination of necessity was based on site-specific conditions that were described by a producer or handler in an organic system plan or updates to an organic system plan and reviewed by the certifying agent. We requested comments as to the conditions under which an incidental additive might be considered necessary and requested comment as to whether handlers who handle only products sold, labeled, or represented as “made with certain organic ingredients” should be exempted from the restriction of using incidental additives only if necessary. An incidental additive was defined as an additive that is present in an agricultural product at an insignificant level, does not have any technical or functional effect in the product, and is not considered an active ingredient. This definition is consistent with 21 CFR 101.100(a)(3)(ii) and is the basis for the definition of an incidental additive in this proposal.

Although thousands of consumers objected to the use of synthetic substances in processed organic products, many others specified that an incidental additive that had been reviewed and approved by the NOSB would be acceptable. Few respondents supported exempting products labeled as “made with organic ingredients” from restrictions on the use of incidental additives. The NOSB recommended that documentation be required for use of synthetic incidental additives and that handlers demonstrate progress over time in finding replacements. Organic industry groups also commented that hundreds of incidental additives are currently being used to process organic products and that prohibiting the use of such substances would severely restrict the choices available to consumers and limit the growth of the organic sector. The NOSB recommended several synthetic incidental additives for the National List, recognizing that a wide range of organic products could not be feasibly manufactured without the use

of incidental additives such as defoaming agents, adjuvants, clarifiers, filtering agents, and equipment cleansers. Therefore, this proposal requires that any incidental additive used to process agricultural products that are intended to be sold, labeled, or represented as "organic" or "made with organic (specified ingredients)" must be included on the National List of allowed nonagricultural (nonorganic) substances in § 205.605. A product labeled as "100 percent organic" could not be produced through the use of any synthetic processing aid.

(3) *Prevention and Control of Facility Pests.* The first proposal addressed the prevention and control of facility pests and authorized the NOP to require such terms and conditions as are determined necessary. These provisions were based on existing organic certification programs and NOSB recommendations. The first proposal included a three-step order of preference, which commenters found to be overly complex and difficult to enforce. This proposal retains similar provisions but simplifies the scheme so that there are only two levels of distinction between preferable and less preferable practices. In this proposal, pest prevention and control methods that do not entail use of biological, botanical, or synthetic substances are equally acceptable, and the producer or handler may only use biological, botanical, or synthetic substances if other approved methods are not effective. Paragraph (c) of § 205.271 parallels the provision proposed in § 205.206(d) addressing crop pest, weed, and disease management. Accordingly, it requires an operator of an organic handling operation who applies any biological, botanical, or synthetic substance for the prevention or control of pests to implement measures to evaluate the effects of repetitive use of the same or similar materials on pest resistance and shifts in pest types.

(4) *Storage Containers.* Sections 205.272 (b)(1) and (b)(2) of this proposal contain provisions similar to the first proposal which prohibit the use of storage containers or bins, including packages and packaging materials, that contain synthetic fungicides, preservatives, or fumigants. These requirements also prohibit the use or reuse of any bag or container that was previously in contact with any substance that could compromise the organic integrity of its contents. This proposal adds a provision to permit the reuse of a bag or container originally used for conventional products if the reusable bin or container has been thoroughly cleaned and poses no risk of prohibited materials contacting organic

products. Producers and handlers commented that it is possible and desirable to reuse some kinds of containers if precautions are taken. This modification is consistent with the OFPA, which requires that the organic quality of a product not be compromised.

(5) *Agricultural Fibers.* Some commenters stated that the labeling provisions in the first proposal for processed commodities containing organically produced cotton fibers were excessively restrictive. The OFPA provides the Secretary with the authority to implement standards for organically produced agricultural fibers, including cotton, used for nonfood purposes. This authority includes standards for the production of the agricultural fiber as well as handling standards to regulate the practices and materials that are used in the manufacture of the nonfood commodity. State and private certification agents have made substantial progress in developing and implementing handling standards for organically produced agricultural fibers that are gaining acceptance in the marketplace. We are reviewing the existing certification guidelines and industry practices and anticipate developing standards for processing organically produced agricultural fibers.

Handling—Changes Requested But Not Made

This subpart retains from our first proposal regulations on which we received comments as follows:

(1) *Facility Pest Control Substances.* The first proposal permitted the use of any substance to control facility pests, as long as the intended use was approved by the appropriate regulatory authority and the substance was applied in a manner that prevents it from coming into contact with any organic product. Many consumers objected to this provision and suggested that prohibited substances should never be allowed to be used in any organic operation. However, comments from a number of organic handlers and one industry association stated that, because handling operations must comply with health regulations that require elimination of any pests that may invade food handling facilities, prohibited substances must sometimes be used. The NOSB also acknowledged this possibility in its recommendations, and most organic certification programs similarly allow for such an occurrence, with strict provisions for safeguarding the integrity of organic products. In agreement with these comments, we have proposed a similar allowance in

§ 205.271(c). The handler must fully document in his or her organic plan the evidence that such a measure was necessary and the measures taken to protect organic products or ingredients from coming into contact with any pest control substance.

(2) *Waxes.* We propose to retain the definition of packaging included in the first proposal, which encompasses waxes used in contact with an edible surface of an agricultural product. A number of commenters disagreed with the inclusion of waxes in the definition of packaging, arguing that waxes should be considered nonagricultural ingredients and, therefore, should be required to appear on the National List of nonagricultural (nonorganic) substances allowed as ingredients in or on processed products labeled as "organic" or "made with organic (specified ingredients)." However, the first proposal did require carnauba and other waxes to be on the National List of nonagricultural ingredients allowed for use in organic processed products, and this proposal contains a similar provision. These provisions adequately address the concerns expressed by the commenters that only waxes meeting the criteria for ingredients in organic processed products be permitted. It is appropriate to include waxes in the definition of packaging to ensure that prohibited substances are not added to approved waxes that may be applied to the edible surface of organic products, in accordance with the OFPA, which prohibits use of any packaging materials that contain synthetic fungicides, preservatives, or fumigants.

Subpart D—Labels, Labeling, and Market Information

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

subpart proposes a new USDA organic seal or shield (hereafter referred to as the USDA Seal) and regulations for display of the USDA seal and display of the seals, logos, or other identifying marks of certifying agents.

The intent of these sections is to ensure that organically produced agricultural products are consistently labeled to aid consumers in selection of organic products and to prevent labeling abuses. These provisions cover the labeling of a product as "organic" and are not intended to supersede other labeling requirements specified in various Federal labeling regulations. For instance, we propose that the percent of organic ingredients and the name of the certifying agent be displayed on the information panel of packaged products and that the organic ingredients be identified as "organic" in the ingredient statement. The Food and Drug Administration (FDA) has authority to regulate the placement of information on package information panels and, thus, FDA labeling requirements in 21 CFR parts 100 through 169 must be complied with by handler when affixing organic labels to product packages. Display of the USDA Seal and certifying agent seals, logos, or other identifying marks also must be in accordance with those regulations. The requirements of FDA's Fair Packaging and Labeling Act (FPLA) and the Federal Food, Drug, and Cosmetic Act (FFDCA) must be followed. Likewise, the Federal Trade Commission has authority over product advertising and the extent to which a handler or retail food establishment engages in advertising as part of its market information activities. The Federal Trade Commission (FTC) regulations in 16 CFR must be followed. USDA's Food Safety and Inspection Service's (FSIS) Federal Meat Inspection Act, Poultry Products Inspection Act, and Egg Products Inspection Act also have implementing regulations in 9 CFR which must be followed. The labeling requirements specified in this subpart must not be applied in a manner so that they would conflict with the labeling requirements of these and other Federal and State programs.

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

In this proposal, assembly, packaging, and labeling of a multiingredient organic product are considered handling activities. The certification of handling

operations is covered in subpart C of this regulation. No claims, statements, or marks using the term, "organic," or display of certification seals, other than as provided in this regulation, may be used. A handler which chooses not to use these required and prohibited labeling provisions may not otherwise label or represent a product as organic.

Once a handler makes a decision to market a product as organic or containing organic ingredients, the handler is required to follow the provisions in this subpart regarding use, display, and location of organic claims and certification seals. Handlers who may produce organic ingredients and/or assemble multiingredient products composed of more than 50 percent organic ingredients must be certified as an organic handling operation. Handlers of products of less-than-50-percent organic ingredients do not have to be certified unless the handler actually produces one or more of the ingredients used in the less-than-50-percent product. Repackers who purchase certified organic product from other entities for repackaging and labeling must be certified as an organic operation. Entities which simply relabel a product package would be subject to recordkeeping requirements to show proof that the product purchased prior to relabeling was, indeed, organically produced. Distributors which receive and transport labeled product to market are not subject to certification or any handling requirements of this regulation.

Proposal Description

The general labeling principle employed in this proposal, and to which we think most commenters would subscribe, is that labeling or identification of the organic nature of a product should increase as the organic content of the product increases. In other words, the higher the organic content of a product, the more prominently its organic nature can be displayed. This is consistent with provisions of the Act which establishes the three percentage categories for organic content and basic labeling requirements in two of those categories.

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

that is organically produced and handled. Products not organically produced and handled will not be able to use the term, "organic," on any package panel or in market information in any way that implies the product is organically produced.

Categories of Organic Content. The type of labeling and market information that can be used and its placement on different panels of consumer packages will be based on the percentage of organic ingredients in the product. The percentage will reflect the actual weight or fluid volume (excluding water and salt) of the organic ingredients in the product. Four categories of organic content are proposed: 100 percent organic; 95 percent or more organic content; 50 to 95 percent organic content; and less than 50 percent organic content.

100 Percent Organic

For labeling and market information purposes, this proposal allows a "100 percent organic" label for an agricultural product that is composed of a single ingredient such as raw, organically produced fruits and vegetables. The product also may be composed of two or more organically produced ingredients, provided that the individual ingredients are organically produced and handled consistent with provisions in subpart C of this regulation. No processing aids may be used in the production of 100 percent organic products. This proposal provides that labeling provisions for "100 percent organic" products be the same as provisions for the 95 percent "organic" products specified below.

Organic

Products labeled or represented as "organic" will contain, by weight (excluding water and salt), at least 95 percent organically produced raw or processed agricultural product. The organic ingredients must be produced using production and handling practices pursuant to subpart C of this regulation. The nonorganic (5 percent or less) ingredients may be composed of nonorganic or nonagricultural substances. The difference between 100 percent organic products and 95 percent-plus products is that the latter may contain up to 5 percent nonorganic or nonagricultural products.

Multiingredient Product: 50–95 Percent Organic Ingredients

For labeling and market information purposes, the third category of agricultural products are multiingredient products containing by weight or fluid volume (excluding water

and salt) between 50 and 95 percent organic agricultural ingredients produced pursuant to these regulations. Such products may be labeled or represented as "made with organic (specified ingredients)." By "specified," we mean the name of the agricultural product forming the organic ingredient. The organic ingredients must be produced using substances on the approved National List in subpart G and employing organic production and handling practices consistent with subpart C of this regulation. For instance, breakfast cereal made with 75 percent organically produced and processed wheat and 25 percent other, nonorganically produced grains, raisins, and nuts can be labeled as "made with organic wheat" on the principal display panel. To qualify for this organic labeling, the nonorganic ingredients (grains, raisins, and nuts) must be produced and handled without use of the first three prohibited practices specified in paragraph (e) (excluded methods, sewage sludge, or ionizing radiation). However, those nonorganic ingredients may be produced or handled using practices prohibited in paragraphs (e)(4) through (e)(7) (using substances not on the National List; containing added sulfites, nitrates, or nitrites; using nonorganic ingredients when organic ingredients are available; and using

organic and nonorganic forms of the same ingredient).

Multiingredient Product: Less Than 50 Percent Organic Ingredients

The final labeling category covers multiingredient products with less than 50 percent organic ingredients (by weight or fluid volume, excluding water and salt). The organic ingredients must be produced using substances on the approved National List in subpart G and employing organic production and handling practices consistent with subpart C of this part. The remaining nonorganic ingredients (50 percent or more of the product) may be produced, handled, and assembled without regard to these regulations (using prohibited substances and prohibited production and handling practices). Organic labeling of these products is limited to the information panel only as provided in § 205.305.

Prohibited Practices. This proposal prohibits labeling of whole products or ingredients as "organic" if those products or ingredients are produced using any of the following production or handling practices: (1) Ingredients or processing aids containing or created using excluded methods (genetically modified organisms (GMO)) or the products of excluded methods; (2) ingredients that have been produced using applications of sewage sludge

(biosolids) as fertilizer; (3) ingredients that have been processed with ionizing radiation; (4) processing aids not approved on the National List; (5) sulfites, nitrates, or nitrites added to or used in processing of an organic product in addition to those substances occurring naturally in a commodity; (6) use of the phrase, "organic when available," or similar statement on labels or in market information when referring to products composed of nonorganic ingredients used in place of specified organic ingredients; and (7) labeling as "organic" any product containing both organic and nonorganic forms of an ingredient specified as "organic" on the label. The prohibitions on the use of excluded methods, sewage sludge, irradiated products, and prohibited processing aids are included here to be consistent with the revised National List of Approved and Prohibited Substances in subpart G.

These seven prohibitions apply to the four labeling categories of products and are not individually repeated as prohibited practices in the following sections. Table 1, Prohibited Production and Handling Practices for Organic Labeling, is a summary reference of how the seven prohibited practices must be applied in the production and handling of organic and nonorganic ingredients of products in the four labeling categories.

TABLE 1.—PROHIBITED PRODUCTION AND HANDLING PRACTICES FOR LABELING CATEGORIES

Labeling category	Use excluded methods	Use sewage sludge	Use irradiation	Use processing aids not on national list	Contain added sulfites, nitrates, nitrites	Use organic ingredients when available	Use both organic & nonorganic forms of same ingredient
"100 percent Organic" Single/multiingredients completely organic	NO	NO	NO	Use NO Processing Aids.	NO	NO	NO.
"Organic" Organic Ingredients (95% or more)	NO	NO	NO	NO	NO	NO	NO.
Nonorganic Ingredients (5% or less)	NO	NO	NO	NO	NO	NO	NO.
"Made with Organic (specified ingredients)" Organic Ingredients (50–95%)	NO	NO	NO	NO	NO	NO	NO.
Nonorganic Ingredients (49% or less)	NO	NO	NO	OK	OK	NA*	NA*.
Less-than 50% Organic Ingredients Organic Ingredients (49% or less)	NO	NO	NO	NO	NO	NO	NO.
Nonorganic Ingredients (50% or more)	OK	OK	OK	OK	OK	NA*	NA*

* Not applicable.

Calculating the Percentage of Organic Ingredients. This proposal specifies procedures for calculating the percentage, by weight or fluid volume, of organically produced ingredients in an agricultural product labeled or represented as "organic."

The organic percentage of liquid products and liquid ingredients will be determined based on the fluid volume of the product and ingredients (excluding water and salt). When a product is identified on the principal display panel or the information panel as being reconstituted with water from

a concentrate, the organic content will be calculated on the basis of a single-strength concentration.

Some products may contain both dry and liquid ingredients that are produced organically. In such cases, this proposal provides that the percentage of total organic ingredients will be based on the

combined weight of the dry organic ingredient(s) and the weight of the liquid organic ingredient(s), excluding water and salt. For example, a product may be made using organically produced vegetable oils or grain oils or contain organic liquid flavoring extracts in addition to other organic and nonorganic ingredients. In these cases, the weight of the liquid organic oils or flavoring extracts, less any added water and salt, would be added to other solid organic ingredients in the product, and their combined weight would be the basis for calculating the percentage of organic ingredients. We believe this process provides the most appropriate and least burdensome method for calculating the organic percentage of such multiingredient products.

Only one figure providing the total percentage of all organic ingredients will be shown on the information panel. The total percentage will be displayed on the information panel of the consumer package above or below the ingredient statement with the words, "contains X percent organic ingredients," or a similar phrase. If the total percentage is a fraction, it will be rounded down to the nearest whole number. The percentage of each organic ingredient will not be required to be displayed.

Labeling "100 Percent Organic" and "Organic" Products. This proposal includes optional, required, and prohibited practices for labeling packages of agricultural products that are "100 percent organic" or "organic" (at least 95 percent organic). Only products that are composed of a wholly organic single ingredient or entirely of certified organic ingredients may be identified with a percentage number (100 percent) on the principal display panel. Products between 95 and 100 percent organic composition, when identified as "organic" on the principal display panel, will be required to state on the information panel the percentage of organic ingredients in the finished product and identify each organic ingredient in the ingredient statement.

The handler may display the following information on the principal display panel, the information panel, and any other part of the package and in market information representing the product: (1) The term, "100 percent organic" or "organic," as applicable, to the content of the product; (2) the USDA Seal; and (3) the seal, logo, or other identifying mark of the certifying agent (hereafter referred to as "seal or logo") which certified the handler of the finished product. The seals or logos of other certifying agents which certified organic raw materials or organic

ingredients used in the product also may be displayed, at the discretion of the handler. If multiple organic ingredients are identified on the ingredient statement, the handler of the finished product that combined the various organic ingredients must maintain documentation, pursuant to subpart B of this regulation, certifying the organic content of the added ingredients.

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

This proposal specifies three labeling practices that will be required if a handler labels a product "100 percent organic" or "organic" on the principal display panel. If a product is labeled as "100 percent organic" the ingredients may also be modified with the term, "organic," but would not have to be so labeled because it is assumed from the 100 percent label that all ingredients are organic. For 95 percent-plus products that contain more than one ingredient, each organic ingredient listed in the ingredient statement must be modified with the term, "organic." Water and salt in the ingredient will not be identified as "organic." Secondly, the total percentage of organic ingredients in the product must be shown on the information panel. The percentage statement should be placed in a manner that it can be viewed in relation to the ingredient statement.

The handler also must display on the information panel the name of the certifying agent which certified the handler producing the finished product. The handler has the option to include the business address or telephone number of the certifying agent. This information must be placed below or otherwise near the manufacturer or distributor's name.

Labeling Products "Made with Organic (Specified Ingredients)". With regard to agricultural products "made with organic (specified ingredients)"—those products containing between 50 and 95 percent organic ingredients—this proposal establishes the following optional, required, and prohibited labeling practices.

Under optional practices, the statement, "made with organic (specified ingredients)," may be placed on the principal display panel and other panels of the package. The same statement can also be used in market

information representing the product. However, the following restrictions will be placed on the statement, "made with organic (specified ingredients)," when it appears on the principal display panel: (1) The statement cannot list more than three organic ingredients in the product; (2) the statement cannot appear in print that is larger than one half (50 percent) of the size of the largest print or type appearing on the principal display panel; and (3) the statement must appear in its entirety in the same type size, style, and color without highlighting. Display of the statement, "made with organic (specified ingredients)," on other panels must be similarly consistent with the size of print used on those panels. These restrictions are consistent with FDA regulations and similar to the recommendations of the National Organic Standards Board (NOSB). This provision will help assure that the statement, "made with organic (specified ingredients)," is not displayed in such a manner as to misrepresent the actual organic composition of the product.

We also propose that, at the handler's option, the certifying agent's seal or logo may be displayed on the principal display panel or other package panel.

Packages of products labeled as "made with organic (specified ingredients)" will be required to display on the information panel the total percentage of organic ingredients in the product and modify each organic ingredient listed in the ingredient statement with the term, "organic." The percentage of organic ingredients must be displayed so that it can be viewed in relation to the ingredient statement.

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

Labeling Products with Less Than 50 Percent Organic Ingredients. The final labeling category covers packaged multiingredient agricultural product containing less than 50 percent organic ingredients.

Handlers of "less than 50 percent" multiingredient products, who choose to declare the organic nature of the

product, may do so only on the information panel by declaring the total percentage of organic ingredients in the product and, in the ingredient statement, modifying the organic ingredients with the term, "organic." The percentage statement must be displayed so that it can be viewed in relation to the ingredient statement.

Products composed of less than 50 percent organic content cannot display the USDA Seal or any certifying agent's seal or logo anywhere on the product package or in market information.

Handlers of such products will be subject to this regulation in the following ways. Those handlers who only purchase organic and nonorganic

ingredients and assemble a finished product of less than 50 percent organic content do not have to be certified as organic handlers. They will be responsible for appropriate handling and storage of the organic ingredients prior to product assembly and for maintaining records verifying the organic certification of the ingredients used in the product. To the extent that the packaging process includes affixing the label to finished product package, those handlers will be responsible for meeting the labeling requirements of this subpart. Handlers who produce an organic ingredient prior to assembly into a finished product, even though the finished product contains less than 50

percent organic content, and must be certified as to the source of the organic ingredient(s). The nonorganic ingredients may be produced, handled, and assembled without regard to the requirements of this part.

The handler who affixes the label to the product package will be responsible for calculating the percentage of organic ingredients in an organic product. As part of the certifying agent's annual certification of the handler, the certifier will verify the calculation and labeling of packages.

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

TABLE 2.—LABELING CONSUMER PRODUCT PACKAGES

Labeling category	Principal display panel	Information panel	Ingredient statement	Other package panels
"100 percent Organic" (Entirely organic; whole, raw or processed product).	"100 percent organic" USDA Seal and Certifying agent sets(s).	"100% Organic" Certifying agent name (required); business address, tele. # (optional).	If multiingredient product, identify each ingredient as "organic".	"100 percent Organic". USDA Seal and Certifying agent seal(s).
"Organic" (95% or more organic ingredients).	"Organic" USDA Seal and Certifying agent seals(s).	"X% Organic Ingredients". Certifying agent name (required); business address, tele. # (optional).	Identify organic ingredients as "organic".	"Organic". USDA Seal and Certifying agent seal(s).
"Made with Organic (specified ingredients)" (50 to 95% organic ingredients).	"Made with organic (specified ingredients)". Certifying agent seal of final product handler.	"X% Organic Ingredients". Certifying agent name (required); business address, tele. # (optional).	Identify organic ingredients as "organic". Identify organic ingredients as "organic".	"Made with organic (specified ingredients)". "Made with organic (specified ingredients)".
Less-than 50% Organic Ingredients (49% or less organic ingredients).	<i>Prohibited: USDA Seal ..</i> <i>Prohibited: Any reference to organic content of product.</i> <i>Prohibited: USDA Seal & Certifying agent seal.</i>	<i>Prohibited: USDA Seal ..</i> <i>"X% Organic Ingredients".</i> <i>Prohibited: USDA Seal & Certifying agent seal.</i>	Identify organic ingredients as "organic".	<i>Prohibited: USDA Seal.</i> <i>Prohibited: Any reference to organic content of product.</i> <i>Prohibited: USDA Seal & Certifying agent seal.</i>

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

After consideration of alternative labeling terms that handlers might wish to use to qualify or modify the term,

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

different from other "organic" products that are not so

Moreover, "pure," "healthy," and other similar terms are regulated by FSIS and FDA. These terms may be used only in accordance with the labeling requirements of FDA and FSIS. For example, the regulations implemented by FSIS, 9 CFR 317.363, define the terms, "healthy," "health," and similar derivations and the conditions of use as a nutritional claim. Also, according to FSIS regulations, 9 CFR 317.8(b)(34), the term, "pure," as well as the terms, "all," "100 percent," and similar terms, may only be used to indicate that a single ingredient product is composed of 100 percent of the product ingredient and contains no other ingredients. The term, "healthy," is regulated by FDA (21 CFR

101.14) and can be used, with documentation, only to indicate or characterize a relationship of the product to a disease or health-related condition. The prohibition on use of these terms to modify "organic" does not otherwise preclude their use in other labeling claims.

We also intend to monitor the use of the term, "organic," in corporate or company names and seek additional guidance from the FTC. We do not believe that the term, "organic," in a brand name context inherently implies an organic production or handling claim or inherently constitutes a false or misleading statement.

The determination as to whether the use of the term, "organic," in a brand name conveys a message about the product's attributes must be made by the Secretary. We will monitor use of the term, "organic," in product and company names at this time. However, if we find that the term is being used in a false or misleading way to misrepresent the organic nature of the product, we have the authority under section 6519(b) of the Act to take action against such use. Such determinations and actions will be taken on a case-by-case basis.

Labeling of Products Shipped in International Markets. Domestically produced organic products intended for export may be labeled to meet the requirements of the country of destination or any labeling requirements specified by a particular foreign buyer. For instance, a product label may require a statement that the product has been certified to, or meets, certain European Union organic standards. Such factual statements regarding the organic nature of the product will be permitted. However, those packages must be exported and cannot be sold in the United States with such a statement on the label because the statement indicates certification to standards other than are required under this program. As a safeguard for this requirement, we require that shipping containers and bills of lading for such exported products display the statement, "for export only," in bold letters. Handlers also will be expected to maintain records, such as bills of lading and U.S. Customs Service documentation, showing export of the products. Only products which have been certified and labeled consistent with the requirements of the National Organic Program (NOP) may be shipped to international markets without marking the shipping containers "for export only."

Organic product produced under a foreign country's or international

association's organic standards deemed equivalent to these standards and certified by a certifying agent accredited by the Secretary may be imported into the United States provided that the product labels are consistent with the requirements of this subpart. Any labeling on the product package or in market representation cannot imply that the product is also certified to other organic standards or requirements that are more restrictive than this national program. These provisions are consistent with international standards and will facilitate international trade of organically produced products and, thus, benefit the global organic industry.

Labeling Nonretail Containers. Section 205.306 provides for labeling nonretail containers used to ship or store raw or processed organic agricultural products that are labeled "100 percent organic," "organic," and "made with organic (specified ingredients)." These labeling provisions are not intended for shipping or storage containers that also will be used in displays at the point of retail sale. They would be used for easy identification of the product to help prevent commingling with nonorganic product or handling of the product which would destroy the organic nature of the product (fumigation, etc.). Retail containers will have to meet labeling provisions specified in § 205.307.

Containers used only for shipping and storage of any product labeled as containing 50 percent or more organic content may, at the handler's discretion, display the following information: (1) The name and contact information of the certifying agent which certified the handler of the finished product; (2) the term, "organic," modifying the product name; (3) any special handling instructions that must be followed to maintain the organic integrity of the product; and (4) the USDA Seal and the appropriate certifying agent seal. This information is optional if handlers believe display of the information helps ensure special handling or storage practices which are consistent with organic practices.

Containers used for shipping and storage of organic product must display a production lot number if such a number is used in the processing and handling of the organic product being shipped or stored. The lot number must be included for inventory control and quality assurance purposes. To help assure export of organic product produced and labeled to foreign specifications, the shipping containers and shipping documents (bills of lading) must be marked with the phrase, "for export only," in bold letters. The

handler also must maintain records showing export of the product to a foreign country.

Much of the required information may overlap information that the handler normally affixes to shipping and storage containers or information that is required under other Federal labeling regulations. Provisions in this proposal do not take precedence over food safety or quality control provisions which may be required for specified products or types of products covered by such Federal regulations. There are no restrictions on size or display of the term, "organic product," or the certifying agent seal unless otherwise required by other Federal or State statutes.

Labeling Products at the Point of Retail Sale Section 205.101(b)(2) of subpart B on Applicability provides regulations regarding the certification of retail food establishments under this program. Those operations are subject to labeling and market information requirements concerning products offered to consumers at the point of retail sale. Such labeling and market information must truthfully represent the organic nature and handling of the product.

Section 205.307 applies to organically produced products that are not prepackaged prior to sale and are presented in a manner which allows the consumer to select the quantity of the product purchased.

To be labeled as "100 percent organic" or "organic" at the point of retail sale, the processing and assembly of such products must be carried out by a certified manufacturing facility for distribution to a retail food establishment. For instance, a tossed salad may be labeled as "100 percent organic tossed salad" or "organic tossed salad" (consistent with the percentage of organic ingredients in the salad) provided the salad and ingredients have been produced and assembled under organic certification. If the multiingredient product is identified as "organic" at the point of retail sale, any ingredient statement displayed at retail sale must identify the organic ingredients as "organic." The retail materials may also display the USDA Seal and the seal or logo of the certifying agent. If shown, the certifying agent seal must not be larger than the USDA Seal.

Using the same example, a product made with 95 percent or more certified organic salad components but which is assembled at an uncertified operation may be labeled "tossed salad made with organic (specified ingredients)." The retail food establishment may not

display the USDA Seal or the seal or seals of certifying agents involved in ingredient certifications because the final assembly of the product was not certified pursuant to the handling requirements of this regulation.

Our position on the applicability of these regulations to different business entities is more completely explained in subpart B, Applicability, of this regulation.

“Section 205.308 addresses processed products “made with organic (specified ingredients)” that are not prepackaged prior to sale and are presented in a manner which allows the consumer to select the quantity of the product purchased. These products will include, but will not be limited to, multiingredient products containing between 50 and 95 percent organic ingredients. Retail displays, display containers, and market information for such products may display the phrase, “made with organic (specified ingredients)” provided that the product has been assembled by a manufacturing facility certified pursuant to this regulation. Up to three organic ingredients may be identified in the statement. If such statement is declared in market information at the point of retail sale, the ingredient statement must identify the organic ingredients as “organic.” Retail display and market information of such bulk products cannot use the USDA Seal but may display the seal or logo of the certifying agent which certified the finished product, provided that assembly of the product was carried out at a certified manufacturing facility. The certifying agent’s seal or logo may be displayed at the option of the retail food establishment. If such a product has not been assembled at a certified manufacturing facility, the retail display and market information may not identify the product as “made with organic (specified ingredients).”

Prepared food products containing less than 50 percent organic ingredients at retail sale may not be identified as organic or containing organic ingredients. The USDA Seal and any certifying agent seal or logo may not be displayed.

Labeling Products Produced on Exempt or Excluded Operations. This proposal provides limited organic labeling provisions for organic product produced or handled on exempt and excluded operations. Such operations would include retail food establishments, certain manufacturing facilities, and production and handling operations with annual organic sales of less than \$5,000. They are discussed

more thoroughly in subpart B, Applicability.

Under this proposal, any such operation that is exempt or excluded from certification, or which chooses not to be certified, may not label its products in a way which indicates that the operation has been certified as organic. Primarily, this means that the exempt or excluded operation may not display the USDA Seal or any seal or logo of a certifying agent. Any packaged organic product from an exempt or excluded operation may not use the labeling terms “100 percent organic,” or “organic,” or “made with organic (specified ingredients),” on the principal display panel. Those labeling terms are reserved for products produced by certified operations. The organic representation of exempt or excluded operation products may only be made on the information panel where the organic percentage can be displayed and the organic ingredients identified as “organic.”

Retail displays and market representation of such products may not indicate that the product has been certified as organic. For instance, a whole, raw, organic product marketed directly to consumers at a farmers market or roadside stand as “organic apples” or “organic tomatoes.” However, no terms may be used which indicate “certified” organic apples, etc. No organic seal or logo may be displayed with the product at the point of retail sale.

We propose these restrictions simply as truth in labeling provisions because use of terms or phrases reserved for certified operations and products and display a certification seal will indicate that the product has been certified. We believe this requirement will help differentiate between certified and not certified products and help maintain the integrity of certified products while providing limited organic labeling opportunities for exempt and excluded operations.

Finally, this rule proposes that exempt organic producers cannot sell their product to a handler for use as an ingredient or for processing into an ingredient that will be labeled as “organic” on the information panel. However, this restriction is raised for public comment in subpart B, Applicability, of this part.

Small producers or handlers who qualify for exemption but who choose to be certified pursuant to these regulations can label their product as certified organic and can sell that product to certified handlers for further processing as an organic ingredient.

USDA Seal. This proposal introduces a new, redesigned, USDA Seal, that can be placed on consumer packages, displayed at retail food establishments, and used in market information to show that products have been produced and handled in accordance with these regulations. The Seal can only be used to identify raw and processed products that are labeled as “100 percent organic” or “organic.” It cannot be used for products labeled as “made with organic (specified ingredients)” (50 to 95 percent organic ingredients) or on multiingredient products with less than 50 percent organic ingredients.

The USDA Seal presented in this proposal will consist of the phrase, “USDA Certified Organic,” on a shield or badge design. When used, the seal must be the same form and design as shown in figure 1 of § 205.310 of this proposal. The seal must be printed legibly and conspicuously. On consumer packages, retail displays, and labeling and market information, the Seal may be printed on a white, light colored, or transparent background with contrasting dark colored words and shield outline or on a dark colored background with contrasting words and shield outline in one or two light colors. The Seal also may be printed in the colors red, white, and blue as follows: a white background, with dark blue shield outline, and red words. The choice of color scheme is left to the discretion of the producer, handler, or retail food establishment based on other colors on the product package and other considerations.

Labeling—Changes Based On Comments

This subpart differs from our first proposal in several respects as follows:

(1) *Use of terms other than “organic.”* The first proposal stated that informational statements which imply “organic” production and handling should be used only on products that are produced and handled in accordance with these regulations. The proposal identified several informational statements commonly referred to as “eco-label” or “green” terms and phrases such as: “produced without synthetic fertilizers,” “pesticide free farm,” “no drugs or growth hormones used,” “raised without antibiotics,” “ecologically produced,” “sustainably harvested,” etc. We asked for comments on these and other terms or phrases which directly or indirectly imply that a product was organically produced and handled.

Commenters favored use of “eco-label” and “green” terms and phrases on any product labels. The general consensus expressed in the comments is

that producers and handlers should be able to make claims about their product provided the claims are truthful.

While commenters did not oppose the use of eco-label terms or phrases on nonorganic products, they made it clear that the term, "organic," should only be used on products produced and handled in accordance with these regulations. Several commented that consumers respond favorably to the term, "organic," when used on a product label, and, therefore, proper use of the term must be closely protected.

We also received several comments regarding use of the terms, "biological" and "ecological," on product labels. A few comments indicated that the terms should be allowed on nonorganic products to truthfully describe an alternative agricultural system under which the product was produced or processed. However, most commenters opposed use of the terms as substitutes for the term "organic" on product labels.

We agree with the majority of comments received on this subject, and we, therefore, propose to regulate the term, "organic," and no other terms. We propose that the term, "organic," may only be used on labeling and market information of products that are produced and handled in accordance with these regulations. We understand that the terms, "ecological" and "biological," are a special case in that they are used synonymously with the term, "organic," in other countries. However, they cannot be used interchangeably with the term, "organic," in this country. These terms may be used as eco-labels at this time. However, we will proceed to restrict use of these or any other terms if we find that they are used on product packages in the United States to represent "organic" when the products are not produced to the requirements of this regulation.

(2) *100 percent organic category.* Our first proposal did not provide for a "100 percent organic" category because that level of organic composition is not specifically provided for in the Act. While the Act and the first proposal provide for a labeling category of 95 percent or higher organic content, commenters appealed for a labeling category for product that is 100 percent organic. Many suggested that being able to use the term, "100 percent," will give handlers added incentive to use only certified ingredients in multiingredient products. Some commenters suggested that if a product is composed only of organic ingredients, with no additives or other substances, it should be allowed

to be labeled and represented in market information as 100 percent.

We agree that a "100 percent organic" labeling category may increase the effectiveness of marketing efforts and may provide incentives for handlers to use more certified organic ingredients in their multiingredient products. Therefore, this proposal will allow the term, "100 percent organic," to be used on labels affixed to or market information representing raw or processed organic products that are composed entirely of organically produced agricultural product.

(3) *Identification of private certifying agents.* Under the first proposal, identification of private certifying agents was not permitted on the principal display panel with the USDA Seal and the State organic seal. While a few commenters suggested that only the USDA Seal should be displayed on the principal display panel, the majority of those commenting on this topic requested that private certifying agent seals be displayed on an equal basis with a seal of the appropriate State's organic program. Although the number of State certifying agents is relatively small, private certifying agents believe that State organic programs and State certifying agents may implement measures in States that work against the interests of private certifying agents. The Department believes those concerns to be unfounded. Under the NOP, the Secretary will approve all State organic programs and accredit all State certifying agents. However, any of those programs or agents that might discriminate or work against the interests of private certifying agents in the State would not be approved by the Secretary.

Some commenters suggested that many private certifying agent seals are widely recognized and respected and their seals influence consumer choices in product purchases. It is appropriate that private certifying agents be afforded the same treatment with regard to labeling as the State certifying agent. We agree with commenters' requests for equal treatment of certifying agents and that certifier seals may have marketing potential in some areas. Therefore, we specify in this proposal that a private certifying agent's seal or logo can be displayed to the same extent as the seal of a State certifying agent. This change is reflected throughout this subpart.

(4) *Use of a certifying agent's seal or logo.* Many commenters believe that the certifying agent's seal, logo, or identifying mark shown on "100 percent organic" and "organic" products should be the seal or mark of the certifying agent that certifies the handler of

finished product. Commenters also stated that labels should not be used to misrepresent one product as being more organic than another product, which might happen if multiple seals are displayed on one product package and only two are displayed on a competing product package. While we understand the commenters' points, we believe that display of certifying agent seals on products labeled "100 percent organic," "organic," and "made with organic (specified ingredients)" should remain optional for handlers. If two or more certifying agents are involved in certifying raw organic agricultural product and organic ingredients used in a finished product, the seals or marks of those certifying agents may be displayed, at the discretion of the handler. There should be only two restrictions to using multiple certifying agent seals: (1) The seal of the certifier of the handling operation producing the finished product should be displayed; and (2) only the seals of those certifying agents actually involved with certification of the product or ingredients may be displayed. For instance, a private certifying agent may certify a product assembled using organic ingredients produced in Texas and certified by the Texas State certifying agent. The product package may, at the handler's option, display the Texas State agent's seal in addition to the seal of the private certifying agent which certified the operation creating other organic ingredients and creating the finished product. Likewise, display of a seal of a foreign country's organic program or foreign certifying agent will be permitted only if the foreign agent certified the finished product or a product ingredient.

Some commenters say that display of two State agent seals may confuse consumers. However, we do not believe it is likely that handlers will choose to display multiple certifying agent seals to misrepresent a product. We also do not believe that possible consumer confusion from display of multiple seals should take precedence over the handler's right to provide product information. If multiple certifying agent seals or marks are displayed on a product package or in market information, the handler or retail food establishment must maintain appropriate records showing proof of all organic certifications.

(5) *Display of certifying agent name and business address.* Commenters also suggested that the certifying agent's name and business address be displayed adjacent to identification of the handler or distributor of products labeled "organic" and "made with organic

(specified ingredients).” The commenters stated that such information should be available for consumers who may have questions about the organic nature of a product or product ingredients. We agree that the name of the certifying agent should be included on a product package but believe that display of the business address or telephone number should be optional to the handler who assembles the finished product and affixes the label on the package. If a consumer wants to inquire about the organic nature of a purchased product, the consumer can obtain contact information through the certifying agent database listed on the NOP homepage. Finally, to clearly identify the information provided, the statement, “Certified organic by * * *” or “Ingredients certified as organically produced by * * *,” may be used to distinguish the certifying agent from the manufacturer or distributor of the product.

The statement and agent identification is intended for information purposes only and is not to promote the organic nature of the product. The certifying agent identification may be placed below the manufacturer or distributor information and must not interfere with display of that information.

(6) *Size of certifying agent seal.* There was a general consensus among commenters that the seals of State and private certification agents should not be larger than the USDA Seal. To emphasize the market value of such a national organic seal and maintain some consistency of treatment with regard to the different organic content categories, we propose that State and private certifying agent seals can be the same size as but must not exceed the size of the USDA Seal on any package label or in market information. The size of the USDA Seal on a package is left to the discretion of the handler.

(7) *Displaying the percentage of organic ingredients.* The first proposal permitted use of the word, “organic,” in the ingredient statements to modify those ingredients that were produced and handled pursuant to these regulations, but did not require the percentage of organic ingredients to be displayed on the label. Most all commenters responding to this labeling issue stated that identification of organic ingredients as “organic” will encourage handlers to increase the organic composition of multiingredient products. However, some commenters did not favor any use of the word, “organic,” on packages of multiingredient products containing

less than 50 percent organic ingredients. Some commenters also suggested that including the total percentage of organic content adjacent to the ingredient statement (in which the organic ingredients are identified) would give relevance to the ingredient statement. We concur with commenters’ recommendations about the display of the total percentage of organic content and propose that the percentage of organic ingredients be placed on the information panel. The percentage statement and the ingredient statement should be shown in a way that indicates the relationship of the information. If a product is labeled “100 percent organic,” all ingredients (except water and salt), by definition, would have to be certified organic ingredients, and each ingredient may be but would not have to be identified as “organic.” Identification of organic ingredients would be required for products labeled “organic” and “made with organic (specified ingredients),” and for products containing less than 50 percent organic ingredients. We did not change the identification of organic ingredients for products containing less than 50 percent organic ingredients because we believe the uses of the term on the information panel and ingredient statement of such product packages do not imply that the product is organic.

(8) *Labeling of products containing 50–95 percent organic ingredients.* The first proposal specified that products with 50–95 percent organic content could use “made with certain organic ingredients” on the label. Many commenters suggested that the word, “certain,” may appear confusing to consumers and that a stronger statement is needed to identify the organic nature of the product. One commenter sought clarification of whether the term, “certain,” is a substitute for the name of the ingredient in a single-ingredient product. Many requested that the statement be changed to allow specific identification of the organic ingredients on the principal display panel. Because that is the panel first and most often observed by consumers, the commenters indicated that the information presented on the principal display panel should be clear and accurate to assist consumers in making their purchasing decisions.

After review of the comments, we believe that, if the statement is going to be displayed on the principal display panel, it should state the specified organic ingredient in the product; e.g., “made with organic (specified ingredients).” Replacing the word, “certain,” with the actual organic commodity name or organic ingredient will add the specificity sought by

commenters and assist consumers in making more informed choices. Under this proposal, the statement, “made with organic (specified ingredients),” must be used on the principal display panel and on other package panels of a product containing between 50 and 95 percent organic ingredients.

Several commenters suggested that the size of the letters in the phrase be limited to a fraction of the size of the product name as it appears on the principal display panel. They stated that limiting the size of the letters will keep the statement from making the product appear more organic than products with 95 percent organic ingredients. For instance, if a product contains 55 percent organic ingredients and the statement, “made with organic (specified ingredients),” is displayed on the principal display panel in large, bold letters, the product may appear more organic than a 97-percent product simply labeled “organic.” Commenters recommended letter sizes from one-half to three-fourths the size of the product name as it appears on the principal display panel.

We also believe that the labeling for these products should not use typeface or letter sizes which would mislead consumers. FDA labeling requirements in 21 CFR 101.3(d) specify that required statement of identity of the product shall be in a size most reasonably related to the largest printed matter on a panel. FDA enforces “reasonably related” as being one half the size of the largest printed matter, which is usually the product name. Therefore, to be consistent with FDA labeling requirements, we have established the print size of the statement, “made with organic (specified ingredients),” to be not more than 50 percent, or one half, of the largest print size appearing on the principal display panel. This print size is consistent with the recommendation of many commenters but is smaller than the 75 percent recommended by the NOSB. We propose that the statement, “made with organic (specified ingredients),” appear in only one print style and color, without highlighting.

We believe that these additional restrictions on display of the statement will enable the message to be delivered and yet provide some structure and consistency to display of the statement. It is our intention that the statement not be used to disproportionately dominate the principal display panel or other panels and not be used to misrepresent the organic nature of the product.

(9) *Limiting the number of organic ingredients listed.* Some commenters suggested limiting the number of organic ingredients that could be

included in the statement “made with organic ingredients.” This topic was the subject of much NOSB deliberation and public discussion. Commenters reasoned that if the list of organic ingredients became too long, the product could appear to be more organic than “95 percent” products. For instance, a product could have 10 organic ingredients, but those 10 ingredients may comprise only 51 percent of the product. The consensus of comments suggested that the statement should be limited to three organic ingredients, which is the industry standard. We believe their recommendation has merit and, therefore, propose that up to three organic ingredients can be shown in the statement. We encourage additional comments on the maximum number of ingredients that should be allowed to appear in the statement on the principal display panel. Commenters should provide reasons for the number they recommend.

(10) *Qualifications for display of the USDA Seal.* In the first proposal, we permitted the display of the USDA seal on products with 50 percent or more organic ingredients. Commenters objected. They overwhelmingly endorsed a high organic content standard for a product to be labeled as “organic.” They believe products containing less than 95 percent organic ingredients do not have sufficient organic content to justify an “organic” label on the principal display panel, and should not be so labeled under the NOP regulations. Commenters also stated that display of the USDA Seal will be very desirable. Many stated that a prohibition on display of the USDA Seal on 50-to-95-percent products would encourage handlers who assemble multiingredient products to use more organically produced ingredients and fewer nonorganic ingredients. They suggested that the USDA Seal and the certifying agent’s seal or logo not be displayed on any package panel of products “made with organic (specified ingredients)” or on products with less than 50 percent organic ingredients.

We agree that some distinction should be made between 95 percent-plus organic products and the 50–95 percent organic products. Handlers of 95 percent-plus organic products may display both the USDA Seal and the certifying agent seal or logo on the principal display panel of the product. The commenters propose that handlers of 50–95 percent organic products not be allowed to display either seal on the principal display panel. However, we believe that, because handlers of 50–95 percent organic product are required to

be certified under this program, it is appropriate that they should be allowed to display some evidence of that certification. We propose, therefore, that handlers of 50–95 percent organic product may display the seal or logo of the certifying agent which certified the finished product. Display of the USDA Seal will still be restricted to only 100 percent organic products and to 95 percent-plus products. We believe this provision will provide more equitable treatment for handlers of 50–95 percent products who are required under this regulation to obtain and maintain organic certification in order to label their organic product. It will also maintain a distinction between the two product levels by continuing the restriction on display of the USDA Seal. We believe that, while display of the USDA Seal is less likely to be an incentive for handlers of products at the lower end of the 50 to 95 percent range of organic content, handlers of products at the higher end of the 50 to 95 percent organic content range may be encouraged to increase the organic content in order to display the USDA Seal.

An organic product produced or handled by an exempt or excluded operation, including those with less than \$5,000 annual organic sales, may not display the USDA Seal or the seal of a certified agent because the operation has not been certified. Even if the organic content of the product is 95 percent or higher, the product still cannot be labeled as “certified” organic or marketed using an organic seal or logo.

(11) *Design of the USDA Seal.* The final change prompted by comments is redesign of the USDA Seal. The Seal in the first proposal was a triangular shape behind a circle of recycling arrows around a globe figure with the word, “organic,” printed diagonally across the globe. That proposed seal was opposed by hundreds of commenters. Comments included: The triangle resembles a radioactive warning symbol or fallout shelter sign; the diagonal line across the circle appears to be the universal “no” sign (such as “no walking,” “no smoking”); the globe design doesn’t show up; the globe design implies an international program; the design is too busy; simplify the design; use the words, “certified organic”; use a text logo; the seal will be too costly to produce; and the triangle points will puncture or tear plastic when printed.

Given the overwhelming negative response to the first seal, we propose a simplified design composed of the words, “USDA CERTIFIED ORGANIC,” inside a shield or badge design. This

design is consistent with comments requesting simplicity and use of the words, “certified organic.” At the request of commenters, this proposal provides for labeling on transparent material. We believe the proposed basic dark on light or light on dark requirement is broad enough to allow handlers the flexibility needed to match color schemes compatible with their product packages. The alternative red, white, and blue color scheme offers handlers what consumers may identify as a more official or patriotic display of the Seal. We believe it is important that the Seal be displayed in a consistent manner, within general light/dark guidelines so that the Seal becomes easily recognizable to consumers.

Labeling—Changes Requested But Not Made

Comments reflecting different opinions on the same topic are covered above (e.g., the number of organic ingredients listed on the principal display panel, the size of “organic” letters on the principal display panel, a recommended redesign of the USDA Seal, etc.). Obviously, not all such conflicting recommendations can be accepted. Two comments were received which are not accepted but which we believe warrant further consideration by the public and the organic community. We request additional comments regarding the following two recommendations. Commenters should specify their recommendation regarding each topic and provide reasons for their recommendation.

(1) *Changing the “organic” threshold for multiingredient products.* At least one commenter suggested that the 50–95 percent labeling category sets too low a threshold for organic labeling of multiingredient products. The commenter suggested that, for increased international acceptance of USDA standards, the lowest acceptable percentage for receiving an organic label should be 70 percent organic ingredients, based on the European Union (EU) standard which now requires a minimum of 70 percent organic ingredients for the product to be labeled as “organic” (or, “biological” or “ecological”).

The EU standard allows products with a 70 percent organic content to be labeled as “organic,” where our proposal will require at least 95 percent organic content before a product could be labeled as “organic.” This 95 percent standard is in the Act. Where the two standards differ is that the EU standard does not have a “made with organic (specified ingredients)” category proposed in this rule.

While the Act establishes a 50-percent minimum ingredient content, that percentage can be adjusted upward if doing so would further the purposes of the Act. To do so, however, the Secretary must have good cause and justification for establishing a higher minimum organic ingredient content. In other words, we could raise the minimum organic ingredient content threshold to 70 percent, redefining two of our four categories. The four categories would be: less than 70 percent, 70–95 percent, greater than 95 percent, and 100 percent. Under this scenario, the prohibitions on excluded methods, irradiation, and sewage sludge would not apply to the nonorganic ingredients of products with less than 70 percent organic content. At the same time, these products would only be able to list the organic ingredients on the information panel. The “made with organic ingredients” category, to which the prohibition would apply, would be 70–95 percent organic content. The only products that would get the “organic” designation would still be those with at least 95 percent organic content.

Because we find no compelling reason to raise the 50-percent minimum ingredient content threshold established in the Act, we have not accepted the commentor’s recommendation in this proposal. However, if comments on this proposal suggest an appropriate justification, the minimum ingredient content threshold could be raised in the final rule.

(2) *Minimum content requirements for organic ingredients.* One commenter suggested that a minimum percentage of the entire product weight be established to qualify for a single ingredient to be included in the statement, “made with organic (specified ingredients).” The commenter suggested that this would help prevent misrepresentation of the organic nature of a product. The commenter suggested that the minimum content for any ingredient should be 15 percent. The commenter did not justify the 15-percent minimum (as opposed to another minimum percentage). Because such a recommendation could prevent important ingredients from being specified on a product label, we have not incorporated the comment in this proposal. However, we believe the comment may have merit. One factor in establishing a minimum percentage for any individual ingredient listed on the principal display panel would be the established minimum percentage for all organic ingredients in a product, the question raised in the paragraph above. For instance, if the minimum percentage of all ingredients is established at 70 percent to conform to EU standards,

should there be a minimum percentage for any individual organic ingredient that could be listed on the principal display panel as one of three organic ingredients in the product? Would such a labeling restriction prevent identification of an important organic ingredient from being displayed on the principal display panel?

Commenters on questions (1) and (2) should state whether they think the recommendations would further the marketing of organic products and, if so, clearly state the recommended percentage for each question and the reasons for their opinions regarding each issue.

(3) *Labeling requirements for small operations.* A majority of those who commented on the exemption for small operations (less than \$5,000 organic sales) in the first proposal stated that such operations are not exempt from labeling requirements under the Act. In this proposal, we provide limited labeling provisions which prohibit exempt and excluded operations, including those with less than \$5,000 in annual organic sales, from labeling their products in a way that indicates the operations or the products have been certified as organic. These provisions will not allow such operations to use labeling terms and organic seals and logos specified for certified operations. We believe those terms, logos and seals should be reserved for operations and products that are certified under these regulations.

Labeling—Additional Provisions

Upon further review of the label and market information provisions in the first proposal, we propose the following additions and changes.

(1) *Display of a State organic seal.* Under the first proposal, each State organic certification program would have been allowed to display a seal or logo of its State organic program. The first preamble stated that it was appropriate for a State to have a seal representing its organic program, thus allowing product produced under that program to bear the State’s seal.

Currently, 13 State departments of agriculture (or other State agency) and approximately 40 private agents certify to a variety of private and State organic requirements. After establishing a policy which more clearly defines the criteria for approval of a State organic program, we believe that, in the interest of consistent and uniform national standards, product packages should not display the seal of a State organic program if the seal is different from the seal or mark used by the State’s organic certifying agent.

This determination is based on a proposed change in State programs. A State organic program will be approved by the Secretary for specific, need-based reasons particular to that State (see State Programs under subpart G). To establish and maintain uniform national standards, States will not be authorized to implement more restrictive organic standards simply to promote State products that are “more organic” than products produced and handled in other States or under NOP requirements. Rather, the Secretary will approve only those State programs that need more restrictive requirements to protect or preserve unique environmental conditions or to accommodate product and handling practices unique to a State or portion of a State. In the absence of such environmental conditions or production practice needs, a State’s organic program must have the same requirements as this NOP. If this is the case and if a relatively few State programs are approved to have more restrictive requirements, then no real purpose is served by permitting State organic programs to display a separate and distinct seal on a product label. Such a seal would not represent a “more organic” product.

In the place of a State organic program seal, this proposal provides for the seal or logo of a State certifying agent to be displayed on packages, if that certifying agent certifies the organic operation producing the product. Selection of a State or private certifying agent is the choice of the organic producer or handler being certified. A State’s department of agriculture (or other equivalent State agency) may establish one or more State certifying agent offices as part of its governmental operations, or the State may license a private certifying agent to certify organic operations on behalf of the State. In either case, the certifying agent would certify these national requirements and not the particular requirements of a State organic program unless those requirements were approved by the Secretary. Therefore, the only organic seal or mark representing a State will be the seal or mark of a State’s certifying agent or licensed certifying agent. Any certifying agent licensed by the State must be accredited by the Secretary pursuant to subpart F of this proposal.

(2) *Labeling for international markets.* We have added two paragraphs under section 205.300 to provide for labeling of products intended for international markets. Domestically produced organic products intended for export may be labeled to meet the requirements of the country of destination or any labeling

requirements specified by a particular foreign buyer.

If labeled to meet foreign labeling requirements, such packaged products cannot be sold in the United States. Pursuant to § 205.306, shipping containers and bills of lading for these products would have to be marked “for export only” to assure that the product was not distributed domestically. We are providing this exception to labeling requirements for the convenience of exporters only. If the foreign country or buyer does not require different product labeling, domestic product which has been produced, certified, and labeled pursuant to these regulations may be shipped without the statement, “for export only,” on the containers and bills of lading.

Organic product produced in another country for export to the United States may be certified to the requirements of this regulation or to an approved foreign organic certification program that has been recognized as equivalent to the requirements of the NOP. Such products must be labeled pursuant to the requirements of this subpart.

(3) *Product composition.* Under new § 205.301, Product Composition, we have clarified the composition of organic and nonorganic ingredients in products covered in the four labeling categories. All ingredients labeled as “organic” in the ingredient statement of the product package must be produced and handled pursuant to these requirements. No substances prohibited on the National List in subpart G and no production or handling practices prohibited in § 205.301(e) may be used in the production or handling of any ingredient labeled as “organic.” Regulations covering the production and handling of nonorganic ingredients varies with the labeling category. The higher the percentage of a product’s organic composition, the more restrictive the production and handling requirements of the nonorganic ingredients in the product. These requirements are found under § 205.301 and explained above under Proposal Description.

(4) *Prohibited practices.* Section 205.301(e) lists seven production and handling practices that are prohibited from being used to produce whole products or product ingredients that would be labeled as “organic” under the NOP. Some of these prohibited practices appear for the first time in this proposal, and others were specified in the first proposal and were supported by all those who addressed them in their comments.

The first proposal prohibited organic labeling of a product or ingredient

produced using water that does not meet requirements of the Safe Drinking Water Act (42 U.S.C. 300(f) *et seq.*). We have not included that provision in this proposal because potable water is required in other FDA and FSIS processing regulations and does not need to be repeated as a requirement in this regulation.

The first three practices (use of excluded methods, sewage sludge, and irradiation) are discussed elsewhere in this proposal and are added as prohibited practices in this labeling section for consistency purposes.

Only processing aids and substances on the National List in subpart G of this regulation may be used in the production and handling of 95 percent-plus organic products and 50–95 percent organic products and in any ingredient labeled as organic on a product package.

The first proposal prohibited use of sulfites, nitrates, and nitrites in production or processing of organic products or ingredients. We have amended the wording of this provision to clarify that a handler cannot add any sulfites, nitrates, and nitrites to a product and still label the finished product or ingredient as “organic.” We make this clarification because these substances are found naturally in many products and may appear naturally in potable water used in processing.

The last two processing practices that would prohibit an “organic” label appeared in separate sections of the first proposal and are included in this proposal in § 205.301(e)(6) and (e)(7). The first is that products and organic ingredients assembled using organic or nonorganic forms of the same ingredient or component ingredients—depending on availability of the organic ingredients—cannot be labeled as “organic when available” or a similar phrase. Similarly, products and organic ingredients assembled using both organic and nonorganic forms of the same ingredient or component ingredients cannot be labeled as organic if that ingredient is identified as organic on the ingredient statement and included in the percentage of organic content on the information panel.

(5) *Calculating organic content.* Because labeling requirements are based on the amount of organic ingredients in a product, we have added new section 205.302, which addresses the calculation of organic percentages. Provisions in this new section were not included in the first proposal. While this should be a simple mathematical procedure, the section proposes certain guidelines for calculating and labeling organic percentages.

Only one percentage figure for total organic ingredients will be shown on a package. The percentage of individual organic ingredients will not be displayed.

An organic product may be constituted completely of organic liquid products. Therefore, this proposal adds the phrase, “or fluid volume,” in several places in the proposal when referring to liquid products and ingredients. For ingredients in liquid form that are reconstituted with water from a concentrate, the calculation would be based on a single-strength solution of the liquid concentrate. For products that may contain both dry and liquid organic ingredients, the percentage calculation would be based on the combined weight of the organic ingredients, including the weight of the liquid ingredients, minus water and salt.

(6) *Labeling of nonretail containers.* We have added new § 205.306, covering labeling of nonretail containers—those used only for shipping and storage of agricultural products labeled as organic or containing organic ingredients. While the same containers are commonly used for both shipping and storage, the first proposal did not reference storage containers or specify labeling requirements for those containers. These provisions are proposed only for products labeled as “100 percent organic,” “organic,” and “made with organic (specified ingredients).” Some may believe that use of the USDA Seal on a shipping container of products “made with organic (specified ingredients)” may be inconsistent with other labeling provisions prohibiting display of the Seal on consumer packages of those products. However, in the case of shipping and storage containers, the display of seals is not intended for marketing purposes but would be used for easy identification of the product to help prevent commingling with nonorganic product or handling of the product which would destroy the organic nature of the product (fumigation, etc.). These provisions will not apply to shipping and storage containers of products containing less than 50 percent organic ingredients.

(7) *Retail Food Establishments.* The extent of the regulatory authority of this regulation has been the subject of intense discussions in comments received, NOSB deliberations, and AMS discussions. Commenters claimed that it makes no sense to regulate and certify the production and handling of organic product but not require certification and regulate retail food establishments where some fresh foods containing organic ingredients are processed and

assembled and where they can become adulterated or misrepresented to the consuming public.

Retail food establishments that market organic product, whether produced in-store, in a corporate commissary, or by others, will be subject to the labeling provisions of this subpart as that labeling applies to: (1) Point-of-purchase, in-store displays describing the organic nature of the product; and (2) other market information and media advertising regarding the product being marketed at the retail food establishment. Food retail establishments must describe the product in in-store retail displays, market information, and media advertising that is consistent with the organic content of the finished product. Any labeling of a product that is inconsistent with the percentage of organic content of the product will be considered a violation of truth in labeling and/or truth in advertising regulations of FDA and the FTC. Multiingredient products which are described as organic product in retail displays and market information must be assembled by a certified manufacturing facility, pursuant to the Applicability subpart of this regulation.

Packaged organic products, organic fresh produce, and organic bulk bin food items must be described in point-of-purchase displays, pricing information, and consumer information in terms consistent with the organic content of the product. For instance, an in-store retail display would describe an 87 percent organic product by specifying the percentage of organic content of the product and identifying the organic ingredients in the ingredient statement, as may be required by FDA. The market information for such a product must not, for instance, label the product as "organic" or "100 percent organic." This would be a violation of truth in labeling and advertising regulations of FDA and FTC. The USDA Seal and the seal of the certifying agent may be displayed at retail sales and in market information on products certified as containing 95 percent or more organic content. Multiingredient products containing 50–95 percent organic ingredients may display the seal or logo of the certifying agent of the organic handling operation.

We believe these labeling practices will help assure appropriate representation of bulk organic products at retail sale and will encourage handlers to use more organic ingredients.

Products containing less than 50 percent organic ingredients at the point of retail sale may not be identified in

any way as "organic" or containing organic ingredients. In addition, the USDA Seal and seal, logo, or other identifying mark of the certifying agent is prohibited from being used in retail displays and market information.

(8) *Change in calculating the \$5,000 exemption.* We are proposing a change in calculating the \$5,000 exemption for producers and handlers. The \$5,000 annual exemption will be calculated on sales of organically produced product and not on all agricultural products marketed by the exempt producer or handler, as provided in the first proposal. This exemption means that qualifying exempt organic producers and handlers may annually sell up to \$5,000 of organically produced products and not be certified as an organic operation under this regulation. The exemption could apply to a large, conventional agricultural operation that also has a small amount of acreage designated for organic production—the products of which, for example, is sold at a roadside stand. Any sale of other, nonorganic products will not count against the \$5,000 sales total. The labeling and market information requirements for organic products produced by such exempt operations are specified in § 205.309 of this regulation.

Subpart E—Certification

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

Proposal Description

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

As discussed in Subpart B, certified operations must maintain records concerning the production and handling of agricultural products that are sold, labeled, or represented as "100 percent organic," "organic," or "made with organic (specified ingredients)" sufficient to demonstrate compliance with the Act and regulations. Records

applicable to the organic operation must be maintained for not less than 5 years beyond their creation. Authorized representatives of the Secretary, the applicable State program's governing State official, and the certifying agent must be allowed access to the operation's records during normal business hours. Access to the operation's records will be for the purpose of reviewing and copying the records to determine compliance with the Act and regulations.

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

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

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

The certifying agent will decide whether to accept the applicant's application for certification. Certifying agents may decline to accept an application for certification but may not decline to accept an application on the basis of race, color, national origin, gender, religion, age, disability, political beliefs, sexual orientation, or marital or family status.

Upon acceptance of an application for certification, a certifying agent will review the application to ensure completeness and to determine whether the applicant appears to comply or may be able to comply with the applicable production or handling regulations. As part of its review, the certifying agent will verify that an applicant has submitted documentation to support the correction of any deficiencies identified in a previously received notification of noncompliance. The certifying agent

will also review any available U.S. Department of Agriculture (USDA) data on production and handling operations for information concerning the applicant.

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

After a complete review of the application, the certifying agent will communicate its findings to the applicant. If the review of the application reveals that the applicant may be in compliance with the applicable production or handling regulations, the certifying agent will schedule an on-site inspection of the applicant's operation to determine whether the applicant qualifies for certification. The initial on-site inspection must be conducted within a reasonable time following a determination that the applicant appears to comply or may be able to comply with the requirements for certification.

The certifying agent will conduct an initial on-site inspection of each production unit, facility, and site included in the applicant's operation. As a benchmark, certifying agents should follow auditing guidelines prescribed by the International Organization for Standardization Guide 10011-1, "Guidelines for auditing quality systems—Part 1: Auditing" (ISO Guide 10011-1).¹ The certifying agent will use the on-site inspection in determining whether to approve the request for certification and to verify the operation's compliance or capability to comply with the Act and regulations.

Certifying agents will conduct on-site inspections when the applicant or an authorized representative of the applicant who is knowledgeable about the operation is present. An on-site inspection must also be conducted when land, facilities, and activities that demonstrate the operation's compliance with or capability to comply with the applicable production or handling regulations can be observed.

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

The inspector will conduct an exit interview with an authorized representative of the inspected operation to confirm the accuracy and completeness of inspection observations and information gathered during the on-site inspection. The main purpose of this exit interview is to present the inspection observations to those in charge of the firm in such a manner so as to ensure they clearly understand the results of the inspection. The firm is not required to volunteer any information during the exit interview but would be required to respond to questions or requests for additional information. The inspector will raise and discuss during the exit interview any known issues of concern, taking into account their perceived significance. As a general rule, the inspector will not make recommendations for improvements to the operation during the exit interview. However, the certifying agent will have the discretion to decide the extent to which an inspector may discuss any compliance issue.

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

Upon determining the applicant's compliance and ability to comply, the

agent will approve certification and issue a "certificate of organic operation." The approval may include restrictions regarding minor deficiencies that would not prevent certification as a condition of continued certification. A certificate of organic operation will specify the name and address of the certified operation; the effective date of certification; the categories of organic operation, including crops, wild crops, livestock, or processed products produced by the certified operation; and the name, address, and telephone number of the certifying agent. Once certified, a production or handling operation's organic certification continues in effect until surrendered by the organic operation or suspended or revoked by the certifying agent, the State program's governing State official, or the Administrator.

Denial of Certification. Should the certifying agent determine that the applicant is not able to comply or is not in compliance with the act, the certifying agent will issue a written notification of noncompliance to the applicant. Applicants who receive a notification of noncompliance may correct the deficiencies and submit, by the date specified, a description of correction and supporting documentation to the certifying agent. As an alternative, the applicant may submit a new application to another certifying agent, along with the notification of noncompliance and a description of correction of the deficiencies and supporting documentation. Applicants may also submit, by the date specified, written information to the certifying agent to rebut the noncompliance described in the notification of noncompliance. When a noncompliance cannot be corrected, a notification of noncompliance and a "notification of denial of certification" may be combined in one notification.

The certifying agent will evaluate the applicant's corrective actions taken and supporting documentation submitted or the written rebuttal. If necessary, the certifying agent will conduct a followup on-site inspection of the applicant's operation. When the corrective action or rebuttal is sufficient for the applicant to qualify for certification, the certifying agent will approve certification. When the corrective action or rebuttal is not sufficient for the applicant to qualify for certification, the certifying agent will issue the applicant a written notice of denial of certification. The certifying agent will also issue a written notice of denial of certification when an applicant fails to respond to the notification of noncompliance. The

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

notice of denial of certification will state the reasons for denial and the applicant's right to reapply for certification, request mediation, or file an appeal.

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

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

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

Following receipt of the certified operation's updated information, the certifying agent will arrange and conduct an on-site inspection of the certified operation. As a benchmark, certifying agents should follow auditing guidelines prescribed by ISO Guide 10011-1. Upon completion of the inspection and a review of updated information, the certifying agent will determine whether the operation

continues to comply with the Act and regulations. If the certifying agent determines that the operation is in compliance, certification will continue. If any of the information specified on the certificate of organic operation has changed, the certifying agent will issue an updated certificate of organic operation. If the certifying agent finds that the operation is not complying with the Act and regulations, a written notification of noncompliance will be issued as described in § 205.662.

In addition to annual inspections, a certifying agent may conduct additional on-site inspections of certified operations to determine compliance with the Act and regulations. The Administrator or State program's governing State official may also require that additional inspections be performed by the certifying agent to determine compliance with the Act and regulations. Additional inspections may be announced or unannounced and would be conducted, as necessary, to obtain information needed to determine compliance with identified requirements.

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

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

agent's file on the certified operation to the operation's new certifying agent.

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

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

Certification—Changes Based on Comments

This subpart differs from our first proposal in several respects as follows:

(1) *On-site Inspection Requirements.* We have amended the general requirements provision concerning on-site inspections. The first proposal required production and handling operations to permit an annual on-site

inspection by the certifying agent. A few commenters suggested that the term, "inspection," be made plural and that the section citations be amended to include the section on additional inspections. The section on additional inspections addressed the certifying agent's authority to perform on-site inspections in addition to the annual on-site inspection.

The commenters believe that "inspection" should apply to all situations when on-site inspections must be or could be performed, including the initial site inspection for a new certification as well as, for instance, compliance inspections. Commenters believe that these changes are needed to assure access to the certified operation and that an applicant's agreement to permit any and all necessary on-site inspections should be clearly stated as a general requirement for certification.

We had intended for the general requirements provision concerning on-site inspections to include all instances in which an on-site inspection might be appropriate. Accordingly, we have amended the requirement by replacing the phrase, "an annual on-site inspection," with the phrase, "on-site inspections." This terminology would cover initial, annual, and additional inspections needed for certification, continuation of certification, and to determine whether the operation is in compliance with program requirements. To ensure complete access to the production or handling operation for the purpose of conducting on-site inspections and determining compliance with the requirements of the National Organic Program (NOP), we have added a requirement that the operation permit complete access to the production or handling operation, including noncertified areas and structures. The general requirements provision on on-site inspections is found at § 205.400(c).

(2) *Providing Access to Records.* We have clarified the meaning of providing access to the records that the certified operation must maintain by adding "during normal business hours for review and copying" to the regulation. The first proposal required that certified organic operations maintain records for not less than 5 years from the date of their creation. It also required the certified operation to 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 regulations.

Several comments were received regarding these recordkeeping

requirements. Most of these comments were received from organic producer organizations and certifying agents. A few commenters questioned the necessity of maintaining records for 5 years, requested a different period for different records, and requested clarification on the meaning of providing access. Section 6511(d) of the Act requires organic production or handling operations to maintain records for 5 years. Accordingly, we have made no change to the retention period in this proposal. The clarification on the meaning of providing access to records is found at § 205.400(d).

(3) *Notification of Drift.* We have amended the requirement that production and handling operations immediately notify the certifying agent concerning any application of a prohibited substance by adding the phrase, "including drift." A few commenters suggested adding a requirement that the certified operation notify the certifying agent when an organically certified field is contaminated by drift. They stated that drift is the most common reason for prohibiting the organic label on otherwise organically produced product.

We agree that the certified operation should immediately report any drift of a prohibited substance onto an organic field to its certifying agent. Accordingly, § 205.400(f)(1) provides that an applicant seeking to receive or maintain organic certification must immediately notify the certifying agent concerning any application, including drift, of a prohibited substance. This provision applies to new applicants as well as to ongoing certified operations. Contamination by drift could occur during the time period between application for and approval of certification. Accordingly, an applicant for certification would be required to notify the certifying agent of any contact with a prohibited substance.

(4) *Applicant Requirements.* We have added the requirement that applicants for certification include other information necessary to determine compliance with the Act and regulations. Commenters suggested that we add a provision to the application regulations requiring applicants for certification to submit other information deemed necessary by the certifying agent. They stated that this authority is needed to assure that applicants are fully cooperative and responsive throughout the certification process.

We believe the requested authority would be helpful to certifying agents. However, we believe the authority for

certifying agents to request other information they deem necessary must be qualified by the requirement that the information be necessary to determine compliance with the Act and regulations. Accordingly, we have provided certifying agents with the authority to request other information necessary to determine compliance with the Act and regulations. This addition is found at § 205.401(d).

(5) *Requirement for Notification of Noncompliance.* We have replaced the first proposal's section on "preliminary evaluation of an applicant for certification" with a new section on "review of application." We have revised the section to clarify that certifying agents will issue notices of noncompliance only after the initial on-site inspection of an applicant's operations. We also allow applicants to voluntarily withdraw their application for certification at any time.

This change was in response to comments on the first proposal's requirement that applicants for certification report, to the certifying agent with whom they have applied, the receipt of a notice of noncompliance received from another certifying agent. A State organic growers association stated that this requirement places a stigma on applicants who, for example, applied for certification before the operation was ready to meet all requirements for certification. This commenter suggested that notification of previous denial only be required after an applicant has been denied certification. The commenter went on to say that, if the language in the original proposal is maintained, there should be a time limit of within the past 3 or 5 years of denial. Another commenter suggested that certifying agents have the option of recommending that noncompliant applicants withdraw their applications rather than be denied certification. As an alternative, one of the commenters suggested that denial of certification to an unprepared applicant should not have to be reported on a subsequent application to another certifying agent unless the first noncompliance notice led to a denial of certification.

We continue to believe that it is in the best interest of the program and consumers to require applicants to report the receipt of notices of noncompliance and denial of certification to any certifying agent to whom they make application. However, we also believe that operations should not be unnecessarily stigmatized because they applied for certification before the operation was ready to meet all requirements for certification.

Accordingly, this proposal requires that an applicant report the receipt of a notice of noncompliance or denial of certification to any certifying agent to whom application is made but allows applicants to voluntarily withdraw their application at any time.

An applicant that voluntarily withdrew its application prior to the issuance of a notice of noncompliance would not be issued a notice of noncompliance. Similarly, an applicant that voluntarily withdrew its application prior to the issuance of a notice of certification denial would not be issued a notice of certification denial.

(6) *Residue Testing.* We have revised the verification of information provisions to provide that the on-site inspection of an operation must verify that prohibited substances have not been and are not being applied to the operation. Verification would be through means which, at the discretion of the certifying agent, may include the collection and testing of soil; water; waste; seeds; plant tissue; and plant, animal, and processed products samples.

Comments from certifying agents suggested adding a provision that would allow a certifying agent to collect samples of substances from the operation for residue testing. They stated that such testing is necessary to detect unreported use or accumulation of prohibited substances. Section 6506(a)(6) of the Act requires periodic residue testing by certifying agents of products produced by certified organic operations. It is our intent that collection of samples for residue testing may be conducted as part of initial on-site inspections, as well as during on-site inspections of certified organic operations. The inspector could collect samples of soil; water; waste; seeds; plant tissues; and plant, animal, and processed products. Collection of such samples would be at the discretion of the certifying agent. To maintain the integrity of the inspection process, it is necessary that the certifying agent or inspector collect such samples first hand, rather than receive the samples from the applicant. We have made the requested addition at § 205.403(c)(3).

(7) *Postinspection Conference Requirements.* We have amended the postinspection conference requirements. We have changed all references to "postinspection conference" to "exit interview." We have removed the requirement that the inspector discuss his or her observations regarding the operation's compliance or ability to comply with the Act and regulations. This requirement has been replaced with the requirement that the inspector

confirm the accuracy and completeness of inspection observations and information gathered during the on-site inspection. The inspector can use the exit interview to request any additional information necessary to establish eligibility for certification. Finally, this amendment requires the inspector to raise and discuss during the exit interview any known issues of concern.

Certifying agents commented that it would be inappropriate for an inspector to discuss observations and possible violations of compliance at an exit interview. They stated that requiring exit interviews places the inspector in the position of providing observations and feedback to the applicant before the inspector is able to confer with the certifying agent. Some certifying agents expressed concern that exit interviews could result in inspectors providing false or misleading information to the applicant. Some commenters requested that exit interviews be held only for the purpose of checking the accuracy and completeness of inspector observations made and the information obtained during the inspection. Other commenters requested that the exit interviews requirement be removed from these regulations.

We believe that qualified inspectors should be capable of competently discussing an applicant's compliance or ability to comply with these regulations. However, we also believe that a certifying agent should have the opportunity to decide whether to allow its inspectors to discuss issues of compliance at an exit interview. Accordingly, we have amended the exit interview requirements as noted above. These amended requirements are found at § 205.403(d).

(8) *Additional Inspections.* We have added a new provision that additional inspections may be announced or unannounced at the discretion of the certifying agent or as required by the Administrator or State program's governing State official. This change was made in response to commenters who requested the addition of a requirement that certifying agents conduct unannounced site visits in addition to the initial and annual inspections. We believe that unannounced on-site inspections are appropriate and valuable in both monitoring and investigating compliance with the Act and regulations. The requested addition is found at § 205.403(a)(2)(iii).

(9) *Requirements for Written Inspection Reports.* We have removed the requirement that the certifying agent require an inspector to prepare and submit to the certifying agent, within 30

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 regulations. A variety of comments, pro and con, were received on this requirement. Certifying agents questioned whether the 30-day timeframe was reasonable. Other commenters suggested that, rather than specifying a time period, the section should stress the need for timely reporting. A commenter suggested that an inspector's observations and assessments on the inspected operation include the inspector's recommendations on approval of certification. Other commenters stated that the requirement amounted to micro management of a certifying agent's business. This latter group of commenters believe that the setting of a time period for inspector reporting involves a policy matter that should be determined by the certifying agent. We agree with the commenters who stated that setting deadlines for the filing of inspection reports is an internal policy matter better left to certifying agents.

We believe that policies and procedures regarding inspector reporting are the purview of the certifying agent. Certifying agents would be expected to develop and implement inspector reporting requirements for on-site inspections internal to their own operations. Such policies and procedures and a certifying agent's performance in making timely certification decisions would be subject to review during accreditation and reaccreditation of the certifying agent. Accordingly, we have removed the provision.

Removal of this requirement does not eliminate the need for a written on-site inspection report or the importance of timely inspection reporting by an inspector to the certifying agent. Certifying agents are expected to make timely decisions regarding whether to certify an applicant and whether a certified operation is in compliance with the Act and regulations. Applicants with complaints regarding timeliness of service could forward their complaints to the Administrator.

(10) *Responsibilities of Certifier in the Application Process.* We have replaced the list of requirements to be reviewed by a certifying agent in determining an applicant's eligibility for certification with a general statement on determination of eligibility. Commenters requested the addition of a provision requiring certifying agents to verify implementation of the organic system plan. We agree that an on-site

inspection of an ongoing operation must include assessment of the operation's application of its organic system plan. Because an on-site inspection of a new applicant's operation would be conducted at a time when the operation can demonstrate its organic capabilities, the operation must be able to show that it is satisfactorily carrying out its organic system plan.

It was our intent that certifying agents would verify implementation of the applicant's organic system plan during the certifying agent's review of the on-site inspection report and application. However, our list of requirements to be reviewed by a certifying agent in determining an applicant's eligibility for certification did not specifically reference verification of implementation of the organic system plan. We have decided to replace the list of requirements to be reviewed with a general statement on determination of eligibility. This statement provides: "If the certifying agent determines that the organic system plan and all procedures and activities of the applicant's operation are in compliance with the requirements of this part and that the applicant is able to conduct operations in accordance with the plan, the agent shall approve certification." We believe this general statement, in combination with the requirement that the certifying agent review the application, the on-site inspection report, the results of any analyses for substances conducted, and any additional information requested from or supplied by the applicant, adequately addresses the commenters' concerns. This revision to the approval of certification requirements is found at § 205.404(a).

(11) *Information Included on the Certificate of Organic Operation.* We have amended the regulations specifying what information must be included on a certificate of organic operation. Comments received from organic operations, certifying agents, and consumers recommended that certifying agents provide additional information on certificates of organic operation. Specifically, they recommended that all certificates include: (1) The certifying agent's name and address; (2) an expiration date; (3) the physical location of certified operations, including separate fields and facilities; (4) the name of the certified operation's contact person responsible for compliance with program requirements; (5) the name and address of the certified operation; and (6) the crops and products certified. The commenters believe such information, especially a date on which the certificate expires, to be vital to assuring

accountability and compliance with the program.

We believe it would be beneficial to persons with concerns regarding a certified production or handling operation to have ready access to information concerning the name, address, and telephone number of the certifying agent. Further, because the certificate of organic operation would be an official document of the certifying agent, it would be appropriate for this information to appear on every certificate. Accordingly, we have added the name, address, and telephone number of the certifying agent to the information which must be included on every certificate. This addition is found at § 205.404(b)(4).

We disagree with the commenters who requested that certificates of organic operation display an expiration date. We believe annual expiration of a certificate would place an unnecessary burden on certifying agents and certified operations. Annual expiration of certificates is also inconsistent with the fact that an operation's certification does not expire. In fact, once an operation is certified as an organic operation, its certification remains in effect until surrendered by the certified operation or suspended or revoked by the certifying agent, the State program's governing State official, or the Administrator. All certified operations are required to annually update their organic system plan. If the updated plan causes information on the certificate to be incorrect, the certifying agent will issue a new certificate with the correct information. This provides a mechanism for ensuring that certificates are updated as necessary on an annual bases. We have not included the recommended addition in this proposal.

For clarification, we have added § 205.404(c). This section provides that once certified a production or handling operation's organic certification continues in effect until surrendered by the organic operation or suspended or revoked by the certifying agent, the State program's governing State official, or the Administrator.

We disagree with the commenters who requested that certificates display the physical location of certified operations, including separate fields and facilities, and the name of the certified operation's contact person responsible for compliance with program requirements. We believe that the location of a certified operation's fields and facilities has no relationship to the operation's status as a certified organic operation. Therefore, such information should only be made available with the written consent of the

certified operation. The name of the certified operation's contact person would be releasable information. We believe, however, that such detail is unnecessarily burdensome to the certifying agent and will only serve to clutter the certificate. By requiring the name, address, and telephone number of the certifying agent, as noted above, the certificate would provide interested persons with a contact for obtaining releasable information concerning the certified operation. Further, the certifying agent is the first line of compliance under this program and, as such, is the person to whom all questions and concerns should be addressed about certified operations.

We agree with the commenters who requested that certificates display the name and address of the certified operation because such information is potentially beneficial to consumers. Accordingly, we have added the name and address of the certified operation to the information which must be included on every certificate. This addition is found at § 205.404(b)(1).

The first proposal required that the certificate list the category(ies) and type(s) of products produced by the certified operation. Commenters were apparently confused about the meaning of category(ies) and type(s) of products. We have, therefore, revised the requirement to provide that a certificate of organic operation would specify the categories of organic operation, including, crops, wild crops, livestock, or processed products produced by the certified operation. This revision is found at § 205.404(b)(3).

(12) *Certifiers Authority to Deny Certification.* We have added authority for certifying agents to deny certification to applicants who do not meet the requirements for certification. The first proposal required certifying agents to forward their recommendations for denial of certification to the Administrator. Commenters stated that authority for denial of certification should rest with the certifying agents. They also contended that referral to the Administrator for denial of certification establishes a bureaucratic process, which would create unnecessary delays to the denial process and increased cost to applicants. Many commenters suggested the appeals process is sufficient to protect the interests of the Secretary.

We have determined that it is reasonable to authorize certifying agents to deny certification. Denial by the certifying agent would provide the applicant with a more timely decision on its eligibility for certification. A more timely decision would provide an

earlier opportunity for applicants to appeal a denial of certification. Authority for certifying agents to deny certification to applicants who do not meet the requirements for certification is found at section 205.405.

This proposal requires certifying agents to evaluate the applicant's corrective actions taken and supporting documentation or written rebuttal submitted in response to a notification of noncompliance. Certifying agents are authorized to perform on-site inspections to verify corrections to deficiencies or statements contained in a rebuttal, if necessary, to assure full compliance with the certification requirements. The certifying agent will issue the applicant a written notice of denial of certification if the corrective action or rebuttal is not sufficient for the applicant to qualify for certification.

We believe the denial of certification provisions should clearly state an applicant's options and rights upon receiving a notice of denial of certification. Accordingly, § 205.405(c)(1)(ii) provides that a notice of denial of certification must state the reasons for denial and the applicant's right to reapply for certification, request mediation, or file an appeal. An applicant who has received a written notice of denial of certification may apply for certification again at any time with any certifying agent, may request mediation to resolve a dispute with the certifying agent, or may file an appeal with the Administrator as outlined in § 205.663 for mediation and § 205.681 for appeals. Applicants subject to an approved State program would seek mediation or appeal in accordance with the rules of the approved State program.

(13) *Willful Misrepresentations or False Statements by Applicants.* We have included authority for certifying agents to deny certification if the agent has reason to believe that the applicant has willfully made a false statement or otherwise purposefully misrepresented its operation or compliance with the certification requirements. Such false statements would, in most cases, be verified during an on-site inspection. This authority was provided to certifying agents in the first proposal relative to certified operations. The first proposal, however, did not reference an applicant's willful making of a false statement or otherwise purposefully misrepresenting its operation or compliance with the certification requirements. Certifying agents commented that applicants for certification also may make false statements or misrepresent facts. They suggested that the regulations reflect a certifying agent's authority in such

cases. We agree with the commenters and have added § 205.405(f). This section authorizes denial of certification without first issuing a notification of noncompliance when the certifying agent has reason to believe that the applicant has willfully made a false statement or otherwise purposefully misrepresented its operation or compliance with the certification requirements.

Certification—Changes Requested But Not Made

This subpart retains from our first proposal regulations on which we received comments as follows:

(1) *Timeliness of Applicant's Notification to Certifiers.* A commenter suggested that "immediately" in the requirement that production and handling operations immediately notify the certifying agent concerning any application of a prohibited substance be replaced with "within 2 days." No justification was given for the recommended change, and the change has not been made. "Immediately notify" means that the applicant or certified operation must at once notify its certifying agent upon learning that a prohibited substance has come in contact with any portion of its operation or production. The certifying agent will evaluate the circumstances surrounding the event and decide whether the certified operation acted within the intent of this requirement. This requirement is found at § 205.400(f)(1).

(2) *Notification of Changes to Certifying Agent.* Commenters questioned how the certified operation would know what changes in its certified operation or any portion of its operation would require reporting to its certifier. Certified operations are responsible for being familiar with the requirements of the Act and these regulations. Further, they have an obligation to contact their certifying agent when they have questions regarding compliance with this program. As a rule, certified operations should contact their certifying agent whenever the change is not covered under their approved organic system plan. The requirement that a certified operation notify its certifying agent concerning any change in its certified operation that may affect its compliance with the Act and regulations is found at § 205.400(f)(2).

(3) *Tests for Soil Fertility and Irrigation Water.* Certifying agents suggested that applicants for certification be required to submit test results for soil fertility and irrigation water quality to prove compliance with the NOP. We recognize that increasing

soil fertility through organic production practices is a goal of the organic industry. However, soil fertility will not qualify or disqualify an applicant for organic certification. An applicant who has independently had such tests conducted may, but is not required to, include them with the application. While the Act requires that handlers only use in their products water that meets all Safe Drinking Water Act requirements, no similar requirements are placed on producers and the water they use to irrigate their crops. For these reasons, we are not requiring applicants for certification to submit soil fertility or irrigation water quality test results.

(4) *Timeliness of On-site Inspection.* The first proposal required a certifying agent to conduct an initial on-site inspection within a reasonable time following a favorable preliminary evaluation of an application for certification. Several commenters asked what constitutes reasonable time between submission of an application and an on-site inspection. Others stated that, when determining what constitutes reasonable time, consideration should be given to factors such as when the application was submitted relative to when activities demonstrating compliance can be observed and when the inspection can be scheduled to assure the presence of the applicant.

We stated in the first proposal that we did not specify a time within which an inspection must be conducted because the time would vary according to when the application was submitted and the type of operation to be inspected. Timely service will be in the best interest of certifying agents since applicants may forward complaints regarding service to the Administrator. Such complaints could have an impact on a certifying agent's reaccreditation or continued accreditation. Further, our original position is consistent with those commenters requesting flexibility in determining what constitutes reasonable time. Accordingly, we have made no changes in this proposal regarding what constitutes reasonable time. This requirement is found at § 205.403(b).

(5) *Additional On-site Inspections.* Some organic associations asked what would trigger a decision to conduct an additional on-site inspection. Commenters expressed the concern that certifying agents could conduct additional, unneeded inspections at the expense of operators who would have to pay the costs of the inspections. Other commenters asked who would pay for the additional on-site inspections. Some certifying agents suggested that guidelines need to be established under

which additional inspections must be conducted. A certifying agent suggested that additional inspections could be conducted based on the inspector's observations, the certifier's recommendation, and, possibly, third-party complaints.

The authority for on-site inspections is necessary for monitoring and compliance purposes at the discretion of the certifying agent, the Administrator, or a State program's governing State official. Such on-site inspections would likely be precipitated by reasons to believe that the certified operation was operating in violation of one or more requirements of the Act or these regulations. The on-site inspection would be conducted, as necessary, to obtain information needed to determine compliance with identified requirements.

We believe policies and procedures regarding additional inspections, including how the costs of such inspections are handled, are the responsibility of each certifying agent. Misuse of such authority would be subject to review by the Department during its evaluation of a certifying agent for reaccreditation and at other times in response to complaints. Certified production and handling operations could file complaints with the Department at any time should they believe a certifying agent abuses its authority to perform additional inspections. Accordingly, we have made no changes in this proposal based on these comments.

(6) *Annual Renewal of Certification.* Commenters requested annual renewal of certification rather than updates to a continuing certification program. Other commenters requested that the notice of certification have an ending date or be issued for an established period of time. An industry association commented that the proposed continuation of certification regulations requires a certified operation to annually certify that it is complying with the Act and these regulations. This commenter stated that the proposed continuation of certification procedures changes the process of recertification to one more closely resembling self-certification. Another industry association stated that certification until surrendered by the certified operation or suspended or revoked would make the assurance of compliance extremely difficult, if not impossible. This commenter further stated that certifying agents will be unable to effectively monitor applicants or gain needed information. This commenter recommended that renewal paperwork include the items specified in the continuation of certification

regulations but that certifying agents use their own discretion as to the forms and information needed. Similarly, a certifying agent commented that certification must be renewed with an application on an annual basis and that no operation can be certified for life. This commenter recommended requiring a yearly application and other documentation deemed necessary by the certifying agent.

We disagree with the commenters. We prefer continuous certification due to the very real possibility that the renewal process might not always be completed before expiration of the certification period. Expiration of the certification period would result in termination of the operation's certification. Even a short period of interruption in an operation's organic status could have severe economic ramifications. Further, we believe that a regular schedule of expiration of certification is unnecessary inasmuch as all certified operations are required to annually update their organic system plan and submit any changes to their certifying agent. Accordingly, this proposal retains the provision for continuous certification.

(7) *Timing of On-site Inspections.* A State certifying agent and an industry organization stated that requiring an on-site inspection after receipt of the renewal application is not consistent with current practice. The State certifying agent stated that it moved the renewal date to January 1 of each year to make the renewal process less burdensome to its certified producers. This commenter went on to say that the annual inspection conducted during the appropriate growing or processing season is used to evaluate the organic operation in the renewal process. The State certifying agent further stated that an additional inspection at renewal time would not be useful if it was not an appropriate time to observe production practices at the organic operation. Both commenters requested elimination of the requirement that the certifying agent arrange and conduct an on-site inspection following receipt of the operation's annual submission of information. These commenters also requested that a determination of noncompliance be based on on-site inspections conducted during the previous certification year and a review of the information annually submitted by the certified operation.

We disagree with the commenters. Certifying agents are required to schedule on-site inspections for a time when land, facilities, and activities that demonstrate the operation's compliance or capability to comply with the

applicable production or handling provisions of the NOP may be observed. Accordingly, the initial certification must have followed an on-site inspection performed when the operation was able to demonstrate its compliance or capability to comply. The certified operation, therefore, should be fulfilling its annual continuation of certification obligations at a time when it can demonstrate its compliance with the Act and regulations. The commenters' recommendations are not accepted.

Certification—Additional Provisions

Upon further review of the certification provisions in the first proposal, we have decided to propose the following additions and changes.

(1) *Requirements for Business Information.* We have revised the business information required of all applicants for certification as an organic operation. First, the application must include the name of the person who completed the application. Certifying agents will use this information when following up on information within the application. Second, we have removed the requirement that the application include the names of personnel responsible for maintaining compliance with the Act and regulations. We believe this information is unnecessary since the person responsible for overseeing compliance is the certifying agent. Third, we have added the requirement that when the applicant is a corporation, the application must include the name, address, and telephone number of the person authorized to act on the applicant's behalf. Fourth, we have removed the requirement that the applicant for certification submit a statement of compliance. We have also removed the "Statement of Compliance" section which required the submission of a statement of compliance with the application for certification. We have removed this requirement because we have determined that it creates an unnecessary burden upon applicants for certification. Section 205.400(a) requires that a person seeking to receive or maintain organic certification must comply with the Act and applicable production and handling regulations. Accordingly, it is unnecessary to require a separate document through which the applicant for certification agrees to comply with the Act and regulations. The requirements for the submission of business information with the request for certification are found at § 205.401(b).

(2) *Disclosure of Previous Applications.* The first proposal

required that the request for certification include the name(s) of any organic certifying agent(s) to which application had previously been made, the year(s) of application, and the outcome of the application(s) submission. We have amended this requirement by adding "including a copy of any notification of noncompliance or denial of certification issued to the applicant for certification and a description of the actions taken by the applicant to correct the deficiencies noted in the notification of noncompliance, including evidence of such correction." We have added this provision to clarify what we mean by "the outcome of the application(s) submitted." This provision is found at § 205.401(c).

(3) *On-site Inspections.* We have combined the arranging for inspection, verification of information, postinspection conference, and additional inspection regulations of the first proposal into a new on-site inspections section, § 205.403. We made this change for the purposes of clarification and the removal of redundancies.

(4) *Additional Inspections.* We have revised the on-site inspections requirements to provide that a State program's governing State official may require a certifying agent to conduct an additional inspection of a production or handling operation to determine the operation's compliance with the Act and these regulations. We have provided State program governing State officials with authority to require additional inspections because such officials will have compliance responsibilities under their State programs and will need such authority to carry out their responsibilities. These requirements are found at § 205.403(a).

(5) *Notifications of Noncompliance.* We have added at § 205.405(b) a provision which identifies for applicants for certification what their options are when they receive a notification of noncompliance. Such applicants may correct the deficiencies and submit a description and supporting documentation of correction to the certifying agent, correct the deficiencies and submit a new application to another certifying agent along with the notification of noncompliance and a description and supporting documentation of correction, or submit written information to the certifying agent to rebut the noncompliance described in the notification of noncompliance.

(6) *Reapplying After a Notice of Noncompliance or Denial of Certification.* We have added a new provision which requires a certifying

agent to treat an application for certification as a new application when such application includes a notification of noncompliance or a notice of denial of certification. While the new application may contain the same organic system plan and other information provided in the unsuccessful application for certification, it must also provide any new information or changes in operations which may have occurred since the filing of the unsuccessful application. The updated information concerning the applicant's operation must include a description of actions taken, with supporting documentation, to correct the deficiencies identified in the notification of noncompliance. This new provision is found at § 205.405(e).

Subpart F—Accreditation of Certifying Agents

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

This National Organic Program (NOP) accreditation process will facilitate national and international acceptance of United States organically produced agricultural commodities. The accreditation requirements in these regulations will replace the organic assessment voluntary, fee-for-service program, established by AMS under the Agricultural Marketing Act of 1946. That assessment program verifies that State and private organic certifying agents comply with the requirements prescribed under the International Organization for Standardization/International Electrotechnical Commission Guide 65, "General Requirements for Bodies Operating Product Certification Systems" (ISO Guide 65).² ISO Guide 65 provides the

² ISO/IEC Guide 65 is available for viewing at USDA-AMS, Transportation and Marketing Programs, Room 2945-South Building, 14th and Independence Ave., SW, Washington, DC, from 9:00

general requirements that a certifying agent would need to meet to be recognized as competent and reliable. That assessment program was originally established to enable organic certifying agents in the absence of a U.S. national organic program to comply with European Union (EU) requirements beginning on June 30, 1999. That assessment program verifies that State and private organic certifying agents are operating third-party certification systems in a consistent and reliable manner, thereby facilitating uninterrupted exports of U.S. organic agricultural commodities to the EU. ISO Guide 65 is used as a benchmark in developing the accreditation program described in this proposed rule. Certifying agents accredited under the NOP that maintain compliance with the Act and these regulations will meet or exceed the requirements of ISO Guide 65; therefore, the organic assessment program is no longer needed.

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

Proposal Description

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

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

a.m. to 4:00 p.m., Monday through Friday (except official Federal holidays). A copy may be obtained from the American National Standards Institute, 11 West 42nd Street, New York, NY 10036; Website: www.ansi.org; E-mail: ansionline@ansi.org; Telephone: 212-642-4900; Facsimile: 212-398-0023.

Certifying agents must also submit personnel, administrative, conflict of interest, current certification, and other documents and information to demonstrate their expertise in organic production or handling techniques, their ability to comply with and implement the organic certification program, and their ability to comply with the requirements for accreditation.

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

The personnel information submitted with the application should demonstrate that the applicant uses a sufficient number of adequately trained personnel to comply with and implement the organic certification program. The certifying agent will also have to provide evidence that its responsibly connected persons, employees, and contractors with inspection, analysis, and decision-making responsibilities have sufficient expertise in organic production or handling techniques to successfully perform the duties assigned. They must also show that these employees have revealed existing or potential conflicts of interest.

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

Certifying agents are prohibited from providing advice concerning organic practices or techniques to any certification applicant or certified

operation for a fee, other than as part of the fees under the certification program. The Administrator will provide oversight of the fees to ensure that the schedule of fees filed with the Administrator is applied uniformly and in a nondiscriminatory manner. The Administrator may inform a certifying agent that its fees appear to be unreasonable and require that the certifying agent justify the fees. The Administrator will investigate the level of fees charged by an accredited certifying agent upon receipt of a valid complaint or under compelling circumstances warranting such an investigation. Certifying agents are prohibited from providing advice concerning organic practices or techniques to any certification applicant or certified operation for a fee, other than as part of the fees under the certification program.

Statement of Agreement. Upon receipt of the certifying agent's application for accreditation, the Administrator will send a statement of agreement to the person responsible for the certifying agent's day-to-day operations for signature. The statement of agreement affirms that, if granted accreditation as a certifying agent under this subpart, the applicant will carry out the provisions of the Act and the regulations in this part. Accreditation will not be approved until this statement is signed and returned to the Administrator.

The statement of agreement will include the applicant's agreement to accept the certification decisions made by another U.S. Department of Agriculture (USDA)-accredited certifying agent as equivalent to its own and the applicant's agreement to refrain from making false or misleading claims about its accreditation status, the USDA accreditation program, or the nature or qualities of products labeled as organically produced. Further, the statement will include the applicant's agreement to pay and submit the fees charged by AMS and to comply with, implement, and carry out any other terms and conditions determined by the Administrator to be necessary. Applicants are also required to affirm through this statement of agreement that they will: (1) Conduct an annual performance appraisal for each inspector used; (2) have an annual program evaluation conducted of their certification activities by their staff, an outside auditor, or a consultant who has expertise to conduct such evaluations; and (3) implement measures to correct any deficiencies in compliance with the Act and regulations identified in an inspector performance appraisal or program evaluation.

A private entity certifying agent must additionally agree to hold the Secretary harmless for any failure on the agent's part to carry out the provisions of the Act and regulations. A private entity certifying agent's statement will also include an agreement to furnish reasonable security for the purpose of protecting the rights of operations certified by such certifying agent. Such security will be in an amount and according to such terms as the Administrator may by regulation prescribe. A private entity certifying agent must agree to transfer all records or copies of records concerning its certification activities to the Administrator if it dissolves or loses its accreditation. A private entity certifying agent must also agree to make such records available to any applicable State program's governing State official.

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

Certifying agents who apply for accreditation and do not meet the requirements for accreditation will be provided, in accordance with § 205.665, with a notification of noncompliance and given an opportunity to come into compliance. After receipt of a notification of noncompliance, the applicant may submit a description of the actions taken to correct the noted deficiencies and evidence demonstrating such corrections or file an appeal with the Administrator. If the applicant is successful in its appeal or provides acceptable evidence demonstrating correction of the deficiencies, the Administrator will notify the applicant of accreditation. If the applicant fails to correct the deficiencies, fails to report the corrections by the date specified in the notification of noncompliance, fails to file an appeal by the date specified in the notification of noncompliance, or is unsuccessful in its appeal, the Administrator will issue a written notification of accreditation denial to the applicant. An applicant who has

received written notification of accreditation denial may apply for accreditation again at any time.

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

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

As noted above, a certifying agent may be accredited prior to a site evaluation. If the Administrator finds, following the site evaluation, that an accredited certifying agent is not in compliance with the Act or regulations, the Administrator will issue the certifying agent a written notification of noncompliance. If the certifying agent fails to correct the deficiencies, report the corrections by the date specified in the notification of noncompliance, or file an appeal by the date specified in the notification of noncompliance, the Administrator will begin proceedings to suspend or revoke the accreditation. A certifying agent that has had its accreditation suspended may apply for accreditation again at any time. A

private-entity certifying agent whose accreditation is revoked will be ineligible for accreditation for a period of not less than 3 years following the date of such determination.

Peer Review Panels. The Administrator may establish a peer review panel to assist in evaluating applicants for accreditation. Peer review panels will be used at the discretion of the Administrator following the site evaluation of a certifying agent, but under no circumstances will the Administrator convene a peer review panel when the peer review pool does not contain sufficient persons qualified to peer review the certifying agent.

To be eligible to serve on a peer review panel, the applicant for membership in the peer review pool must provide the Administrator with a written description and, upon request, supporting documentation of its qualifications to conduct peer reviews. The applicant for membership in the peer review pool must address possible limitations on availability to serve and include information concerning commercial interests with any person who may seek to become or who is an accredited certifying agent. No person who has or has had a commercial interest, including an immediate family interest or the provision of consulting services, in an applicant for accreditation or renewal of accreditation will be appointed to a panel evaluating such applicant for accreditation or renewal of accreditation. Persons accepted to the pool may serve until notified that their appointment has been rescinded by the Administrator or until they are no longer qualified, whichever occurs first. Peer reviewers will serve without compensation.

Peer review panels will consist of at least three but no more than five members. A Department representative will preside over the panel. A peer review panel will include no fewer than two members who possess sufficient expertise in the certifying agent's areas of accreditation. Peer review panels may include up to two members with expertise in other disciplines, including organizational management and finance; member(s) from the approved State organic certification program when the applicant is a private entity that will operate within the State; and member(s) from a foreign government's organic program when the applicant is a private entity that will operate within the country.

Each person on a peer review panel must individually review the site evaluation report prepared by the Department's evaluator(s) and any other information that may be provided by the

Administrator relevant to continuing or renewing the accreditation status of a certifying agent. Information about the certifying agent received as part of the review process is confidential information, and peer reviewers must not release, copy, quote, or otherwise use material from the information received other than in the report required to be submitted. Each peer reviewer must agree to treat the information received for review as confidential.

A peer review panel meeting will be held solely for the purposes of exchanging information. Any meeting or conference call will be conducted in a manner that will ensure the actions of panel members are carried out on an individual basis with any opinions and recommendations by a member being made individually. We do not believe that it is usual to have consensus in peer review or that it is the best use of USDA resources or the time of peer reviewers to seek consensus under a single report. Further, requiring a consensus report may make peer review panels subject to the Federal Advisory Committee Act, which might stifle meaningful dialog between reviewers, increase the cost and time required of peer reviewers for peer review service, and result in problems obtaining volunteers for service on peer review panels.

Peer review panel members will prepare and submit individual reports, including recommendations, to the Administrator regarding a certifying agent's ability to conduct and perform certification activities. The Administrator will consider the reports when determining whether to continue or renew the certifying agent's accreditation. Copies of the peer review panel reports will be provided, upon request, to the certifying agent, and written responses from the certifying agent may be submitted for consideration by the Administrator. Copies of peer review panel reports may be provided to any person requesting such reports under the Freedom of Information Act.

Continuing Accreditation. An accredited certifying agent must submit annually to the Administrator, on or before the anniversary date of the issuance of the notification of accreditation, the following reports and fees: (1) A complete and accurate update of its business information, including its fees, and information evidencing its expertise in organic production or handling and its ability to comply with these regulations; (2) information supporting any changes requested in the areas of accreditation; (3) a description of measures implemented in the

previous year and any measures to be implemented in the coming year to satisfy any terms and conditions specified in the most recent notification of accreditation or notice of renewal of accreditation; (4) the results of the most recent inspector performance appraisals and annual program evaluation and a description of adjustments to the certifying agent's operation and procedures implemented or to be implemented in response to the appraisals and evaluation; and (5) the required AMS fees.

Certifying agents will keep the Administrator informed of their certification activities by: (1) Providing the Administrator with a copy of any notice of denial of certification, notification of noncompliance, notification of noncompliance correction, notification of proposed suspension or revocation, and notification of suspension or revocation issued simultaneously with its issuance; and (2) on a quarterly calendar basis, the name, address, and telephone number of each operation granted certification.

One or more site evaluations will occur during the 5-year period of accreditation to determine whether an accredited certifying agent is complying with the Act and regulations. USDA will establish an accredited certifying agent compliance monitoring program, which will involve no less than one randomly selected site evaluation of each certifying agent during its 5-year period of accreditation. Larger and more diverse operations, operations with clients marketing their products internationally, and operations with a history of problems should expect more frequent site evaluations by USDA. Operations with clients marketing their products internationally will be annually site evaluated to meet the ISO-Guide 61³ requirement for periodic surveillance of accredited certifying agents. USDA may also conduct site evaluations during investigations of alleged or suspected violations of the Act or regulations and in followup to such investigations. Such investigations will generally be the result of complaints filed with the Administrator alleging violations by the certifying agent. Compliance site evaluations may be announced or unannounced at the

discretion of the Administrator. Certifying agents will not be billed by USDA for USDA-initiated site evaluations conducted to determine compliance with the Act and regulations.

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

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

and certified operations include certification certificates, notice of denial of certification, notification of noncompliance, notification of noncompliance correction, notification of proposed suspension or revocation, notification of suspension or revocation, correspondence with applicants and certified operations, on-site inspection reports, documents concerning residue testing, and internal working papers and memoranda concerning applicants and certified operations. Examples of records created or received by the certifying agent pursuant to the accreditation requirements include operations manuals; policies and procedures documents (personnel, administrative); training records; annual performance appraisals and supporting documents; conflict of interest disclosure reports and supporting documents; annual program evaluation working papers, memoranda, letters, and reports; fee schedules; quarterly reports of operations granted certification; application materials submitted to the NOP; correspondence received from and sent to USDA; and annual reports to the Administrator.

The certifying agent must make all records available for inspection and copying during normal business hours by authorized representatives of the Secretary and the applicable State program's governing State official. In the event that the certifying agent dissolves or loses its accreditation, it must transfer to the Administrator and make available to any applicable State program's governing State official all records or copies of records concerning its certification activities.

Certifying agents are also required to prevent conflicts of interest and to require the completion of an annual conflict of interest disclosure report by all personnel designated to be used in the certification operation. Coverage of the conflict of interest provisions extends to immediate family members of the certifying agent; responsibly connected persons of the certifying agent; and any employee, inspector, contractor, or other personnel of the certifying agent. A certifying agent may not certify a production or handling operation if the certifying agent or a responsibly connected party of such certifying agent has or has held a commercial interest in the production or handling operation, including an immediate family interest or the provision of consulting services, within the 12-month period prior to the application for certification. A certifying agent may certify a production or handling operation if any employee, inspector, contractor, or other personnel

³ ISO/IEC Guide 61 is available for viewing at USDA-AMS, Transportation and Marketing Programs, Room 2945—South Building, 14th and Independence Ave., SW, Washington, DC, from 9:00 a.m. to 4:00 p.m., Monday through Friday (except official Federal holidays). A copy may be obtained from the American National Standards Institute, 11 West 42nd Street, New York, NY 10036; Website: www.ansi.org; E-mail: ansionline@ansi.org; Telephone: 212-642-4900; Facsimile: 212-398-0023.

of the certifying agent has or has held a commercial interest, including an immediate family interest or the provision of consulting services, within the 12-month period prior to the application for certification. However, any such person must be excluded from work, discussions, and decisions in all stages of the certification process and the monitoring of the entity in which they have or have held a commercial interest. The acceptance of payment, gifts, or favors of any kind, other than prescribed fees, from any business inspected is prohibited. However, a certifying agent that is a not-for-profit organization with an Internal Revenue Code tax exemption or, in the case of a foreign certifying agent, a comparable recognition of not-for-profit status from its government, may accept voluntary labor from certified operations. Certifying agents are also prohibited from providing advice concerning organic practices or techniques to any certification applicant or certified operation for a fee, other than as part of the fees under the certification program.

No accredited certifying agent may exclude from participation in or deny the benefits of the NOP to any person due to discrimination because of race, color, national origin, gender, religion, age, disability, political beliefs, sexual orientation, or marital or family status.

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

Following receipt of the certifying agent's annual report and fees, the results of a site evaluation, and, when applicable, the reports submitted by a peer review panel, the Administrator will determine whether the certifying agent remains in compliance with the Act and regulations and should have its accreditation renewed. Upon a determination that the certifying agent is in compliance with the Act and regulations, the Administrator will issue a notice of renewal of accreditation. The notice of renewal will specify any terms and conditions that must be addressed

by the certifying agent and the time within which those terms and conditions must be satisfied. Renewal of accreditation will be for 5 years. Upon a determination that the certifying agent is not in compliance with the Act and regulations, the Administrator will initiate proceedings to suspend or revoke the certifying agent's accreditation. Any certifying agent subject to a proceeding to suspend or revoke its accreditation may continue to perform certification activities pending resolution of the proceedings to suspend or revoke the accreditation.

Accreditation—Changes Based on Comments

This subpart differs from our first proposal in several respects as follows:

(1) *Equivalency of Imported Organic Products.* We have removed the regulations on equivalency of imported organic products included in the first proposal. In this proposal, we have added foreign certifying agents as entities eligible for accreditation as certifying agents qualified to certify domestic and foreign organic production and handling operations. We have also added to subpart A definitions for private entity and State entity. We have defined "private entity" as any domestic or foreign nongovernmental for-profit or not-for-profit organization providing certification services. We have defined "State entity" as any domestic or foreign governmental subdivision providing certification services.

In commenting on the first proposal, several commenters expressed confusion as to how the Secretary would determine equivalency of imported organic products. They also expressed confusion as to how the Secretary would ensure that imported products met the same requirements as those produced domestically. We have addressed these concerns by adding foreign certifying agents as private or state entities that may be accredited under the NOP. We have also provided that USDA will accept a foreign certifying agent's accreditation to certify organic production or handling operations if: (1) USDA determines, upon the request of a foreign government, that the standards under which the foreign government authority accredited the foreign certifying agent meet the requirements of this part; or (2) the foreign governmental authority that accredited the certifying agent acted under an equivalency agreement negotiated between the United States Government and the foreign government. These changes ensure that all certifying agents, including foreign

private and state certifying agents, will be required to meet the same requirements to be recognized as qualified to certify organic production or handling operations. This change provides foreign private and state certifying agents with transparent standards for accreditation.

A commenter raised concerns that we acted in violation of international agreements and domestic policy by proposing rules that were contrary to internationally accepted organic standards and, thus, created an unacceptable barrier to trade. The Act directs the Secretary to establish national standards governing the marketing of certain agricultural products as organically produced products. In accordance with our international agreements, this proposal ensures that, with respect to accreditation under this subpart, products imported from the territory of any country are being accorded treatment no less favorable than that accorded to products of U.S. origin. However, in accordance with our international trade agreements and upon implementation of this program, the Administrator will give positive consideration to accepting as equivalent technical regulations of other countries, even if these regulations differ from our own, provided such regulations fulfill the objectives of this proposed program. Any such equivalency agreements will be negotiated on a case-by-case basis, and ample opportunity for public comment will be provided before and during the negotiation process.

Two commenters requested that the Secretary recognize international accreditation systems for foreign organic certification programs and establish the requirements for approval of such systems in this proposal. We have instead proposed for the purposes of this rule that all certifying agents, regardless of their country of origin, meet the same requirements for accreditation through the provisions of this subpart.

One commenter requested that all imported organic products be labeled by their respective country of origin. The purpose of this proposal is to provide the requirements for the marketing of agricultural products in the United States that are labeled or sold as organic. The issue of country-of-origin labeling of imported products is not related to this proposal or the Act. Further, regulations pertaining to the labeling of organic agricultural products should not be used to enforce country-of-origin labeling requirements.

Several commenters stated that the first proposal did not take into account

the use of equivalency to ensure the marketing of U.S. organic products in foreign markets. The Department will work to oppose other countries' organic regulations that would prohibit entry of U.S. organic product produced under the Act or these regulations. As appropriate, the U.S. Government may represent U.S. organic interests in international government-to-government bodies. However, neither of these objectives is intended to be achieved by this rule.

(2) *Accreditation Requirements Regarding Expertise of Employees.* We have added a new regulation to the general requirements for accreditation. This regulation requires that the certifying agent ensure that its responsibly connected persons, employees, and contractors with inspection, analysis, and decision-making responsibilities have sufficient expertise in organic production or handling techniques to sufficiently perform the duties assigned. Certifying agents were required under the first proposal to use a sufficient number of adequately trained personnel, including inspectors. They were also required to conduct an annual performance appraisal of each inspector.

Commenters felt that the proposed rule did not sufficiently ensure that certifying agents would employ qualified individuals. One of these commenters requested that we require organic certification inspectors to participate in an inspector accreditation program, such as that offered by the Independent Organic Inspectors Association. We believe that inspector participation in an inspector accreditation program should be left to the discretion of the inspector and certifying agent. However, we believe that the new requirement combined with the requirements from the first proposal should ensure that responsibly connected persons, employees, and contractors of an accredited certifying agent are qualified to perform their inspection, analysis, and decision-making duties. This new regulation is found at § 205.501(a)(5) of this proposal.

(3) *Recordkeeping Requirements.* We have proposed a new § 205.510(b), which identifies three categories of records and their retention periods. This new paragraph was added to address commenter concern that the requirement that an accredited certifying agent maintain records about all of its activities for 10 years was excessive and unnecessary. Commenters suggested a 5- to 7-year retention period. We agree that for some records, a retention period of 10 years may be excessive. Accordingly, in this proposal,

we are proposing three retention periods. First, records created by the certifying agent regarding applicants for certification and certified operations would have to be maintained for not less than 10 years beyond their creation. We believe this retention period to be consistent with the Act's requirement that the certifying agent maintain all records concerning its activities for a period of not less than 10 years. Second, records obtained from applicants for certification and certified operations would have to be maintained for not less than 5 years beyond their receipt. This retention period is the same as that required by the Act for the retention of records by the certified operation. Since the certified operation can dispose of its records 5 years after their creation, the certifying agent should also be able to dispose of those records it receives from the certified operation 5 years after their receipt. Third, records created or received by the certifying agent for USDA accreditation would have to be maintained for not less than 5 years beyond their creation or receipt.

(4) *Conflict of Interest Provisions.* We have made three changes which we believe will strengthen the conflict of interest provisions. We have made these changes because we concur with the comment from a research foundation stating that the provisions for preventing conflicts of interest needed to be significantly strengthened. First, we have added a new § 205.501(a)(11)(v), which requires the completion of an annual conflict of interest disclosure report by all personnel designated to be used in the certification of an operation, including administrative staff, certification inspectors, members of any certification review and program evaluation committees, contractors, and all parties responsibly connected to the certifying agent. Second, coverage of the conflict of interest provisions has been extended to immediate family members of the certifying agent; responsibly connected persons of the certifying agent; and any employee, inspector, contractor (to be used in the certification of an operation), or other personnel of the certifying agent. Immediate family members would include the spouse; minor children, including legally adopted children; or blood relatives who reside in the immediate household of a certifying agent; responsibly connected person of the certifying agent; or any employee, inspector, contractor, or other personnel of the certifying agent. Third, this proposal lists contractors among those persons who are prohibited from accepting payment,

gifts, or favors of any kind, other than regular fees from any business inspected by the certifying agent. This addition, which is found at § 205.501(a)(11), was made to clarify that contractors, including contract inspectors, are prohibited from accepting payment, gifts, or favors of any kind, other than regular fees.

(5) *Use of Voluntary Labor.* We have added an exception to the prohibition of the acceptance of payment, gifts, or favors of any kind. The exception provides that any certifying agent that is a not-for-profit organization with an Internal Revenue Code tax exemption or, in the case of a foreign certifying agent, a comparable recognition of not-for-profit status from its government may accept voluntary labor from certified operations. Internal Revenue Code tax exemption or, in the case of a foreign certifying agent, a comparable recognition from its government is required as verification of the certifying agent's status as a not-for-profit organization. This change was made to clarify our original intent that not-for-profit certifying agents would be allowed to accept volunteer labor from persons certified by the certifying agent.

In the preamble to the first proposal, we stated that 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. We have made this clarification because a commenter expressed the belief that the certifying agent should be allowed to receive donations of time, food, and money beyond any mandatory fees from persons they certify. The Act prohibits certifying agents from accepting payments, gifts, or favors of any kind from a business inspected, other than prescribed fees. Accordingly, this exception is limited to acceptance of voluntary labor by not-for-profit certifying agents. While § 205.501(a)(11)(iii) prohibits the acceptance of payments, gifts, or favors of any kind, other than prescribed fees, from any business inspected for certification as a producer or handler of organic agricultural products, the paragraph does not prohibit the accredited certifying agent from accepting payments, gifts, or favors of any kind, including time, food, or money, from persons for whom they do not provide inspections for certification as a producer or handler of organic agricultural products.

(6) *Certification Fees.* We have removed the requirement that a certifying agent charge only such fees to applicants for certification and operations it certifies that the Secretary determines are reasonable. We have made this change because we concur with those commenters who expressed the belief that certifying agents should be permitted to set their own fees without the approval of the Secretary. However, we continue to believe that the Administrator should retain oversight of the fees, not for the purpose of setting the fees or of dictating the level of the fees, but for the purpose of determining if any certifying agent's fees are so high as to be unreasonable and to ensure that the schedule of fees filed with the Administrator are applied uniformly and in a nondiscriminatory manner. The Administrator should also retain the ability to inform a certifying agent that its fees appear to be unreasonable and to require a justification for the level of fees set by the certifying agent. We further believe that the Administrator should retain the ability to investigate the level of fees charged by an accredited certifying agent if a complaint is made or if compelling circumstances warrant such an investigation. Accordingly, we have proposed at § 205.501(a)(15) that a certifying agent must charge applicants for certification and certified production and handling operations only those fees and charges that it has filed with the Administrator. We have also included at § 205.642 regulations with respect to fees charged by certifying agents to producers and handlers. Section 205.642 is discussed under fees in subpart G of this preamble.

(7) *State Standards That Vary From the National Organic Program.* We have added an exception to the regulation which prohibited certifying agents from requiring, as a condition for use of the certifying agent's identifying mark, compliance with any farming or handling requirements other than those provided for in the Act and regulations. The exception provides that the requirement does not apply to States with more restrictive requirements approved by the Secretary or private entity certifying agents certifying production or handling operations within States with more restrictive requirements approved by the Secretary. This change was made because we agree with the State commenters who stated that the prohibition on requiring compliance with any farming or handling requirements other than those provided for in the Act and regulations would prohibit States from requiring

that their more restrictive standards, approved by the USDA, be met as a requirement for use of the State's logo on organically produced products. We did not intend to prohibit States from requiring that their more restrictive standards be met as a requirement for use of the State's logo on organically produced products. Including this exception in § 205.501(b)(2) will permit States with more restrictive requirements approved by the Secretary and private entity certifying agents certifying production or handling operations within the borders of such States to require that the State's more restrictive standards be met as a requirement for use of their logo or other identifying mark on organically produced products.

Certifying agents may not require a certified operation to meet production or handling standards greater than those established by the Department or, when applicable, an approved State organic certification program as a condition for using its logo or other identifying mark. However, a certifying agent may verify, upon the request of a producer or handler certified by the certifying agent, that the producer or handler is meeting contractual specifications which include requirements in addition to those of the Act and regulations.

(8) *Time Period for Public Access to Information.* For the requirement that certifying agents describe the procedures they will use for making information available to the public, we have changed the time period from "during the 10-year period preceding the receipt of the request from the public" to "during the current and 3 preceding calendar years." Commenters stated that the required 10-year period was excessive and unnecessary. The Act requires public access to certification documents and laboratory analyses that pertain to certification. However, the Act does not specify that a certifying agent must provide access to its records throughout their 10-year retention period. We agree with the commenters that public access to the records the certifying agent is required to keep should be limited to a reasonable period short of the full retention period. Such a reasonable period, we believe, would be the current calendar year and the 3 calendar years preceding the calendar year of the request. Accordingly, § 205.504(b)(5) requires certifying agents to describe the procedures they will use for making information available to the public during the current and 3 preceding calendar years. This time period will lessen the burden on certifying agents while assuring

reasonable public access to such records.

(9) *Scope of Information for Public Release.* We have expanded the scope of information for public release which must be included in the list of producers and handlers whose operations the certifying agent has certified. Specifically, certifying agents will have to include the name of the operation and type(s) of operation in its list of producers and handlers it has certified. This change is included in section § 205.504(b)(5)(ii). Commenters requested that the list be expanded to include the name of the operation, its physical location(s), certification history, type(s) of operation, acreage (when applicable), and person responsible for organic regulation compliance. While we agree that the name of the operation and type(s) of operation should be available to the public, we believe that the certified operation's physical location(s), certification history, and acreage are confidential information which has no relationship to the operation's status as a certified organic operation. Therefore, such information should only be made available with the written consent of the certified operation. We also believe that it is unnecessary to list a person responsible for organic regulation compliance since the applicant ultimately has that responsibility. Therefore, these requested additions have not been made. We have also removed the separate requirement that certifying agents identify for the public the organic agricultural products produced by each certified operation. We have taken this action because the information is available on the certificates and the list of producers and handlers required to be released by the certifying agent to the public. These requirements are found at § 205.504(b)(5)(i) and (ii).

(10) *Release of Nonconfidential Business Information.* We have removed the requirement that certifying agents provide a description of the procedures to be used to make nonconfidential business information, as permitted by the producer or handler and approved by the Secretary, available to the public. This requirement has been replaced with the requirement that the certifying agent provide a description of the procedures to be used to make other business information, as permitted in writing by the producer or handler, available to the public. Commenters objected to the requirement that the Secretary approve the release of nonconfidential business information that the producer or handler had authorized the certifying agent to

release. They believed that this requirement lacked justification and created unnecessary costs. We concur that this requirement is unnecessary. However, we believe that the producer's or handler's approval must be obtained in writing, which is reflected in this proposal at § 205.504(b)(5)(v).

(11) *Submission of Applicant's Financial Policies and Procedures.* We have removed the requirement that a certifying agent include with its application for accreditation a description of its policies and procedures for collection and disbursement of funds and documents that identify anticipated sources of income, including all fees to be collected from producers and handlers. Commenters stated that they did not believe the submission of applicant financial policies and procedures was necessary. We have decided that the information requested probably would not fully meet our needs in determining that certification decisions were not influenced by the certifying agent's concern for the certification decision's financial impact on the certifying agent or in determining compliance with the conflict of interest provisions of the Act and these regulations. Accordingly, this requirement is not included in this proposal.

(12) *Submission of Information Concerning Current Certification Activities.* We have changed the voluntary submission of information and documents concerning current certification activities to a required submission. Commenters stated that the submission of a list of all farms, wild-crop harvesting operations, and handling operations currently certified by the applicant should be required. They went on to say that the submission of copies of the inspection reports and certification evaluation documents for production or handling operations certified by the applicant during the previous year should remain optional. They also said the submission of results from any accreditation process of the applicant's operation by an accrediting body during the previous year for the purpose of evaluating its certification activities should remain optional.

We agree with the commenters that a list of all operations currently certified by the applicant should be a required submission. We also believe that copies of inspection reports, certification evaluation documents, and accreditation results should be a required submission from all applicants currently certifying production or handling operations. Accordingly, at § 205.504(d) we have made the submission of information and

documents concerning current certification activities mandatory for certifying agents currently certifying production or handling operations.

This change has been made because of the value such information and documents would have in assisting the Department in evaluating an applicant for accreditation. However, we have limited the submission of inspection reports and certification evaluation documents for production and handling operations certified by the applicant. The applicant is required to submit copies of at least 3 different inspection reports and certification evaluation documents for production or handling operations certified by the applicant during the previous year for each area of operation for which accreditation is requested. We have limited the submission to reduce the reporting burden on certifying agents. The Administrator may, however, require that the certifying agent submit additional inspection reports and certification evaluation documents.

We recognize that a newly organized certifying agent with no experience would be unable to supply the information. An applicant's inability to provide the information and documentation required by the revised paragraph due to lack of experience would not be prejudicial to the Department's evaluation of the application.

(13) *Site Evaluations.* We have revised the site evaluation provisions to clarify the scope of an evaluation, to specify that the evaluation will be arranged and conducted by a representative of the Administrator, and to specify when evaluations shall or may be conducted. These changes are made in response to commenters who suggested adding details to the regulatory text regarding the nature of site evaluations. The revised section provides that site evaluations of accredited certifying agents shall: (1) Be conducted for the purpose of examining the certifying agent's operations and evaluating its compliance with the Act and regulations; (2) include an on-site review of the certifying agent's certification procedures, decisions, facilities, administrative and management systems, and production or handling operations certified by the certifying agent; (3) be conducted by a representative(s) of the Administrator; and (4) be conducted after application for renewal of accreditation but prior to the issuance of a notice of renewal of accreditation. This revised section provides that an initial site evaluation of an accreditation applicant would be conducted before or within a reasonable

period of time after issuance of the applicant's notification of accreditation. Section 205.508 also provides that one or more site evaluations will be conducted during the period of accreditation to determine whether an accredited certifying agent is complying with the general requirements for accreditation.

(14) *Eligibility for Peer Review Panels.*

We have added a new regulation addressing eligibility for peer review panels. Commenters expressed concern that peer review pool applicants be free of conflicts of interest and possess the necessary expertise in organic production or handling. The first proposal provided that candidates for membership in the peer review panel pool would be required to submit a letter to the Program Manager of the NOP requesting appointment, describing their qualifications, and identifying conflicts of interest. We believe that there is value to the applicants for membership in the peer review panel pool and the general public in addressing eligibility for peer review panels in the regulatory text. Accordingly, we have added a new regulation at § 205.509(b) which provides that applicants for membership in the peer review panel pool must provide the Administrator with a written description and, upon request, supporting documentation of their qualifications to conduct peer reviews. Such description must include information concerning the applicant's training and expertise in organic production or handling methods and in evaluating whether production or handling operations are using a system of organic production or handling. Applicants must also address their possible limitations on availability to serve. Further, applicants would be required to include information concerning their commercial interests and those of their immediate family members, within the 12-month period prior to application, with any person who may seek to become or who is an accredited certifying agent. No person who has or has had a commercial interest, including an immediate family interest or the provision of consulting services, in an applicant for accreditation or renewal of accreditation will be appointed to or accept appointment to a panel evaluating the applicant. This provision was added for the purpose of avoiding conflicts of interest by peer reviewers. This new regulation also provides that persons accepted to the pool may serve until notified that their appointment has been rescinded by the Administrator or until

they are no longer qualified, whichever occurs first.

(15) *Composition of Peer Review Panels.* We have revised the regulations concerning the composition of peer review panels. Commenters requested that the peer review panel consist of at least two members who are not USDA employees, rather than not AMS employees. We agree with this suggested change, which clarifies what had been our intent. This change is included in § 205.509(c). Section 205.509(c) provides that peer review panels shall consist of at least three but no more than five members. This section provides that peer review panels must include a Department representative who will preside over the panel and no fewer than two members from the peer review pool who possess sufficient expertise in the relevant areas of accreditation. Additionally, section 205.509(c) provides that peer review panels may include up to two members with expertise in other disciplines, including organizational management and finance; member(s) from the approved State organic certification program when the applicant is a private entity seeking accreditation within the State; and member(s) from a foreign government's organic program when the applicant is a private entity that will operate within the country. We have added authorization for these additional members to broaden the scope and depth of expertise available to peer review panels.

Commenters also expressed concern that the peer review panels consist of at least one member from a State organic certification program. We do not believe that the composition of peer review panels regulations needs to be amended to accommodate this concern. To the extent possible, accredited private certifying agents will peer review private certifying agents, and accredited State certifying agents will peer review State certifying agents.

(16) *Renewal of Accreditation.* We have revised the renewal of accreditation provisions to, among other things, require that an accredited certifying agent's application for accreditation renewal be received 6 months prior to the fifth anniversary of issuance of the notification of accreditation and each subsequent renewal of accreditation. The first proposal provided that an accredited certifying agent would request renewal of accreditation on or before the fifth anniversary of issuance of the notice of confirmation of accreditation and each subsequent renewal of accreditation. Commenters expressed concern about whether the accredited certifying agent's

accreditation would lapse during the renewal process. They suggested that certifying agents should submit their application for renewal of accreditation 6 months prior to the fifth anniversary of issuance of the notice of confirmation.

We believe that clarification regarding the status of the certifying agent's accreditation during the renewal process is appropriate. We also concur with the commenters' suggestion that certifying agents should submit their applications for renewal of accreditation 6 months prior to the fifth anniversary of issuance of the notice of confirmation. We have replaced "notice of confirmation of accreditation," however, with "notification of accreditation" because this proposal eliminates the section on confirmation of accreditation. Accordingly, we have provided in this proposal at § 205.510(c) that: (1) An accredited certifying agent's application for accreditation renewal must be received 6 months prior to the fifth anniversary of issuance of the notification of accreditation and each subsequent renewal of accreditation; (2) the accreditation of certifying agents who make timely application for renewal of accreditation will not expire during the renewal process; (3) the accreditation of certifying agents who fail to make timely application for renewal of accreditation will expire as scheduled unless renewed prior to the scheduled expiration date; (4) certifying agents with an expired accreditation must not perform certification activities under the Act and regulations; and (5) following receipt of the information submitted by the certifying agent, the results of any site evaluation, and, when applicable, the reports submitted by a peer review panel, the Administrator will determine whether the certifying agent remains in compliance with the Act and regulations and should have its accreditation renewed.

These changes would provide the Department with sufficient time to fully process the certifying agent's application for accreditation renewal prior to the accreditation's scheduled date of expiration. This revised regulation also clarifies that a certifying agent's accreditation will not expire during the accreditation renewal process if the certifying agent has made timely application for renewal. It also makes clear that the accreditation of certifying agents who fail to make timely application for renewal of accreditation will expire as scheduled unless renewed prior to the scheduled expiration date. This regulation also provides that certifying agents with an expired accreditation must not perform

certification activities under the Act and these regulations.

(17) *Denial of Accreditation.* We have revised the denial of accreditation regulations to clarify that after receipt of a notification of noncompliance, the applicant may submit a description of the actions taken to correct the noted deficiencies and evidence demonstrating such corrections, rather than submitting a new application. We have taken this action because commenters were confused by our reference to a new application in the denial of accreditation regulations. The denial of accreditation regulations are found at § 205.507 in this proposal.

Accreditation—Changes Requested But Not Made

This subpart retains from our first proposal regulations on which we received comments as follows:

(1) *Durations of Accreditation and Reporting Requirements.* Commenters expressed concern regarding the duration of accreditation and whether the interval of required reporting is adequate. An association expressed concern regarding the economic impact of accreditation on small certifying agents. This commenter stated that small certifying agents should not be accredited more often than every 5 years. An international organic federation expressed the belief that accreditation for 5 years is too long. The commenter went on to say that certification bodies are expanding rapidly and that annual reports cannot be relied upon to fully convey the consequent changes. This commenter believes that many of the conditions of accreditation may relate to operational aspects that cannot be addressed in an annual report.

Annual reporting by the certifying agent, under this proposal, would provide: (1) A complete and accurate update of applicant information and expertise and ability information previously submitted; (2) information supporting any changes being requested in the areas of accreditation; (3) the measures that were implemented in the previous year and any measures to be implemented in the coming year to satisfy any terms and conditions determined by the Administrator to be necessary as specified in the most recent notification of accreditation; and (4) the results of the most recent inspector performance appraisal and program evaluation and adjustments to the certifying agent's operation and procedures implemented and intended to be implemented in response to the appraisals and evaluations. This proposal includes a requirement at

§ 205.501(a)(14) that the certifying agent submit to the Administrator a copy of each notification of: (1) Denial of certification; (2) noncompliance; (3) noncompliance correction; (4) proposed suspension or revocation; and (5) suspension or revocation, simultaneously with its issuance.

We believe that these reporting requirements, coupled with feedback from applicants for certification, certified operations, and other interested parties, will provide the Department with sufficient information regarding the certifying agent and its operation to determine whether a site visit is necessary to evaluate the certifying agent's suitability to remain accredited. Under this proposal, the Department will conduct one or more site evaluations during the period of accreditation to determine whether the accredited certifying agent is complying with the requirements for accreditation. Accordingly, we believe the duration of accreditation period first proposed was correct, and we are, therefore, reproposing this time period at § 205.500(b).

(2) *Performance Appraisals and Program Evaluation.* Comments from State departments of agriculture and some certifiers indicated that the annual inspector performance appraisal and annual program evaluation requirements duplicated State requirements. The commenters asked what the required scope and depth of evaluations was expected to be, whether third party evaluators would be required to be used to assess the performance of the operation, and whether existing performance appraisal and program evaluation practices of a certifying agent would be used to meet the annual inspector performance appraisal and program evaluation requirements.

We do not intend for States to develop dual performance appraisal and program evaluation programs. We believe that performance appraisals and program evaluations conducted to meet State requirements will also meet the requirements of this proposal. State and private agency personnel performance appraisals and program evaluations would be expected to be consistent with good management practices and appropriate to the organization's size and structure. This could be different for different organizations. Therefore, we are not prescribing the specific performance appraisal system or instrument to be used to assess inspector performance, the specific program evaluation methods that must be used, or that third parties must conduct the required program evaluation. Accordingly, we have not

changed the questioned provisions, which appear at §§ 205.501(a)(6) and (7). We have, however, revised § 205.501(a)(7) to clarify that the annual program evaluation can be conducted by the certifying agency staff, an auditing entity, or a consultant who has expertise to conduct program evaluations.

(3) *"Open Records" Requirements.* Commenters expressed the belief that confidentiality requirements for certifying agents might conflict with State requirements for "open records." We recognize this potential for conflicting requirements. Records collected and maintained under the NOP are subject to the confidentiality provisions of the Act and these regulations. However, a State-entity certifying agent will be subject to its State "open records" laws when such laws conflict with the confidentiality provisions of the Act and these regulations. Records collected and maintained under the NOP by a private entity certifying agent will always be subject to the confidentiality requirements of the Act and these regulations. Accordingly, pursuant to the Act, we are reproposing the confidentiality provisions at § 205.501(a)(10).

To clarify that authorized representatives of the Secretary or the applicable State program's governing State official may act on behalf of the Secretary or the State program's governing State official and must be given access to the records, we have added the phrase, "or their authorized representatives," to § 205.501(a)(10). Such representative could be a member of the NOP staff, a Department compliance officer, or other official. This provision is standard practice and is necessary for Government oversight of a regulatory program.

(4) *List of Confidential Records.* One commenter requested a definitive list of the records that had to be kept confidential. We cannot create such a list because it is not possible to describe every record that would be characterized as a business-related record. Such records would include, however, organic production and handling plans, records that are related to trade secrets and commercial or financial information obtained from applicants for certification, and records or information compiled for an investigation into alleged noncompliance with the Act and regulations.

(5) *Time Period for Prohibition of Commercial Interest.* We received many comments regarding the prohibition of commercial interest in an organic production or handling operation

during the 12 months prior to certification. Several States and industry associations stated that the prohibition of commercial interest should apply to the 12 months after as well as the 12 months prior to certification. These commenters offered no reasoning for their position. A research foundation recommended that the prohibition of commercial interest should be for 3 years before and after the application for certification. This commenter stated that the conflict of interest provisions needed significant strengthening. A producer commenter stated that the prohibition of commercial interest should be for an indefinite period, not for 12 months. Some commenters recommended that certifying agents and responsible parties and employees of certifying agents be barred from accepting employment for 1 to 3 years from any certified production or handling operation in which they participated in any manner in the operation's certification. An accreditation service stated it believed there would be a conflict of interest should a consulting or business connection arise between an inspector and a production or handling operation following the site evaluation. This commenter presented the example of an inspector being offered employment during the site evaluation but not taking the position until 6 months after the site evaluation. Many commenters, however, supported our proposed prohibition of commercial interest in an organic operation during the 12 months prior to certification.

We disagree with the recommendations calling for a longer precertification conflict of interest prohibition period and with the recommendations for a postcertification prohibition period for those persons no longer associated with the certifying agent. Regarding the recommendations for a longer precertification prohibition period, we continue to believe that 12 months is a sufficient period to ensure that any previous commercial interest would not create a conflict of interest situation for two reasons. First, this time period is consistent with similar provisions governing conflicts of interest for government employees. Second, we have added a new section, 205.501(a)(11)(v), which requires the completion of an annual conflict of interest disclosure report by all personnel designated to be used in the certification operation, including administrative staff, certification inspectors, members of any certification review and program evaluation committees, contractors, and all parties

responsibly connected to the certification operation. This requirement will assist certifying agents in complying with the requirements to prevent conflicts of interest. We also continue to believe that a longer prohibition period would have the effect of severely curtailing most certifying agents' ability to comply with the Act's requirement that they employ persons with sufficient expertise to implement the applicable certification program. Accordingly, we have decided to repropose the prohibition on commercial interest in an applicant for certification for a 12-month period prior to the application for certification at section § 205.501(a)(11).

Regarding the recommendations for a postcertification prohibition period for those persons no longer associated with the certifying agent, we believe such a period is unnecessary. We take this position because certifying agents and their responsibly connected parties, employees, inspectors, contractors, and other personnel are prohibited from engaging in activities or associations at any time during their affiliation with the certifying agent which would result in a conflict of interest. While associated with the certifying agent, all employees, inspectors, contractors, and other personnel are expected to disclose to the certifying agent any offer of employment they have received and not immediately refused. They are also expected to disclose any employment they are seeking and any arrangement they have concerning future employment with an applicant for certification or a certified operation. The certifying agent would then have to exclude that person from work, discussions, and decisions in all stages of the certification or monitoring of the operation making the employment offer. If a certifying agent or a responsibly connected party of the certifying agent has received and not immediately refused an offer of employment, is seeking employment, or has an arrangement concerning future employment with an applicant for certification, the certifying agent may not accept or process the application. Further, certifying agents and responsibly connected parties may not seek employment or have an arrangement concerning future employment with an operation certified by the certifying agent while associated with that certifying agent. Certifying agents and responsibly connected parties must sever their association with the certifying agent when such person does not immediately refuse an offer of employment from a certified operation. Accordingly, we have decided not to

include a postcertification prohibition period in this proposal.

(6) *Conflicts of Interest.* Some commenters stated that they understood the proposed conflict of interest provisions to prohibit certifying agents from certifying any organic operation owned or operated by a member of the certifying agent's board of directors or from certifying any organic operation owned or operated by an employee of the certifying agent. One commenter stated that because certification arose from the ranks of organic farmers, there are many certification personnel, including inspectors, who also farm or have family who farm. This commenter stated that it should be permissible for a certifying agent to review and certify an organic operation owned or operated by a responsibly connected person or employee, provided that the responsibly connected person or employee is excluded from the decision-making process with respect to the organic operation to be certified.

The commenters are correct in their interpretation that the first proposal prohibited certifying agents from certifying an operation when the certifying agent or a responsibly connected party of such certifying agent has or has held a commercial interest in the operation. This prohibition is limited, however, to the 12-month period prior to the application for certification. The first proposal did not prohibit certifying agents from certifying an operation when an employee of the certifying agent has or has held a commercial interest in the operation. The first proposal prohibited a certifying agent from using an employee in any phase of the certification process when such employee has or has held a commercial interest in an operation making application for certification within the 12-month period prior to the application for certification. A responsibly connected party is any person who is a partner, officer, director, holder, manager, or owner of 10 percent or more of the voting stock of an applicant for or a recipient of certification or accreditation.

We believe that a certifying agent and a responsibly connected party of such certifying agent hold positions of power and authority which preclude the certification of an operation in which they have or have held a commercial interest during the 12-month period prior to an application for certification. The certifying agent's control over the employment of an agent's employee makes it unreasonable to expect an employee of a certifying agent to impartially carry out the employee's duties when the certifying agent or a

responsibly connected party of such agent has an interest in the applicant. Such is not true of an employee who is subordinate to the certifying agent or a responsibly connected party of the certifying agent. Accordingly, we have reproposed the requirement that a certifying agent prevent conflicts of interest by: (1) Not certifying a production or handling operation if the certifying agent or a responsibly connected party of such certifying agent has or has held a commercial interest within the 12-month period prior to the application for certification and (2) excluding any person with a conflict of interest from work, discussions, and decisions in all stages of the certification process and the monitoring of certified production or handling operations for all entities in which the person has or has held a commercial interest within the 12-month period prior to the application for certification. Both of these provisions are found in § 205.501(a)(11).

(7) *Defining Commercial Interest.* A research foundation recommended that the provisions for preventing conflicts, found in this proposal at § 205.501(a)(11), be strengthened by changing "a commercial interest in the operation" to "a commercial interest in the operation or the marketing or distribution of its products." We believe that the recommended addition is unnecessary because "commercial interest" covers all business transactions between the certifying agent or responsibly connected parties, employees, inspectors, contractors, or other personnel of the certifying agent and the applicant for certification or certified operation. This interpretation would not apply to voluntary labor provided, in accordance with § 205.501(a)(11)(iii), by a certified operation to a certifying agent that is a not-for-profit organization with an Internal Revenue Code tax exemption. Further, this interpretation would not apply to the providing of advice, in accordance with § 205.501(a)(11)(iv), concerning organic practices or techniques to any certification applicant or certified operation when such advice is covered by fees under the applicable certification program established under the Act.

(8) *Provision of Information to Producers and Conflicts of Interest.* Commenters were concerned about the effect that some of the conflict of interest provisions would have on certifying agents that provide producers with information on organic practices through forums such as in-house publications, conferences, workshops, informational meetings, and field days

for a fee. Specifically, they were concerned about the impact of the conflict of interest provision requiring that certifying agents prevent conflicts of interest by not providing advice concerning organic practices or techniques to any certification applicant or certified organic production or handling operation for a fee, other than as part of the fees established under the applicable certification program established under the Act. These commenters requested that the paragraph be rewritten to clarify that such activities would not be prohibited. We also received a comment stating that advice relating to improving production yields, market access, etc., is not the function of an inspector and can lead to a nonmonetary conflict of interest. This commenter stated that advice, where given, should be restricted to issues related to the understanding and implementation of the standards.

Certifying agents have historically provided advice concerning organic practices or techniques to any certification applicant or certified organic production or handling operation for a fee through forums such as in-house publications, conferences, workshops, informational meetings, and field days. Such activities and their fees would not be prohibited under the Act or these regulations, provided that such activities were not required as a condition for production or handling certification. Section 205.503(c) would require that the applicant for accreditation provide a copy of the applicant's schedule of fees for all services to be provided under these regulations by the applicant. We would consider such activities to be voluntary participation activities provided by the certifying agent to producers, handlers, and other interested persons under the NOP. We also believe that it is appropriate, as well as industry practice, during an on-site inspection for inspectors to provide advice on a wide range of issues related to an on-site inspection of a production or handling operation. Accordingly, the conflict of interest provisions found at § 205.501(a)(11) have not been rewritten as requested by the commenters.

(9) *Equivalency of Certification Decisions.* We received a variety of comments suggesting changes to the requirement that accredited certifying agents accept the certification decisions made by another USDA-accredited certifying agent as equivalent to its own. Several of these commenters asked whether States with more restrictive standards could challenge certification decisions made by any accredited certifying agents. A few commenters

representing State programs stated that States should be able to maintain control over which certifying agents operate within their State. Other commenters suggested that the requirement be amended to: (1) Require that a certifying agent accept the certification decisions made by another USDA-accredited certifying agent as equivalent to its own only after the certifying agent's accreditation has been confirmed by the Department; (2) provide that if a certifying agent doubts the accuracy of another certifying agent's determination, the certifying agent questioning the accuracy can file a complaint with the Secretary; and (3) authorize an accredited certifying agent to request additional documentation from another certifying agent if questions arise regarding the other certifying agent's certification activities or the activities or product of a production or handling operation certified by the other certifying agent.

No organic product may be produced or handled to organic standards lower than the standards of the NOP. To certify organic production or handling operations to the national standards or to more restrictive State standards approved by the Secretary, the certifying agent must be accredited by the Administrator. While States may set more restrictive standards than the national organic standards for product produced or handled within their State, those requirements do not apply to organic product produced or handled outside of such State. Further, a State government may not prevent the marketing or sale in the State of organic product produced in another State to this program's national organic standards. State organic certification programs approved by the Secretary would be required to treat all accredited certifying agents equally. Likewise under this program, accredited certifying agents in one State cannot refuse to recognize another State's product which is certified to these national organic standards.

We disagree with the suggestion to allow certifying agents to challenge the decisions of certifying agents that have not yet had their accreditation confirmed by the Department. We believe that allowing a certifying agent to challenge the certification decisions made by a certifying agent that has not had its site evaluation would create an insurmountable barrier for persons wanting to become accredited under the NOP, especially persons establishing new operations. The proposed accreditation procedures are sufficiently rigorous to permit a well-founded assessment of the applicant's

capabilities and qualifications and will allow all eligible certifying agents to receive timely accreditation. We will only accredit certifying agents that we believe possess the expertise and ability to implement the proposed certification program. This includes newly established certifying agents who might require a longer period of time between accreditation and a site evaluation to allow the certifying agent to perform sufficient certification activities for the Department to perform a meaningful site evaluation.

Should questions arise regarding a certifying agent's certification activities, a certified production or handling operation's activities, or the organic status of a certified production or handling operation's product, the questioning certifying agent could report a complaint or allegation of noncompliance, with the certification provisions of this part, to the State program's governing State official or the Administrator. As appropriate, the State program's governing State official or the Administrator will investigate such complaints or allegations. Certifying agents are not authorized to investigate allegations or suspicions of noncompliance by other certifying agents, nor are certifying agents allowed to take unilateral action against an accredited certifying agent, such as refusal to recognize the certification decisions made by another certifying agent.

For the above reasons, we have not changed the requirement that a certifying agent accept the certification decisions made by another USDA-accredited certifying agent as equivalent to its own. This requirement is located at § 205.501(a)(12).

(10) *False or Misleading Claims.* Commenters objected to the requirements that an accredited certifying agent must 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. A few of these commenters stated that the requirements exceed the authority given by the Act by introducing claims other than those concerning representations of nonorganic product as organic. Additionally, a few commenters believed that the term, "misleading," is too broad and could be interpreted to mean that the certifying agent could make no negative claims about the USDA accreditation program. They suggested that the requirements be amended by removing the reference to misleading claims. Another commenter

believed that the phrase, "or the nature or qualities of products labeled as organically produced," should be deleted because it is vague and would unduly limit the freedom of certifying agents to share information with consumers, farmers, processors, and other interested parties regarding the attributes of organic food and organic production systems, including nutritional properties, freshness, taste, and less reliance on synthetic substances.

We disagree with the commenters who stated that the requirements exceed the authority given by the Act by introducing claims other than those concerning representations of nonorganic product as organic. Claims regarding accreditation status, the USDA accreditation program for certifying agents, and the nature and quality of products labeled as organically produced all fall under the authority of the Act. We believe that the requirements are needed to prevent the dissemination of inaccurate or misleading information to consumers about organically produced products. We further believe that the changes suggested by the commenters would undermine the goal of a uniform NOP by allowing certifying agents to make claims that would state or imply that organic products produced by operations that they certify are superior to those of operations certified by other certifying agents. These requirements would not prohibit certifying agents from sharing factual information with consumers, farmers, processors, and other interested parties regarding verifiable attributes of organic food and organic production systems. Accordingly, the requirements are repropose in this proposal without change at § 205.501(a)(13).

(11) *Notification of Status of Certified Operations.* Comments received on the requirements addressing documentation to be submitted by certifying agents to the Department regarding the status of certified operations suggested that: (1) The public should have access to the notification of certification status documentation; (2) annual reporting by certifying agents of the name of each operation whose application for certification has been approved is sufficient; and (3) the required reporting should only include the name of those operations certified during the quarter being reported rather than a listing of all operations certified by the certifying agent. First, we believe that the Freedom of Information Act adequately provides for public access to information. Second, we need the required information to facilitate oversight and to

ensure that we have relatively current data for responding to inquiries involving the granting of certifications by certifying agents. It was not our intent to have certifying agents update their list of certified entities quarterly. Our intent was to receive on a quarterly basis a listing of all certifications granted by the certifying agent during the quarter being reported. Accordingly, no changes have been made on the basis of these comments to the requirements found in this proposal at § 205.501(a)(14).

(12) *Certifier Compliance With Terms and Conditions Deemed Necessary.* Commenters objected to the requirement that certifying agents must comply with and implement other terms and conditions deemed necessary by the Secretary. This requirement is consistent with § 6515(d)(2) of the Act, which requires a certifying agent to enter into an agreement with the Secretary under which such agent shall agree to such other terms and conditions as the Secretary determines appropriate. Accordingly, this requirement, found at § 205.501(a)(17), is unchanged in this proposal except to change "Secretary" to "Administrator" since the Administrator will be responsible for administration of the NOP.

(13) *Limitations on the Use of Certifying Agent's Marks.* Private certifying agents disagreed with the provision that prohibited certifying agents from requiring, as a condition of use of the certifying agent's identifying mark, compliance with any production or handling requirements other than those provided for in the Act and regulations. Private certifying agents commented that they should be allowed to use their identifying mark to recognize additional achievements by producers and handlers that exceed the requirements proposed in the national organic standards. The commenters' position is the same as that suggested by public input prior to publication of the first proposal.

We believe that the private certifying agents' position advocating the use of their identifying mark to recognize additional achievements is inconsistent with § 6501(2) of the Act, which provides that a stated purpose of the Act is to assure consumers that organically produced products meet a consistent national standard. Accordingly, we are repropose the provision prohibiting certifying agents from requiring, as a condition of use of the certifying agent's identifying mark, compliance with any production or handling requirements other than those provided for in the Act and regulations or under an approved State organic certification program. This

reproposed provision is found at § 205.501(b).

(14) *Additional Requirements for Private Certifying Agents.* Commenters expressed concern regarding the three additional requirements for a certifying agent who is a private person. First, private certifying agents expressed concern regarding the requirement that private certifying agents hold the Secretary harmless for any failure on their part to carry out the provisions of the Act and regulations. Their concern focused on the fact that applicants for certification can appeal a certifying agent's refusal to certify to the Secretary and that a certifying agent's recommendation to suspend or revoke a certification can be appealed to the Secretary. They believe that, without the authority to independently deny, suspend, or revoke certification, the certifying agent becomes liable for the actions of the Secretary.

We disagree with the assertion that the certifying agent becomes liable for the actions of the Secretary. The provision clearly states that private certifying agents hold the Secretary harmless for any failure on their part. This in no way would make the certifying agent responsible for any failure on the part of the Department. Further, the wording of this provision is consistent with § 6515(e)(1) of the Act, which provides that private certifying agents shall agree to hold the Secretary harmless for any failure on the part of the certifying agent to carry out the provisions of the Act. Accordingly, we are repropose this regulation at § 205.501(c)(1).

Second, commenters expressed concern regarding the requirement that certifying agents furnish reasonable security, in an amount and according to terms as the Secretary may by regulation prescribe, for the purpose of protecting the rights of production and handling operations certified by such certifying agent. The commenters expressed concern regarding what would be the dollar amount of the security, how the dollar amount of the security would be determined, and in what form the security might be furnished. Several commenters expressed concern over the availability of errors and omissions insurance. The commenters also expressed a belief that guidance on what reasonable security might entail will be needed by accreditation applicants to evaluate their costs for accreditation.

A private-entity certifying agent must furnish reasonable security for the purpose of protecting the rights of operations certified by such certifying agent. This security is to ensure the performance of the certifying agent's

contractual obligations. As noted elsewhere in this proposed rule, the specific amount and type of security that must be furnished by a private certifying agent will be the subject of future rulemaking by the Department. Such rulemaking will provide for public input and will occur prior to the call for applications for accreditation. We anticipate that the amount of the security will be tied to the number of clients served by the certifying agent and the anticipated costs of certification that may be incurred by its clients in the event that the certifying agent's accreditation is suspended or revoked. We anticipate that the security may be in the form of cash, surety bonds, or other financial instrument (such as a letter of credit) administered in a manner comparable to cash or surety bonds held under the Perishable Agricultural Commodities Act. Accordingly, we are reproposing this regulation at § 205.501(c)(2).

Third, commenters expressed concern regarding the requirement that a private person accredited as a certifying agent must transfer to the Secretary and make available to any applicable State program's governing State official all records or copies of records concerning the private certifying agent's certification activities in the event that the certifying agent dissolves or loses its accreditation. This requirement is consistent with § 6515(c)(3) of the Act, which provides that if any private person that was certified under the Act is dissolved or loses its accreditation, all records or copies of records concerning such person's activities under the Act shall be transferred to the Secretary and made available to the applicable State program's governing State official. In addition to being consistent with the Act, we believe that this regulation is necessary to ensure the continuity and integrity of the NOP. Accordingly, we are reproposing this regulation at § 205.501(c)(3).

(15) *Public Access to Applicant Information.* The first proposal included provisions regarding what information had to be submitted by an accreditation applicant. Commenters requested the addition of a paragraph addressing public access to this information about the applicant's organization and intended certification activities. We have not made this requested change because the proposed recordkeeping and availability requirements under this program, coupled with the Freedom of Information Act, adequately provide for public access to information. The regulations on applicant information are found at § 205.503 and include two additions to the provisions of the first

proposal. This proposal requires the applicant to provide the name of the person responsible for the certifying agency's day-to-day operations and to submit a copy of its schedule of fees for all services to be provided under these regulations.

(16) *Application Requirements for States.* Commenters stated that State certifying agents should not be required to submit documents and information regarding personnel, administrative policies and procedures, and financial policies and procedures to demonstrate evidence of expertise and ability. They believe that the requirements should not apply to States that have established hiring procedures, standard qualifications for job descriptions, and statewide policies for training, evaluating, and supervising personnel. They also stated that administrative policy and procedure review should be limited to organic program administration, not to agencywide policies or procedures such as financial policies.

We acknowledge that States have established hiring procedures, standard qualifications for job descriptions, administrative procedures, and statewide policies for training, evaluating, and supervising personnel and that such policies and procedures would be applicable to State certifying agents. This fact, however, does not make States uniquely different from private accreditation applicants who would have similar policies and procedures in exercising good business practices. State certifying agents cannot be exempt from these requirements simply because they are a government agency.

We anticipate that a State will submit its established policies and procedures to meet the requirements for demonstrating its expertise in organic production and handling techniques and its ability to fully comply with and implement the national organic certification program. A stated purpose of the Act is the establishment of national standards. We believe such national standards extend to uniform requirements for State and private certifying agents unless otherwise provided by the Act. We further believe the required information is essential to enable the Administrator to make a determination concerning approval of an application for accreditation. Accordingly, the requirements for demonstrating expertise in organic production and handling techniques and an ability to fully comply with and implement the national organic certification program remain the same for private and State certifying agents.

These requirements are found at § 205.504.

(17) *Public Access to Information on Certified Operations.* Commenters requested that the public be provided information about a certified operation's farming practices, use of pesticides, and livestock production practices. All production and handling operations must meet the requirements of the national organic certification program to be certified. An accredited certifying agent will determine whether an operation meets those requirements. Certified operations can be held to no other standards except, if applicable, the requirements of an approved State organic certification program. Accordingly, we believe access to the requested information is unnecessary. We also believe the information to be confidential business information that should not be released to the public. Therefore, we have made no changes to the proposed rule to accommodate the commenters' request.

(18) *Conflicts of Interest.* The first proposal required a description of procedures intended to be implemented to prevent the occurrence of conflicts of interest. It also required the identification of any food or agriculture-related business interests of all personnel intended to be used in the certification operation, including administrative staff, certification inspectors, members of any certification review and evaluation committees, all parties responsibly connected to the certification operation, and immediate family members, that may result in a conflict of interest. Commenters stated that existing State policies should be sufficient to prevent conflicts of interest. They also stated that lists of the business interests of all inspectors, program staff, and their families are unnecessary.

We agree with the commenters that existing State policies should be sufficient to prevent conflicts of interest. However, we disagree with the commenters' assertion that lists of the business interests of all inspectors, program staff, and their families are unnecessary. At § 6515(h), the Act places responsibility for the prevention of conflicts of interest with the certifying agent. We, however, have responsibility for ensuring that the certifying agent complies with that responsibility. We believe these requirements will provide the Administrator with information essential to the identification of conflicts of interest. A stated purpose of the Act is the establishment of national standards. We believe such national standards extend to uniform conflict of

interest requirements for State and private certifying agents. Further, for conflict of interest standards to achieve their intended effectiveness, they must be uniformly applied to both State and private certifying agents. The required information is also essential to the Administrator's determination of the applicant's suitability for accreditation. As the commenters point out, States have established conflict of interest policies and procedures. Thus, the required information should be readily available for submission to the Administrator with minimal inconvenience to the certifying agent. Accordingly, we have made no changes in this proposal based on these comments. Regulations concerning conflicts of interest are found at §§ 205.501(a)(11) and 205.504(c) in this proposal.

(19) *Accreditation Prior to Site Evaluation.* Commenters expressed concern that applicants could be accredited prior to a site evaluation of the applicant's facilities and operations. Most, however, recognized the need for accreditation decisions on written materials as opposed to further delay to program implementation. A few of the commenters urged USDA to complete the site evaluations during the implementation phase. The first proposal provided that an initial site evaluation of the operation of each certifying agent must be performed for the purpose of verifying its compliance with the Act and regulations. Two restrictions concerning timing were placed on the performance of an initial site evaluation. First, the site evaluation had to be performed within a reasonable period of time after the date on which the agent's notice of approval of accreditation was issued. Second, the site evaluation had to be performed after the agent had conducted sufficient certification activities for the Administrator to examine its operations and evaluate its compliance with the general requirements for accreditation.

We never intended that a site evaluation be required prior to accreditation. While site evaluations could be conducted before approval, we believe accreditation approval without a site evaluation is appropriate. We believe that the commenters' concerns are adequately addressed by the first proposal, which provided for a well-founded assessment of the applicant's qualifications and capabilities through a sufficiently rigorous review of the application and supporting documentation. In cases where the document review raises concerns regarding the applicant's qualifications and capabilities and the Administrator

deems it necessary, a preapproval site evaluation would be conducted.

As noted above, a site evaluation to verify compliance with the Act and regulations would be conducted within a reasonable time period after the date on which the agent's notice of approval of accreditation was issued. Following the site evaluation, the certifying agent's accreditation would be continued provided the certifying agent is in compliance with the Act and regulations. Should it be found that the accredited certifying agent is not in compliance with the Act and regulations, the Administrator will issue the certifying agent a notification of noncompliance and afford the certifying agent an opportunity to correct the deficiencies. If the deficiencies are not corrected, the Administrator will begin proceedings to suspend or revoke the certifying agent's accreditation.

We also believe that: (1) 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 the Department's evaluation; (2) previously existing certifying agents also would need time to make adjustments in their operations to comply with the NOP regulations; and (3) requiring full site evaluations and peer reviews to be conducted prior to granting accreditation would further delay implementation of the Act. Accordingly, we have made no changes to the application requirements found at § 205.502 or the site evaluation requirements found at § 205.508 on the basis of these comments.

(20) *Conditional Accreditation.* Commenters suggested that the rule provide for conditional accreditation of certifying agents. We disagree with the concept of conditional accreditation. We believe accreditation before a site evaluation to be the most effective means of providing new certifying agents with the opportunity to participate in the NOP. New certifying agents need to be unconditionally accredited to sell their services to potential organic clients. Such certifying agents need organic clients to demonstrate to the Administrator their compliance with the Act and regulations relative to the certification of organic producers or handlers. Furthermore, the Act does not provide for conditional accreditation. Accordingly, the proposed accreditation program for initial accreditation provides for: (1) Review and analysis of the applicant's application and evidence of expertise and ability, (2) approval of accreditation upon determination that the applicant meets the requirements for

accreditation, and (3) site evaluation to determine compliance with the Act and regulations.

(21) *Application Fees Incurred From Notifications of Noncompliance.* Commenters questioned whether a new application for accreditation, following the correction of deficiencies identified in the notification of noncompliance, would require a second application fee. The commenters stated that fees paid for the initial application should cover timely resubmission of the application after correction of deficiencies. In this proposal, we have replaced the flat fee for accreditation with an hourly user fee system, which will involve billing for actual time used in the accreditation process. Accordingly, there will be additional costs to applicants who submit a description of the actions taken to correct the deficiencies noted in the notification of noncompliance.

(22) *Peer Review Panels.* Comments were received expressing various opinions regarding the peer review panel provisions of the first proposal. First, commenters stated that peer review panels should participate in site evaluations. Prior to publishing the first proposal, the Department received some public input which also suggested the use of peer reviewers in the site evaluation process. As noted in the first proposal, we did not provide for such participation because we believed that the use of peer reviewers could pose an excessive burden on the certifying agents, would increase the costs of conducting site evaluations, and could delay site evaluations and because AMS staff are well qualified to perform the site evaluations. We have made no change to our proposal as a result of this comment.

Second, commenters stated that peer review panels should participate in the initial review of an application for accreditation. We believe this would not be an effective use of panel members' talents and expertise and would not be cost effective. We have made no change to our proposal as a result of this comment.

Third, an industry association stated that section 6516(a) of the Act clearly states that the Secretary shall consider a report, not three to five individual reports, in determining whether to approve an applicant for accreditation. We do not agree that the Act requires a single report, nor do we believe that it is usual to have consensus in peer review. We also believe that it is impractical to bring peer reviewers together for the purpose of reviewing the information provided and drafting a single report. The Administrator could convene a peer review panel meeting or

conference call if necessary. Such meeting or conference call would be conducted in a manner that would ensure the actions of panel members are carried out on an individual basis with any opinions and recommendations by a member being made individually. A peer review panel meeting or conference call will be held solely to give and receive information. Such meeting or conference call will not be held for the purpose of achieving consensus by the peer review panel. The written report of each panel member would reflect the particular knowledge, expertise, and opinion that its author-member brings to the panel. The Administrator will consider all points in the individual reports in making a determination as to the continued operation of the accredited certifying agent. We have made no change to our proposal as a result of this comment.

Fourth, commenters stated that the peer review panel regulations should be revised to specify what situations, other than continuation or renewal of accreditation, would trigger a peer review; that a peer review panel should be used in determining noncompliance with accreditation requirements; and that a peer review panel should be convened to review any decision of noncompliance prior to initiation of proceedings to suspend or revoke a certifying agent's accreditation. The first proposal provided that the Administrator may convene a peer review panel at any time for the purpose of evaluating a certifying agent's activities under the Act and 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 regulations. We do not believe that it is practical or necessary to require the use of peer review panels in determining noncompliance and decisions to suspend or revoke an accreditation. We have made no change to our proposal as a result of these comments.

(23) *Purpose of Annual Reporting Requirements.* At least one commenter was confused regarding the purpose for having certifying agents submit annual reports to the Administrator. The reports would update information and evidence of expertise and ability previously submitted by the certifying agent; support any changes being requested in the areas of accreditation; describe the measures that were implemented in the previous year and any measures to be implemented in the coming year to satisfy any terms and conditions determined by the

Administrator to be necessary, as specified in the most recent notification of accreditation; and describe the results of the most recent inspector performance appraisals and program evaluation and adjustments to the certifying agent's operation and procedures implemented and intended to be implemented in response to the appraisals and program evaluation. The first proposal stated that this information would be reviewed by the Administrator to determine whether the certifying agent was maintaining its accreditation by satisfying the requirements of the Act and regulations and to assess the need for a site evaluation. 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 the certifying agents. We have made no change to our proposal as a result of this comment.

Accreditation—Additional Provisions

Upon further review of the accreditation provisions in the first proposal, we have decided to propose the following additions and changes.

(1) *Access to Records.* We have added the requirement that the records maintained by the certifying agent under the Act and regulations be made available for copying by authorized representatives of the Secretary and the applicable State program's governing State official. This addition is necessary to ensure that authorized representatives are able to obtain copies of records applicable to a review or an investigation regarding compliance with the Act and regulations. This addition, found at § 205.501(a)(9), is authorized under section 6506 of the Act.

(2) *Conflicts of Interest.* A conflict of interest regulation in the first proposal required that certifying agents prevent conflicts of interest by not certifying an operation through the use of any employee that has or has held a commercial interest in the operation, including the provision of consulting services, within the 12-month period prior to the application for certification. This regulation was closely related to a second regulation which required certifying agents to prevent conflicts of interest by not assigning an inspector to perform an inspection of an operation if the inspector has or has held a commercial interest in the operation, including the provision of consulting services, within the 12 months prior to conducting the inspection. For clarification, this proposal combines the regulations at § 205.501(a)(11)(ii). This

new regulation provides for excluding any person, including contractors, with conflicts of interest from work, discussions, and decisions in all stages of the certification process and the monitoring of certified production and handling operations for all entities in which such person has or has held a commercial interest, including an immediate family interest or the provision of consulting services, within the 12-month period prior to the application for certification. This regulation would permit a certifying agent to certify the operation of an employee or contractor or an employee's or contractor's immediate family member provided the employee or contractor was not used in certifying the production or handling operation.

(3) *Reporting Requirements for Certifying Agents.* The first proposal required a certifying agent to submit to the Administrator a copy of each notification of noncompliance issued simultaneously with its issuance to the certification applicant or the certified operation. It also required a certifying agent to submit to the Administrator on a quarterly calendar basis the name of each operation certified. In this proposal, we have expanded the provision to provide that certifying agents must submit to the Administrator: (1) A copy of any notice of denial of certification, notification of noncompliance, notification of noncompliance correction, notification of proposed suspension or revocation, and notification of suspension or revocation issued simultaneously with its issuance; and (2) on a quarterly calendar basis, the name, address, and telephone number of each operation granted certification. This information is needed to facilitate oversight and to ensure that we have relatively current data for responding to inquiries involving the granting of certifications by certifying agents. These changes are included in § 205.501(a)(14).

We anticipate using the data collected under § 205.501(a)(14) to establish and maintain 2 Internet databases. The first Internet database would be accessible to the general public and would include the names and other appropriate data on certified organic production and handling operations. The second Internet database would be password protected and only available to accredited certifying agents and USDA. This second database would include data on production and handling operations issued a notification of noncompliance, noncompliance correction, denial of certification, certification, proposed suspension or revocation of certification, and

suspension or revocation of certification. Certifying agents would use the second Internet database during their review of an application for certification.

(4) *Requirements for Nondiscrimination.* We have included at § 205.501(d) the provision that no private or State entity accredited as a certifying agent under subpart F shall exclude from participation in or deny the benefits of the NOP to any person due to discrimination because of race, color, national origin, gender, religion, age, disability, political beliefs, sexual orientation, or marital or family status. This regulation is consistent with USDA regulations which prohibit discrimination in its programs and activities.

(5) *Submission of Policies and Procedures.* The first proposal required an applicant for accreditation as a certifying agent to submit documents and information to demonstrate the applicant's expertise in organic farming or handling techniques, its ability to fully comply with and implement the organic certification program, and its ability to comply with the requirements for accreditation. Much of the documentation and information required involved submission of a description of a policy or procedure to be used by the certifying agent. In this proposal we have changed the requirement from submission of a description of the policy or procedure to submission of a copy of the actual policy or procedure. This will facilitate the Department's determination of an applicant's eligibility for accreditation by providing more complete information. By requiring a copy of each policy and procedure, which should already be in the possession of the applicant, rather than a description of each, we have lessened the burden on applicants for accreditation. This change is found in § 205.504 of this proposal.

(6) *Public Access to Certification Certificates.* In this proposal, we have added the requirement that certifying agents make copies of certification certificates issued during the current and 3 preceding calendar years available to the public. Such documents may be useful to consumers wishing to verify that an operation is certified to produce and label agricultural products as organic. Copies of certification certificates will be especially valuable in assisting handlers in assuring that the products they receive labeled as organic were produced and handled by certified organic operations. This requirement is found at § 205.504(b)(5)(i).

(7) *Submission of Residue Testing Procedures.* We believe that applicants for accreditation should provide evidence of expertise and ability in meeting the sampling and residue testing requirements of these regulations. Therefore, we have added the requirement that applicants for accreditation submit a copy of the procedures to be used for residue testing. This requirement is found at § 205.504(b)(6). Residue testing requirements are found at § 205.670.

(8) *Elimination of Section on Confirmation of Accreditation.* We have amended the section on approval of accreditation by adding the duration of accreditation provision formerly included in the first proposal's section on confirmation of accreditation. We have also eliminated the section on confirmation of accreditation. We have taken this action to eliminate the confusion created by having a section on approval of accreditation and a section on confirmation of accreditation.

(9) *Denial of Accreditation.* We have amended the denial of accreditation regulations and eliminated the section on denial of confirmation of accreditation. We have taken this action to eliminate the confusion created by having a section on denial of accreditation and a section on denial of confirmation of accreditation. We have added to the denial of accreditation regulations that a notification of noncompliance can be issued based on the findings of a site evaluation.

Under the first proposal's denial of accreditation regulations, the Administrator could institute proceedings to deny accreditation to an applicant who did not correct the deficiencies noted in a notification of noncompliance within the time specified. In this proposal, we have amended these regulations to provide that the Administrator will provide the applicant with a written notification of accreditation denial or begin proceedings to suspend or revoke the certifying agent's accreditation if accredited prior to a site evaluation. Such action will be taken when the applicant fails to correct the deficiencies, report the corrections by the date specified, or file an appeal by the date specified in the notification of noncompliance.

We have also clarified that an applicant who has received written notification of accreditation denial or had its accreditation suspended may apply for accreditation again at any time. Additionally, we have provided that a private certifying agent whose initial accreditation is revoked following an initial site evaluation will

be ineligible for accreditation for a period of not less than 3 years following the date of such determination. This period of ineligibility is consistent with section 6519(e) of the Act. These changes are included in § 205.507.

A certifying agent accredited prior to an initial site evaluation whose site evaluation reveals that the certifying agent is not properly adhering to the provisions of the Act or these regulations will be subject to suspension of its accreditation. A private certifying agent accredited prior to an initial site evaluation who's site evaluation reveals that the certifying agent has violated the provisions of the Act and these regulations or that falsely or negligently certifies any production or handling operation that does not meet the terms and conditions of this national organic certification program as an organic operation will be subject to revocation of its accreditation. Section 205.660(b) of subpart G provides that the Secretary may initiate suspension or revocation proceedings against a certified operation upon initiation of suspension or revocation proceedings against or upon suspension or revocation of the certified operation's certifying agent's accreditation.

(10) *Peer Review Panels.* We have removed the provision which provided that the Administrator may convene a peer review panel at any time for the purpose of evaluating an applicant for accreditation or a certifying agent's activities under the Act and regulations. This change has been made because peer review panels will only be used to assist in the evaluation of applicants for accreditation, amendment to an accreditation, and renewal of accreditation.

Subpart G—Administrative

The National List of Allowed and Prohibited Substances

Proposal Description

This subpart contains criteria for determining which substances and ingredients are allowed or prohibited in products to be sold, labeled, or represented as "organic" or "made with organic (specified ingredients)." It establishes the National List of Allowed and Prohibited Substances (National List) and identifies specific substances which may or may not be used in organic production and handling operations. Sections 6504, 6510, 6517, and 6518 of the Organic Foods Production Act (OFPA) of 1990 provide the Secretary with the authority to develop the National List. The contents of the National List are based upon a Proposed National List, with

annotations, as recommended to the Secretary by the National Organic Standards Board (NOSB). The NOSB is established by the OFPA to advise the Secretary on all aspects of the National Organic Program (NOP). The OFPA prohibits synthetic substances in the production and handling of organically produced agricultural products unless such synthetic substances are placed on the National List.

The first category of the National List includes synthetic substances allowed for use in organic crop production. The second category includes nonsynthetic substances prohibited for use in organic crop production. The third category of the National List includes synthetic substances allowed for use in organic livestock production. The fourth category includes nonsynthetic substances prohibited for use in organic livestock production. The fifth category of the National List includes nonagricultural (nonorganic) substances allowed as ingredients in or on processed products labeled as "organic" or "made with organic (specified ingredients)." The final category of the National List includes nonorganically produced agricultural products allowed as ingredients in or on processed products labeled as "organic" or "made with organic (specified ingredients)." This subpart also outlines procedures through which an individual may petition the Secretary to evaluate substances for developing proposed National List amendments and deletions.

National List (General)

The NOSB is responsible for making the recommendation of whether a substance is suitable for use in organic production and handling. The OFPA authorizes the NOSB to develop and forward to the Secretary a Proposed National List and any subsequent proposed amendments. In March 1995, the NOSB initiated a petition process to solicit public participation in identifying specific materials to be added to the National List. The NOSB convened a Technical Advisory Panel (TAP) to review substances identified in the petition process and made extensive recommendations on a Proposed National List during its meetings in 1995 and 1996. In 1999, the NOSB selected materials left from the original petition process to authorize a second round of TAP reviews. The NOSB used these updated TAP reviews to make additional recommendations on the Proposed National List at its October 1999 meeting. With the exception of four substances on which the Secretary did not concur with the NOSB

recommendations and minor formatting changes, the National List in this proposal corresponds to the recommendations on allowed and prohibited substances made by the NOSB. The National List in this proposal has also been developed in consultation with the Food and Drug Administration (FDA), the Environmental Protection Agency (EPA), and the Food Safety Inspection Service (FSIS) of USDA. Additionally, we have made changes in response to public comment received on the first proposal.

Nothing in this subpart alters the authority of other Federal agencies to regulate substances appearing on the National List. FDA establishes safety regulations on approved and prohibited uses of substances in food production and processing. FSIS has the authority to determine efficacy and suitability regarding the production and processing of meat, poultry, and egg products. FDA and FSIS restrictions on use or combinations of food additives or ingredients take precedence over the approved and prohibited uses specified in this proposal. Any combinations of substances in food processing not already addressed in FDA and FSIS regulations must be approved by FDA and FSIS prior to use. Use-of-substance requirements are proposed by FDA and FSIS in rulemaking actions and are frequently updated with revised use requirements. It is important that certified organic producers and handlers of both crop and livestock products consult with FDA regulations in 21 CFR parts 170 through 199 and FSIS regulations in this regard. All feeds, feed ingredients, and additives for feeds used in the production of livestock in an organic operation must comply with the Federal Food, Drug, and Cosmetic Act (FFD&CA). Animal feed labeling requirements are published in 21 CFR part 501, and new animal drug requirements and a listing of approved animal drugs are published in 21 CFR parts 510–558. Food (feed) additive requirements, a list of approved food (feed) additives generally recognized as safe substances (GRAS), substances affirmed as GRAS, and substances prohibited from use in animal food or feed are published in 21 CFR parts 570–571, 21 CFR part 573, 21 CFR part 582, 21 CFR part 584, and 21 CFR part 589, respectively. Furthermore, the Food and Drug Administration has worked closely with the Association of American Feed Control Officials (AAFCO) and recognizes the list of additives and feedstuffs published in the AAFCO

Official Publication, which is updated annually.

National List—Changes Based On Comments

This subpart differs from our first proposal in several respects as follows:

(1) *Genetically Engineered Organisms (GEO's)*. To solicit public comment on the use of genetically engineered organisms in organic production and handling, we included two such materials on the National List in the first proposal. As discussed in Production and Handling—Subpart C, we received many thousands of comments opposing the use of substances or organisms produced through genetic engineering in organic production and handling. Many commenters expressed strong concerns that GEO's do not meet current consumer expectations of organic agriculture or an organically produced product. They stated that existing national and international organic certification standards clearly and consistently prohibit GEO's. Accordingly, this proposal prohibits GEO's and their derivatives and the products of GEO's and their derivatives in any product or ingredient that is sold, labeled, or represented as organic. As a result of the prohibition, the National List does not contain any materials derived from GEO's.

(2) *Inclusion of Substances not Recommended by the NOSB*. The first proposal allowed some synthetic substances in organic crop production and handling that the NOSB had not included on the proposed National List. Citing the statutory requirements of the OFPA, commenters were overwhelmingly opposed to adding substances to the National List that had not been recommended by the NOSB. Every substance on the National List in this proposal was favorably recommended by the NOSB.

With four exceptions, the National List included in this proposal contains every substance that the NOSB recommended to allow in organic production and handling. The Secretary has not accepted the NOSB recommendations to allow sulfur dioxide in the production of wine labeled as "made with organic grapes." Additionally, the Secretary has not concurred with the NOSB recommendation to allow the antibiotics, Streptomycin and Terramycin, in organic crop production or to allow livestock producers to administer synthetic Oxytocin for approved organic veterinary practices. The Secretary decided not to add sulfur dioxide to the National List because its use produces sulfites, which are

prohibited in the OFPA. Streptomycin and Terramycin were not added to the National List for use in crop production in order to be consistent with this proposal's prohibition on the use of all antibiotics in animal production. The Secretary's decision not to allow livestock producers to administer synthetic Oxytocin is based on extensive public comment that opposed the use of animal drugs including hormones in organic livestock operations. Many certifying agencies have allowed producers to administer Oxytocin to animals that experience severe complications resulting from labor. While most of the public comment strongly opposed the use of synthetic hormones in organic dairy production, Oxytocin has some uses that do not involve lactation but are instead related to an animal's postpartum survival. Not allowing Oxytocin in organic operations is responsive to the public comment opposing the use of synthetic hormones but does preclude the use of an animal medication that some producers have previously been able to use in emergency situations.

(3) *Prohibited Nonsynthetic Substances.* The National List in the first proposal contained no prohibited nonsynthetic (natural) substances. Many commenters requested that the four nonsynthetic substances which the NOSB proposed to prohibit be added to the National List. We agree with this position, and this proposal lists ash from manure burning, mined sodium fluoaluminate, strychnine, and tobacco dust as natural substances that are prohibited in organic crop production and handling. In addition, we have included arsenic and lead salts on the National List of prohibited natural substances in accordance with provisions of the OFPA.

(4) *Annotations on National List Substances.* The National List in the first proposal did not include all of the annotations originally developed by the NOSB for the materials it recommended to include on the National List. The OFPA stipulates that when basing the National List upon the NOSB's recommendations, the Secretary shall include "an itemization, by specific use or application," of each synthetic substance permitted or natural substance prohibited. This itemization, commonly known within the organic industry as an annotation, has been used by existing State and private certification agents to regulate the use of allowed materials. Annotations can establish allowable sources or procedures for obtaining a substance, specify the crops or conditions for

which it may be applied, establish use restrictions based on environmental monitoring, or create other conditions to govern the use of a substance.

Many commenters stated that removing annotations diminished the NOSB's role in advising the Secretary on the content of the National List. Commenters also stated that annotations are essential for ensuring that substances are used in a manner which is consistent and compatible with a system of organic production and handling. Considering how annotations have been applied in regulating the use of allowed substances by State and private certifying agents, we have incorporated every feasible NOSB-proposed annotation in this proposal.

(5) *Incidental Additives.* The first proposal stated that a nonagricultural synthetic substance occurring as an incidental additive, including a processing aid, could be used in organic production and handling without having to be added to the National List. This position was based on FDA and FSIS regulations which require that active ingredients, but not incidental additives, appear on a product label. Because incidental additives were not active ingredients in organically processed food under these regulations, the first proposal maintained that they were not prohibited by the OFPA and would not need to be added to the National List.

Thousands of commenters responded with varying opinions on this subject. Many commenters approved of the proposed approach, generally stating that processing aids are essential and needed for most agricultural products. These commenters felt that eliminating their use entirely would greatly limit handlers' ability to produce a wide variety of organic products. However, other commenters strongly opposed allowing the use of any nonagricultural synthetic substance that had not been petitioned, reviewed, and recommended by the NOSB; published for comment in the **Federal Register**; and then added by the Secretary to the National List. Some commenters protested the use of any synthetic incidental additives in organic handling operations. They stated that their use is not consistent with the principles of organic agriculture and that consumers currently do not believe that such aids and additives are used in organically processed products.

Prior to the first proposal, the NOSB reviewed this issue and recommended allowing both synthetic and nonsynthetic incidental additives in processed organic products. The NOSB's 1995 recommendation stated that nonsynthetic, nonagricultural

products used as ingredients, processing aids, or incidental food additives should be categorically allowed in organically processed products unless specifically prohibited and that synthetic, nonagricultural products should not be used as ingredients, processing aids, or incidental food additives unless specifically included on the National List. The NOSB applied these recommendations to processed foods labeled "organic" and "made with organic (specified ingredients)." However, the OFPA does not allow the categorical allowance for nonsynthetic, nonagricultural products. Section 6510(a)(4) of the OFPA requires that any nonorganically produced ingredient added to an organic product must be included on the National List.

The NOSB revisited this issue at its February 1999 meeting when it adopted criteria for accepting (adding to the National List) a synthetic processing aid or adjuvant. These criteria are an interpretation and application of the general evaluation criteria for synthetic substances contained in the OFPA that the NOSB will apply to processing aids and adjuvants. To review the adopted criteria, the public can visit the USDA NOP website: www.ams.usda.gov/nop/nosbfeb99.html or write Program Manager, Room 2945 South Building, U.S. Department of Agriculture, AMS, Transportation and Marketing Programs, NOP, PO Box 96456, Washington, DC 20090-6456. The NOSB adopted these criteria as internal guidelines for evaluating processing aids and adjuvants. The adopted criteria do not supercede the criteria contained in the OFPA, or replace FDA's authority to regulate food additives.

We are proposing that to be used in or on a processed product labeled as "organic" or "made with organic (specified ingredients)," a nonagricultural substance, whether synthetic or nonsynthetic, must be included on the National List. This position supports the NOSB recommendation that synthetic substances be allowed in organic processed foods but incorporates the National List requirement reflected in public comment. We have divided the materials on this list (§ 205.605) in the current proposal to reflect the recommended distinction made by the NOSB between synthetic and nonsynthetic substances. This distinction does not affect how the substances may be used. We recognize that many commenters, basing their argument on the OFPA, objected to allowing any synthetic substances in processed organic products. However, we believe that the OFPA does allow

synthetic substances, when added to the National List, to be used in this manner. The criteria utilized by the NOSB for evaluating processing aids and adjuvants are very restrictive and, if applied to all incidental additives, should minimize the number of substances added to the National List.

(6) *Inert Ingredients in Formulated Products.* The first proposal addressed the presence of synthetic inert ingredients in formulated products used as production inputs in organic crop or livestock operations. Formulated products are multiingredient compounds including pesticides, fertilizers, and animal drugs and feeds. In accordance with the OFPA, we proposed that a formulated product containing an inert ingredient could be used, provided that the substance did not appear on EPA's List 1 as an Inert of Toxicological Concern. We also prohibited the use of synthetic inerts not on EPA List 1 if the substance was also used as an active ingredient that had not been added to the National List. To review or to receive the most current listing of the EPA Inerts, the public can visit EPA's Internet home page at <http://www.epa.gov/opprd001/inerts/lists.html>, or write to Registration Support Branch (Inerts), Registration Division (Mail Code 7505C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460.

The first proposal interpreted the statutory prohibition on EPA List 1 inerts as allowing the use of synthetic inert ingredients that were not specifically prohibited. This allowed the use of products containing synthetic inert substances (provided that they were not also used as active substances) included on the other EPA inert lists: List 2, Potentially Toxic Inerts; List 3, Inerts of Unknown Toxicity; and List 4, Inerts of Minimal Concern. We also applied the term, "inert," to all nonactive ingredients contained in any formulated product used in organic production. This meant that the nonactive ingredients in animal feeds (fillers or additives), animal drugs (excipients), and fertilizers (carriers or adjuvants) would only be prohibited if they were classified by the EPA as List 1 inerts.

We received many comments stating that our restrictions on inert ingredients were too permissive and would result in many traditionally prohibited materials being used in organic production. Commenters stated that the statutory prohibition on EPA List 1 inerts did not imply that all other inerts should be allowed and argued that the NOSB had the authority to prohibit additional

substances. Citing the uncertainty associated with EPA List 2 (potentially toxic) and EPA List 3 (unknown toxicity) inert ingredients, they questioned how such substances could satisfy the criteria in OFPA for adding synthetic substances to the National List. Commenters also opposed expanding the definition of inert to include nonactive ingredients in all formulated products. They stated that the EPA classifies only those inerts used in pesticides, and that many of the substances routinely used in other types of formulated products were not subject to review. Therefore, substances not used in pesticides would not appear on any EPA list and would be allowed. Finally, commenters cited the disparity between the allowance for synthetic inert ingredients in the first proposal and the more restrictive substance review procedures used by existing organic certifying agents.

The NOSB responded to the provisions for inert ingredients contained in the first proposal. At its meeting in March 1998, the NOSB stated that synthetic compounds should not be allowed in production inputs unless they appear on the National List. In February 1999, the NOSB voted to prohibit EPA List 1 and 2 inerts, prohibit EPA List 3 inerts unless specifically allowed by the NOSB, and allow EPA List 4 inerts unless specifically prohibited. The NOSB also recommended full disclosure of all ingredients in formulated products, called for an expedited review of EPA List 3 inerts currently in common use in organic production, and endorsed an 18-month phase-out period for EPA List 3 inerts not ultimately allowed.

In this proposal, only EPA List 4 inerts are allowed as ingredients in formulated products used in organic production. This would not include varieties of EPA List 4 substances such as corn starch, lecithin, or citric acid that are the product of excluded methods. Additionally, the term inert is restricted to nonactive ingredients in pesticides. Synthetic nonactive ingredients in formulated products used as production inputs, including fertilizers, animal drugs, and feeds, must be included the National List. While the OFPA prohibits using a fertilizer containing synthetic ingredients or a commercially blended fertilizer containing prohibited materials, the requirement does not apply to synthetic substances included on the National List. The NOSB recommended and the Secretary concurs that certain synthetic substances used in fertilizer-formulated products should be included on the

National List. We have retained the provision from the first proposal prohibiting the use of any formulated product containing a EPA List 1 Inert. Using the criteria established in the OFPA for evaluating synthetic substances, the NOSB may review inert ingredients on EPA List 2 or 3 as well as other synthetic, nonactive substances used in formulated products for inclusion on the Proposed National List it forwards to the Secretary.

We recognize that inert ingredients in pesticides and similar substances in other formulated products pose one of the most problematic examples of the use of synthetic materials in organic production. For example, verifying the use of inerts and similar substances such as fillers, carriers, additives, and excipients has been difficult because they are not required to appear on ingredient labels, and formulators typically treat product formulas as confidential information. At times, certifying agents have been unable to determine the exact composition of formulated products proposed for use in organic production. In other instances, organic producers have applied formulated products containing inert ingredients and similar substances that are not specifically allowed. We are challenged with balancing standard practice with the strict statutory requirement that producers and handlers apply only those synthetic substances added to the National List. As sanctioned by OFPA, synthetic substances can be used in organic production as long as they appear on the National List. The development and maintenance of the National List has been and will be designed to allow the use of a minimal number of synthetic substances that are acceptable to the organic industry and meet the OFPA criteria.

Two principles will be essential for responding to this challenge: greater disclosure of the contents of formulated products and an expedited review of inert ingredients and other nonactive substances. The OFPA recognized the need for disclosure by requiring the NOSB to work with formulators to obtain a complete list of ingredients in their products. The NOSB has initiated this work, and its effort is ongoing as of the date of this publication. It is our understanding from the comments, hearings, and information considered by the NOSB that the organic industry has made considerable progress on disclosure of inert ingredients since the passage of OFPA. Formulators have responded to the incentive to provide products using EPA List 4 inert ingredients, and certifying agents have

gained greater access to information on product composition. EPA has expressed its willingness to expedite the review of its List 2 and 3 inerts, which the NOSB identifies as particularly important in formulated products widely used in organic operations. The organic industry should clearly understand that NOSB evaluation of the wide variety of inert ingredients and other nonactive substances will require considerable coordination between the NOP, the NOSB, and industry. Materials review can be anticipated as the NOSB's primary activity during NOP implementation. Considering the critical nature of this task, the organic industry should make a collaborative effort to prioritize for NOSB review those substances which are essential to organic production and handling.

We recognize that more work is needed for this policy to satisfy the needs of organic producers and handlers, product formulators, and consumers. We are requesting comment on the proposed requirements for inert ingredients in formulated products. We are sensitive that an abrupt prohibition on synthetic substances which may have knowingly or unknowingly been used in the past but which are not added to the National List may disrupt many well-established and accepted production systems. However, our assessment is that the benefits of a clear policy consistent with the OFPA, NOSB recommendations, and public comment outweigh the costs. The net effect will be greater consumer confidence in USDA's organic label and more products that are tailored to the needs of organic producers.

(7) *Use of Veterinary Medicines.* The OFPA prohibits certain routine uses of veterinary medications (specifically subtherapeutic doses of antibiotics) but allows their administration in the presence of illness. The first proposal added antibiotics to the National List because their use had been evaluated and approved by applicable regulatory agencies, pursuant to FDA requirements, and because they had to be included on the National List to be used in organic livestock production.

We received many comments opposing the use of antibiotics in organic livestock production. Commenters expressed general concern over microbial resistance to antibiotics and expressed a desire to source food products without antibiotics. This proposal removes antibiotics from the National List of approved synthetic substances for livestock use.

(8) *Removal of Substances from the National List.* The first proposal outlined a petition process for amending

the National List and included an extensive list of information to be provided for reviewing a substance. Some commenters recommended that this section be amended to include procedures for deleting substances from the National List. The OFPA and the first proposal indicated that the NOSB would review substances added to the National List at least on a 5-year basis and recommend to the Secretary any substances that should be removed. We concur with commenters that removal of a substance should not have to wait for such a review cycle. Thus, a petition to remove a substance from the National List may be filed at any time. The information contained in the petition for removal of a substance will be provided by AMS upon request. The NOSB will evaluate substance removal petitions and forward a recommendation to the Secretary. Commenters suggested that any changes to the National List be published in the **Federal Register** for public comment. All proposed changes to the National List will be published in the **Federal Register**.

(9) *Use of Sulfur Dioxide.* The first proposal allowed the use of sulfur dioxide in crop production and as an ingredient in or on organic processed products. The NOSB had recommended that sulfur dioxide be permitted in the processing of organic wine and for smoke bombs used underground to control rodents. Numerous commenters opposed the use of sulfur dioxide in organic wine because its use produces sulfites, which are prohibited in the OFPA, as a by-product. We concur with the commenters and further believe that the trend in the organic industry, as evidenced by the California Department of Food and Agriculture's Preliminary Organic Materials List of September 1998, is to prohibit all uses of sulfur dioxide except in underground rodent control. Therefore, we are proposing to allow sulfur dioxide for underground control of rodents and to prohibit its use as an ingredient in or processed food including the production of organic wine.

National List—Additional Provisions

Upon further review of the provisions in the first proposal, we have decided to propose the following additions and changes.

(1) *New Additions to the National List.* During the October 1999 meeting, the NOSB reviewed substances and made new recommendations to the Proposed National List. The Secretary concurs with the recommendations from that meeting and this proposal adds those substances with the applicable annotations to the National List. These

substances are: Potassium Bicarbonate (205.601(d)), Glycerin (205.603(a)), Phosphoric Acid (205.603(a) and 205.605(b)), Ivermectin (205.603(a)), Chlorhexidine (205.603(a)), and Ethylene (205.605(b)). This proposal establishes conditions that allow producers to administer the parasiticide Ivermectin to breeder stock and dairy stock in organic livestock operations. Treating organically managed slaughter stock with Ivermectin is prohibited. These provisions are based on the recommendations developed by the NOSB at its October 1999 meeting. The NOSB's recommendations from that meeting were derivative of many years of work addressing how to establish and enforce the conditions allowing use of synthetic parasiticides. The OFPA identifies livestock parasiticides as a category of substances which may be included on the National List and also prohibits the use of synthetic internal parasiticides on a routine basis. The determination of what constitutes a routine basis for parasiticide use has been challenging given the diversity of animals, production systems, and environmental factors which are covered by a national organic standard.

In this proposal, the conditions under which Ivermectin may be used apply to the health care history of the animal prior to treatment and the certification of products derived from the animal after treatment. The pretreatment conditions are designed to ensure that the producer is using a comprehensive management system to prevent the introduction and transmission of parasites among the animals in his or her care. Producers must document in their organic system plan preventative practices such as quarantine and fecal exams for all incoming stock, appropriate pasture rotation and management, culling of infested livestock, and vector and intermediate host control. A producer may administer an allowed synthetic parasiticide only after all applicable management practices and nonsynthetic treatments have been employed. A producer must receive the approval of their certifying agent before using a synthetic parasiticide. In collaboration with the NOSB, we will be developing program manuals detailing preventive management practices for specific livestock species to assist producers and certifying agents in determining when the use of synthetic parasiticides is allowable.

This proposal also contains provisions addressing the posttreatment condition of livestock which are administered Ivermectin. These conditions are included as an

annotation to Ivermectin on the National List and are consistent with the requirements contained in § 205.238(b)(1)(2) of the regulatory text for administering any allowed synthetic parasiticide. In compliance with the recommendations of the NOSB, we are proposing that a producer may not administer Ivermectin to breeder stock during the last third of gestation if the progeny is to be sold, labeled, or represented as organically produced. Additionally, a producer must observe a 90-day withdrawal period before selling milk or milk products produced from an animal treated with Ivermectin as organically produced. The Food and Drug Administration exercises responsibility for determining and enforcing the withdrawal intervals for animal drugs. No food safety arguments are used or implied to support the use of extended withdrawal periods. Rather, we determined that extended withdrawal periods are more compatible with consumer expectations of organically raised animals.

Ivermectin is the first synthetic parasiticide that the Secretary has proposed adding to the National List, and allowing its use could significantly affect organic management practices. The FDA has approved 18 animal drugs containing Ivermectin that are labeled for use on one or more animals including beef and dairy cattle, sheep, swine, and several minor species. A total of 11 of these drugs are not covered by this proposed rule: three have additional synthetic active ingredients not on the National List and eight others are labeled for nonfood uses. (They are used on horses not for food use, dogs, and cats.) While there are no approved uses of Ivermectin on lactating dairy animals, the remaining seven food-use products could be administered to breeder stock and dairy stock either prior to lactation or during a dry period.

Future NOSB meetings will consider new proposals of substances to be added to the National List.

(2) *Petition Process to Amend the National List.* We are modifying the contents of the petition for amending the National List that was contained in the first proposal. We are proposing that any person requesting a change in the National List should request a copy of the petition procedures from the NOP Program Manager. The procedures will include a list of information that has to be provided for consideration of a change in the National List. Under the provisions in the first proposal, the NOP would be required to go through rulemaking every time it sought to update contents of the petition. Under this proposal, the NOP will amend the

requirements of the petition process and publish the changes in the **Federal Register**. This revised process will help to expedite amending the National List and keep the National List more current. We anticipate that amendments to the National List will be made on an annual basis, depending upon the number of substance petitions filed. Substances petitioned for inclusion onto the National List will be reviewed by the NOSB, which will forward a recommendation to the Secretary. All amendments to the National List will be published for comment in the **Federal Register**.

State Organic Certification Programs

The Act provides that each State may implement a certification program for producers and handlers of agricultural products that have been produced and handled within the State, using organic methods that meet the requirements of this regulation. Each State organic certification program must be approved by the Secretary. A State organic certification program's organic standards and requirements cannot exceed these National Organic Program (NOP) regulations unless the State petitions for, and the Secretary approves, more restrictive requirements. The sections covering State programs, beginning with § 205.620, establish: (1) The requirements for a State organic certification program and amending such a program; and (2) the process for initial approvals of programs and program amendments. A process for review and approval of a State's organic certification program every 5 years will be addressed in subsequent rulemaking.

Proposal Description

There are a wide variety of organic certification programs now operating in different States. Approximately 31 States currently have, or are developing, their own State organic certification programs. At least 13 of those use State government agencies or contracted private certifying agents to certify organic operations in the State. Thus, at least 19 States do not have State organic programs and approximately 37 States do not have State Government or State-designated private certifying agents. Under this proposal, States may utilize these NOP standards and requirements and not have State oversight or responsibility for administration of the NOP in the State. On the other hand, a State may petition the Secretary for approval to add its unique State requirements to the NOP and agree to administer the national program in the State.

Requirements of a State Organic Certification Program. Under the Act and the NOP, a State, through the State program's governing State official, must submit to the Secretary a copy of the proposed State organic certification program. The governing State official must submit an affidavit or memorandum of understanding agreeing to meet the 11 general requirements of an organic program, as specified in section 6506(a) of the Act. Specifically, the governing State official must agree to: (1) Require that product sold or represented as organic must be produced and handled only by certified organic operations; (2) require that participating organic producers and handlers establish organic plans for their operations; (3) allow certified producers and handlers to appeal adverse decisions under appeal provisions of these regulations; (4) require that certified operations certify annually that they have complied with the NOP; (5) provide for annual on-site inspections of certified operations by certifying agents; (6) require periodic residue testing by certifying agents; (7) provide for appropriate and adequate enforcement procedures which are consistent with the NOP; (8) protect against conflict of interests as specified in these regulations; (9) provide for public access to certification documents; (10) provide for collection of reasonable fees; and (11) require other terms and conditions as may be established by the Secretary. The NOP will assume these responsibilities in States that do not have an approved State organic certification program.

Supporting materials must be submitted addressing these general requirements, including such documentation as: authorizing State statutes, program goals and objectives, a description of the State's organic program office, codified compliance and appeals processes, and other information as may be requested by the Secretary. Written material must assess the State organic certification program's ability and willingness to administer the 11 general requirements for organic programs. Administration of these general requirements may require development of a unique working relationship between the State organic program and the NOP.

With the approval of its State organic certification program, the State must assume responsibility for administration of these 11 general requirements and any approved, more restrictive requirements in the State. For instance, a State's responsibilities will include oversight of certified organic production and handling operations to ensure that

products sold or represented as organic are produced and handled pursuant to these regulations. A State's organic certification program must include noncompliance and appeals procedures similar in force and effect to those outlined in the Compliance and Appeals provisions of this subpart. We expect that every State has in place official compliance procedures and formal appeal procedures which are used to enforce the State's regulatory programs. Those procedures should provide opportunity, as do the procedures in this subpart, for entities that may not be in compliance with State regulations, to come into compliance with those regulations. Such procedures should be clearly addressed in the State's organic certification application.

A proposed State organic certification program and any proposed amendment to such a program must be approved by the Secretary prior to being implemented by the State. A State may have other organic State sponsored projects, such as research and promotion programs, tax incentives, or transition assistance for organic producers within the State. Such programs would not be subject to the Secretary's approval, provided they do not conflict with the purposes of the Act.

Under certain circumstances, a State organic program may have more restrictive requirements in the State than corresponding NOP requirements for production and handling of organic product and certification of organic production and handling operations. These more restrictive requirements must be based on unique environmental conditions or specific production or handling practices particular to the State or portion of the State. Any environmental condition cited in the proposed amendment must be of a nature that implementation of these NOP regulations will be insufficient to correct the condition. The environmental condition must necessitate use of more restrictive practices or requirements rather than the corresponding practices and requirements provided in these regulations. Any such condition that is limited to a specific geographic area of the State will be required of organic production and handling operations active only in that geographic area. If approved by the Secretary, the more restrictive requirements will become the NOP regulations for appropriate organic producers and handlers in the State or area of the State.

We do not expect that a State's request for more restrictive requirements will cover a wide range of

organic production and handling standards. Rather, the increased requirements are likely to be limited to a specific production or handling practice or a more restricted use of approved National List substances to address needs or critical conditions in a specified geographic area(s). For instance, to protect an endangered lake or estuary, a State may have more restrictive buffer zone requirements than are provided in this regulation. Such a State may request that its more restrictive buffer zone requirements be established as the minimum buffer zone requirements of this regulation.

A State's more restrictive standards will not be applied to production and handling activities outside the State or a specified geographic area in the State. Further, the more restrictive standards do not apply to marketing of organic product and, thus, will not be used to restrict access of organic product produced in other States.

Section 205.621 provides that a State program's governing State official will submit to the Secretary a copy of a proposed State organic program or request for approval of any substantive amendment to a State's approved program.

State Program Approval Process. We envision the request and approval process will occur during the period between publication of the final rule and the projected effective date of the this national program (which will be announced in the final rule). Because requirements of a State organic program cannot exceed the requirements of this program unless warranted by unique conditions in the State, some State organic programs currently in effect may elect to discontinue their programs when the NOP becomes effective. Those programs simply will not request approval of their programs and their State organic requirements, in effect under the State program, will be superseded on the effective date of the NOP. State organic certification programs which seek approval of their programs will submit the required material and continue operations until the effective date of the NOP. We envision that all approved State organic certification programs will become effective under the NOP on the day the program becomes effective. A State wishing to establish a new State organic certification program under the NOP may submit the State program request and supporting material at any time. New programs submitted after this program becomes effective will be subject to the same review and approval process.

The submitted copy of the State organic certification program must be in its final form and ready for implementation. It cannot be altered by the State during the review process unless the change is cleared with the Secretary.

Amendments to State Programs. For amendment of a State organic program, the State program's governing State official must submit a copy of the proposed amendments and justification for them. The supporting material must document the unique environmental or ecological conditions or production practices in the State that necessitate use of more restrictive organic requirements. The supporting material must also explain how the more restrictive requirements will address the environmental condition. Likewise, the supporting material must explain how the increased requirements are better suited to agricultural conditions in the State.

Because State organic certification program requirements cannot be less restrictive than NOP requirements, any amendment to lower such requirements could only entail a relaxation of a more restrictive requirement previously approved by the Secretary. Thus, an amendment to relax a State program's requirement also must be reviewed by the Secretary. A decrease in a State organic certification program's more restrictive requirements must be justified, based on documented changes in the unique conditions or practices which warranted the increase in requirements.

Written materials supporting an amendment must assess how the more restrictive requirements further the purposes of and are consistent with the Act and these regulations. The written material should acknowledge that the more restrictive State requirements will not be used to limit or restrict access of organic products produced in other States or foreign countries to markets in the State. Also, supporting materials must explain how the amended requirements would affect the State program's governing State official's ability to administer the 11 general requirements. A request to relax a requirement also must address these issues.

The Secretary will review each State's application based on how closely it complies with the purposes and intent of the Act and the provisions of the NOP and how well its administrative capabilities and processes match up with the needs of the State's program.

The Act provides that the Secretary's review and determination of a new State organic certification program or a

program amendment will take no more than 6 months. AMS will notify the public upon approval of each State program. The public information will be made available to national agricultural news media and to all news media in the State. AMS will identify, among other things, any more restrictive certification requirements that are included in the approved State program.

A denial of a new program or program amendment will include a written explanation of why the proposal is denied and what changes will be needed for the program to be approved. The State may implement needed changes and submit a new program or program amendment.

Section 205.622 establishes that State organic certification programs will be reviewed at least once every 5 years by the Secretary and that a determination will be made within 6 months of the anniversary date as to continuation of the State organic certification program. We will issue appropriate procedures regarding this requirement at a later date, after AMS and the States have had an opportunity to administer the NOP and State programs.

State Programs—Changes Based On Comments

There are no changes based on comments.

State Programs—Changes Requested But Not Made

(1) *Allowing more restrictive State standards.* About a third of those commenting on State organic certification program provisions complained that the first proposal gave USDA complete control over State organic standards. A few suggested that a State with higher organic requirements should be able to prohibit the in-State sale of products certified only to the NOP or other State organic program requirements. Another commented that the NOP should “defer” to other State organic certification programs with higher standards.

While paragraph (b)(1) of section 6507 of the Act provides that States may establish more restrictive organic certification requirements, paragraph (b)(2) establishes parameters for those requirements. More restrictive State organic program requirements must: Further the purposes of the Act; be consistent with the Act; not discriminate against other States’ agricultural commodities; and be approved by the Secretary before becoming effective. As noted above, we expect that a State’s more restrictive requirements are likely to cover specific production or handling practices such

as more restricted use of approved National List substances or farming practices to address a State or area’s particular environmental conditions.

The Secretary must employ some consistent and common criteria for approving States requests for more restrictive State organic programs. The criteria for establishing such requirements must be consistent with the purposes of the Act. We believe the need to preserve, protect, and enhance unique environmental or farming conditions is a common criterion for all States. We believe such criteria are consistent with the stated goals of most, if not all, State organic programs and organic trade and farming organizations.

The more restrictive standards will not be applied to production and handling activities outside the geographic area of the State. Further, the more restrictive standards do not apply to marketing of organic product and, thus, will not be used to restrict access of organic product produced in other States. Clearly, prohibiting the sale of other States’ products is prohibited by the Act as well as other national laws covering interstate commerce in the United States. If some States were to restrict access to State markets, the purposes and the benefits of the national program would be lost.

Discriminatory marketing practices are prohibited under section 6507(b)(2)(c) of the Act. Thus, the purpose of more restrictive State organic requirements cannot be, as the commenters suggest, to allow claims of more organic or purer product. States will not be able to promote their products as being more organic because their products were produced under more restrictive State requirements. More restrictive State organic requirements will be authorized only as needed to respond to special environmental or production conditions in the State which necessitate more restrictive requirements. Any State’s request for less restrictive or lower organic standards than are required under this program will not be approved by the Secretary.

(2) *Treatment of private and State certifying agents.* Some private certifying agents commented that the first proposal would permit accredited State certifying agents to establish more restrictive standards than these regulations but prohibit private certifying agents from establishing their own more restrictive requirements. Under this program, State certifying agents will not unilaterally establish organic standards or requirements in a State. A State program’s governing State official may, upon approval of the

Secretary, establish a State organic certification program as an entity of the State’s department of agriculture or other similar State government agency. The Act provides this authority to the State government and does not provide similar authority to private certifying agents. Private certifying agents are not government entities and have no official regulatory or administrative authorities over agricultural activities in the State. State certifying agents as well as private certifying agents will act as service providers, certifying to national and, where applicable, to particular State organic requirements.

Again, commenters appear to miss an essential point of this national program. The only mandatory organic standards and requirements are those of the NOP and the unique requirements approved for a State organic certification program by the Secretary. A private certifying agent may believe its more restrictive requirements result in a more organic or purer product and may want to certify producers and handlers only to those requirements. However, neither State certifying agents nor private certifying agents will be able to require that client operations or organic product be certified to more restrictive standards than the standards of this program or approved State standards. The only other more restrictive requirements that may be certified to may be requirements made at the request of handlers or manufacturers who are purchasing the organic product or ingredient. For example, a producer could request a certifying agent to certify certain production practices required for export to a foreign manufacturer. Such certification can be made only at the request of the producer or handler being certified. Both State and private certifying agents may certify to the requested more restrictive contract requirements, provided those more restrictive requirements are consistent with these regulations and provided the certifying agents have the necessary technical qualifications to carry out the certification.

Similarly, one commenter stated that the NOP should not prevent a private certifying agent from having and advertising its own higher organic standards. While a private certifying agent may have the capability to certify to certain higher organic requirements, a handler certified by the certifying agent may not claim on product labels or in market information that its products are more organic, purer, or better than product certified by other certifying agents or State organic programs.

In this regard, certifying agents, whether they are State or private certifying agents, may not use different seals, logos, or other identifying marks to distinguish between organic operations certified to NOP requirements and a State's approved more restrictive requirements, the certifying agent's preferred requirements, or the client's requested higher requirements. We believe that if certifying agents were allowed to use more than one seal or identifying mark, based on various standards certified to, the marketplace would be inundated with a variety of different certifying agent seals, logos, and identifying marks. This would add to consumer confusion, complicate the marketplace, and jeopardize benefits of this program.

(3) *Private certifying agent concerns.* Several commenters expressed concern that private certifying agents are at a disadvantage vis-a-vis State certifying agents. They stated that a State organic program or a State certifying agent could initiate policies that would limit the activities or effectiveness of private certifying agents. However, this proposed program does not alter the current situation in that State and private certifying agents operate in the same States. If a requested State organic certification program proposes a requirement or procedure that will have a negative affect or discriminate against private certifying agents operating in the State, the Secretary will not approve the requirement or procedure.

Some commenters asked whether these national regulations will affect a State's accreditation of private certifying agents operating in the State. A few believe that States should be allowed to continue or establish separate accreditation programs for private certifying agents.

We believe accreditation of certifying agents is a core responsibility for USDA. Establishment of a single national accreditation program is an essential part of the NOP. States will not accredit private certifying agents. As stated elsewhere in this proposal, any accreditation responsibilities of a State's current organic certification program will cease with implementation of this program. Pursuant to the Compliance provisions of this subpart, the governing State official or designee charged with compliance oversight under the State program may investigate and notify the NOP of possible compliance violations on the part of certifying agents operating in the State. However, the State may not pursue compliance actions or remove accreditation of any certifying agent accredited by the Secretary. That

authority is the sole responsibility of the Secretary.

If more restrictive State requirements are approved by the Secretary, we will review certifying agent qualifications in the State and determine whether they are able to certify to the approved, more restrictive requirements. Our accreditation responsibilities must include oversight of both State and private certifying agents, including any foreign certifying agents that may operate in a State, and to monitoring their compliance with accreditation requirements.

(4) *Public comment on State applications.* One commenter suggested that USDA publish for comment in the **Federal Register**, a summary of each State's proposed organic program and any requested program amendments. The commenter claimed that an approved State organic certification program will effectively substitute the State's program for the NOP in the State. Thus, the commenter contends, those proposed State programs and program amendments should be made available for public comment. After consideration of the implications of the comment, we do not believe that the **Federal Register** notification process is the proper venue for receiving comments on a proposed State program which is applicable only to residents and business entities in the State. We assume that the governing State official is submitting the request on behalf of the organic producers and handlers in the State. Further, the appropriateness of the State's requested more restrictive requirements should stand on the merits of each proposal and not on whether commenters in other States believe the proposed requirements are warranted. Certified organic producers and handlers outside the State will not be subject to the more restrictive standards or requirements of the State program. The more restrictive standards will not be used to restrict market access of organic product produced in other States or countries. Thus, there is no reason to receive public comment on requested State requirements from individuals not directly affected by the proposed requirements.

The commenter suggested that AMS also publish a summary of each proposed program and any amendments to a program in a newspaper of general circulation in the State. AMS will issue a public information notices which will announce each approved State organic certification program and any approved amendments of a State program. The notices will identify the unique characteristics of the approved State program that warranted the more

restrictive organic production or handling requirements. We also will include a summary of the new program on the NOP homepage.

(5) *State program consistencies.* Several commenters asked for clarification of the first proposal's terms, "consistent" and "substantive amendments," used in regard to State programs operating under the NOP. Being "consistent" with the NOP means that a State program's written standards or requirements must be at least equal to the standards and requirements of the NOP. This is provided for in the Act. Further, in allowing State organic programs to have more restrictive or higher standards, the Act requires that those more restrictive standards and requirements be consistent with the purposes of the Act. To be "consistent" with the purposes of the Act means that the requested, more restrictive standards or requirements are of such a nature that they do not undermine the application of uniform national organic standards. Thus, if a request for more restrictive State organic standards is determined to not be consistent with uniform national organic standards, the State program will not be approved by the Secretary. The administrative procedures used by the State in administering the 11 general requirements of the State's organic program should have the same force and effect of the procedures use by AMS in administering this program.

The same commenters asked for clarification of the term, "substantive amendments," in obtaining USDA approval of more strict amendments for one State's organic certification program. "Substantive amendments" means changes that would increase the quantitative or qualitative standards or specific requirements for an operation's or a product's certification under the State organic program. Once this national program is operating, if a question arises as to whether a desired change in a State organic certification program is considered substantive or not, the State program's governing State official should raise the issue with the Secretary.

State Programs—Additional Provisions

(1) *State program responsibilities.* This subpart establishes that a State organic certification program which petitions for approval by the Secretary will have increased responsibilities under the NOP. Our first proposal did not suggest qualifying factors or other information that had to be submitted by the State program's governing State official. This proposal specifies the 11 general requirements, addressed above, and the needs-based environmental

conditions or special production practices for establishing more restrictive requirements. Those factors establish our revised position that a State must agree to incurring increased responsibilities and obligations to be approved as a State organic certification program under the NOP. For instance, as discussed above, a State with an approved organic certification program will oversee compliance and appeals procedures for certified organic operations in the State. Those procedures must provide due process opportunities such as rebuttal, mediation, and correction procedures in this proposal. Once approved by the Secretary, the State governing official or designee must effectively administer the State's organic certification program in a manner that is consistent and equitable for the certified parties involved in compliance actions.

A State's organic certification program may include other programs and projects which the State government may conduct to promote or increase organic production and handling in the State. Such programs may include organic promotion and research projects, transition assistance, a directory of organic production and handling operations in the State, a consumer referral program, or certifications given to retail operations which market organic foods. This proposal will not prohibit such State activities, provided those activities do not establish production or handling standards that work against the purposes of the NOP. Such programs may not advertise, promote, or otherwise infer that the State's organic products are more organic or better than organic product produced in other States. Such programs and projects should be beyond the scope of this national program and, if so, will not be subject to the Secretary's review.

(2) *Renewal of State program.* The final section provides that reviews of State organic certification programs will be conducted at least once every 5 years, as required in paragraph (c) of section 6507. The intent of the provision is not changed in this proposal. We will provide further information regarding reviews of State programs before the first 5-year period is completed. We expect that, with experiences gained from a few years of program operation, we will be able to propose more appropriate procedures, guidelines, and requirements to assure proper reviews of operating State organic programs.

Fees. This portion of subpart G sets forth the regulations on fees and other charges to be assessed for accreditation and certification services under the

National Organic Program (NOP). These regulations address the kinds of fees and charges to be assessed by the Department for the accreditation of certifying agents, the level of such fees and charges, and the payment of such fees and charges. These regulations also address general requirements to be met by certifying agents in assessing fees and other charges for the certification of producers and handlers as certified organic operations. Finally, these regulations address the Secretary's oversight of a certifying agent's fees and charges for certification services.

Proposal Description

Fees and Other Charges for Accreditation. Fees and other charges will be assessed and collected from applicants for initial accreditation and accredited certifying agents submitting annual reports or seeking renewal of accreditation. Such fees will be equal as nearly as may be to the cost of the accreditation services rendered under these regulations. Fees-for-service will be based on the time required to render the service provided calculated to the nearest 15-minute period. Activities to be billed on the basis of time used include the review of applications and accompanying documents and information, evaluator travel, the conduct of on-site evaluations, review of annual reports and updated documents and information, and the preparation of reports and any other documents in connection with the performance of service. The hourly rate will be the same as that charged by the Agricultural Marketing Service (AMS), through its Quality System Certification Program, to certification bodies requesting conformity assessment to the International Organization for Standardization "General Requirements for Bodies Operating Product Certification Systems" (ISO Guide 65).

Applicants for initial accreditation and accredited certifying agents submitting annual reports or seeking renewal of accreditation during the first 18 months following the effective date of subpart F will receive service without incurring an hourly charge for such service.

Applicants for initial accreditation and renewal of accreditation must pay at the time of application, effective 18 months following the effective date of Subpart F, a nonrefundable fee of \$500.00. This fee will be applied to the applicant's fees-for-service account.

When service is requested at a place so distant from the evaluator's headquarters that a total of one-half hour or more is required for the evaluator(s) to travel to such place and

back to the headquarters, or at a place of prior assignment on circuitous routing requiring a total of one-half hour or more to travel to the next place of assignment on the circuitous routing, the charge for such service will include all applicable travel charges. Travel charges may include a mileage charge administratively determined by the Department, travel tolls, or, where the travel is made by public transportation (including hired vehicles), a fee equal to the actual cost thereof. If the service is provided on a circuitous routing the travel charges will be prorated among all the applicants and certifying agents furnished the service involved on an equitable basis. Travel charges will become effective for all applicants for initial accreditation and accredited certifying agents on the effective date of subpart F. The applicant or certifying agent will not be charged a new mileage rate without notification before the service is rendered.

When service is requested at a place away from the evaluator's headquarters, the fee for such service shall include a per diem charge if the employee(s) performing the service is paid per diem in accordance with existing travel regulations. Per diem charges to applicants and certifying agents will cover the same period of time for which the evaluator(s) receives per diem reimbursement. The per diem rate will be administratively determined by the Department. Per diem charges shall become effective for all applicants for initial accreditation and accredited certifying agents on the effective date of subpart F. The applicant or certifying agent will not be charged a new per diem rate without notification before the service is rendered.

When costs, other than fees-for-service, travel charges, and per diem charges are associated with providing the services, the applicant or certifying agent will be charged for these costs. Such costs include, but are not limited to, equipment rental, photocopying, delivery, facsimile, telephone, or translation charges incurred in association with accreditation services. The amount of the costs charged will be determined administratively by the Department. Such costs will become effective for all applicants for initial accreditation and accredited certifying agents on the effective date of subpart F.

Payment of Fees and Other Charges. Applicants for initial accreditation and renewal of accreditation must remit the nonrefundable fee along with their application. Remittance must be made payable to the Agricultural Marketing Service, USDA, and mailed to: Program Manager, USDA-AMS-TMP-NOP,

Room 2945-South Building, PO Box 96456, Washington, DC 20090-6456 or such other address as required by the Program Manager. All other payments for fees and other charges must be received by the due date shown on the bill for collection, made payable to the Agricultural Marketing Service, USDA, and mailed to the address provided on the bill for collection. The Administrator will assess interest, penalties, and administrative costs on debts not paid by the due date shown on a bill for collection and collect delinquent debts or refer such debts to the Department of Justice for litigation.

Fees and Other Charges for Certification. Fees charged by a certifying agent must be reasonable, and a certifying agent may charge applicants for certification and certified production and handling operations only those fees and charges that it has filed with the Administrator. The certifying agent must provide each applicant with an estimate of the total cost of certification and an estimate of the annual cost of updating the certification. The certifying agent may require applicants for certification to pay at the time of application a nonrefundable fee of no more than \$250.00 which must be applied to the applicant's fees-for-service account. The certifying agent must provide all persons inquiring about the application process with a copy of its fee schedule.

Fees—Changes Based on Comments. This portion of subpart G differs from our first proposal in several respects as follows:

(1) *Application and Administrative Fees.* We have removed the provisions which required certifying agents to pay application and administrative fees. These fee provisions have been replaced with provisions for the assessment of fees for service equal as nearly as may be to the cost of the accreditation services rendered under these regulations. In other words, we will be assessing fees and charges only for activities related to accreditation. These fees and charges will be assessed and collected from applicants for initial accreditation and accredited certifying agents submitting annual reports or seeking renewal of accreditation. The balance of costs incurred by the NOP will be funded through appropriations. We have retained the requirement, with modification, that certifying agents reimburse the Department for travel, per diem, and related other costs associated with providing accreditation services. We have taken these actions in an attempt to minimize the cost of this program on certifying agents. Certifying agents will be charged for the actual

time and travel expenses necessary for the NOP to perform accreditation services.

This proposed program is similar to the Quality Systems Certification Program (QSCP) established pursuant to 7 CFR part 54. The QSCP is an audit-based program administered by AMS through its Livestock and Seed Program, which provides meatpackers, processors, producers, and other businesses in the livestock and meat trade with the opportunity to have special processes or documented quality management systems verified. Since the procedures used for accrediting State and private entities as accredited organic certifying agents are similar to those used to certify other types of product or system certification programs under the QSCP, we have decided to use this existing program and its staff in examining certifying agents' operations and evaluating their compliance with the Act and these regulations. Using the QSCP and its staff will enable the NOP to provide the necessary services without creating a separate bureaucracy. Hourly fees to be charged for services under this program will be the same as those under the QSCP, currently estimated at \$95.00 per hour.

This fee of approximately \$95.00 is greater than the \$42.20 base rate charged under the voluntary user-fee-funded program established by AMS to verify that State and private organic certifying agents in the United States comply with the requirements prescribed under ISO Guide 65. This program, administered by the AMS Livestock and Seed Program, applied the aggregate meat grading rate for services to this ISO Guide 65 verification program for State and private organic certifying agents. The grading rate of \$42.20 was the only rate for which AMS was authorized to charge at the time that the program to assess ISO Guide 65 conformity by organic certifying agents was implemented. This was not the actual audit rate of approximately \$95.00 for such services. The AMS Livestock and Seed Program will engage in rulemaking to establish audit fees for its QSCP. As noted above, those fees are expected to be approximately \$95.00 per hour. The NOP will notify accredited certifying agents of proposed rate changes and final actions on such rates by AMS.

To minimize the economic impact of implementing the NOP on certifying agents, we have decided to provide services for accreditation during the first 18 months following the effective date of new subpart F without an hourly charge for all applicants for initial accreditation and accredited certifying agents. This represents full

subsidization of the hourly costs for accreditation by the Department during the first 18 months of operation. This 18-month subsidization of the hourly costs will prove especially beneficial to any applicant for accreditation that submits a substandard application or has difficulty establishing eligibility for accreditation. Certifying agents will be charged for accreditation service at the published hourly rate on the first day of the nineteenth month following the effective date of subpart F.

Over 15,000 comments were received on fees, with all opposing the first proposal's fee provisions. In addition to comments from consumers, comments were received from State agencies, organic growers, grower associations, and certifying agents. Most of these commenters expressed the belief that the proposed fees would price small certifying agents out of the organic industry. Almost half of the over 15,000 comments suggested a sliding-scale fee system, rather than the flat fee system in the first proposal, to accommodate the economic needs of small certifying agents. We have not accepted the concept of a sliding-scale fee system. Rather, as noted above, we are proposing that certifying agents be charged for the actual time and travel expenses necessary for the NOP to perform accreditation services. Under this fee system, smaller certifying agents should pay less in hourly charges to obtain and maintain certification than larger certifying agents. This assumption, however, is contingent on the quality of all documentation submitted to the Department, certifying agent recordkeeping, and the efficiency of the certifying agent in meeting the requirements of this part. The fees and other charges for accreditation regulations are found in § 205.640.

(2) *Payment by Certified Check.* We have removed the requirement that the payment of fees and charges to the Department be by certified check or money order. We have made this change because we agree with commenters that this requirement is unnecessary and potentially burdensome.

Nearly all industry commenters opposed the form and method of payments stated throughout the original fee sections. Commenters stated that payment by certified check or money order was unnecessary and would create an additional burden on individual producers, handlers, and private certifiers. A few State commenters stated that it was insulting for the U.S. Department of Agriculture (USDA) to require a State government agency to pay for its accreditation with a certified check.

(3) *Producer and Handler Fees to the Department.* We have removed the provisions which required the payment of certification fees by producers and handlers to the Department. We have taken this action because we believe that the goal of recovering program costs through fees and other costs charged to producers and handlers for certification as certified organic operations should be balanced against the Act's purpose to facilitate interstate commerce in fresh and processed food.

We received over 15,000 comments all opposing the first proposal's fee provisions for producers and handlers. Comments were received from consumers, State agencies, organic growers, grower associations, and certifying agents. Most of these commenters stated that the proposed fees would price small producers and handlers out of the organic industry. Hundreds of these commenters stated that the proposed fees favor large production operations. Almost half of the over 15,000 comments suggested a sliding-scale fee system, rather than the flat fee system proposed in the first proposal, to accommodate the economic needs of small producers and handlers. Hundreds more suggested that small producers and processors be exempt from the payment of fees.

Most of the State agency, organic grower, grower association, and certifying agent (industry) commenters spoke to the very small size and family-farm nature of the average organic production operation and how those operations would be affected by the proposed fees. Commenters from this group who offered estimates suggested that one-third to over one-half of organic producers in their area or State are very small organic producers operating at or near the exemption level of \$5,000 in annual sales. They said those operating just above the exemption level could be forced out of organic production by the extra fee and the increased certification charges passed down by certifying agents who would have to pay the proposed accreditation charges.

Commenters, industry and consumer, stated that, rather than encouraging growth and new participation in organic agriculture, the costs of certification would stifle growth and discourage small producer participation in organic agriculture. An industry commenter stated that exempt producers who might want to be certified so they could market their product as organic would be dissuaded from doing so because of the cost of certification. Industry commenters also stated that the additional USDA fee on small handlers would make small organic handling

operations marginal. A few State agencies commented that many small organic producers also conduct their own on-farm handling and that these operations would be forced out of the organic industry by the excessive handler fee and reporting burdens.

The comment, that exempt producers who might want to be certified so they could market their product as organic would be dissuaded from doing so because of the cost of certification, requires clarification. It may be true that such producers would be dissuaded from seeking certification because of the cost of certification. It is not true, however, that exempt producers must be certified to sell or label their production as organic. The Act exempts small producers, those who produce no more than \$5,000 in agricultural products, from the requirement that a person may sell or label an agricultural product as organically produced only if such product is produced and handled in accordance with the Act.

Industry commenters recommended complete changes to the proposed fee structure. Most, like the consumer commenters, suggested a sliding scale for fees based on either size or sales volume. Several industry commenters stated that the Act does not require that USDA recover all program costs from assessments on producers, handlers, and certifying agents. They cited section 6522 of the Act as authorizing the use of appropriated funds to carry out the program. Some industry commenters suggested that appropriated funds should be used to cover all administrative and overhead costs and that fees collected from the industry should only be used for specific program activities such as accreditation. A few industry commenters suggested that organic farmers not be charged an AMS fee but that each be required to sign an affidavit of compliance with program requirements.

After further discussions within the Department and review of the comments, we have determined that the fee structure for the NOP should be modified to reduce costs to all organic sectors. We acknowledge that the fees proposed in the first proposal might have discouraged industry growth and might not have facilitated interstate commerce of organic products. Because we believe that fees and other costs charged to producers and handlers for certification as certified organic operations should be kept to a minimum to encourage industry participation and growth, we have removed the regulations which provided for the payment of fees to the Department by

certified production and handling operations.

(4) *Estimated Cost of Certification.* We have added, at § 205.642, the requirement that the certifying agent must provide each applicant with an estimate of the total cost of certification and an estimate of the annual cost of updating the certification. Additionally, the certifying agent must provide all persons inquiring about the application process with a copy of its fee schedule. We have added these provisions to ensure that producers and handlers have early and ready access to the information they need to consider cost in selecting an agent to certify their production or handling operation. We consider this to be especially important because, as noted in the preamble to subpart F, we have removed the requirement that the certifying agent charge only such fees to applicants for certification and operations it certifies that the Secretary determines are reasonable. We have removed this requirement because we concur with those commenters who expressed the belief that certifying agents should be permitted to set their own fees without the approval of the Secretary. We have also removed this requirement because we concur with the commenters' belief that production and handling operations are free to consider cost in selecting an agent to certify their production or handling operation.

Fees—Changes Requested But Not Made. This subpart retains from our first proposal regulations on which we received comments as follows:

(1) *Accreditation Charges Billed to State Certifying Agents.* Several State certifying agents stated that State certifying agents should not be assessed accreditation charges. Commenters stated that most State certifying agents could face large accreditation costs because they have many county or regional offices which would be considered subsidiaries of the headquarters office. They stated that these charges would have to be passed on to producers and handlers or paid with supplemental State funds. A few State certifying agents stated that USDA should pay the States, rather than vice versa, because of the State organic programs' contributions to the national program. At least one State representative commented that accreditation fees for State certifying agents should be less than for private certifying agents because State certifying agents should require less review and oversight by AMS.

We disagree with those commenters who recommended that State certifying agents not be assessed accreditation

charges, be charged less for accreditation, or be paid to certify production or handling operations. We view such actions as constituting unacceptable preferential treatment of State certifying agents to the detriment of private-entity certifying agents. Accordingly, under this proposal, State-entity certifying agents will be assessed fees for accreditation under the same fee structure as private-entity certifying agents.

(2) *Subsidization.* Some industry commenters stated that national governments in Europe provide direct subsidies and other economic incentives for their farmers to grow organic. A few questioned why the organic industry would be charged for services while some USDA programs are provided without cost to other agricultural sectors, and USDA actually pays some farmers not to grow some commodities. Industry commenters and many consumer commenters stated that it was unfair for this proposed program to charge all costs to a fledgling agricultural industry composed mostly of small, family farmers and marginal operations. Finally, a few industry commenters proposed the philosophical argument that program fees penalize those who protect the earth and that USDA should charge traditional producers who damage the earth with chemical applications and unsustainable cultural practices.

AMS is primarily a user-fee-based Federal agency. The Act at section 6506(a)(10) requires the collection of fees from producers, handlers, and certifying agents. We are, therefore, unable to provide for the full subsidization of producers, handlers, and certifying agents as espoused by some commenters. Accordingly, this proposal provides for the payment of fees by producers, handlers, and certifying agents. We have, however, proposed regulations in this proposal which we believe will minimize the economic impact of the NOP on producers, handlers, and certifying agents.

Fees—Additional Provisions. Upon further review of the fee provisions in the first proposal, we have decided to propose the following additions.

(1) *Certification Fees Charged by Certifying Agents.* We have added, at § 205.642, regulations addressing general requirements to be met by certifying agents in assessing fees and other charges for the certification of producers and handlers as certified organic operations. First, fees charged by a certifying agent must be reasonable, and a certifying agent may charge applicants for certification and certified

production and handling operations only those fees and charges that it has filed with the Administrator. This is a general requirement for accreditation and is also found at § 205.501(a)(15) in subpart F on accreditation. This regulation does not prohibit certifying agents from providing and charging for services outside the NOP. Services that certifying agents might provide outside the NOP include in-house publications, conferences, workshops, informational meetings, and field days. Certifying agents cannot require participation in such activities by certified operations or applicants for certification as a condition of certification.

Second, the certifying agent may require applicants for certification to pay at the time of application a nonrefundable fee of no more than \$250.00 which must be applied to the applicant's fees-for-service account. We believe that this fee will help ensure that certifying agents are compensated for certification services provided to an applicant that is found to be not qualified to receive certification as an organic production or handling operation.

(2) *Fees Charged to Foreign Certifying Agents.* We have removed the provisions which required the payment of fees for import programs. We have taken this action because this proposal includes foreign State entities and foreign private entities which provide certification services under the accreditation requirements of this part. Accordingly, such entities are covered under the fees for accreditation provisions of § 205.640.

Compliance

This portion of subpart G sets forth the enforcement procedures for the National Organic Program (NOP). These procedures describe the compliance responsibilities of the Secretary, USDA, and Agricultural Marketing Service (AMS) officials acting on behalf of the Secretary. These procedures also describe responsibilities of State programs' governing State officials (governing State officials) and State and private certifying agents for compliance under the NOP. The NOP is the AMS office that reviews applications and initiates approvals of accreditation of new certifying agents, conducts oversight of accredited certifying agents, and reviews and recommends continuation of accreditation of certifying agents. These provisions also address the rights of certified production and handling operations and accredited certifying agents operating under the NOP. Approval or denial of applications for certification and

accreditation are addressed under subparts E and F, respectively.

Proposal Description

The Secretary is required under the Act to review the operations of State organic certification programs, accredited certifying agents, and certified production or handling operations for compliance with the Act and these regulations. The Program Manager of the NOP may carry out oversight of compliance proceedings on behalf of the Secretary and the Administrator. However, most reviews and analyses of certification noncompliance will be conducted by the certifying agent which certified the operation. With regard to certifying agents, the Program Manager may initiate proceedings to suspend or revoke the accreditation of a certifying agent for failure to conduct accreditation activities or maintain accreditation requirements pursuant to subpart F of this regulation.

In States with an approved State organic certification program, the State program's governing State official is responsible for administration of the State's compliance program for certified operations. Governing State officials also may review and investigate complaints of certifying agents operating in the State who may not be in compliance with the accreditation requirements of the Act and these regulations. They must notify the Program Manager of such noncompliance activities and make information regarding the violation available to the NOP for appropriate action.

The Program Manager may initiate proceedings to suspend or revoke a certified operation's certification if a certifying agent or State program's governing State official fails to take appropriate enforcement action or if an operation is found to be erroneously certified by a certifying agent whose accreditation has been suspended or revoked.

The compliance provisions of the NOP are consistent with the requirements of the Administrative Procedure Act (APA) (5 U.S.C. 553–559) in that this program provides for due process including an opportunity for hearing, appeal procedures, written notifications of noncompliance, and opportunities to demonstrate or achieve compliance before any suspension or revocation of organic certification or accreditation is invoked. An exception to the initial due process steps under the APA is provided in instances of willful violations. However, willful violations may be appealed pursuant to

the Appeals procedure in this subpart. A compliance action regarding certification carried out under an approved State program's compliance procedures will have the same force and effect as a certification compliance action carried out under these NOP compliance procedures. The notification process for denying applications for certification and applications for accreditation is laid out in subparts E and F respectively.

Noncompliance Procedure for Certified Operations. The Act provides for the enforcement of certified operations. Statutory oversight of production and handling operations by certifying agents includes review of organic plans, residue and tissue testing, authority to conduct investigations, and responsibility to report violations. Applicants for certification must meet certification requirements of the NOP, as determined by certifying agents.

Notification of Noncompliance. As noted above, the Program Manager or the governing State official may review and investigate a certified operation based on complaints and may initiate noncompliance proceedings established in this subpart. However, we expect that most compliance procedures will begin with a certifying agent's inspection, review, or investigation of such certified operation. Thus, this noncompliance procedure is proposed based on that process.

A written notification of noncompliance will be sent to the certified operation if a certifying agent's inspection, review, or investigation reveals any noncompliance with the Act or these regulations. Noncompliance may include, among other things, production or handling practices or conditions, use of substances, or labeling which are not in compliance with subparts C, Production and Handling, or E, Certification, of this regulation. The results of a residue test may trigger a noncompliance notification. A noncompliance notification may encompass the entire operation or a portion of the operation. For instance, a violation at one farm may not warrant loss of certification at other farms of the certified operation not affected by the violation.

A notification of noncompliance will provide: (1) A description of each condition, action, or item of noncompliance; (2) the facts upon which the notification is based; and (3) the date by which the certified operation must rebut the notification or correct the noncompliance. A certified operation may continue to sell its product as organic upon receiving a notification of noncompliance and

throughout the noncompliance proceeding and any appeal procedure which might follow the compliance proceeding.

All written notifications sent by certifying agents and governing State officials, as well as rebuttals, requests for mediation, and notices of correction of deficiencies sent by certified operations will be sent to the addressee's place of business by a delivery service which provides dated return receipts. This will help assure completed communications and timely compliance procedures.

If a certified operation believes the notification of noncompliance is incorrect or not well-founded, the operation may submit a rebuttal to the certifying agent, providing supporting data to refute the facts stated in the notification. Rebuttals are provided to allow certifying agents and certified operations to informally resolve noncompliance notices. Rebuttals should be helpful in resolving differences which may be the result of misinterpretation of requirements, misunderstandings, or incomplete information. Alternatively, the certified operation may correct the identified deficiencies and submit proof of such corrections. When the operation demonstrates that each noncompliance has been corrected or otherwise resolved, the certifying agent will send the certified operation a written notification of noncompliance resolution.

Proposed Suspension or Revocation of Certification. If the noncompliance is not resolved and is not in the process of being resolved by the date specified in the notification, the certifying agent will send the certified operation a written notification of proposed suspension or revocation of certification for the entire operation or a portion of the operation affected by the noncompliance. The notification will state: (1) The reasons for the proposed suspension or revocation; (2) the proposed effective date of the suspension or revocation; (3) the impact of the suspension or revocation on the certified operation's future eligibility for certification; and (4) that the certified operation has a right to request mediation or to file an appeal. The impact of a proposed suspension or revocation may include the suspension period or whether the suspension or revocation applies to the entire operation or to a portion or portions of the operation. A governing State official may not suspend or revoke certification of an entity's certified operations in other States. Likewise, a certifying agent may not suspend or revoke certification

of an entity's operations which the certifying agent does not certify.

If a certifying agent determines that correction of a noncompliance is not possible, the notification of noncompliance and the proposed suspension or revocation of certification may be combined in one notification of proposed suspension or revocation. The certified operation will have an opportunity to appeal that suspension or revocation decision.

Mediation. A certified operation may request mediation of any dispute regarding denial of certification or proposed suspension or revocation of certification. Mediation is not required prior to filing an appeal but is offered as an option which may resolve the noncompliance more quickly than the next step, which is filing an appeal. If a State program is in effect, the mediation procedures established in the State program, as approved by the Secretary, must be followed. Mediation will be requested in writing to the applicable certifying agent. The dispute will be mediated by a qualified mediator mutually agreed upon by the parties to the mediation. The parties to the mediation will have no more than 30 days to reach an agreement following a mediation session. If mediation is unsuccessful, the certified operation will have 30 days from termination of mediation to appeal the proposed suspension or revocation to the Administrator.

Any agreement reached during or as a result of the mediation process must be in compliance with the Act and these regulations. Also, the Secretary reserves the right to review any mediated settlement to assure that the terms of the settlement conform with the requirements of the Act and the NOP.

Suspension or Revocation. The certifying agent will suspend or revoke the certified operation's certification when the operation fails to resolve the issue through rebuttal or mediation, fails to complete needed corrections, or does not file an appeal. The operation will be notified of the suspension or revocation by written notification. The certifying agent must not send a notification of suspension or revocation to a certified operation that has requested mediation or filed an appeal.

The decision to suspend or revoke certification will be based on the seriousness of the noncompliance and on whether the noncompliance is a willful action by the certified operation. Such decisions must be made on a case-by-case basis. Section 6519 of the Act establishes that willful violations include making a false statement, knowingly affixing a false label, or

otherwise violating the purposes of the Act. Certifying agents are responsible for investigating whether a violation is a willful act and advising the Program Manager or governing State official of the results of such investigation. However, only the Program Manager or governing State official may make the final determination that a violation is willful.

If a suspected willful noncompliance is not a serious violation, a proposed suspension rather than revocation may be issued. Revocation is reserved for serious instances of willful noncompliance and other serious violations.

The certifying agent may determine that a lesser penalty of suspension is warranted by the noncompliance. A proposal to suspend certification may be issued for violations that are inadvertent or cannot be proven to be willful. A suspension may be applicable only to one area of operation or one field or farm unit where the noncompliance occurred.

A certified operation that has had its certification revoked will not be eligible to receive certification for an operation in which such operation or person has an interest for 5 years following the date of revocation. If an individual is the owner of a certified operation or is the principal officer or director of operations who is fully responsible for complying with certification requirements of this part, a suspension or revocation could be issued in the individual's name. The effect would be that another operation would be ineligible for organic certification if that individual is listed as a principal in the operation. The Secretary may waive an ineligibility period when it is in the best interests of the certification program.

Noncompliance Procedure for Certifying Agents. The Program Manager, on behalf of the Secretary, may initiate a compliance action against an accredited certifying agent who fails to carry out responsibilities entrusted to the certifying agent or maintain resources sufficient to meet accreditation requirements in subpart F. Compliance proceedings may be initiated as a result of annual reviews for continuation of accreditation, as a result of site visits, or as a result of investigations initiated in response to complaints of noncompliant activities. Compliance proceedings also may be initiated on recommendation of a governing State official.

A written notification of noncompliance will be sent by the Program Manager to an accredited certifying agent when an inspection, review, or investigation of such person

reveals any noncompliance with the Act or these regulations. A notification of noncompliance will provide a description of each noncompliance found and the facts upon which the notification is based. Additionally, the notification will provide the date by which the certifying agent must rebut the noncompliance notice or correct each noncompliance described.

When documentation received by the Program Manager demonstrates that each noncompliance has been resolved, the Program Manager will send the certifying agent a written notification of noncompliance resolution.

If a noncompliance is not resolved by rebuttal or correction of violations, the Program Manager will issue a proposed suspension or revocation of accreditation. The notification will state whether the certifying agent's entire business, field office, or offices in a geographic area or in a specified technical field of accreditation are to be suspended or revoked. For instance, if a private certifying agent with field offices in different geographic areas is cited for a compliance violation in one area, the Program Manager could determine that only the accreditation of the noncompliant operation should be suspended or revoked.

If the Program Manager determines that the noncompliance cannot be immediately or easily corrected, the Program Manager may combine the notification of noncompliance and the proposed suspension or revocation in one notification. The notification of proposed suspension or revocation of accreditation will state the reasons and effective date for the proposed suspension or revocation. Such notification will also state the impact of a suspension or revocation on future eligibility for accreditation and the certifying agent's right to file an appeal.

If the Program Manager has reason to believe that a certifying agent has willfully violated the Act or regulations, the Program Manager may issue a notification of proposed revocation of accreditation. The proposed revocation may be for the certifying agent's entire accreditation business, a particular field office, or a specified technical area of accreditation. This notification, because it involves a willful violation, will be sent without first issuing a notification of noncompliance.

The certifying agent may file an appeal of the Program Manager's determination, pursuant to § 205.681. If the certifying agent fails to file an appeal of the proposed suspension or revocation, the Program Manager will suspend or revoke the certifying agent's accreditation. The certifying agent will

be notified of the suspension or revocation by written notification.

A certifying agent whose accreditation is suspended or revoked must cease all certification activities in each area of accreditation and in each State for which its accreditation is suspended or revoked. Any certifying agent whose accreditation has been suspended or revoked must transfer to the Secretary all records concerning its certification activities that were suspended or revoked. The certifying agent must also make such records available to any applicable governing State official. The records will be used to determine whether operations certified by the certifying agent may retain their organic certification.

A certifying agent whose accreditation is suspended by the Secretary may at any time submit a new request for accreditation. Such request must be accompanied by evidence demonstrating correction of each noncompliance and actions taken to comply with and remain in compliance with the Act and regulations. A certifying agent whose accreditation is revoked by the Secretary will be ineligible to be accredited as a certifying agent under the Act and regulations for a period of not less than 3 years following the date of revocation.

State Programs' Compliance Procedures. A State program's governing State official may initiate noncompliance proceedings of certified organic operations operating in the State. Such proceedings may be initiated for failure of a certified operation to meet the production or handling requirements of this part or the State's more restrictive requirements, as approved by the Secretary. The governing State official must attempt to resolve the compliance violations through State mediation and reviews of corrections to operations.

The governing State official must promptly notify the Program Manager of commencement of enforcement proceedings initiated against certified operations. An enforcement proceeding, brought by a governing State official against a certified operation may be appealed in accordance with the appeal procedures of the State organic certification program. There will be no subsequent rights of appeal to the Secretary.

Compliance—Changes Based On Comments

This portion of subpart G differs from our first proposal in several respects as follows:

(1) *Authority of certifying agents.* We have provided accredited certifying

agents with authority to initiate noncompliance proceedings which may result in suspension or revocation of producer and handler certifications. A certifying agent's notification of proposed suspension or revocation of certification provides an opportunity for the certified operation to file an appeal in accordance with the appeal provisions of § 205.681. If a noncompliance procedure initiated by a certifying agent is not corrected, remains unresolved, and is not appealed, the certified operation's certification will be suspended or revoked. If the certified operation files an appeal, the action is turned over to the Program Manager or applicable governing State official for further resolution. The suspension or revocation will not become effective unless upheld by a ruling on the appeal.

Commenters expressed opposition to the notification of noncompliance with certification requirements and termination of certification provisions of the first proposal. Those provisions required a certifying agent to submit to the Administrator a notice of its recommendation to terminate the certification of a certified operation or any portion of a certified operation if the certifying agent had reason to believe the operation had ceased to comply with the Act and regulations. The commenters were opposed to the Secretary assuming authority for suspension or revocation of certification. The commenters stated that such decisions are the duty and responsibility of certifying agents, with the Secretary providing for appeals. Some commenters expressed the belief that the certifying agent's position is undermined by not having authority to suspend or revoke a certification for cause. Many commenters stated that certifying agents must have such authority in order to: (1) Achieve producer and handler compliance with the regulations; and (2) expedite the enforcement process. They believe that providing certifying agents with the authority to suspend or revoke a certification will preserve the NOP's integrity and increase consumer confidence in the quality of the organic products they purchase. Commenters stressed that, in addition to providing procedures for producer and handler appeals, the Department provides a system of checks and balances through the accreditation program.

We agree that certifying agents should have an important role to play in the suspension or revocation of the certification of production or handling operation that they certify. This proposal will enhance the certifying

agent's authority to ensure that any production or handling operation it certifies is in compliance with the Act and regulations. We also agree that providing certifying agents with a more direct role in suspension or revocation proceedings will shorten the compliance process.

Accordingly, as noted above, we have provided accredited certifying agents with increased authorities in enforcement proceedings. They will make determinations to accept or reject rebuttals submitted in response to notifications of noncompliance. They will be responsible for defending their determinations, which must be consistent with the position of the NOP, in mediation processes. Finally, their decisions to propose suspension or revocation of producer and handler certifications will become effective unless appealed by the certified operation. Authority for certifying agents to take enforcement actions against certified operations is found in § 205.662.

(2) *Mediation.* We have added a new section authorizing certified operations to request mediation of any dispute regarding denial of certification or proposed suspension or revocation of certification. This section addresses the request for mediation, selection of the mediator, the time period for reaching an agreement, requirements of an agreement, and appealing a noncompliance decision if mediation is unsuccessful. The parties in the procedure must make administrative arrangements for the mediation and arrange for payment of any costs involved in the mediation. The Department will not finance or participate in such mediation. This additional provision is found at § 205.663.

Commenters requested that the Department authorize the use of alternative dispute resolution procedures and mediation. We support the idea of using mediation to resolve disputes with respect to denial of certification or proposed suspension or revocation of certification. Some States use mediation as a component of their appeal process. We believe mediation could prove effective in resolving many of the possible disputes between applicants for certification or certified operations and certifying agents. Without mediation, such disputes would probably be referred to the Administrator in the form of appeals. Mediation in some cases, however, may be of limited value because all agreements reached during mediation or as a result of the mediation process must be in compliance with the Act,

these regulations, and any policies or procedures governing the NOP. While we presume a mediated settlement will be in accordance with the Act, the Secretary has authority to review and overrule a mediated settlement if the Secretary determines the settlement is not in accordance with Act and these regulations.

(3) *State certification program.* Commenters generally requested that States administer and enforce their own organic certification programs. We have added regulations in these provisions addressing States' enforcement of their programs regarding certified producers and handlers operating in the State. These regulations clarify a State's responsibility to provide for enforcement and appeal proceedings which are consistent with these regulations and for keeping the Secretary informed of such proceedings. We have added these regulations because we believe that a State must have the authority to initiate compliance actions to enforce its organic certification program. The regulations are found at § 205.668.

Regarding accreditation authorities, commenters stated that a State program's governing State official should have authority to suspend or revoke the accreditation of private certifying agents operating within the State. Sections 6515(j) and 6519(e) of the Act address suspension and revocation of accreditation by the Secretary or governing State official. While the Act may provide for the possibility of such authority being used by governing State officials, it also requires the Secretary to establish a workable accreditation program and it grants sole authority to the Secretary to accredit certifying agents. Therefore, the Secretary must have sole authority to suspend or revoke that accreditation.

This does not mean that governing State officials are denied a role in oversight of certifying agents operating in their States. If a governing State official believes a certifying agent operating in the State is not in compliance with the accreditation requirements of the Act or is not properly certifying producers or handlers to NOP and the State's approved unique organic certification requirements, the governing State official must investigate the possible noncompliance. If evidence of noncompliance is found, the governing State official must notify the Program Manager of such noncompliance activities and document those activities. The Program Manager will investigate such complaints of noncompliance.

(4) *Right of appeal.* We have added the requirement that any notification of proposed suspension or revocation must include a notice to the certified operation's or certifying agent's of its right to file an appeal. Commenters requested that the notification of proposed suspension or revocation provisions for certifying agents reference the appeals section. We agree with the commenters' request and add that all recipients of a notification of proposed suspension or revocation should be made aware of their appeal rights. Notification of appeal rights is found in § 205.662 for certified operations and § 205.665 for certifying agents.

Compliance—Changes Requested But Not Made

This subpart retains from our first proposal regulations on which we received comments as follows:

(1) *Revocation period.* Commenters stated that a 5-year period of ineligibility for certification after revocation of certification is too harsh a punishment to apply in all cases. Some commenters suggested that "shall not be eligible" should be replaced with "may be deemed ineligible" so that the penalty provision would be available for flagrant violations of the Act but would not have to be applied to all violations. A commenter suggested a maximum period of ineligibility of 3 years be established for certified operations. The commenter's justification was that organically produced agricultural products must be produced on land to which no prohibited substances have been applied for 3 years prior to harvest. This commenter also stated that the ineligibility waiver should be a local decision with notice to the Administrator.

Section 6519(c) of the Act requires certification ineligibility for 5 years unless reduced or eliminated by the Secretary. Revocation of a certification is a serious action subject to due process for the accused certified producer or handler. We believe that any noncompliance action, combination of noncompliance actions, or history of noncompliance activities deemed to warrant the revocation of certification also warrants ineligibility from certification for 5 years unless reduced or eliminated by the Secretary. If the noncompliance is not significant enough to warrant revocation of the operation's certification, the certifying agent, State program's governing State official, or Secretary may choose to suspend the operation's certification for a period of time less than the 5-year revocation period. We disagree with the

suggestion that ineligibility waivers should be decided at the local level. Actions which are finalized by the governing State official, Administrator, or Secretary cannot be subject to reversal or waivers by certifying agents. Additionally, a national program such as this must have uniformity in application, which would be less likely if individual certifying agents were permitted to establish their own criteria for ineligibility waivers. Accordingly, the ineligibility and waiver provisions are unchanged in this proposal.

(2) *Accreditation sanctions.* Commenters stated that suspension and revocation of accreditation should be applied fairly to both private and State certifying agents. Governing State officials do not have any accreditation authorities under this proposal—which may reduce private certifying agents' concerns of unfair or unequal treatment. Accreditation compliance actions by the Program Manager and the Administrator will be conducted impartially and in accordance with the Administrative Procedure Act and Department policies.

Revocation would be based on a determination that a private certifying agent willfully violated the Act or these regulations or falsely or negligently certified a production or handling operation as an organic operation. The Act does not authorize the revocation of a State certifying agent's accreditation. However, because suspension of such entity can be established for any period of time, a suspension can be effectively equivalent to a revocation of accreditation. Accordingly, this proposal retains the provisions for the suspension of accreditation for private and State certifying agents and the revocation of accreditation for private certifying agents.

Compliance—Additional Provisions

Upon further review of the accreditation provisions in the first proposal, we have decided to propose the following additions and changes.

(1) *Enforcement rights of the Secretary.* We have added a general section addressing specific enforcement rights of the Secretary. First, this section clarifies that the Program Manager on behalf of the Secretary and the Administrator may inspect and review State organic certification programs, accredited certifying agents, and certified production or handling operations for compliance with the Act or regulations. The Program Manager has this oversight authority in States with State organic certification programs as well as in States without such programs.

Second, this section provides that the Program Manager may initiate proceedings to suspend or revoke a certified operation's certification when a certifying agent or governing State official fails to take appropriate enforcement action against a certified operation that is not in compliance with the Act or these regulations. We have added this provision because this proposal provides certifying agents and governing State officials with enforcement authorities, including the suspension and revocation of certifications. However, we believe the Secretary, through the Program Manager, must have authority to take such actions if a certifying agent or governing State official fails to carry out its responsibilities.

Third, this section provides that the Program Manager may initiate proceedings to suspend or revoke a certified operation's certification upon suspension or revocation of the operation's certifying agent's accreditation. We have added this provision to enable the Program Manager to suspend or revoke certification of any operation that a certifying agent certified following procedures or practices that are not in compliance with the Act or these regulations. This addition is found at § 205.660.

(2) *Certifying agent investigations.* We have added a section to clarify that certifying agents may investigate complaints of noncompliance with the Act or regulations concerning operations that they have certified. This section does not authorize a certifying agent to investigate certified operations that the certifying agent has not certified. Such complaints should be reported to the certifying agent that certifies the operation in question. This addition is found at § 205.661.

(3) *Certified operation rebuttals.* We have added a certified operation's right to rebut any noncompliance described in a notice of noncompliance. We believe this provision is necessary to clarify that certified operations should be able to present facts or arguments refuting the certifying agent's findings. We see this as an informal process between the certified operation and the certifying agent to clarify possible misunderstandings or misinterpretation of requirements, data, or information. The APA requires such opportunities prior to suspension or revocation. Certified operations that successfully refute a finding of noncompliance will receive a notification of noncompliance resolution. Any certified operation unable to successfully refute a finding of noncompliance must correct the

noncompliance or face possible suspension or revocation of its certification. This addition is found at § 205.662(a)(3).

(4) *Certifying agent rebuttals.* We also have added a certifying agent's right to rebut any accreditation noncompliance described in a notice of noncompliance issued by the Program Manager. This also will be an informal process and is consistent with the intent of the APA. We believe this provision is necessary to clarify that certifying agents should be able to present facts or arguments refuting the Program Manager's findings. Certifying agents that successfully refute a finding of noncompliance will receive a notification of noncompliance resolution. Any certifying agent unable to successfully refute a finding of noncompliance must correct the noncompliance or face possible suspension or revocation of its accreditation. This addition is found at § 205.665(a)(3).

(5) *Willful noncompliance.* We have also added authority for certifying agents and governing State officials to move directly to a notice of proposed revocation if a certification noncompliance is a willful, serious violation of these regulations. This will allow expedited action in dealing with serious violations of certification. The due process provisions of the APA provide an exception in cases of willful violations. Even though a noncompliance may be a willful act, the certified operation maintains the right to file an appeal of a proposed suspension or revocation of certification. Revocation of certification is reserved for serious instances of willful noncompliance and other serious violations. If a suspected willful violation is deemed not serious, a proposed suspension of certification rather than revocation may be issued.

Inspection and Testing, Reporting, and Exclusion From Sale

This portion of subpart G sets forth the inspection and testing requirements for agricultural products that have been produced on organic production operations or handled through organic handling operations.

Based on comments received regarding the first proposal, we have modified and restructured our residue testing requirements. Commenters were concerned about the cost of residue testing to certified operations and certifying agents, the determination of detectable levels of prohibited substances, and the exclusion of contaminated products from sale as organically produced.

Residue testing plays an important role in organic certification by providing a means for monitoring compliance with the National Organic Program (NOP) and by discouraging the mislabeling of agricultural products. This testing program provides State programs' governing State officials and certifying agents with a tool for ensuring compliance with three areas for testing: (1) Preharvest residue testing, (2) postharvest residue testing, and (3) testing for unavoidable residual environmental contamination levels.

Proposal Description

Under the residue testing requirements of the NOP, we propose that all agricultural products sold, labeled, or represented as organically produced be available for inspection by the Administrator, State program's governing State official, or certifying agent. Organic farms and handling operations must be made available for inspection under proposed Subpart E, Certification. In addition, products from the aforementioned organic operations may be required by the State program's governing State official or certifying agent to undergo preharvest or postharvest testing when there is reason to believe that agricultural products to be sold or labeled as organically produced have come into contact with prohibited substances. *The cost of such testing will be borne by the applicable certifying party and is considered a cost of doing business. Accordingly, certifying agents should make provisions for the cost of preharvest or postharvest residue testing when structuring certification fees.*

Preharvest and Postharvest Residue Testing. The main objectives of the residue testing program are to: (1) Ensure that certified organic production and handling operations are in compliance with the requirements set forth in this proposal; and (2) serve as a means for monitoring drift and unavoidable residue contamination of agricultural products to be sold or labeled as organically produced. Any detectable residues of a prohibited substance found in or on samples during chemical analysis will serve as a warning indicator to the State program's governing State official or certifying agent.

The request for preharvest or postharvest residue testing is based on the Administrator's, State program's governing State official's, or certifying agent's belief that an agricultural product has come into contact with one or more prohibited substances. The "reason to believe" could be triggered by various situations, for example: (1)

The applicable authority receiving formal written complaint regarding the practices of a certified organic operation; (2) an open container of a prohibited substance found on the premises of a certified organic operation; (3) the proximity of a certified organic operation to a potential source of drift; (4) suspected soil contamination by historically persistent substances; or (5) when the product from a certified organic operation is unaffected when neighboring fields or crops are infested with pests. These situations do not represent all of the possible occurrences that would trigger an investigation. Preharvest or postharvest residue testing will occur on a case-by-case basis.

In each case, an inspector representing the Administrator, certifying agent, or State program's governing State official will conduct sampling. Testing for chemical residues must be performed in an accredited laboratory, defined as a laboratory that has met and continues to meet the requirements specified in the Food, Agriculture, Conservation, and Trade Act of 1990 (7 U.S.C. 138) (FACT Act) for pesticide residue analyses of fresh fruit and vegetables and/or pesticide analysis of products derived from livestock and fowl. AMS is currently developing a regulation for the National Laboratory Accreditation Program (NLAP), which will accredit laboratories under the FACT Act. We expect that the NLAP will be implemented before or at the same time as the NOP. When conducting chemical analyses, the laboratory must incorporate the analytical methods described in the 16th edition of the *Official Methods of Analysis of the AOAC International* or other applicable validated methodology for determining the presence of contaminants in agricultural products.

When testing indicates that an agricultural product to be sold or labeled as organically produced contains residues of prohibited substances, certifying agents will compare the level of detected residues with a national mean of detection for the specific commodity/pesticide combination generated by the U.S. Department of Agriculture's (USDA) Pesticide Data Program (PDP). This national mean is defined as the mean level of detected pesticide residues as described in certain pesticide/commodity pairs or combinations established by USDA's Pesticide Data Program. The national mean for specific commodity/pesticide combinations will serve as a standard for the Administrator, State programs' governing State officials, and certifying

agents to assist in monitoring for illegal use violations. This information will be made available by USDA to aid State programs' governing State officials and certifying agents in making sound evaluations and decisions regarding detected levels of prohibited substances.

In addition, levels of unavoidable residual environmental contamination will be determined for crop- and site-specific agricultural commodities to be sold, labeled, or represented as "100 percent organic," "organic," or "made with organic (specified ingredients)." These levels will represent limits at which the Department may take compliance action to suspend the use of the contaminated area for organic agricultural production. Initially, unavoidable residual environmental contamination levels will be set for persistent prohibited substances (aldrin, dieldrin, chlordane, DDE, etc.) in the environment. In time, they may become more inclusive of prohibited residues as additional information becomes available. Unavoidable residual environmental contamination levels will be based on the unavoidability of the chemical substances and do not represent permissible levels of contamination where it is avoidable. Historical residue data gathered from Federal and State monitoring and testing programs will be used to determine these levels. They will be set by the Administrator, in consultation with the Food and Drug Administration (FDA) and Environmental Protection Agency (EPA).

After all tests and analyses have been concluded, the results must be provided to the Administrator. The results of analyses and tests will be available, kept on record, and reviewed by the Department to evaluate concentration levels of prohibited substances for specific regions and agricultural crops. Analyses and test results will also be available for public access, unless the residue testing is part of an ongoing compliance investigation. Information relative to an ongoing compliance investigation will be confidential and restricted to the public.

Detection of Prohibited Substances. In the case of residue testing and the detection of prohibited substances in or on agricultural products to be sold, labeled, or represented "100 percent organic," "organic," or "made with organic (specified ingredients)," detectable residues of prohibited substances that exceed the national mean of detection for the respective commodity/pesticide combination or unavoidable residual contamination levels cannot be sold or labeled as organically produced. When such an

agricultural crop is in violation of these requirements, the certification of that crop will be suspended for the period that the crop is in production. Certifying agents must follow the requirements specified in §§ 205.662 and 205.663 of Subpart G, Compliance. In addition, when a State program's governing State official or a certifying agent detects a prohibited substance in or on agricultural products to be sold or labeled as organically produced, the State program's governing State official or certifying agent may conduct an investigation to determine the cause of the prohibited substance.

If the investigation into the cause of a detectable residue level in a product indicates that the residue was the result of an intentional application of a prohibited substance, the Administrator is authorized to initiate proceedings to revoke or suspend the certification status of an operation or portion of that operation. When testing indicates that an agricultural product contains prohibited substances that exceed either the EPA tolerance level or FDA action level, as applicable, for the prohibited substance, the data revealing such information will be promptly reported to the appropriate regulatory health agencies.

Emergency Pest Eradication or Disease Treatment Programs. When a prohibited substance is applied to an organic production or handling operation due to a Federal or State emergency pest eradication or disease treatment program and the organic handling or production operation otherwise meets the requirements of this proposal, the certification status of the operation shall not be affected as a result of the application of the prohibited substance, provided that: (1) Any harvested crop or plant part to be harvested that has contact with a prohibited substance applied as the result of a Federal or State emergency pest eradication or disease treatment program cannot be sold, labeled, or represented as "100 percent organic," "organic," or "made with organic (specified ingredients)"; and (2) any livestock that are treated with a prohibited substance applied as the result of a Federal or State emergency pest or disease treatment program or product derived from such treated livestock cannot be sold, labeled, or represented as "100 percent organic," "organic," or "made with organic (specified ingredients)."

However, milk or milk products may be labeled or sold as organically produced beginning 12 months following the last date that the dairy animal was treated with the prohibited

substance. Additionally, the offspring of gestating mammalian breeder stock treated with a prohibited substance may be considered organic if the breeder stock was not in the last third of gestation on the date that the breeder stock was treated with the prohibited substance.

Residue Testing—Changes Based on Comments

This portion of subpart G differs from our first proposal in several respects as follows:

Residue Testing. (1) We have revised the first proposal's section on residue testing and repositioned it under § 205.670(b).

Commenters disagreed with the provisions in the first proposal which required certifying agents to conduct residue testing of products produced and handled on operations that they had certified not less frequently than every 5 years. They stated that the first proposal's requirements for residue testing: (1) Were in excess of what the Act actually requires; (2) were more stringent than that of the industry norm; (3) would create an unnecessary burden on certifying agents and organic production and handling operations; and (4) would increase costs for certified production and handling operations. The commenters stated that the NOP's residue testing requirements should utilize existing Federal and State testing programs for the detection of pesticide residues. They also stated that residue testing should only be required when it is known or suspected that prohibited substances have been applied to organic products.

We disagree with the commenters' assertions regarding the first proposal's requirements for residue testing. However, in an attempt to minimize the burdens of residue testing, we have proposed that State programs' governing State officials and certifying agents may test agricultural inputs used for organic production and require preharvest or postharvest testing of any agricultural product to be sold, labeled, or represented as "100 percent organic," "organic," or "made with organic (specified ingredients)" when there is reason to believe that the agricultural product has come into contact with prohibited substances. This change allows State programs' governing State officials and certifying agents to perform preharvest and postharvest residue testing on a case-by-case basis.

Commenters requested that the rule specify which laboratories are authorized to perform residue testing and what tests each laboratory would be accredited to perform. We have defined

an accredited laboratory as a laboratory that has met and continues to meet the requirements specified in the Food, Agriculture, Conservation, and Trade Act of 1990 (7 U.S.C. 138) for pesticide residue analyses of fresh fruit and vegetables and/or pesticide residue analysis of products derived from livestock and fowl. Any laboratory that meets the specified requirements therein may be used in conducting residue tests. We have required that accredited laboratories be used to ensure consistency among data, testing methodology, reporting procedures, and other testing criteria needed to maintain analytical uniformity in the residue testing program. Validated analytical methodologies for determining the presence of contaminants in agricultural products, such as those described in the 16th edition of the *Official Methods of Analysis of the AOAC International*, may be used.

Tolerance Levels for Pesticide Residues. (2) We have prohibited the sale and labeling of agricultural products as organic when such products have been tested for prohibited substances and found to contain residues of prohibited substances at levels greater than the national mean of detection for the specific commodity/pesticide combination or levels greater than the unavoidable residual environmental contamination. Such agricultural products cannot be sold, labeled, or represented as "100 percent organic," "organic," or "made with organic (specified ingredients)." The Administrator, State program's governing State official, or certifying agent may conduct an investigation of the applicable production or handling operation to determine the cause of the presence of any prohibited substance. If the investigation reveals that the presence of a prohibited substance was the result of intentional application of the prohibited substance, the Administrator may initiate proceedings to suspend or revoke the production or handling operation's certification.

(3) Commenters suggested that USDA adopt a uniform standard for the maximum allowable residue levels. Some commenters expressed the belief that it is impractical or too expensive to establish site-specific, unavoidable residual environmental contamination levels for every commodity/pesticide combination in every growing area. Others argued that the cause of contamination is irrelevant and that crops that exceed the maximum residue levels should not be allowed to be sold as organic. Finally, others argued that a single standard was needed because contaminated products would not be

removed from the market immediately, pending determination of cause.

Organic standards, including provisions governing prohibited substances, are based on the method of production, not the content. The primary purpose of the residue testing approaches described in this proposal, then, is to provide an additional tool for State programs' governing State officials and certifying agents to use in monitoring and ensuring compliance with the NOP. We acknowledge that consumers have a reasonable expectation that organic products will contain minimal residues of prohibited substances. We are not allowing the use of prohibited substances. We are making provisions for the unavoidable occurrences of prohibited substances while ensuring that residue levels are consistent with consumer expectations.

This proposal adopts PDP's national means of detected residue for specific commodity/pesticide combinations and the unavoidable residual environmental contamination levels. Both standards have been adopted for the purpose of determining excessive prohibited substances on agricultural products to be sold, labeled, or represented as "100 percent organic," "organic," or "made with organic (specified ingredients)."

The national mean of detected residue for a specific commodity/pesticide combination is derived from detections in the PDP monitoring program. As a result of mean values being based on conventional substances, we believe that residue values that fall above this mean, then, would be beyond reasonable consumer expectations for minimal residues. The situation is very similar with respect to unavoidable residual environmental contamination levels. Even though the presence of residues of certain persistent substances may not be the result of intentional application, we believe that excessive residue levels would not be consistent with the intentions of the Act. Accordingly, when levels of a persistent substance are detected above the unavoidable residual environmental contamination level, the product cannot be sold or labeled as organically produced.

Some commenters suggested that we use a percentage of the EPA tolerance of FDA action level, such as 5 or 10 percent, as a uniform standard for the maximum allowable residue level. We considered the comments but decided not to adopt them for the following reasons. The EPA tolerances for pesticides are defined as the maximum legal level of a pesticide residue in or on a raw or processed agricultural commodity, as set by the Environmental

Protection Agency under the Federal Food Drug and Cosmetic Act, section 408. FDA action levels represent limits, at or above which FDA will take legal action against a food product to prevent poisonous or deleterious substances from entering the food supply. Both EPA tolerances and FDA action levels are public health-based standards. Our rationale for residue testing, as a tool for State programs' governing State officials and certifying agents to monitor compliance with the NOP, is different from these public health programs.

Accepting a percentage of EPA tolerance or FDA action levels could also pose a significant problem for analytical laboratories trying to analyze for prohibited substances. In some cases, pesticides have tolerances that are set near their analytical method's Limit of Quantification (LOQ). The LOQ is defined as the lowest level where analytical measurement becomes quantitatively meaningful. If the EPA tolerances are near the analytical method LOQ's, accurate determination of the levels at 5 to 10 percent of the tolerance may not be attainable for analytical instrumentation currently employed. Therefore, the Department could be setting a level of concern below the LOQ for some substances if it adopted this recommendation. As a fundamental principle, we have chosen not to set an enforcement level that could be below detection limits for some substances. As an alternative, we are proposing to use the PDP national mean of detected residues for specific commodity/pesticide combinations.

Other commenters suggested that USDA adopt a "zero tolerance" for residues of prohibited substances. Under this suggestion, products containing any detectable residues of a prohibited substance would not be allowed to be labeled as organically produced. This proposal does not adopt this suggestion. While standards strictly prohibit use of any substance not found on the approved National List, we recognize that some minimal residues may still be found in organic foods. We believe our proposed residue testing system and compliance provisions should be adequate to protect the integrity of agricultural products sold, labeled, or represented as "100 percent organic," "organic," or "made with organic (specified ingredients)."

Several commenters expressed opposition to the first proposal not requiring residue testing in the event of drift. These commenters stated that organic producers should report all incidences of drift to their certifying agent. The commenters further stated that a crop should be tested for the

presence of prohibited substances when drift has or is suspected to have occurred. They also stated that when the test indicates levels of residues of prohibited substances that exceed 5 percent of the EPA tolerance level, the crop should be prohibited from being sold or labeled as organically produced.

In response to commenters' concern about contamination from drift, we have used some of their reasoning in the development of our residue testing program. Drift is defined as the physical movement of prohibited substances from the intended target site onto an organic production operation or any portion thereof. The National Organic Standards Board (NOSB or Board) recommended that agricultural products exposed to drift not be sold, labeled, or represented as "100 percent organic," "organic," or "made with organic (specified ingredients)" or fed to livestock on organic operations. The NOSB also recommended that preharvest tissue testing of crops suspected of receiving drift be required to verify the presence or absence of prohibited substances. This proposal addresses the problem of drift through the use of preharvest testing of crops suspected of receiving drift of a prohibited substance. Although drift may occur, especially in those agricultural regions where pesticide use on nonorganic lands is routine and heavy, exposure to drift does not constitute use of a prohibited substance. Therefore, preharvest testing provisions have been established for State programs' governing State officials and certifying agents to test when there is a reason to believe that agricultural products intended to be sold or labeled as organically produced have come into contact with prohibited substances. This will allow a State program's governing State official or certifying agent to determine whether the integrity of the product has been affected. We believe our proposed residue testing program and compliance provisions should be adequate to protect the integrity of agricultural products.

Residue Testing—Changes Requested but Not Made

(1) The original proposal provided that land subject to a Federal or State emergency disease or pest treatment program should not lose its organic certification and should not be required to be withheld from organic production for a period of 3 years. A few commenters stated that a field treated under such emergency situations should lose its certification and should be restricted for organic use for 3 years following the emergency treatment. The

commenters stated this is necessary to maintain consumer confidence in organically produced products. We believe the first proposal is consistent with the requirements of the Act. The proposal provided that crops and livestock that had contact or been treated with a prohibited substance under such an official emergency treatment program could not be sold or labeled as organic. This proposal retains that prohibition.

Commenters suggested that producers work with the Federal or State agency which requires an emergency treatment program and arrange for use of materials that are compatible with organic production. While this may be possible under certain emergency treatment situations, it cannot be relied on as a solution to every emergency treatment situation. Appropriate alternative treatments may not be available, or the jurisdiction requiring the emergency program may not grant alternative treatments. Commenters also suggested that producers avoid planting crops that might be subject to pests or diseases targeted by emergency treatment programs to avoid emergency treatments. We do not believe that is a reasonable solution for producers. Emergency treatment programs are used in response to unforeseen infestations and diseases. Only hindsight would help organic producers determine which crops to produce. Further, the possibilities of damaging insect infestations or plant or animal diseases warranting an emergency treatment program are so numerous that an organic producer could be left with few or no alternative crops or livestock to produce. Cultural conditions and market factors also would limit selection of alternative organic production. Accordingly, the commenters' recommendation that loss of organic certification and an automatic 3-year prohibition on organic production from land or livestock treated under an official emergency treatment program is not accepted.

Residue Testing. (2) Commenters suggested that some of the responsibility of residue testing be removed from certifying agent responsibilities. They also suggested that residue testing requirements take into account current Federal and State testing requirements already in place for the detection of pesticide residues.

We have not adopted language that the Department would use current Federal and State testing requirements for the detection of pesticide residues in the residue testing program. Although State and Federal testing provide good sources of data on pesticide residues,

the data may reflect criteria developed for different sampling purposes, showing wide variations in sample selection and indicating different laboratory capabilities and different levels of quantification between and within laboratories.

Residue Testing—Additional Provisions

Section 205.670(a) has been added. It provides that the Administrator, the State program's governing State official, and the applicable certifying agent have access, for inspection purposes, to all agricultural products being sold, labeled, or represented as "100 percent organic," "organic," or "made with organic (specified ingredients)." In addition, the organic products must be made available for examination by said authorities in the manner that they prescribe.

Public comments did not suggest this action. However, we believe it is necessary to officially grant the Administrator, the State program's governing State official, and the applicable certifying agent the authority to access all agricultural products subject to inspection under this section. This authority will help resolve conflicts that may arise regarding product accessibility during inspection and testing.

Adverse Action Appeal Process. This portion of subpart G sets forth the general framework for an appeal process for persons subject to compliance determinations under the National Organic Program (NOP). In this proposal, we are empowering certifying agents with the authority to make decisions concerning denial of certification and the suspension or revocation of certified operations. This empowerment of certifying agents makes the appeal process very important.

We envision two kinds of appeals will be filed under these procedures: (1) Producers and handlers appealing denial of certification and proposed suspension and revocation of certification decisions by certifying agents; and (2) certifying agents appealing denial of accreditation and proposed suspension and revocation decisions by the NOP Program Manager. The Administrative Procedure Act (APA) (5 U.S.C. 553–559) provides that entities such as certified operations and accredited certifying agents have the right to appeal any adverse actions taken against their certification or accreditation, respectively. Applicants for certification and applicants for accreditation who receive a denial of certification or accreditation may appeal that denial following this appeal

procedure. The appeal process is the same for applicants as for certified operations and accredited certifying agents.

The informal appeal process described in this section is an extension of the noncompliance proceeding outlined in the Compliance section of this subpart.

For certification proceedings, the NOP and the Administrator will oversee compliance proceedings and handle certification appeals from operations in States that do not have an approved State organic certification program. The Administrator will issue decisions to sustain or deny appeals. If an appeal is denied, the Secretary will initiate a formal administrative review process, which includes a hearing before an administrative law judge and review by the Department's Judicial Officer. The formal administrative review process will be conducted pursuant to the Department's Uniform Rules of Practice, 7 CFR 1.130 through 1.151. The formal administrative review will be the Department's final determination on the noncompliance proceeding. That decision may be appealed to the District Courts. This section addresses the informal appeal process which is used to arrive at the Administrator's decision to sustain or deny an appeal.

In States with approved State organic certification programs, the governing State official or designee will oversee certification compliance proceedings and handle appeals from certified operations in the State. The governing State official or designated appeals official will rule on appeals filed under a State organic certification program. Further appeal of that decision may be made to the district court system.

Proposal Description

These appeal procedures provide that persons subject to the Act who believe that they are adversely affected by a noncompliance decision of a certifying agent, Program Manager, or governing State official may appeal such decision to the Administrator or to the applicable State's appeal process. Under Compliance provision in this subpart, accredited certifying agents initiate noncompliance proceedings. If an appeal of a certification decision is filed, the process is referred to the Administrator or governing State official or designee, as applicable, to the State where the applicant or certified operation resides.

Certification Appeals

Applicants for certification may appeal a certifying agent's denial of certification. Certified operations may

appeal a certifying agent's notification of proposed suspension or revocation of the operation's certification. These appeals will be made to the Administrator or to the applicable governing State official or designated official in the approved State organic certification program.

Certification appeals may be filed only after an applicant or a certified operation has been given opportunity to come into compliance with these regulations or otherwise resolve the specified noncompliance. Prior to filing an appeal, the applicant or certified operation must have failed in rebuttal, refused to make specified corrections, or made corrections which the certifying agent subsequently determined to not meet certification requirements of the NOP.

If the Administrator or governing State official sustains an appeal, the applicant or certified operation will be granted certification or continued certification, as applicable to the operation's status. The applicant or certified operation will not be required to correct the actions or conditions cited in the noncompliance notification. The act of sustaining the appeal will not be considered an adverse action and may not be appealed by the certifying agent which issued the notification.

If the Administrator or governing State official denies an appeal, a formal administrative proceeding will be initiated to deny, suspend, or revoke the certification. Such proceeding will be conducted pursuant to the Department's Uniform Rules of Practice or pursuant to the State's formal appeal procedures. Certified operations may continue to operate throughout this informal appeals process and the formal administrative proceedings.

Accreditation Appeals

Pursuant to § 205.665 of this subpart, all accredited certifying agents are subject to the Program Manager's review of their operations and any noncompliance actions resulting from such reviews. As provided in § 205.668, a State program's governing State official must advise the Program Manager if an investigation of a certifying agent reveals that the certifying agent is not in compliance with the Act or these regulations. The appeal process for applicants is the same as for accredited certifying agents.

An appeal may be filed with the Administrator only after the certifying agent fails to rebut the noncompliance notice and fails to correct the noncompliance specified. If the Administrator sustains an appeal, the applicant or certified operation will be

granted certification or continued certification, as applicable to the operation's status. The applicant or certified operation will not be required to correct the actions or conditions cited in the compliance notification. If the appeal is denied, a formal administrative proceeding will be initiated to deny, suspend, or revoke the accreditation.

The certifying agent may continue to operate as a certifying agent throughout the informal appeals process and the formal administrative proceeding.

All appeals to the Administrator must be filed in writing and sent to: Administrator, USDA-AMS, Room 3071-S, PO Box 96456, Washington, DC 20090-6456. An appeal must include a copy of the adverse decision to be reviewed and a statement of the appellant's reasons for believing that the decision was not proper and not made in accordance with applicable program regulations, policies, or procedures. A certified operation must send a copy of its appeal, to its certifying agent. All written communications between parties involved in appeal proceedings must be sent to the recipient's place of business by a delivery service which provides dated return receipts. Appeals under a State's procedure will be filed pursuant to the State's appeal process, which should include addresses and filing periods, etc.

An appeal must be filed within the time provided in the letter of notification or at least 30 days from the date of receipt of the notice to deny, suspend, or revoke certification or accreditation. The appeal will be considered "filed" on the date received by the Administrator or, when applicable, the State program's governing State official or such official's designee. The Administrator will notify the appellant and the appellant's certifying agent that the appeal was received. Unless appealed in a timely manner, a notification to deny, suspend, or revoke a certification or an accreditation will become final. The applicant, certified operation, or certifying agent that does not file an appeal in the time period provided waives the right to further appeal of the compliance proceeding.

Appeals—Changes Based On Comments

These appeal regulations differ from our first proposal as follows:

(1) *Decision-making.* We have clarified who will be making decisions that may be appealed to the Administrator. This proposal provides that persons subject to the Act who, during noncompliance proceedings described in this subpart, believe that

they are adversely affected by a noncompliance decision of a certifying agent, Program Manager, or governing State official may appeal such decision to the Administrator or the State's designated appeals official. This clarification is found in § 205.680.

Commenters stated that the proposed appeals procedures limited appeals to decisions of the NOP staff. Commenters requested that the appeals procedures be available for decisions by the Secretary, any representative of the Secretary, and decisions by any certifying agent. What we meant in the first proposal was that appeals would be filed on decisions made by the Program Manager and certifying agents.

As noted above, we are empowering certifying agents to make decisions concerning denials of certification and suspension or revocation of certified operations' certifications. Certifying agents accredited under this program act on behalf of the Secretary and the Administrator to carry out certification services, including noncompliance actions. The Administrator or designated governing State official will make decisions to either sustain or deny appeals by certification applicants and certified operations, as applicable to the State.

The Program Manager will make decisions to deny applications for accreditation and to suspend or revoke certifying agents' accreditations. The Administrator will make all decisions to either sustain or deny appeals by accreditation applicants and certifying agents.

(2) *Appeal procedures.* Commenters requested detailed appeal procedures or the use of citations to identify existing Departmental appeal procedures which would be used for appeals filed under this program. We acknowledge that the first proposal lacked detailed appeals provisions. However, we believe this explanation is more informative and helpful for the commenters. The formal administrative procedure following the Department's Uniform Rules of Practice is required under the APA. The rules of practice are not included in individual rulemaking actions but may be found under 7 CFR 1.130 through 1.151. The combination of this informal appeal procedure followed by the formal administrative proceeding assures applicants, certified operations, and accredited certifying agents that they will be given full opportunity to respond to any noncompliance proceeding brought against their application or operation. Individual State programs will have their own, approved appeal procedures.

Commenters also recommended that the Department should use an independent USDA appeals division to avoid conflict of interest by the Program Manager or the Administrator in the handling of appeals. We believe this proposed appeal procedure ensures that appeals will be administered by persons not involved in the decision being appealed. This appeals procedure is consistent with the requirements of the APA.

Paragraph (a)(1) of § 205.681 provides that if the Administrator sustains an applicant's or certified operation's appeal of a certifying agent's noncompliance decision, the act of sustaining the appeal shall not be an adverse action subject to appeal by the affected certifying agent. We have included this provision because, as noted above, certifying agents are accredited by the Secretary to provide certification services as agents of the Secretary and the Administrator. Therefore, if the Administrator overrules a decision of an accredited certifying agent, that certifying agent cannot request an appeal of the Administrator's decision.

Appeals—Changes Requested But Not Made

None.

Appeals—Additional Provisions

(1) *State appeals procedures.* We are proposing that appeal proceedings in States with organic certification programs approved by the Secretary will be carried out in accordance with the official administrative appeal proceedings in each State. A State's appeal process will be included as part of the State's organic certification program. Because a State's appeal procedure is approved by the Secretary, the final determination for a certification appeal arrived at under that procedure is considered to have the effect of a decision by the Secretary. Approved State appeal processes are unique to each State and are not included in this regulation.

Certification appeals are made to the State program's governing State official or such official's designee. The governing State official or designee will administer the appeal pursuant to appeal procedures which have been approved by the Secretary. Rulings on such appeals, as noted in § 205.668, may not be appealed to the Secretary. The certification applicant or certified operation may make subsequent appeal to the Court of Appeals of the United States for the circuit in which such applicant or certified operation carries on business or in the United States

Court of Appeals for the District of Columbia Circuit.

(2) *Accreditation appeals.* This proposal provides that the Program Manager carries out all compliance proceedings on accredited certifying agents. The Secretary has sole authority for accrediting certifying agents and, therefore, must retain sole authority for suspending or revoking that accreditation. A State program's governing State official must investigate any complaints of noncompliance on the part of a certifying agent operating in the State. If noncompliance activities or conditions are found, the governing State official must notify the Program Manager of those compliance violations or suspected compliance violations.

Miscellaneous

Section 205.690 provisions the Office of Management and Budget control number assigned to the information collection requirements of these regulations. Sections 205.691 through 205.699 are reserved.

List of Subjects in 7 CFR Part 205

Administrative practice and procedure, Agriculture, Animals, Archives and records, 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 part 205 through 209 is added to read as follows:

SUBCHAPTER M—ORGANIC FOODS PRODUCTION ACT PROVISIONS

PART 205—NATIONAL ORGANIC PROGRAM

Subpart A—Definitions

- Sec.
- 205.1 Meaning of words.
 - 205.2 Terms defined.

Subpart B—Applicability

- 205.100 What has to be certified.
- 205.101 Exemptions and exclusions from certification.
- 205.102 Use of the term, "organic."
- 205.103 Recordkeeping by certified operations.
- 205.104 Foreign applicants.
- 205.105–205.199 [Reserved]

Subpart C—Organic Crop, Wild Crop, Livestock, and Handling Requirements

- 205.200 General.

- 205.201 Organic production and handling system plan.
- 205.202 Land requirements.
- 205.203 Soil fertility and crop nutrient management practice standard.
- 205.204 Seeds and planting stock practice standard.
- 205.205 Crop rotation practice standard.
- 205.206 Crop pest, weed, and disease management practice standard.
- 205.207 Wild-crop harvesting practice standard.
- 205.208–205.235 [Reserved]
- 205.236 Origin of livestock.
- 205.237 Livestock feed.
- 205.238 Livestock health care practice standard.
- 205.239 Livestock living conditions.
- 205.240–205.269 [Reserved]
- 205.270 Organic handling requirements.
- 205.271 Facility pest management practice standard.
- 205.272 Commingling and contact with prohibited substance prevention practice standard.
- 205.290 Temporary variances.

Subpart D—Labels, Labeling, and Market Information

- 205.300 Use of the term, “organic.”
- 205.301 Product composition.
- 205.302 Calculating the percentage of organically produced ingredients.
- 205.303 Packaged products labeled “100 percent organic” or “organic.”
- 205.304 Packaged products labeled “made with organic (specified ingredients).”
- 205.305 Multiingredient packaged products with less than 50 percent organic ingredients.
- 205.306 Labeling of nonretail containers used for only shipping or storage of raw or processed agricultural products labeled as “100 percent organic,” “organic,” or “made with organic (specified ingredients).”
- 205.307 Agricultural products in a form other than packages at the time of retail sale that are labeled or represented as “100 percent organic” or “organic.”
- 205.308 Agricultural products in a form other than packages at the time of retail sale that are sold, labeled, or represented as “made with organic (specified ingredients).”
- 205.309 Agricultural products produced on an exempt production operation.
- 205.310 USDA Seal.

Subpart E—Certification

- 205.400 General requirements for certification.
- 205.401 Application for certification.
- 205.402 Review of application.
- 205.403 On-site inspections.
- 205.404 Approval of certification.
- 205.405 Denial of certification.
- 205.406 Continuation of certification.
- 205.407–205.499 [Reserved]

Subpart F—Accreditation of Certifying Agents

- 205.500 Areas and duration of accreditation.
- 205.501 General requirements for accreditation.
- 205.502 Applying for accreditation.

- 205.503 Applicant information.
- 205.504 Evidence of expertise and ability.
- 205.505 Statement of agreement.
- 205.506 Approval of accreditation.
- 205.507 Denial of accreditation.
- 205.508 Site evaluations.
- 205.509 Peer review panel.
- 205.510 Annual report, recordkeeping, and renewal of accreditation.
- 205.511–205.599 [Reserved]

Subpart G—Administrative

The National List of Allowed and Prohibited Substances

- 205.600 Allowed and prohibited substances and ingredients in organic production and handling.
- ≤205.601 Synthetic substances allowed for use in organic crop production.
- 205.602 Nonsynthetic substances prohibited for use in organic crop production.
- 205.603 Synthetic substances allowed for use in organic livestock production.
- 205.604 Nonsynthetic substances prohibited for use in organic livestock production. [Reserved]
- 205.605 Nonagricultural (nonorganic) substances allowed as ingredients in or on processed products labeled as “organic,” or “made with organic (specified ingredients).”
- 205.606 Nonorganically produced agricultural products allowed as ingredients in or on processed products labeled as “organic” or “made with organic ingredients.”
- 205.607 Amending the National List. State Programs
- 205.620 Requirements of State organic certification programs.
- 205.621 Submission and determination of proposed State organic certification programs and amendments to approved State organic certification programs.
- 205.622 Review of approved State organic certification programs.

Fees

- 205.640 Fees and other charges for accreditation.
- 205.641 Payment of fees and other charges.
- 205.642 Fees and other charges for certification.
- 205.643–205.649 [Reserved]

Compliance

- 205.660 General.
- 205.661 Investigations of certified operations.
- 205.662 Noncompliance procedure for certified operations.
- 205.663 Mediation.
- 205.664 [Reserved]
- 205.665 Noncompliance procedures for certifying agents.
- 205.666–205.667 [Reserved]
- 205.668 Noncompliance procedures under State organic certification programs.
- 205.699 [Reserved]
- Inspection and Testing, Reporting, and Exclusion from Sale
- 205.670 Inspection and testing of agricultural product to be sold or labeled “organic”.
- 205.671 Exclusion from organic sale.
- 205.672 Emergency pest or disease treatment.

- 205.673–205.679 [Reserved]
- Adverse Action Appeal Process
- 205.680 General.
- 205.681 Appeals.
- 205.682–205.689 [Reserved]
- Miscellaneous
- 205.690 OMB control number.
- 205.691–205.699 [Reserved]

Authority: 7 U.S.C. 6501–6522.

Subpart A—Definitions

205.1 Meaning of words.

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

205.2 Terms defined.

Accredited laboratory. A laboratory that has met and continues to meet the requirements specified in the Food, Agriculture, Conservation, and Trade Act of 1990 (7 U.S.C. 138) for pesticide residue analyses of fresh fruit and vegetables and/or pesticide residue analysis of products derived from livestock and fowl.

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

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

Action level. The limit at or above which the Food and Drug Administration will take legal action against a product to remove it from the market. Action levels are based on unavailability of the poisonous or deleterious substances and do not represent permissible levels of contamination where it is avoidable.

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

Agricultural inputs. All substances or materials used in the production or handling of organic agricultural products.

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

Allowed synthetic. A substance that is included on the National List of synthetic substances allowed for use in organic production, or handling.

Agricultural Marketing Service (AMS). The Agricultural Marketing Service of the United States Department of Agriculture.

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

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

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

Audit trail. Documentation that is sufficient to determine the source, transfer of ownership, and transportation of any agricultural product labeled as "100 percent organic," the organic ingredients of any agricultural product labeled as "organic" or "made with organic (specified ingredients)" or the organic ingredients of any agricultural product containing less than 50 percent organic ingredients identified as organic in an ingredients statement.

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

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

Breeder stock. Female livestock whose offspring may be incorporated into an organic operation at the time of their birth.

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

Bulk. The presentation to consumers at retail sale of an agricultural product in unpackaged, loose form, enabling the consumer to determine the individual pieces, amount, or volume of the product purchased.

Certification or certified. A determination made by a certifying agent that a production or handling

operation is in compliance with the Act and the regulations in this part, which is documented by a certificate of organic operation.

Certified operation. A crop or livestock production, wild-crop harvesting, or handling operation or portion of such operation that is certified by an accredited certifying agent as utilizing a system of organic production or handling as described by the Act and the regulations in this part.

Certifying agent. Any entity accredited by the Secretary as a certifying agent for the purpose of certifying a production or handling operation as a certified production or handling operation.

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

Claims. Oral, written, implied, or symbolic representations, statements, or advertising or other forms of communication presented to the public or buyers of agricultural products that relate to the organic certification process or the term, "100 percent organic," "organic," or "made with organic (specified ingredients)," or, in the case of agricultural products containing less than 50 percent organic ingredients, the term, "organic," on the ingredients panel.

Commercially available. The ability to obtain a production input in an appropriate form, quality, or quantity to fulfill an essential function in a system of organic production or handling, as determined by the certifying agent in the course of reviewing the organic plan.

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

Compost. The product of a carefully managed process through which microorganisms break down plant and animal materials into more available forms suitable for application to the soil. Compost used in an organic operation must be produced in a facility in compliance with the Natural Resource Conservation Service's practice standard for a composting facility (Code 317) and must use methods to raise the temperature of the raw materials to the levels needed to stabilize nutrients and kill pathogens.

Control. Any method that reduces or limits damage by populations of pests,

weeds, or diseases to levels that do not significantly reduce productivity.

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

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

Crop rotation. The practice of alternating the annual crops grown on a specific field in a planned pattern or sequence in successive crop years, so that crops of the same species or family are not grown repeatedly without interruption on the same field. Perennial cropping systems employ means such as alley cropping, intercropping, and hedgerows to introduce biological diversity in lieu of crop sequencing.

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

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

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

Detectable residue. The amount or presence of chemical residue or sample component that can be reliably observed or found in the sample matrix by the current approved analytical methodology.

Disease vectors. Plants or animals that harbor or transmit disease organisms or pathogens which may attack crops or livestock.

Drift. The physical movement of prohibited substances from the intended target site onto an organic operation or portion thereof.

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

Employee. Any person providing paid or volunteer services for a certifying agent.

Estimated National Mean. The mean level of detected pesticide residues as described in certain pesticide/commodity pairs or combinations established by USDA's Pesticide Data Program.

Excluded methods. Refers to a variety of methods used to genetically modify organisms or influence their growth and development by means that are not possible under natural conditions or processes and are not considered compatible with organic production. Such methods would include recombinant DNA, cell fusion, and micro- and macroencapsulation. Such methods would not include the use of traditional breeding, conjugation, fermentation, hybridization, in vitro fertilization, or tissue culture.

Feed. Edible materials which are consumed by livestock for their nutritional value. Feed may be concentrates (grains) or roughages (hay, silage, fodder). The term, "feed," encompasses all agricultural commodities, including pasture ingested by livestock for nutritional purposes.

Feed Additive. A substance or combination of substances added to feed in micro quantities to fulfill a specific nutritional need, i.e., nutrients in the form of amino acids, vitamins, and minerals.

Feed Supplement. A feed used with another feed to improve the nutrient balance or performance of the total ration and intended to be:

- (1) Diluted with other feeds when fed to livestock;
- (2) Offered free choice with other parts of the ration if separately available; or
- (3) Further diluted and mixed to produce a complete feed.

Fertilizer. A single or blended substance containing one or more recognized plant nutrient(s) which is used primarily for its plant nutrient content and which is designed for use or claimed to have value in promoting plant growth.

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

Forage. Vegetable material in a fresh, dried, or ensiled state (pasture, hay, or silage) which is fed to livestock.

Handle. To sell, process, or package agricultural products, except such term shall not include the sale, transportation, or delivery of crops or livestock by the producer thereof to a handler.

Handler. Any person engaged in the business of handling agricultural products, including producers who handle crops or livestock of their own production, except such term shall not include final retailers of agricultural products that do not process agricultural products.

Handling operation. Any operation or portion of an operation (except final

retailers of agricultural products that do not process agricultural products) that receives or otherwise acquires agricultural products and processes, packages, or stores such products.

Immediate family. The spouse, minor children, or blood relatives who reside in the immediate household of a certifying agent or an employee, inspector, contractor, or other personnel of the certifying agent. For the purpose of this part, the interest of a spouse, minor child, or blood relative who is a resident of the immediate household of a certifying agent or an employee, inspector, contractor, or other personnel of the certifying agent shall be considered to be an interest of the certifying agent or an employee, inspector, contractor, or other personnel of the certifying agent.

Inert ingredient. Any substance (or group of substances with similar chemical structures if designated by the Environmental Protection Agency) other than an active ingredient which is intentionally included in any pesticide product used in organic crop or livestock production and handling (40 CFR 152.3(m)).

Information panel. That part of the label of a packaged product that is immediately contiguous to and to the right of the principal display panel as observed by an individual facing the principal display panel, unless another section of the label is designated as the information panel because of package size or other package attributes (e.g., irregular shape with one usable surface).

Ingredient. Any substance used in the preparation of an agricultural product that is still present in the final commercial product as consumed.

Ingredients statement. The list of ingredients contained in a product shown in their common and usual names in the descending order of predominance.

Inspector. Any person retained or used by a certifying agent to conduct inspections of certification applicants or certified production or handling operations.

Inspection. The act of examining and evaluating the production or handling operation of an applicant for certification or certified operation to determine compliance with the Act and the regulations in this part.

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

information about the weight of the product.

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

Livestock. Any cattle, sheep, goat, swine, poultry, or equine animals used for food or in the production of food, fiber, feed, or other agricultural-based consumer products; wild or domesticated game; or other nonplant life, except such term shall not include aquatic animals or bees for the production of food, fiber, feed, or other agricultural-based consumer products.

Lot. Any number of containers which contain an agricultural product of the same kind located in the same conveyance, warehouse, or packing house and which are available for inspection at the same time.

Market information. Any written, printed, audiovisual, or graphic information, including advertising, pamphlets, flyers, catalogues, posters, and signs, distributed, broadcasted, or made available outside of retail outlets that are used to assist in the sale or promotion of a product.

Mulch. Any material, such as wood chips, leaves, straw, paper, or plastic (on the National List), 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 6517 of the Act (7 U.S.C. 6517).

National Organic Program (NOP). The program authorized by the Act for the purpose of implementing its provisions.

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

Natural resources of the operation. The physical, hydrological, and biological features of a production operation, including soil, water, wetlands, woodlands, and wildlife.

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

agricultural product is unrecognizable in the extract, isolate, or fraction.

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

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

Nonretail container. Any container used for shipping or storage of an agricultural product that is not used in the retail display or sale of the product.

Organic. A labeling term that refers to an agricultural product produced in accordance with the Act and the regulations in this part.

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

Organic system plan. A plan of management of an organic production or handling operation that has been agreed to by the producer or handler and the certifying agent and that includes written plans concerning all aspects of agricultural production or handling described in the Act and the regulations in subpart C of this part.

Peer review panel. A panel of individuals who have expertise in organic production and handling methods and certification procedures and who are appointed by the Administrator to assist in evaluating applicants for accreditation as certifying agents.

Person. An individual, group of individuals, contractor, 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.

Practice standard. The guidelines and requirements through which a production or handling operation implements a required component of its production or handling organic system plan. A practice standard integrates a series of allowed and prohibited actions, materials, and conditions to establish a minimum level performance for planning, conducting, and maintaining

a function, such as livestock health care or facility pest management, essential to an organic operation.

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

Private entity. Any domestic or foreign nongovernmental for-profit or not-for-profit organization providing certification services.

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

Producer. A person who engages in the business of growing or producing food, fiber, feed, and other agricultural-based consumer products.

Production lot number/identifier. Identification of a product based on the production sequence of the product showing the date, time, and place of production used for quality control purposes.

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

Records. Any information in written, visual, or electronic form that documents the activities undertaken by a producer, handler, or certifying agent to comply with the Act and regulations in this part.

Residue testing. An official or validated analytical procedure that detects, identifies, and measures the presence of chemical substances, their metabolites, or degradations products in or on raw or processed agricultural products.

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

Retail food establishment. A restaurant; delicatessen; bakery; grocery store; or any retail outlet with an in-store restaurant, delicatessen, bakery, salad bar, or other eat-in or carry-out service of processed or prepared raw and ready-to-eat-food.

Routine use of parasiticide. The regular, planned, or periodic use of parasiticides.

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

Sewage sludge. A solid, semisolid, or liquid residue generated during the treatment of domestic sewage in a treatment works. Sewage sludge includes, but is not limited to: domestic septage; scum or solids removed in primary, secondary, or advanced wastewater treatment processes; and a material derived from sewage sludge. Sewage sludge does not include ash generated during the firing of sewage sludge in a sewage sludge incinerator or grit and screenings generated during preliminary treatment of domestic sewage in a treatment works.

Slaughter stock. Any animal that is intended to be slaughtered for consumption by humans or other animals.

Soil and water quality. Observable indicators of the physical, chemical, or biological condition of soil and water, including the presence of environmental contaminants.

State. Any of the several States of the United States of America, its territories, the District of Columbia, and the Commonwealth of Puerto Rico.

State certifying agent. A certifying agent accredited by the Secretary under the National Organic Program and operated by the State for the purposes of certifying organic production and handling operations in the State.

State entity. Any domestic, tribal government, or foreign governmental subdivision providing certification services.

State organic certification program. A State program that meets the requirements of section 6506 of the Act, is approved by the Secretary, and is designed to ensure that a product that is sold or labeled as organically produced under the Act is produced and handled using organic methods.

State program's governing State official. The chief executive official of a State or, in the case of a State that provides for the statewide election of an official to be responsible solely for the administration of the agricultural operations of the State, such official, who administers a State organic certification program.

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

System of organic production 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. A seedling which has been removed from its original place of production, transported, and replanted.

Tolerance. The maximum legal level of a pesticide residue in or on a raw or processed agricultural commodity as set by the Environmental Protection Agency under FFDCA, Section 408.

Unavoidable residual environmental contamination (UREC). Background levels of naturally occurring or synthetic chemicals that are present in the soil or present in organically produced agricultural products that are below established tolerances.

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

Subpart B—Applicability

§ 205.100 What has to be certified.

(a) Except for operations exempt or excluded in § 205.101, each production or handling operation or specified portion of a production or handling operation that produces or handles crops, livestock, livestock products, or other agricultural products that are intended to be sold, labeled, or represented as “100 percent organic,” “organic,” or “made with organic (specified ingredients)” must be certified according to the provisions of subpart E of this part and must meet all other applicable requirements of this part.

(b) Any production or handling operation that has been certified by a certifying agent on the date that the certifying agent first receives its accreditation under this part shall be considered certified to the national standards until the operation’s anniversary date of certification. Such recognition shall only be available to those operations certified by a certifying agent that receives its accreditation within 18 months from the date of publication of the final rule implementing this part.

§ 205.101 Exemptions and exclusions from certification.

(a) Exemptions.

(1) A production or handling operation that sells agricultural products as “organic” but whose gross agricultural income from organic sales totals \$5,000 or less annually is exempt from certification under subpart E of this part and from submitting an organic system plan for acceptance or approval under § 205.201 but must comply with the applicable organic production and handling requirements of subpart C of this part and the labeling requirements of § 205.309.

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

(3) A handling operation or portion of a handling operation that handles 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 contact of organic products with prohibited substances set forth in § 205.272 with respect to any organically produced ingredients used in an agricultural product;

(ii) The labeling provisions of § 205.309; and

(iii) The recordkeeping provisions in paragraph (c) of this section.

(4) A handling operation or portion of a handling operation that handles agricultural products that contain at least 50 percent organic ingredients by total weight of the finished product (excluding water and salt) that chooses to not use the word, “organic,” on any panel other than the information panel is exempt from the requirements in this part, except:

(i) The provisions for prevention of contact of organic products with prohibited substances set forth in § 205.272 with respect to any organically produced ingredients used in an agricultural product;

(ii) The labeling provisions of § 205.309; and

(iii) The recordkeeping provisions in paragraph (c) of this section.

(b) Exclusions.

(1) A handling operation or portion of a handling operation is excluded from the requirements of this part, except for the requirements for the prevention of commingling and contact with prohibited substances as set forth in § 205.272 with respect to any

organically produced products if such operation or portion of the operation only sells organic agricultural products labeled as “100 percent organic,” “organic,” or “made with organic (specified ingredients)” that:

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

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

(2) A handling operation that is a retail food establishment or portion of a retail food establishment that processes or prepares, on the premises of the retail food establishment, raw and ready-to-eat food from agricultural products that are previously labeled as “100 percent organic,” “organic,” or “made with organic (specified ingredients)” is excluded from the requirements in this part, except:

(i) The requirements for the prevention of contact with prohibited substances as set forth in § 205.272; and

(ii) The labeling provisions of § 205.309.

(c) Records to be maintained by exempt operations.

(1) Any handling operation exempt from certification pursuant to paragraph (a)(3) or (a)(4) of this section must maintain records sufficient to:

(i) Prove that ingredients identified as organic were organically produced and handled; and

(ii) Verify quantities produced from such ingredients.

(2) Records must be maintained for no less than 3 years beyond their creation and the operations must allow representatives of the Secretary and the applicable State program’s governing State official access to these records for inspection and copying during normal business hours to determine compliance with the applicable regulations set forth in this part.

§ 205.102 Use of the term, “organic.”

Any agricultural product that is sold, labeled, or represented as “100 percent organic,” “organic,” or “made with organic (specified ingredients)” must be:

(a) Produced in accordance with the requirements specified in § 205.101 or §§ 205.202 through 205.207 or §§ 205.236 through 205.239 and all other applicable requirements of part 205;

(b) Handled in accordance with the requirements specified in § 205.101 or §§ 205.270 through 205.272 and all other applicable requirements of this part 205; and

(c) Produced and handled in compliance with the Federal Meat

Inspection Act (21 U.S.C. 601 *et seq.*), the Poultry Products Inspection Act (21 U.S.C. 451 *et seq.*), and the Egg Products Inspection Act (21 U.S.C. 1031 *et seq.*), concerning meat, poultry, and egg products; the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 *et seq.*); the Federal Insecticide, Fungicide, and Rodenticide Act (7 U.S.C. 136 *et seq.*); and any other applicable Federal statute and its implementing regulations.

§ 205.103 Recordkeeping by certified operations.

(a) A certified operation must maintain records concerning the production, harvesting, and handling of agricultural products that are or that are intended to be sold, labeled, or represented as “100 percent organic,” “organic,” or “made with organic (specified ingredients).”

(b) Such records must:

(1) Be adapted to the particular business that the certified operation is conducting;

(2) Fully disclose all activities and transactions of the certified operation in sufficient detail as to be readily understood and audited;

(3) Be maintained for not less than 5 years beyond their creation; and

(4) Be sufficient to demonstrate compliance with the Act and the regulations in this part.

(c) The certified operation must make such records available for inspection and copying during normal business hours by authorized representatives of the Secretary, the applicable State program’s governing State official, and the certifying agent.

§ 205.104 Foreign applicants.

The regulations in this part, as applicable, apply equally to domestic and foreign applicants for accreditation, accredited certifying agents, domestic and foreign applicants for certification as organic production or handling operations, and certified organic production and handling operations unless otherwise specified.

§§ 205.105—205.199 [Reserved]

Subpart C—Organic Production and Handling Requirements

§ 205.200 General.

The producer or handler of a production or handling operation wishing to sell, label, or represent agricultural products as “100 percent organic,” “organic,” or “made with organic (specified ingredients)” must comply with the applicable provisions of this subpart. Practices implemented in accordance with this subpart must maintain or improve the natural

resources of the operation, including soil and water quality.

§ 205.201 Organic production and handling system plan.

(a) The producer or handler of a production or handling operation, except as exempt or excluded under § 205.101, wishing to sell, label, or represent agricultural products as “100 percent organic,” “organic,” or “made with organic (specified ingredients)” must develop an organic production or handling system plan that is agreed to by the producer or handler and an accredited certifying agent. An organic system plan must meet the requirements set forth in this section to establish a system of organic production or handling. An organic production or handling system plan must include:

(1) A description of practices and procedures to be performed and maintained, including the frequency with which they will be performed;

(2) A list of each substance to be used as a production or handling input, indicating its composition, source, and location(s) where it will be used;

(3) A description of the monitoring practices and procedures to be performed and maintained, including the frequency with which they will be performed, to verify that the plan is effectively implemented;

(4) A description of the recordkeeping system implemented to comply with the requirements established in § 205.103;

(5) A description of practices and procedures to prevent commingling of organic and nonorganic products and to prevent contact of organic production and handling operations and products with prohibited substances; and

(6) Additional information deemed necessary by the certifying agent to evaluate compliance with the regulations.

(b) A producer may substitute a plan prepared to meet the requirements of another Federal, State, or local government regulatory program for the organic system plan: *Provided*, That, the submitted plan meets all the requirements of this subpart.

§ 205.202 Land requirements.

Any field or farm parcel from which harvested crops are intended to be sold, labeled, or represented as “100 percent organic,” “organic,” or “made with organic (specified ingredients)” must:

(a) Have been managed in accordance with the provisions of §§ 205.203 through 205.206;

(b) Have had no prohibited substances, as listed in § 205.600, applied to it for a period of 3 years immediately preceding harvest of the crop; and

(c) Have distinct, defined boundaries and buffer zones such as runoff diversions to prevent the unintended application of a prohibited substance to the crop or contact with a prohibited substance applied to adjoining land that is not under organic management.

§ 205.203 Soil fertility and crop nutrient management practice standard.

(a) The producer must select and implement tillage and cultivation practices that maintain or improve the physical, chemical, and biological condition of soil and minimize soil erosion.

(b) The producer must budget and supply crop nutrients by properly utilizing manure or other animal and plant materials, mined mineral substances, and substances approved in § 205.601.

(c) The producer must manage animal and plant waste materials to maintain or improve soil organic matter content in a manner that does not contribute to contamination of crops, soil, or water by plant nutrients, pathogenic organisms, heavy metals, or residues of prohibited substances. Animal and plant waste materials include:

(1) Raw animal manure, which must be composted unless it is:

(i) Applied to land used for a crop not intended for human consumption;

(ii) Incorporated into the soil not less than 120 days prior to the harvest of a product whose edible portion has direct contact with the soil surface or soil particles; or

(iii) Incorporated into the soil not less than 90 days prior to the harvest of a product whose edible portion does not have direct contact with the soil surface or soil particles;

(2) Other uncomposted plant or animal wastes, such as aged, fully decomposed animal manure;

(3) A composted product produced in a facility in compliance with the Natural Resources Conservation Service’s practice standard for a composting facility (Code 317); and

(4) A composted or uncomposted plant or animal waste material that has been chemically altered by a manufacturing process: *Provided*, That, the material is included on the National List of synthetic substances allowed for use in organic crop production established in § 205.601.

(d) In addition to crop rotations and plant and animal waste materials, a producer may supply soil and crop nutrients by applying:

(1) A mined substance of low solubility;

(2) A mined substance of high solubility, when justified by soil or crop tissue analysis;

(3) Ash obtained from the burning of a plant or animal material, except as prohibited in paragraph (e) of this section: *Provided*, That, the material burned has not been treated or combined with a prohibited substance or the ash is not included on the National List of nonsynthetic substances prohibited for use in organic crop production; and

(4) A crop nutrient supplement included on the National List of synthetic substances allowed for use in organic production, when justified by soil or crop tissue analysis.

(e) The producer must not use:

(1) Any fertilizer or commercially blended fertilizer or composted product that contains a synthetic substance not included on the National List of synthetic substances allowed for use in organic production;

(2) Sewage sludge (biosolids) as defined in 40 CFR part 503; and

(3) Burning as a means of disposal for crop residues produced on the operation: *Except*, That, prunings from perennial crops may be burned to suppress the spread of disease.

§ 205.204 Seeds and planting stock practice standard.

(a) The producer must use organically grown seeds, annual seedlings, and planting stock: *Except*, That,

(1) Nonorganically produced untreated seeds and planting stock may be used to produce an organic crop when an equivalent organically produced variety is not commercially available;

(2) Nonorganically produced seeds and planting stock that have been treated with a substance included on the National List of synthetic substances allowed for use in organic crop production may be used to produce an organic crop when an equivalent organically produced or untreated variety is not commercially available;

(3) Nonorganically produced annual seedlings may be used to produce an organic crop when a temporary variance has been granted in accordance with § 205.290(a)(2);

(4) Nonorganically produced planting stock to be used to produce a perennial crop may be sold, labeled, or represented as organically produced only after the planting stock has been maintained under a system of organic management for a period of no less than 1 year; and

(5) Seeds, annual seedlings, and planting stock treated with prohibited substances may be used to produce an organic crop when the application of the materials is a requirement of Federal or State phytosanitary regulations.

(b) The producer of an organic operation must not use seeds or planting stock produced with excluded methods.

§ 205.205 Crop rotation practice standard.

The producer must implement a crop rotation including, but not limited to, sod, cover crops, green manure crops, and catch crops that provide the following functions that are applicable to the operation:

(a) Maintain or improve soil organic matter content;

(b) Provide for pest management in annual and perennial crops;

(c) Manage deficient or excess plant nutrients; and

(d) Provide erosion control.

§ 205.206 Crop pest, weed, and disease management practice standard.

(a) The producer must use management practices to prevent crop pests, weeds, and diseases including, but not limited to:

(1) Crop rotation and soil and crop nutrient management practices, as provided for in §§ 205.203 and 205.205;

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

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

(b) Pest problems may be controlled through mechanical or physical methods including, but not limited to:

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

(2) Development of habitat for natural enemies of pests;

(3) Nonsynthetic, nontoxic controls such as lures, traps, and repellents.

(c) Weed problems may be controlled through:

(1) Mulching with fully biodegradable materials;

(2) Mowing;

(3) Livestock grazing;

(4) Hand weeding and mechanical cultivation;

(5) Flame, heat, or electrical means; or

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

(d) Disease problems may be controlled through:

(1) Management practices which suppress the spread of disease organisms; or

(2) Application of nonsynthetic biological, botanical, or mineral inputs.

(e) When the practices provided for in paragraphs (a) through (d) of this section

are insufficient to prevent or control crop pests, weeds, and diseases, a biological or botanical substance or a substance included on the National List of synthetic substances allowed for use in organic production may be applied to prevent, suppress, or control pests, weeds, or diseases: *Provided*, That, the producer implements measures to evaluate and mitigate the effects of repetitive use of the same or similar materials on pest resistance and shifts in pest, weed, or disease types, and the substance is used in compliance with the Federal Insecticide, Fungicide, and Rodenticide Act.

(f) The producer or handler of an organic operation must not use a pest, weed, or disease control substance produced through excluded methods.

§ 205.207 Wild-crop harvesting practice standard.

(a) Any area from which a wild crop that is intended to be sold, labeled, or represented as organic is harvested must have had no prohibited substance, as set forth in § 205.600, applied to it for a period of 3 years immediately preceding the harvest of the wild crop.

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

§§ 205.208—205.235 [Reserved]

§ 205.236 Origin of livestock.

(a) Livestock or edible livestock products that are to be sold, labeled, or represented as organic must be from livestock under continuous organic management from birth or hatching: *Except*, That,

(1) *Poultry*. Poultry or edible poultry products must be from poultry that has been under continuous organic management beginning no later than the second day of life;

(2) *Dairy Animals*. Milk or milk products must be from animals that have been under continuous organic management beginning no later than 1 year prior to the production of the milk or milk products that are to be sold, labeled, or represented as organic.

(3) *Nonedible products*. Nonedible livestock products must be from animals that have been under continuous organic management not less than 1 year prior to harvest of the nonedible product.

(4) *Breeder stock*. Livestock used as breeder stock may be brought from a nonorganic operation onto an organic operation at any time: *Provided*, That, if such livestock are gestating and the offspring are to be raised as organic

livestock, the breeder stock must be brought onto the facility prior to the last third of pregnancy.

(b) The following are prohibited:

(1) Livestock or edible livestock products that are removed from an organic operation and subsequently managed on a nonorganic operation may be not sold, labeled, or represented as organically produced.

(2) Breeder or dairy stock that has not been under continuous organic management since birth may not be sold, labeled, or represented as organic slaughter stock; and

(3) No organism produced by excluded methods may be used for breeding purposes or for the production of livestock products intended to be sold, labeled, or represented as organic.

(c) The producer of an organic livestock operation must maintain records sufficient to preserve the identity of all organically managed animals and edible and nonedible animal products produced on the operation.

§ 205.237 Livestock feed.

(a) The producer of an organic livestock operation must provide livestock with a total feed ration composed of agricultural products, including pasture and forage, that is organically produced and, if applicable, organically handled: *Except*, That, nonagricultural products and synthetic substances allowed under § 205.603 may be used as feed additives and supplements.

(b) The producer of an organic operation must not:

(1) Use animal drugs, including hormones, to promote growth;

(2) Provide feed supplements or additives in amounts above those needed for adequate nutrition and health maintenance for the species at its specific stage of life;

(3) Feed plastic pellets for roughage;

(4) Feed formulas containing urea or manure;

(5) Feed mammalian or poultry slaughter by-products to mammals or poultry; or

(6) Use feed, feed additives, and feed supplements in violation of the Federal Food, Drug, and Cosmetic Act.

§ 205.238 Livestock health care practice standard.

(a) The producer must establish and maintain preventive livestock health care practices, including:

(1) Selection of species and types of livestock with regard to suitability for site-specific conditions and resistance to prevalent diseases and parasites;

(2) Provision of feedstuffs sufficient to meet nutritional requirements,

including vitamins, minerals, and other additives or supplements;

(3) Establishment of appropriate housing, pasture conditions, and sanitation practices to minimize the occurrence and spread of diseases and parasites;

(4) Provision of conditions which allow for exercise, freedom of movement, and reduction of stress appropriate to the species;

(5) Performance of physical alterations as needed to promote the animal's welfare and in a manner that minimizes pain and stress; and

(6) Administration of vaccines and other veterinary biologics.

(b) When preventive practices and veterinary biologics are inadequate to prevent sickness, a producer may administer synthetic medications:

Provided, That, such medications are allowed under § 205.603. Parasiticides allowed under § 205.603 may be used on

(1) Breeder stock, when used prior to the last third of gestation for progeny that are to be sold, labeled, or represented as organically produced; and

(2) Dairy stock, when used a minimum of 90 days prior to the production of milk or milk products that are to be sold, labeled, or represented as organic.

(c) The producer of an organic livestock operation must not:

(1) Sell, label, or represent as organic any animal or edible product derived from any animal treated with antibiotics, any substance that contains a synthetic substance not allowed under § 205.603, or any substance that contains a nonsynthetic substance prohibited in § 205.604.

(2) Administer any animal drug, other than vaccinations, in the absence of illness;

(3) Administer hormones;

(4) Administer synthetic parasiticides on a routine basis;

(5) Administer synthetic parasiticides to slaughter stock;

(6) Administer animal drugs in violation of the Federal Food, Drug, and Cosmetic Act; or

(7) Withhold medical treatment from a sick animal in an effort to preserve its organic status. All appropriate medications must be used to restore an animal to health when methods acceptable to organic production fail. Livestock treated with a prohibited substance must be clearly identified and shall not be sold, labeled, or represented as organically produced.

§ 205.239 Livestock living conditions.

(a) The producer of an organic livestock operation must establish and

maintain livestock living conditions which accommodate the health and natural behavior of animals, including:

(1) Access to shade, shelter, exercise areas, fresh air, and direct sunlight suitable to the species, its stage of production, the climate, and the environment;

(2) Access to pasture for ruminants;

(3) Appropriate clean, dry bedding. If the bedding is typically consumed by the animal species, it must comply with the feed requirements of § 205.237;

(4) Shelter designed to allow for:

(i) Natural maintenance, comfort

behaviors, and opportunity to exercise;

(ii) Temperature level, ventilation,

and air circulation suitable to the species; and

(iii) Reduction of potential for livestock injury;

(b) The producer of an organic livestock operation may provide temporary confinement for an animal because of:

(1) Inclement weather;

(2) The animal's stage of production;

(3) Conditions under which the health, safety, or well being of the animal could be jeopardized; or

(4) Risk to soil or water quality.

(c) The producer of an organic livestock operation must manage manure in a manner that does not contribute to contamination of crops, soil, or water by plant nutrients, heavy metals, or pathogenic organisms and optimizes recycling of nutrients.

§§ 205.240—205.269 [Reserved]

§ 205.270 Organic handling requirements.

(a) Mechanical or biological methods, including, but not limited to, cooking, baking, heating, drying, mixing, grinding, churning, separating, extracting, slaughtering, cutting, fermenting, eviscerating, preserving, dehydrating, freezing, chilling, or otherwise manufacturing, and the packaging, canning, jarring, or otherwise enclosing food in a container may be used to process an agricultural product intended to be sold, labeled, or represented as "100 percent organic," "organic," or "made with organic (specified ingredients)" for the purpose of retarding spoilage or otherwise preparing the agricultural product for market.

(b) Nonagricultural substances allowed under § 205.605 and nonorganically produced agricultural products allowed under § 205.606 may be used in or on a processed agricultural product intended to be sold, labeled, or represented as "organic" or "made with organic (specified ingredients)."

(c) The handler of an organic handling operation must not use in or on an

agricultural product intended to be sold, labeled, or represented as "100 percent organic," "organic," or "made with organic (specified ingredients)":

- (1) Ionizing radiation for any purpose;
- (2) An ingredient produced with excluded methods; or
- (3) A volatile synthetic solvent or any other synthetic processing aid not allowed under § 205.605 as ingredients in or on processed products labeled as organic or made with organic ingredients.

§ 205.271 Facility pest management practice standard.

(a) The producer or handler of an organic facility must use management practices to prevent pests, including, but not limited to:

- (1) Removal of pest habitat, food sources, and breeding areas;
- (2) Prevention of access to handling facilities; or
- (3) Management of environmental factors, such as temperature, light, humidity, atmosphere, and air circulation to prevent pest reproduction.

(b) Pests may be controlled through:

- (1) 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) Nontoxic, nonsynthetic controls, such as lures and repellents.

(c) If the practices provided for in paragraphs (a) and (b) of this section are not effective to prevent or control facility pests, a nonsynthetic biological or botanical substance or a synthetic substance may be applied to prevent, suppress, or control pests: *Provided*, That, the substance is applied in the manner consistent with its label as approved by the Federal, State, and local regulatory authorities.

(d) The handler of an organic handling operation who applies a nonsynthetic biological or botanical substance or a synthetic substance for the prevention or control of a pest must include in the organic handling plan a list of all measures taken or intended to be taken to prevent contact between the substance and any ingredient or finished product intended to be sold, labeled, or represented as "organic" or "made with organic (specified ingredients)."

(e) The handler of an organic handling operation who applies a nonsynthetic biological or botanical substance or a synthetic substance for the prevention or control of a pest must include in the organic handling plan an evaluation of the effects of repetitive use of the same or similar materials on pest resistance and shifts in pest types.

§ 205.272 Commingling and contact with prohibited substance prevention practice standard.

(a) The handler of an organic handling operation must implement measures necessary to prevent the commingling of organic and nonorganic products and protect organic products from contact with prohibited substances.

(b) The following methods and substances are prohibited for use in the handling of any agricultural product intended to be sold, labeled, or represented as "100 per cent organic," "organic," or "made with organic (specified ingredients)":

- (1) Packaging materials and storage containers or bins that contain a synthetic fungicide, preservative, or fumigant;
- (2) The use or reuse of any bag or container that had previously been in contact with any substance in such a manner as to compromise the organic integrity of any products unless, after use for conventional products, the reusable bin or container has been thoroughly cleaned and poses no risk of prohibited materials contacting the organic product.

§§ 205.273—205.289 [Reserved]

§ 205.290 Temporary variances.

(a) Temporary variances from the requirements in §§ 205.203 through 205.207, 205.236 through 205.239, and 205.270 through 205.272 may be established by the Administrator for the following reasons:

- (1) Natural disasters declared by the Secretary;
- (2) Damage caused by wind, flood, excessive moisture, tornado, earthquake, fire, or other business interruption; and
- (3) Practices used for the purpose of conducting research or trials of techniques, varieties, or ingredients used in organic production or handling.

(b) A certifying agent may recommend in writing to the Administrator a temporary variance from a standard set forth in subpart C of this part for organic production or handling operations: *Provided*, That, such variance may only be recommended for the reasons listed in paragraph (a) of this section.

(c) The Administrator will provide written notification to certifying agents upon establishment of a temporary variance applicable to the certifying agent's certified production or handling operations. When establishing a temporary variance, the Administrator shall specify the period of time it shall remain in effect, subject to extension as the Administrator deems necessary.

(d) A certifying agent, upon notification from the Administrator of

the establishment of a temporary variance, must notify each production or handling operation it certifies within the affected geographical area or the individual organic production or handling operation(s) to which the temporary variance applies.

(e) Temporary variances may not be requested for any practice, material, or procedure otherwise prohibited in these regulations.

Subpart D—Labels, Labeling, and Market Information

§ 205.300 Use of the term, "organic."

(a) The term, "organic," may only be used on labels and in labeling of raw or processed agricultural products, including ingredients, that have been produced and handled in accordance with the regulations in this part.

(b) Products for export, produced and certified to foreign national organic standards or foreign contract buyer requirements, may be labeled in accordance with the organic labeling requirements of the receiving country or contract buyer: *Provided*, That, the shipping containers and shipping documents meet the labeling requirements specified in § 205.306(c).

(c) Products produced in a foreign country and exported for sale in the United States must be certified pursuant to subpart E of this part and labeled pursuant to this subpart D.

§ 205.301 Product composition.

(a) *Products sold, labeled, or represented as "100 percent organic."* A raw or processed agricultural product sold, labeled, or represented as "100 percent organic" must contain (by weight or fluid volume, excluding water and salt) not less than 100 percent organically produced raw or processed agricultural product. No such product or product ingredient may contain or be created using excluded methods or be produced using sewage sludge or ionizing radiation. If labeled as an organic food product, such product must be labeled pursuant to § 205.303.

(b) *Products sold, labeled, or represented as "organic."* A raw or processed agricultural product sold, labeled, or represented as "organic" must contain (by weight or fluid volume, excluding water and salt) not less than 95 percent organically produced raw or processed agricultural product. Any remaining product ingredients must consist of nonagricultural substances or nonorganically produced agricultural products approved in the National List of Allowed and Prohibited Substances in subpart G of this part and must not

contain or be created using excluded methods or be produced using sewage sludge or ionizing radiation. If labeled as an organic food product, such products must be labeled pursuant to § 205.303.

(c) *Products sold, labeled, or represented as "made with organic (specified ingredients)."* Multiingredient agricultural product sold, labeled, or represented as "made with organic (specified ingredients)" must contain (by weight or fluid volume, excluding water and salt) at least 50 percent organically produced agricultural products which are produced and handled pursuant to requirements in subpart C of this part. The nonorganic ingredients must not contain or be created using excluded methods or be produced using sewage sludge or ionizing radiation. If labeled as an organic food product, such products must be labeled pursuant to § 205.304.

(d) *Products with less than 50 percent organic ingredients.* The organic ingredients in multiingredient agricultural product containing less than 50 percent organic ingredients (by weight or fluid volume, excluding water and salt) must be produced and handled pursuant to requirements in subpart C of this part. The nonorganic ingredients may be produced and handled without regard to the requirements of this part. Multiingredient agricultural product containing less than 50 percent organically produced ingredients may represent the organic nature of the product only as provided in § 205.305.

(e) All ingredients identified as "organic" in the ingredient statement of any product must not:

- (1) Be produced using excluded methods or products of excluded methods as ingredients or processing aids;
- (2) Be produced using sewage sludge;
- (3) Be processed using ionizing radiation;
- (4) Be processed using processing aids not approved on the National List of Allowed and Prohibited Substances in subpart G of this part: *Except*, That, products labeled as "100 percent organic," if processed, must be processed using no processing aids;
- (5) Contain sulfites, nitrates, or nitrites added during the production or handling process;
- (6) Be produced using nonorganic ingredients when organic ingredients are not available; or
- (7) Include organic and nonorganic forms of the same ingredient.

§ 205.302 Calculating the percentage of organically produced ingredients.

(a) The percentage of all organically produced ingredients in an agricultural product sold, labeled, or represented as "100 percent organic," "organic," or "made with organic (specified ingredients)," or that include organic ingredients must be calculated by:

(1) Dividing the total net weight (excluding water and salt) of combined organic ingredients by the total weight (excluding water and salt) of the finished product.

(2) Dividing the fluid volume of all organic ingredients (excluding water and salt) by the fluid volume of the finished product (excluding water and salt) if the product and ingredients are liquid. If the liquid product is identified on the principal display panel or information panel as being reconstituted from concentrates, the calculation should be made on the basis of single-strength concentrations of the ingredients and finished product.

(3) For products containing organic ingredients in both solid and liquid form, dividing the combined weight of the solid ingredients and the weight of the liquid ingredients (excluding water and salt) by the total weight (excluding water and salt) of the finished product.

(b) The percentage of all organically produced ingredients in an agricultural product must be rounded down to the nearest whole number and indicated on the information panel above the ingredient statement with the words, "contains X percent organic ingredients."

(c) The percentage must be calculated by the handler who affixes the label on the consumer package and verified by the certifying agent of the handler.

§ 205.303 Packaged products labeled "100 percent organic" or "organic."

(a) Agricultural products in packages described in § 205.301(a) and (b) may display, on the principal display panel, information panel, and any other panel of the package and on any labeling or market information concerning the product, the following terms:

- (1) The term, "100 percent organic" or "organic," as applicable, to modify the name of the product;
- (2) The USDA Seal;
- (3) The seal, logo, or other identifying mark of the certifying agent which certified the production or handling operation producing the finished product and any other certifying agent which certified production or handling operations producing raw organic product or organic ingredients used in the finished product: *Provided*, That, the handler producing the finished

product maintain records, pursuant to this part, verifying organic certification of the operations producing such ingredients, and: *Provided further*, That, such seals or marks are not, individually, displayed more prominently than the USDA Seal.

(b) Agricultural products in packages described in § 205.301(a) and (b) must:

(1) On the information panel of multiingredient products and consistent with the labeling requirements of the Food and Drug Administration, declare the total percentage of organic ingredients in the product.

(2) In the ingredient statement, modify each organic ingredient of multiingredient products with the word, "organic": *Except*, That, ingredients in multiingredient products labeled "100 percent organic" are not required to be modified with the term "organic." Any water or salt included as an ingredient will not be identified as organic.

(3) On the information panel, below the information identifying the handler or distributor of the product and preceded by the statement, "Certified organic by * * *," or similar phrase, identify the name of the certifying agent that certified the handler of the finished product: *Except*, That, the business address or telephone number of the certifying agent may be included in such label.

§ 205.304 Packaged products labeled "made with organic (specified ingredients)."

(a) Agricultural products in packages described in § 205.301(c) may display on the principal display panel, information panel, and any other panel and on any labeling or market information concerning the product:

(1) The statement, "made with organic (specified ingredients)": *Provided*, That, display of the statement is consistent with labeling requirements of the Food and Drug Administration and:

- (i) Does not list more than three organic ingredients;
 - (ii) Does not exceed one-half the size of the largest type size on the panel; and
 - (iii) Appears in its entirety in the same type size, style, and color without highlighting; and
- (2) The seal, logo, or other identifying mark of the certifying agent that certified the handler of the finished product.

(b) Agricultural products in packages described in § 205.301(c) must:

(1) On the information panel and consistent with the labeling requirements of the Food and Drug Administration, declare the total percentage of organic ingredients in the product.

(2) In the ingredient statement, modify each organic ingredient with the word, "organic." Any water or salt included as an ingredient will not be identified as organic.

(3) On the information panel, below the information identifying the handler or distributor of the product and preceded by the statement, "Certified organic by * * *," or similar phrase, identify the name of the certifying agent that certified the handler of the finished product: *Except*, That, the business address or telephone number of the certifying agent may be included in such label.

(c) Agricultural products in packages described in § 205.301(c) must not display the USDA Seal.

§ 205.305 Multiingredient packaged products with less than 50 percent organic ingredients.

(a) Agricultural products with less than 50 percent organic ingredients must:

(1) On the information panel and consistent with the labeling requirements of the Food and Drug Administration, declare the total percentage of organic ingredients in the product.

(2) In the ingredient statement, modify each organic ingredient with the word, "organic."

(b) Agricultural products with less than 50 percent organic ingredients must not display:

- (1) The USDA Seal and
- (2) Any certifying agent's seal, logo, or other identifying mark.

§ 205.306 Labeling of nonretail containers used for only shipping or storage of raw or processed agricultural products labeled as "100 percent organic," "organic," or "made with organic (specified ingredients)."

(a) Nonretail containers used only to ship or store raw or processed agricultural product labeled as containing organic ingredients may display the following terms or marks:

(1) The name and contact information of the certifying agent which certified the handler which assembled the final product;

(2) Identification of the product as "organic product";

(3) Special handling instructions needed to maintain the organic integrity of the product;

(4) The USDA Seal;

(5) The seal, logo, or other identifying mark of the certifying agent that certified the organic production or handling operation that produced or handled the finished product.

(b) If not required under other Federal labeling regulations, nonretail containers used to ship or store raw or

processed agricultural product labeled as containing organic ingredients must display the production lot number of the product, if applicable.

(c) Shipping containers of domestically produced product labeled as organic intended for export to international markets may be labeled consistent with any shipping container labeling requirements of the foreign country of destination or the container labeling specifications of a foreign contract buyer: *Provided*, That, the shipping containers and shipping documents accompanying such organic product be clearly marked "For export only" and: *Provided further*, That, proof of such container marking and export must be maintained by the handler, consistent with recordkeeping requirements for exempt and excluded operations under § 205.101.

§ 205.307 Agricultural products in other than packaged form at the point of retail sale that are sold, labeled, or represented as "100 percent organic" or "organic."

(a) Agricultural products labeled or represented as "100 percent organic" or "organic" in retail display, labeling, and display containers may use the term, "100 percent organic" or "organic," as applicable, to modify the name of the product: *Provided*, That, such products are assembled in a manufacturing facility certified in accordance with the requirements of this part; and, *Provided further*, Than, the word, "organic," is used to modify the organic ingredients listed in the ingredient statement of the products.

(b) The retail display, labeling, and display containers may use:

- (1) The USDA Seal;
- (2) The seal, logo, or other identifying mark of the certifying agent that certified the production or handling operation producing the finished product and any other certifying agent which certified operations producing raw organic product or organic ingredients used in the finished product: *Provided*, That, such seals or marks are not, individually, displayed more prominently than the USDA Seal.

§ 205.308 Agricultural products in other than packaged form at the point of retail sale that are sold, labeled, or represented as "made with organic (specified ingredients)."

(a) Retail displays, display containers, and market information of agricultural products containing between 50 and 95 percent organic ingredients may use the phrase, "made with organic (specified ingredients)" *Provided*, That, such products have been assembled at a manufacturing facility certified in

accordance with the requirements of this part, and:

(1) Such statement does not list more than three organic ingredients, and

(2) In any such display of the product's ingredient statement, the organic ingredients must be modified as "organic."

(b) Such agricultural products labeled as "made with organic (specified ingredients)" in retail displays, display containers, and market information may display the certifying agent's seal, logo, or other identifying mark.

§ 205.309 Agricultural products produced on an exempt or excluded operation.

(a) An agricultural product organically produced or handled on an exempt or excluded operation must not:

(1) Display the USDA Seal or any certifying agent's seal or other identifying mark which represents that the production or handling operation is a certified organic operation, or

(2) Be represented as a certified organic product to any buyer.

(b) An agricultural product organically produced or handled on an exempt or excluded operation may be identified as an organic product or organic ingredient in a multiingredient product produced by the exempt or excluded operation. Such product or ingredient must not be identified as "organic" in a product processed by others.

(c) Such product is subject to labeling requirements specified in paragraph (a) of § 205.300, and paragraphs (e)(1) through (e)(7) of § 205.301.

§ 205.310 USDA Seal.

(a) The USDA Seal described in paragraphs (b) and (c) of this section may be used only for agricultural products (raw or processed) described in § 205.301(a) and (b).

(b) The USDA Seal must replicate the form and design of the example in figure 1 and must be printed legibly and conspicuously:

(1) On a white, light colored, or transparent background with contrasting dark color words and shield outline or on a dark colored background with contrasting white or light colored words and shield outline; or

(2) On a white background with dark blue colored words and red shield outline.



Figure 1

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Subpart E—Certification

§ 205.400 General requirements for certification.

A person seeking to receive or maintain organic certification under the regulations in this part must:

- (a) Comply with the Act and applicable organic production and handling regulations of this part;
- (b) Establish, implement, and update annually an organic production or handling system plan that is submitted to an accredited certifying agent as provided for in § 205.200;
- (c) Permit on-site inspections with complete access to the production or handling operation, including noncertified areas and structures, by the certifying agent as provided for in § 205.403;
- (d) Maintain all records applicable to the organic operation for not less than 5 years beyond their creation and allow authorized representatives of the Secretary, the applicable State program's governing State official, and the certifying agent access to such records during normal business hours for review and copying to determine compliance with the Act and the regulations in this part, as provided for in § 205.104;
- (e) Submit the applicable fees charged by the certifying agent; and
- (f) Immediately notify the certifying agent concerning any:
 - (1) Application, including drift, of a prohibited substance to any field, production unit, site, facility, livestock, or product that is part of an operation; and
 - (2) Change in a certified operation or any portion of a certified operation that may affect its compliance with the Act and the regulations in this part.

§ 205.401 Application for Certification.

A person seeking certification of a production or handling operation under this subpart must submit a request for certification to a certifying agent. The

request must include the following information:

- (a) An organic production or handling system plan, as required in § 205.200;
- (b) The name of the person completing the application; the applicant's business name, address, and telephone number; and, when the applicant is a corporation, the name, address, and telephone number of the person authorized to act on the applicant's behalf.
- (c) The name(s) of any organic certifying agent(s) to which application has previously been made, the year(s) of application, and the outcome of the application(s) submission, including a copy of any notification of noncompliance or denial of certification issued to the applicant for certification and a description of the actions taken by the applicant to correct the deficiencies noted in the notification of noncompliance, including evidence of such correction and;
- (d) Other information necessary to determine compliance with the Act and the regulations in this part.

§ 205.402 Review of application.

- (a) Upon acceptance of an application for certification a certifying agent must:
 - (1) Review the application to ensure completeness pursuant to § 205.401;
 - (2) Determine by a review of the application materials whether the applicant appears to comply or may be able to comply with the applicable requirements of subpart C of this part;
 - (3) Verify that an applicant who previously applied to another certifying agent and received a notification of noncompliance, pursuant to § 205.405(a), has submitted documentation to support the correction of any deficiencies identified in such notification, as required in § 205.405(b); and
 - (4) Schedule an on-site inspection of the operation to determine whether the applicant qualifies for certification if the review of application materials reveals that the production or handling operation may be in compliance with the applicable requirements of subpart C of this part.
- (b) The certifying agent shall communicate to the applicant its findings on the review of application materials specified in § 205.402(a).
- (c) The applicant may withdraw its application at any time. An applicant who withdraws its application shall be liable for the costs of services provided up to the time of withdrawal of its application. An applicant that voluntarily withdrew its application prior to the issuance of a notice of noncompliance will not be issued a

notice of noncompliance. Similarly, an applicant that voluntarily withdrew its application prior to the issuance of a notice of certification denial will not be issued a notice of certification denial.

§ 205.403 On-site inspections.

- (a) *On-site inspections.*
 - (1) A certifying agent must conduct an initial on-site inspection of each production unit, facility, and site that is included in an operation for which certification is requested and an on-site inspection of each certified operation annually thereafter, for the purpose of determining whether to approve the request for certification or whether the certification of the operation should continue.
 - (2)(i) A certifying agent may conduct additional on-site inspections of applicants for certification and certified operations to determine compliance with the Act and the regulations in this part.
 - (ii) The Administrator or State program's governing State official may require that additional inspections be performed by the certifying agent for the purpose of determining compliance with the Act and the regulations in this part.
 - (iii) Additional inspections may be announced or unannounced at the discretion of the certifying agent or as required by the Administrator or State program's governing State official.
 - (b) *Scheduling.* The initial on-site inspection must be conducted within a reasonable time following a determination that the applicant appears to comply or may be able to comply with the requirements of subpart C of this part. On-site inspections must be conducted when the applicant or an authorized representative of the applicant who is knowledgeable about the operation is present and at a time when land, facilities, and activities that demonstrate the operation's compliance with or capability to comply with the applicable provisions of subpart C of this part can be observed, except that this requirement does not apply to unannounced on-site inspections.
 - (c) *Verification of information.* The on-site inspection of an operation must verify:
 - (1) The operation's compliance or capability to comply with the Act and the regulations in this part;
 - (2) That the information, including the organic production or handling system plan, provided in accordance with §§ 205.401, 205.406, and 205.200, accurately reflects the practices used or to be used by the applicant for

certification or by the certified operation;

(3) That prohibited substances have not been and are not being applied to the operation through means which, at the discretion of the certifying agent, may include the collection and testing of soil; water; waste; seeds; plant tissue; and plant, animal, and processed products samples.

(d) *Exit interview.* The inspector must conduct an exit interview with an authorized representative of the inspected operation to confirm the accuracy and completeness of inspection observations and information gathered during the on-site inspection. The inspector must also address the need for any additional information as well as any issues of concern.

§ 205.404 Approval of certification.

(a) Within a reasonable time after completion of the initial on-site inspection, a certifying agent must review the on-site inspection report, the results of any analyses for substances conducted, and any additional information requested from or supplied by the applicant. If the certifying agent determines that the organic system plan and all procedures and activities of the applicant's operation are in compliance with the requirements of this part and that the applicant is able to conduct operations in accordance with the plan, the agent shall approve certification. The approval may include restrictions as a condition of continued certification.

(b) The certifying agent must issue a certificate of organic operation which specifies the:

(1) Name and address of the certified operation;

(2) Effective date of certification;

(3) Categories of organic operation, including crops, wild crops, livestock, or processed products produced by the certified operation; and

(4) Name, address, and telephone number of the certifying agent.

(c) Once certified, a production or handling operation's organic certification continues in effect until surrendered by the organic operation or suspended or revoked by the certifying agent, the State program's governing State official, or the Administrator.

§ 205.405 Denial of certification.

(a) When the certifying agent has reason to believe, based on a review of the information specified in § 205.402 or § 205.404, that an applicant for certification is not able to comply or is not in compliance with the requirements of this part, the certifying agent must provide a written notification of noncompliance to the

applicant pursuant to § 205.662(a). When correction of a noncompliance is not possible, a notification of noncompliance and a notification of denial of certification may be combined in one notification.

(b) Upon receipt of such notification of noncompliance, the applicant may:

(1) Correct deficiencies and submit a description of the corrective actions taken with supporting documentation to the certifying agent;

(2) Correct deficiencies and submit a new application to another certifying agent; *Provided*, That, the applicant must include a complete application, the notification of noncompliance received from the first certifying agent, and a description of the corrective actions taken with supporting documentation; or

(3) Submit written information to rebut the noncompliance described in the notification of noncompliance.

(c) After issuance of a notification of noncompliance, the certifying agent must:

(1) Evaluate the applicant's corrective actions taken and supporting documentation submitted or the written rebuttal, conduct an on-site inspection if necessary, and;

(i) When the corrective action or rebuttal is sufficient for the applicant to qualify for certification, issue the applicant an approval of certification pursuant to § 205.404; or

(ii) When the corrective action or rebuttal is not sufficient for the applicant to qualify for certification, issue the applicant a written notice of denial of certification.

(2) Issue a written notice of denial of certification to an applicant who fails to respond to the notification of noncompliance.

(3) Provide notice of approval or denial to the Administrator, pursuant to § 205.501(a)(14).

(d) A notice of denial of certification must state the reason(s) for denial and the applicant's right to:

(1) Reapply for certification pursuant to §§ 205.401 and 205.405(e);

(2) Request mediation pursuant to § 205.663 or, if applicable, pursuant to a State program; or

(3) File an appeal pursuant to § 205.681 or, if applicable, pursuant to a State program of the denial of certification.

(e) An applicant for certification who has received a written notification of noncompliance or a written notice of denial of certification may apply for certification again at any time with any certifying agent, in accordance with §§ 205.401 and 205.405(e). When such applicant submits a new application to

a certifying agent other than the agent who issued the notification of noncompliance or notice of denial of certification, the applicant for certification must include a copy of the notification of noncompliance or notice of denial of certification and a description of the actions taken, with supporting documentation, to correct the deficiencies noted in the notification of noncompliance.

(f) A certifying agent who receives a new application for certification, which includes a notification of noncompliance or a notice of denial of certification, must treat the application as a new application and begin a new application process pursuant to § 205.402.

(g) Notwithstanding paragraph (a) of this section, if a certifying agent has reason to believe that an applicant for certification has willfully made a false statement or otherwise purposefully misrepresented the applicant's operation or its compliance with the certification requirements pursuant to this part, the certifying agent may deny certification pursuant to paragraph (c)(1)(ii) of this section without first issuing a notification of noncompliance.

§ 205.406 Continuation of certification.

(a) To continue certification, a certified operation must annually submit the following information, as applicable, to the certifying agent:

(1) An updated organic production or handling system plan which includes:

(i) A summary statement, supported by documentation, detailing any deviations from, changes to, modifications to, or other amendments made to the previous year's organic system plan during the previous year; and

(ii) Any additions or deletions to the previous year's organic system plan, intended to be undertaken in the coming year, detailed pursuant to § 205.200;

(2) Any additions to or deletions from the information required pursuant to § 205.401(b); and (3) Other information as deemed necessary by the certifying agent to determine compliance with the Act and the regulations in this part.

(b) Following the receipt of the information specified in paragraph (a) of this section, the certifying agent shall arrange and conduct an on-site inspection of the certified operation, pursuant to § 205.403.

(c) If the certifying agent has reason to believe, based on the on-site inspection and a review of the information specified in § 205.404, that a certified operation is not complying with the requirements of the Act and the

regulations in this part, the certifying agent shall provide a written notification of noncompliance to the operation in accordance with § 205.662.

(d) If the certifying agent determines that the certified operation is complying with the Act and the regulations in this part and that any of the information specified on the certificate of organic operation has changed, the certifying agent must issue an updated certificate of organic operation pursuant to § 205.404(b).

§§ 205.407–205.499 [Reserved]

Subpart F—Accreditation of Certifying Agents

§ 205.500 Areas and duration of accreditation.

(a) The Administrator shall accredit a qualified domestic or foreign applicant in the areas of crops, livestock, wild crops, or handling or any combination thereof to certify a domestic or foreign production or handling operation as a certified operation.

(b) Accreditation shall be for a period of 5 years from the date of approval of accreditation pursuant to § 205.506.

(c) In lieu of accreditation under paragraph (a) of this section, USDA will accept a foreign certifying agent's accreditation to certify organic production or handling operations if:

(1) USDA determines, upon the request of a foreign government, that the standards under which the foreign government authority accredited the foreign certifying agent meet the requirements of this part; or

(2) The foreign government authority that accredited the foreign certifying agent acted under an equivalency agreement negotiated between the United States and the foreign government.

§ 205.501 General requirements for accreditation.

(a) A private or State entity accredited as a certifying agent under this subpart must:

(1) Have sufficient expertise in organic production or handling techniques to fully comply with and implement the terms and conditions of the organic certification program established under the Act and the regulations in this part;

(2) Demonstrate the ability to fully comply with the requirements for accreditation set forth in this subpart;

(3) Carry out the provisions of the Act and the regulations in this part, including the provisions of §§ 205.402 through 205.406 and § 205.670;

(4) Use a sufficient number of adequately trained personnel, including

inspectors and certification review personnel, to comply with and implement the organic certification program established under the Act and the regulations in subpart E of this part;

(5) Ensure that its responsibly connected persons, employees, and contractors with inspection, analysis, and decision-making responsibilities have sufficient expertise in organic production or handling techniques to successfully perform the duties assigned.

(6) Conduct an annual performance appraisal for each inspector used by the certifying agent and implement measures to correct any deficiencies in compliance with the Act and the regulations in this part that are identified in the appraisal;

(7) Have an annual program evaluation of its certification activities conducted by the certifying agent's staff, an outside auditor, or a consultant who has expertise to conduct such evaluations and implement measures to correct any deficiencies in compliance with the Act and the regulations in this part that are identified in the evaluation;

(8) Provide sufficient information to persons seeking certification to enable them to comply with the applicable requirements of the Act and the regulations in this part;

(9) Maintain all records pursuant to § 205.510(b) and make all such records available for inspection and copying during normal business hours by authorized representatives of the Secretary and the applicable State program's governing State official;

(10) Maintain strict confidentiality with respect to its clients under the applicable organic certification program and not disclose to third parties (with the exception of the Secretary or the applicable State program's governing State official or their authorized representatives) any business-related information concerning any client obtained while implementing the regulations in this part, except as provided for in § 205.504(b)(5);

(11) Prevent conflicts of interest by:

(i) Not certifying a production or handling operation if the certifying agent or a responsibly connected party of such certifying agent has or has held a commercial interest in the production or handling operation, including an immediate family interest or the provision of consulting services, within the 12-month period prior to the application for certification;

(ii) Excluding any person, including contractors, with conflicts of interest from work, discussions, and decisions in all stages of the certification process and the monitoring of certified

production or handling operations for all entities in which such person has or has held a commercial interest, including an immediate family interest or the provision of consulting services, within the 12-month period prior to the application for certification;

(iii) Not permitting any employee, inspector, contractor, or other personnel to accept payment, gifts, or favors of any kind, other than prescribed fees, from any business inspected, except that a certifying agent that is a not-for-profit organization with an Internal Revenue Code tax exemption, or in the case of a foreign certifying agent a comparable recognition of not-for-profit status from its government, may accept voluntary labor from certified operations;

(iv) Not providing advice concerning organic practices or techniques to any certification applicant or certified operation for a fee, other than as part of the fees under the applicable certification program established under the Act; and

(v) Requiring all persons identified in § 205.504(a)(2) to complete an annual conflict of interest disclosure report.

(12) Accept the certification decisions made by another USDA-accredited certifying agent as equivalent to its own;

(13) 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;

(14) Submit to the Administrator:

(i) A copy of any notice of denial of certification issued pursuant to § 205.405, notification of noncompliance, notification of noncompliance correction, notification of proposed suspension or revocation, and notification of suspension or revocation sent pursuant to § 205.662, simultaneously with its issuance and

(ii) On a quarterly calendar basis, the name, address, and telephone number of each operation granted certification;

(15) Charge applicants for certification and certified production and handling operations only those fees and charges that it has filed with the Administrator;

(16) Pay and submit fees to AMS in accordance with § 205.640; and

(17) Comply with, implement, and carry out any other terms and conditions determined by the Administrator to be necessary.

(b) A private or State entity accredited as a certifying agent under this subpart may establish a seal, logo, or other identifying mark to be used by production and handling operations certified by the certifying agent to indicate affiliation with the certifying

agent: *Provided*, That, the certifying agent:

(1) Does not require use of its seal, logo, or other identifying mark on any product sold, labeled, or represented as organically produced as a condition of certification and

(2) Does not require compliance with any production or handling practices other than those provided for in the Act and the regulations in this part as a condition of use of its identifying mark: *Provided*, That, this provision does not apply to States with more restrictive requirements approved by the Secretary or private entity certifying agents certifying production and handling operations within States with more restrictive requirements approved by the Secretary.

(c) A private entity accredited as a certifying agent must:

(1) Hold the Secretary harmless for any failure on the part of the certifying agent to carry out the provisions of the Act and the regulations in this part;

(2) Furnish reasonable security, in an amount and according to such terms as the Administrator may by regulation prescribe, for the purpose of protecting the rights of production and handling operations certified by such certifying agent under the Act and the regulations in this part; and

(3) Transfer to the Administrator and make available to any applicable State program's governing State official all records or copies of records concerning the person's certification activities in the event that the certifying agent dissolves or loses its accreditation.

(d) No private or State entity accredited as a certifying agent under this subpart shall exclude from participation in or deny the benefits of the National Organic Program to any person due to discrimination because of race, color, national origin, gender, religion, age, disability, political beliefs, sexual orientation, or marital or family status.

§ 205.502 Applying for accreditation.

(a) A private or State entity seeking accreditation as a certifying agent under this subpart must submit an application for accreditation which contains the applicable information and documents set forth in §§ 205.503 through 205.505 and the fees required in § 205.640 to: Program Manager, USDA-AMS-TMP-NOP, Room 2945-South Building, PO Box 96456, Washington, DC 20090-6456.

(b) Following the receipt of the information and documents, the Administrator will determine, pursuant to § 205.506, whether the applicant for

accreditation should be accredited as a certifying agent.

§ 205.503 Applicant information.

A private or State entity seeking accreditation as a certifying agent must submit the following information:

(a) The business name, primary office location, mailing address, name of the person(s) responsible for the certifying agent's day-to-day operations, contact numbers (telephone, facsimile, and Internet address) of the applicant, and, for an applicant who is a private person, the entity's taxpayer identification number;

(b) The name, office location, mailing address, and contact numbers (telephone, facsimile, and Internet address) for each of its organizational units, such as chapters or subsidiary offices, and the name of a contact person for each unit;

(c) Each area of operation (crops, wild crops, livestock, or handling) for which accreditation is requested and the estimated number of each type of operation anticipated to be certified annually by the applicant along with a copy of the applicant's schedule of fees for all services to be provided under these regulations by the applicant;

(d) The type of entity the applicant is (e.g., government agricultural office, for-profit business, not-for-profit membership association) and for:

(1) A State entity, a copy of the official's authority to conduct certification activities under the Act and the regulations in this part,

(2) A private entity, documentation showing the entity's status and organizational purpose, such as articles of incorporation and by-laws or ownership or membership provisions, and its date of establishment; and

(e) A list of each State or foreign country in which the applicant currently certifies production and handling operations and a list of each State or foreign country in which the applicant intends to certify production or handling operations.

§ 205.504 Evidence of expertise and ability.

A private or State entity seeking accreditation as a certifying agent must submit the following documents and information to demonstrate its expertise in organic production or handling techniques; its ability to fully comply with and implement the organic certification program established in §§ 205.100 and 205.101, §§ 205.201 through 205.203, §§ 205.300 through 205.303, §§ 205.400 through 205.406, and §§ 205.661 and 205.662; and its ability to comply with the requirements for accreditation set forth in § 205.501:

(a) *Personnel*.

(1) A copy of the applicant's policies and procedures for training, evaluating, and supervising personnel;

(2) The name and position description of all personnel to be used in the certification operation, including administrative staff, certification inspectors, members of any certification review and evaluation committees, contractors, and all parties responsibly connected to the certifying agent;

(3) A description of the qualifications, including experience, training, and education in agriculture, organic production, and organic handling, for:

(i) Each inspector to be used by the applicant and

(ii) Each person to be designated by the applicant to review or evaluate applications for certification; and

(4) A description of any training that the applicant has provided or intends to provide to personnel to ensure that they comply with and implement the requirements of the Act and the regulations in this part.

(b) *Administrative policies and procedures*.

(1) A copy of the procedures to be used to evaluate certification applicants, make certification decisions, and issue certification certificates;

(2) A copy of the procedures to be used for reviewing and investigating certified operation compliance with the Act and the regulations in this part and the reporting of violations of the Act and the regulations in this part to the Administrator;

(3) A copy of the procedures to be used for complying with the recordkeeping requirements set forth in § 205.501(a)(9);

(4) A copy of the procedures to be used for maintaining the confidentiality of any business-related information as set forth in § 205.501(a)(10);

(5) A copy of the procedures to be used for making the following information available to any member of the public upon request:

(i) Certification certificates issued during the current and 3 preceding calendar years;

(ii) A list of producers and handlers whose operations it has certified, including for each the name of the operation, type(s) of operation, and the effective date of the certification, during the current and 3 preceding calendar years;

(iii) The results of laboratory analyses for residues of pesticides and other prohibited substances conducted during the current and 3 preceding calendar years; and

(iv) Other business information as permitted in writing by the producer or handler; and

(6) A copy of the procedures to be used for sampling and residue testing pursuant to § 205.670.

(c) *Conflicts of interest.*

(1) A copy of procedures intended to be implemented to prevent the occurrence of conflicts of interest, as described in § 205.501(a)(11).

(2) For each person identified in § 205.504(a)(2), a conflict of interest disclosure report, identifying any food- or agriculture-related business interests, including business interests of immediate family members, that cause a conflict of interest.

(d) *Current certification activities.* An applicant who currently certifies production or handling operations must submit:

(1) A list of all production and handling operations currently certified by the applicant;

(2) Copies of at least 3, the Administrator may require additional, different inspection reports and certification evaluation documents for production or handling operations certified by the applicant during the previous year for each area of operation for which accreditation is requested; and

(3) The results of any accreditation process of the applicant's operation by an accrediting body during the previous year for the purpose of evaluating its certification activities.

(e) *Other information.* Any other information the applicant believes may assist in the Administrator's evaluation of the applicant's expertise and ability.

§ 205.505 Statement of agreement.

(a) A private or State entity seeking accreditation under this subpart must sign and return a statement of agreement prepared by the Administrator which affirms that, if granted accreditation as a certifying agent under this subpart, the applicant will carry out the provisions of the Act and the regulations in this part, including:

(1) Accept the certification decisions made by another USDA accredited certifying agent as equivalent to its own;

(2) Refrain from making false or misleading claims about its accreditation status, the USDA accreditation program for certifying agents, or the nature or qualities of products labeled as organically produced;

(3) Conduct an annual performance appraisal for each inspector to be used by the certifying agent and implement measures to correct any possible deficiencies identified in compliance with the Act and the regulations in this part;

(4) Have an annual internal program evaluation conducted of its certification

activities by certifying agent staff, an outside auditor, or a consultant who has the expertise to conduct such evaluations and implement measures to correct any deficiencies identified in compliance with the Act and the regulations in this part;

(5) Pay and submit fees to AMS in accordance with § 205.640; and

(6) Comply with, implement, and carry out any other terms and conditions determined by the Administrator to be necessary.

(b) A private entity seeking accreditation as a certifying agent under this subpart must additionally agree to:

(1) Hold the Secretary harmless for any failure on the part of the certifying agent to carry out the provisions of the Act and the regulations in this part;

(2) Furnish reasonable security, in an amount and according to such terms as the Administrator may by regulation prescribe, for the purpose of protecting the rights of production and handling operations certified by such certifying agent under the Act and the regulations in this part; and

(3) Transfer to the Administrator and make available to the applicable State program's governing State official all records or copies of records concerning the certifying agent's certification activities in the event that the certifying agent dissolves or loses its accreditation.

§ 205.506 Approval of accreditation.

(a) Accreditation will be approved when:

(1) The accreditation applicant has submitted the information required by §§ 205.503 through 205.505;

(2) The accreditation applicant pays the required fee in accordance with § 205.640(c); and

(3) The Administrator determines that the applicant for accreditation meets the requirements for accreditation as stated in § 205.501, as determined by a review of the information submitted in accordance with §§ 205.503 through 205.505 and, if necessary, a review of the information obtained from a site evaluation as provided for in § 205.508.

(b) On making a determination to approve an application for accreditation, the Administrator will notify the applicant of approval of accreditation in writing, stating:

(1) The area(s) for which accreditation is given;

(2) The effective date of the accreditation; and

(3) For a certifying agent who is a private entity, the amount and type of security that must be established to protect the rights of production and handling operations certified by such certifying agent.

(c) The accreditation of a certifying agent shall continue in effect until such time as the certifying agent fails to renew accreditation as provided in § 205.510(b), the certifying agent voluntarily ceases its certification activities, or accreditation is suspended or revoked pursuant to § 205.665.

§ 205.507 Denial of accreditation.

(a) If the Administrator has reason to believe, based on a review of the information specified in §§ 205.503 through 205.505 or after a site evaluation as specified in § 205.508, that an applicant for accreditation is not able to comply or is not in compliance with the requirements of the Act and the regulations in this part, the Administrator shall provide a written notification of noncompliance to the applicant in accordance with § 205.665(a).

(b) The applicant may:

(1) File, with the Administrator, an appeal of the deficiencies identified in the notification of noncompliance; or

(2) Submit to the Administrator a description of the actions taken to correct the deficiencies identified in the notification of noncompliance and evidence demonstrating such corrections.

(c) If an applicant fails to correct the deficiencies, fails to report the corrections by the date specified in the notification of noncompliance, fails to file an appeal of the notification of noncompliance by the date specified, or is unsuccessful in its appeal, the Administrator will provide the applicant with written notification of accreditation denial. An applicant who has received written notification of accreditation denial may apply for accreditation again at any time in accordance with § 205.502.

(d) If the certifying agent was accredited prior to the site evaluation and the certifying agent fails to correct the deficiencies, fails to report the corrections by the date specified in the notification of noncompliance, or fails to file an appeal of the notification of noncompliance by the date specified, the Administrator will begin proceedings to suspend or revoke the certifying agent's accreditation. An applicant who has had its accreditation suspended may apply for accreditation again at any time in accordance with § 205.502. A private entity certifying agent whose accreditation is revoked will be ineligible for accreditation for a period of not less than 3 years following the date of such determination.

§ 205.508 Site evaluations.

(a) Site evaluations of accredited certifying agents shall be conducted for the purpose of examining the certifying agent's operations and evaluating its compliance with the Act and the regulations of this part. Site evaluations shall include an on-site review of the certifying agent's certification procedures, decisions, facilities, administrative and management systems, and production or handling operations certified by the certifying agent. Site evaluations shall be conducted by a representative(s) of the Administrator.

(b) An initial site evaluation of an accreditation applicant shall be conducted before or within a reasonable period of time after issuance of the applicant's "notification of accreditation." A site evaluation shall be conducted after application for renewal of accreditation but prior to the issuance of a notice of renewal of accreditation. One or more site evaluations will be conducted during the period of accreditation to determine whether an accredited certifying agent is complying with the general requirements set forth in § 205.501.

§ 205.509 Peer review panel.

The Administrator may establish a peer review panel to assist in evaluating applicants for accreditation, amendment to an accreditation, and renewal of accreditation as certifying agents. Peer reviewers will serve without compensation.

(a) Peer review panel(s).

(1) A peer review panel shall review the documentation provided by the Administrator after any site evaluation performed pursuant to §§ 205.508 and 205.510.

(2) The Administrator shall consider the reports received from each individual member of a peer review panel when determining whether to continue or renew the accreditation of a certifying agent.

(3) A peer review panel meeting shall be held solely for the purposes of giving and receiving information. Any meeting or conference call shall be conducted in a manner that will ensure the actions of panel members are carried out on an individual basis with any opinions and recommendations by a member being made individually.

(b) Eligibility for peer review panels.

(1) Applicants for membership in the peer review panel pool must:

(i) Provide the Administrator with a written description and, upon request, supporting documentation of their qualifications to conduct peer reviews. Such description must include

information concerning the applicant's training and expertise in organic production or handling methods and in evaluating whether production or handling operations are using a system of organic production or handling.

(ii) Address possible limitations on availability to serve.

(iii) Include information concerning their commercial interests and those of their immediate family members, within the 12-month period prior to application, with any person who may seek to become or who is an accredited certifying agent. No person who has or has had a commercial interest, including an immediate family interest or the provision of consulting services, in an applicant for accreditation or renewal of accreditation within the preceding 12-month period shall be appointed to or accept appointment to a panel evaluating such applicant for accreditation or renewal of accreditation.

(2) Persons accepted to the pool may serve until notified that their appointment has been rescinded by the Administrator or until they are no longer qualified, whichever occurs first.

(c) Composition of peer review panels.

(1) Peer review panels convened by the Administrator shall consist of at least three but no more than five members.

(2) Peer review panels must include:

(i) A Department representative who shall preside over the panel and

(ii) No fewer than two members, drawn from the peer review pool, who possess sufficient expertise, as determined by the Administrator, in the areas of accreditation described in the application for accreditation or the notice of approval of accreditation for each certifying agent whose operations and performance are to be reviewed.

(3) Peer review panels may include:

(i) Up to two members with expertise in other disciplines, including organizational management and finance;

(ii) Member(s) from the approved State organic certification program when the applicant is a private entity that will operate within the State; and

(iii) Member(s) from a foreign government's organic program when the applicant is a private entity that will operate within the country.

(d) Duties and responsibilities of panel members.

(1) Each person on a peer review panel must individually review the site evaluation report prepared by the Department's evaluator(s) and any other information that may be provided by the Administrator relevant to continuing or renewing the accreditation status of a certifying agent;

(2) Information about the certifying agent received as part of the review process is confidential information, and peer reviewers must not release, copy, quote, or otherwise use material from the information received, other than in the report required to be submitted;

(3) Each peer reviewer must agree to treat the information received for review as confidential; and

(4) Each person on a peer review panel must provide an individual written report, including recommendations, to the Administrator regarding a certifying agent's ability to conduct and perform certification activities.

(e) *Peer review panel reports.* Copies of the peer review panel reports will be provided upon request to the certifying agent, and written responses from the certifying agent may be submitted for consideration by the Administrator.

§ 205.510 Annual report, recordkeeping, and renewal of accreditation.

(a) *Annual report and fees.* An accredited certifying agent must submit annually to the Administrator, on or before the anniversary date of the issuance of the notification of accreditation, the following reports and fees:

(1) A complete and accurate update of information submitted pursuant to §§ 205.503 and 205.504;

(2) Information supporting any changes being requested in the areas of accreditation described in § 205.500;

(3) A description of the measures implemented in the previous year and any measures to be implemented in the coming year to satisfy any terms and conditions determined by the Administrator to be necessary, as specified in the most recent notification of accreditation or notice of renewal of accreditation;

(4) The results of the most recent inspector performance appraisals and annual program evaluation and a description of adjustments to the certifying agent's operation and procedures implemented or to be implemented in response to the appraisals and evaluation; and

(5) The fees required in § 205.640(a).

(b) *Recordkeeping.* Certifying agents must maintain records according to the following schedule:

(1) Records obtained from applicants for certification and certified operations must be maintained for not less than 5 years beyond their receipt;

(2) Records created by the certifying agent regarding applicants for certification and certified operations must be maintained for not less than 10 years beyond their creation; and

(3) Records created or received by the certifying agent pursuant to the accreditation requirements of this subpart F, excluding any records covered by §§ 205.510(b)(2), must be maintained for not less than 5 years beyond their creation or receipt.

(c) *Renewal of accreditation.*

(1) An accredited certifying agent's application for accreditation renewal must be received 6 months prior to the fifth anniversary of issuance of the notification of accreditation and each subsequent renewal of accreditation. The accreditation of certifying agents who make timely application for renewal of accreditation will not expire during the renewal process. The accreditation of certifying agents who fail to make timely application for renewal of accreditation will expire as scheduled unless renewed prior to the scheduled expiration date. Certifying agents with an expired accreditation must not perform certification activities under the Act and these regulations.

(2) Following receipt of the information submitted by the certifying agent in accordance with paragraph (a) of this section, the results of a site evaluation, and, if applicable, the reports submitted by a peer review panel, the Administrator will determine whether the certifying agent remains in compliance with the Act and the regulations of this part and should have its accreditation renewed.

(d) *Notice of renewal of accreditation.* Upon a determination that the certifying agent is in compliance with the Act and the regulations of this part, the Administrator will issue a notice of renewal of accreditation. The notice of renewal will specify any terms and conditions that must be addressed by the certifying agent and the time within which those terms and conditions must be satisfied.

(e) *Noncompliance.* Upon a determination that the certifying agent is not in compliance with the Act and the regulations of this part, the Administrator will initiate proceedings to suspend or revoke the certifying agent's accreditation.

§§ 205.511—205.599 [Reserved]

Subpart G—Administrative

The National List of Allowed and Prohibited Substances

§ 205.600 Allowed and prohibited substances and ingredients in organic production and handling.

To be sold or labeled as "organic," or "made with organic (specified ingredients)," the product must be

produced and handled without the use of:

- (a) Synthetic substances and ingredients, except as provided in § 205.601 and § 205.603.
- (b) Nonagricultural substances used in or on processed products, except as otherwise provided in § 205.605;
- (c) Nonsynthetic substances prohibited in § 205.602 or § 205.604; and
- (d) Materials, processes, or techniques prohibited in § 205.301.

§ 205.601 Synthetic substances allowed for use in organic crop production.

In accordance with restrictions specified in this section and § 205.102 and § 205.200 through § 205.207, the following synthetic substances may be used:

- (a) As algicides, disinfectants and sanitizers, including irrigation system cleaning systems
 - (1) Alcohols
 - (i) Ethanol
 - (ii) Isopropanol
 - (2) Chlorine Materials—*Except*, That, residual chlorine levels in the water shall not exceed the maximum residual disinfectant limit under the Safe Drinking Water Act.
 - (i) Calcium Hypochlorite
 - (ii) Chlorine Dioxide
 - (iii) Sodium Hypochlorite
 - (3) Hydrogen Peroxide
 - (4) Soap-Based Algicides/Demosers
- (b) As herbicides, weed barriers, as applicable.
 - (1) Herbicides, Soap-Based—for use in farmstead maintenance (roadways, ditches, right of ways, building perimeters) and ornamental crops
 - (2) Mulches
 - (i) Newspaper or other recycled paper, without glossy or colored inks.
 - (ii) Plastic mulch and covers (petroleum-based other than polyvinyl chloride (PVC))
 - (c) As compost feedstocks—Newspapers or other recycled paper, without glossy or colored inks
 - (d) As animal repellents—Soaps, Ammonium—for use as a large animal repellent only, no contact with soil or edible portion of crop
 - (e) As insecticides (including acaricides or mite control)
 - (1) Ammonium Carbonate—for use as bait in insect traps only, no direct contact with crop or soil
 - (2) Boric Acid—structural pest control, no direct contact with organic food or crops
 - (3) Elemental Sulfur
 - (4) Lime Sulfur—including calcium polysulfide, fungicides, or insecticides if no alternatives
 - (5) Oils, Horticultural—as dormant, suffocating, and summer oils

(6) Petroleum-Based Oils—on woody plants for dormant and summer pest control, *Except*, That, a petroleum-based material allowed as a pesticide is prohibited for use as a herbicide. Aromatic petroleum solvents as a subclass of petroleum-based oils are prohibited.

- (7) Soaps, Insecticidal
- (8) Sticky Traps/Barriers
 - (f) As insect attractants—Pheromones
 - (g) As rodenticides
 - (1) Sulfur Dioxide—underground rodent control only (smoke bombs)
 - (2) Vitamin D3
 - (h) As slug or snail bait—[Reserved]
 - (i) As plant disease control
 - (1) Coppers, Fixed—Copper Hydroxide, Copper Oxide, Copper Oxychloride, Includes products exempted from EPA tolerance, *Except*, That, copper-based materials shall be managed in a way that prevents excessive accumulation in the soil and shall not be used as herbicides.
 - (2) Copper Sulfate—Substance must be used in a manner that minimizes accumulation of copper in the soil.
 - (3) Hydrated Lime—not permitted for soil application or to cauterize mutilations or deodorize animal wastes
 - (4) Hydrogen Peroxide
 - (5) Oils, Horticultural, as dormant, suffocating, and summer oils, insecticides only
 - (6) Petroleum-Based Oils—*Except*, That, aromatic petroleum solvents as a subclass of petroleum-based oils are prohibited.
 - (7) Potassium Bicarbonate
 - (8) Elemental Sulfur
 - (j) As plant or soil amendments.
 - (1) Aquatic Plant Extracts (other than hydrolyzed)—Extraction process is limited to the use of Potassium Hydroxide or Sodium Hydroxide; solvent amount used is limited to that amount necessary for extraction.
 - (2) Humic Acids—naturally occurring deposits, water and alkali extracts only
 - (3) Lignin Sulfonate—chelating agent, dust suppressant, floatation agent
 - (4) Micronutrients—not to be used as a defoliant, herbicide, or desiccant. Those made from nitrates or chlorides are not allowed. Soil deficiency must be documented by soil or tissue test.
 - (i) Soluble Boron Products
 - (ii) Sulfates, carbonates, oxides, or silicates of zinc, iron, magnesium, manganese, molybdenum, selenium, and cobalt
 - (5) Liquid Fish Products—can be pH adjusted with sulfuric, citric or phosphoric acid. The amount of acid used shall not exceed the minimum needed to lower the pH to 3.5
 - (6) Vitamins, B1, C, and E
 - (k) As plant growth regulators—[Reserved]

(l) As floating agents in postharvest handling

(1) Lignin Sulfonate

(2) Sodium Silicate—for tree fruit and fiber processing

(m) As synthetic inert ingredients as classified by the Environmental Protection Agency (EPA), for use with a synthetic substance listed in this section and used as an active ingredient in accordance with any limitations on the use of such synthetic substances—EPA List 4—Inerts of Minimal Concern

(n)–(z) [Reserved]

§ 205.602 Nonsynthetic substances prohibited for use in organic crop production.

(a) Ash from manure burning

(b) Arsenic

(c) Lead salts

(d) Sodium Fluoaluminat (Mined)

(e) Strychnine

(f) Tobacco Dust

(g)–(z) [Reserved]

§ 205.603 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 § 205.102 and § 205.236 through § 205.239.

(a) As disinfectants, sanitizers, and medical treatments as applicable

(1) Alcohols

(i) Ethanol—disinfectant and sanitizer only, prohibited as a feed additive

(ii) Isopropanol—disinfectant only

(2) Aspirin—approved for health care use to reduce inflammation

(3) Chlorine Materials—disinfecting and sanitizing facilities and equipment. Residual chlorine levels in the water shall not exceed the maximum residual disinfectant limit under the Safe Drinking Water Act

(i) Calcium Hypochlorite

(ii) Chlorine Dioxide

(iii) Sodium Hypochlorite

(4) Chlorohexidine—Allowed for surgical procedures conducted by a veterinarian. Allowed for use as a teat dip when alternative germicidal agents and/or physical barriers have lost their effectiveness

(5) Electrolytes—without antibiotics

(6) Glucose

(7) Glycerin—Allowed as a livestock teat dip, must be produced through the hydrolysis of fats or oils

(8) Iodine

(9) Hydrogen Peroxide

(10) Magnesium Sulfate

(11) Parasitocides—Ivermectin—Prohibited in slaughter stock, allowed in emergency treatment for dairy and breeder stock when organic system

plan-approved preventive management does not prevent infestation. Milk or milk products from a treated animal cannot be labeled as provided for in subpart D of this part for 90 days following treatment. In breeder stock, treatment cannot occur during the last third of gestation if the progeny will be sold as organic

(12) Phosphoric Acid—allowed as an equipment cleaner

(13) Vaccines and Biologics

(b) As topical treatment, external parasiticide or local anesthetic as applicable.

(1) Iodine

(2) Lidocaine—as a local anesthetic.

Use requires a withdrawal period of 90 days after administering to livestock intended for slaughter and 7 days after administering to dairy animals

(3) Lime, Hydrated—(Bordeaux mixes)

(4) Mineral Oil—for topical use and as a lubricant

(5) Procaine—as a local anesthetic, use requires a withdrawal period of 90 days after administering to livestock intended for slaughter and 7 days after administering to dairy animals

(6) Copper Sulfate

(c) As feed supplements—Milk Replacers—without antibiotics, as emergency use only, no nonmilk products or products from BST treated animals

(d) As feed additives

(1) Trace Minerals, including:

(i) Copper Sulfate

(ii) Magnesium Sulfate

(2) Vitamins—accepted for enrichment or fortification, limited to those approved by the FDA for livestock use

(e) As fillers and excipients

(f)–(z) [Reserved]

§ 205.604 Nonsynthetic substances prohibited for use in organic livestock production. [Reserved]

§ 205.605 Nonagricultural (nonorganic) substances allowed as ingredients in or on processed products labeled as “organic” or “made with organic (specified ingredients).”

The following nonagricultural substances may be used only in accordance with any restrictions specified in this section and § 205.102, § 205.270, and § 205.300 through § 205.310.

(a) *Nonsynthetics allowed:*

(1) Agar-agar

(2) Acids

(i) Alginic

(ii) Citric—produced by microbial fermentation of carbohydrate substances

(iii) Lactic

(3) Baking Powder—aluminum-free

(4) Bentonite

(5) Calcium Carbonate

(6) Calcium Chloride

(7) Carrageenan

(8) Cornstarch (Native)

(9) Dairy Cultures—non-EM

(10) Diatomaceous Earth—food filtering aid only

(11) Enzymes—must be derived from edible, nontoxic plants, nonpathogenic fungi, or nonpathogenic bacteria

(12) Gums—Water extracted only (arabic, guar, locust bean, carob bean)

(13) Kaolin

(14) Kelp—for use only as a thickener and dietary supplement

(15) Lecithin—unbleached

(16) Nitrogen—Oil-free grades

(17) Oxygen—Oil-free grades

(18) Pectin (high-methoxy)

(19) Perlite—for use only as a filter aid in food processing

(20) Potassium Chloride

(21) Potassium Iodide

(22) Sodium Bicarbonate

(23) Sodium Carbonate

(24) Yeast—Nonsynthetic, non-EM

(i) Autolysate

(ii) Bakers

(iii) Brewers

(iv) Nutritional

(v) Smoked—growth on petrochemical substrate and sulfite waste liquor prohibited. Nonsynthetic smoke flavoring process must be documented

(b) *Synthetics allowed:*

(1) Alginates

(2) Ammonium Bicarbonate—for use only as a leavening agent

(3) Ammonium Carbonate—for use only as a leavening agent

(4) Ascorbic Acid

(5) Calcium Citrate

(6) Calcium Hydroxide

(7) Calcium Phosphates (monobasic and dibasic)

(8) Carbon Dioxide

(9) Chlorine Materials—disinfecting and sanitizing food contact surfaces, *Except*, That, residual chlorine levels in the water shall not exceed the maximum residual disinfectant limit under the Safe Drinking Water Act.

(i) Calcium Hypochlorite

(ii) Chlorine Dioxide

(iii) Sodium Hypochlorite

(10) Ethylene—allowed for post harvest ripening of tropical fruit

(11) Ferrous Sulfate—for iron enrichment or fortification of foods when required by regulation or recommended (independent organization)

(12) Glycerides (mono and di)—for use only in drum drying of food

(13) Glycerin—produced by hydrolysis of fats and oils

(14) Hydrogen peroxide

(15) Lecithin—bleached
 (16) Magnesium Carbonate—for use only in agricultural products labeled “made with organic (specified ingredients),” prohibited in agricultural products labeled “organic”

(17) Magnesium Chloride—derived from sea water

(18) Magnesium Stearate—for use only in agricultural products labeled “made with organic (specified ingredients),” prohibited in agricultural products labeled “organic”

(19) Magnesium Sulfate
 (20) Nutrient vitamins and minerals, in accordance with 21 CFR 104.20, Nutritional Quality Guidelines For Foods

(21) Ozone
 (22) Pectin (low-methoxy)
 (23) Phosphoric Acid—cleaning of food-contact surfaces and equipment only

(24) Potassium Acid Tartrate
 (25) Potassium Tartrate made from Tartaric acid

(26) Potassium Carbonate
 (27) Potassium Citrate
 (28) Potassium Hydroxide—prohibited for use in lye peeling of fruits and vegetables

(29) Potassium Iodide—for use only in agricultural products labeled “made with organic (specified ingredients),” prohibited in agricultural products labeled “organic”

(30) Potassium Phosphate—for use only in agricultural products labeled “made with organic (specific ingredients),” prohibited in agricultural products labeled “organic”

(31) Silicon Dioxide
 (32) Sodium Citrate
 (33) Sodium Hydroxide—prohibited for use in lye peeling of fruits and vegetables

(34) Sodium Phosphates—for use only in dairy foods

(35) Tocopherols—derived from vegetable oil when rosemary extracts are not a suitable alternative

(36) Xanthan gum
 (c)–(z) [Reserved]

§ 205.606 Nonorganically produced agricultural products allowed as ingredients in or on processed products labeled as organic or made with organic ingredients.

Any nonorganically produced agricultural product may be used in accordance with any restrictions specified in this section and § 205.102, § 205.270, and § 205.300 through § 205.310.

§ 205.607 Amending the National List.

(a) Any person may petition the National Organic Standard Board for the purpose of having a substance evaluated

for recommendation to the Secretary for inclusion on or deletion from the National List in accordance with section 6517 of the Act.

(b) A person petitioning for amendment of the National List should request a copy of the petition procedures from the USDA at the address in § 205.607(c).

(c) A petition to amend the National List must be submitted to: Program Manager, USDA/AMS/TM/NOP, Room 2945 South Building, PO Box 96456, Washington, DC 20090–6456.

(d) A substance may be added to the National List only in the following categories:

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

(2) Nonsynthetic substances prohibited for use in organic crop or livestock production; or

(3) Nonagricultural substances allowed for use as ingredients in or on processed products labeled as “organic” or “made with organic (specified ingredients).”

State Programs

§ 205.620 Requirements of State organic certification programs.

(a) A State may establish a State organic certification program for production and handling operations within the State which produces and handles organic agricultural products.

(b) A State organic certification program must meet the general requirements for organic programs specified in the Act and be at least equivalent to the regulations in this part.

(c) A State organic certification program may contain more restrictive requirements based on unique environmental conditions or specific production or handling practices particular to the State or region of the United States, which necessitates the more restrictive requirement. Such additional requirements must further the purposes and be consistent with the Act and regulations in this part.

(d) A State organic certification program must assume enforcement obligations in the State for the requirements of this part and any more restrictive requirements approved by the Secretary.

(e) A State organic certification program and any amendments to such program must be approved by the Secretary prior to being implemented by the State.

§ 205.621 Submission and determination of proposed State organic certification programs and amendments to approved State organic certification programs.

(a) A State program’s governing State official must submit to the Secretary a proposed State organic certification program and any proposed amendments to such approved program.

(1) Such submission must contain supporting materials that include statutory authorities, program description, a statement of acceptance of the general requirements for organic programs specified in the Act, documentation of unique environmental or ecological conditions or specific production practices particular to the State which necessitate more restrictive requirements than the requirements of this part, and other information as may be required by the Secretary.

(2) Submission of a request for amendment of an approved State organic certification program must contain supporting material that includes an explanation and documentation of the unique environmental or ecological conditions or specific production practices particular to the State or region, which necessitates the proposed amendment. Supporting material also must explain how the proposed amendment furthers and is consistent with the purposes of the Act and the regulations of this part.

(b) Within 6 months of receipt of submission, the Secretary will:

(1) Publish in the **Federal Register** for public comment, a summary of a proposed State organic certification program, and a summary of any proposed amendment to such program.

(2) After review of materials and documentation accompanying the proposal and consideration of comments received, notify the State program’s governing State official of approval or disapproval of the proposed program or amendment of an approved program and, if disapproved, the reasons for the disapproval.

(c) After receipt of a notice of disapproval, the State program’s governing State official may resubmit a revised State organic certification program or amendment of such a program at any time.

§ 205.622 Review of approved State organic certification programs.

The Secretary will review a State organic certification program not less than once during each 5-year period following the date of the initial program approval. The Secretary will notify the State program’s governing State official of approval or disapproval of the

program within 6 months after initiation of the review.

Fees

§ 205.640 Fees and other charges for accreditation.

Fees and other charges equal as nearly as may be to the cost of the accreditation services rendered under the regulations, including initial accreditation, review of annual reports, and renewal of accreditation, shall be assessed and collected from applicants for initial accreditation and accredited certifying agents submitting annual reports or seeking renewal of accreditation in accordance with the following provisions.

(a) Fees-for-Service.

(1) Except as otherwise provided in this section, fees-for-service shall be based on the time required to render the service provided calculated to the nearest 15-minute period, including the review of applications and accompanying documents and information, evaluator travel, the conduct of on-site evaluations, review of annual reports and updated documents and information, and the time required to prepare reports and any other documents in connection with the performance of service. The hourly rate shall be the same as that charged by the Agricultural Marketing Service (AMS), through its Quality Systems Certification Program, to certification bodies requesting conformity assessment to the International Organization for Standardization "General Requirements for Bodies Operating Product Certification Systems" (ISO Guide 65).

(2) Applicants for initial accreditation and accredited certifying agents submitting annual reports or seeking renewal of accreditation during the first 18 months following the effective date of subpart F of this part shall receive service without incurring an hourly charge for service.

(3) Applicants for initial accreditation and renewal of accreditation must pay at the time of application, effective 18 months following the effective date of subpart F of this part, a nonrefundable fee of \$500.00 which shall be applied to the applicant's fees-for-service account.

(b) *Travel charges.* When service is requested at a place so distant from the evaluator's headquarters that a total of one-half hour or more is required for the evaluator(s) to travel to such place and back to the headquarters or at a place of prior assignment on circuitous routing requiring a total of one-half hour or more to travel to the next place of assignment on the circuitous routing,

the charge for such service shall include a mileage charge administratively determined by the Department and travel tolls, if applicable, or such travel prorated among all the applicants and certifying agents furnished the service involved on an equitable basis or, where the travel is made by public transportation (including hired vehicles), a fee equal to the actual cost thereof. Travel charges shall become effective for all applicants for initial accreditation and accredited certifying agents on the effective date of subpart F of this part. The applicant or certifying agent will not be charged a new mileage rate without notification before the service is rendered.

(c) *Per diem charges.* When service is requested at a place away from the evaluator's headquarters, the fee for such service shall include a per diem charge if the employee(s) performing the service is paid per diem in accordance with existing travel regulations. Per diem charges to applicants and certifying agents will cover the same period of time for which the evaluator(s) receives per diem reimbursement. The per diem rate will be administratively determined by the Department. Per diem charges shall become effective, for all applicants for initial accreditation and accredited certifying agents on the effective date of subpart F of this part. The applicant or certifying agent will not be charged a new per diem rate without notification before the service is rendered.

(d) *Other costs.* When costs, other than costs specified in paragraphs (a), (b), and (c) of this section are associated with providing the services, the applicant or certifying agent will be charged for these costs. Such costs include, but are not limited to, equipment rental, photocopying, delivery, facsimile, telephone, or translation charges incurred in association with accreditation services. The amount of the costs charged will be determined administratively by the Department. Such costs shall become effective for all applicants for initial accreditation and accredited certifying agents on the effective date of subpart F of this part.

§ 205.641 Payment of fees and other charges.

(a) Applicants for initial accreditation and renewal of accreditation must remit the nonrefundable fee, pursuant to § 205.640(a)(3), along with their application. Remittance must be made payable to the Agricultural Marketing Service, USDA, and mailed to: Program Manager, USDA-AMS-TMP-NOP, Room 2945-South Building, PO Box

96456, Washington, DC 20090-6456 or such other address as required by the Program Manager.

(b) Payments for fees and other charges not covered under paragraph (a) of this section must be:

(1) Received by the due date shown on the bill for collection;

(2) Made payable to the Agricultural Marketing Service, USDA; and

(3) Mailed to the address provided on the bill for collection.

(c) The Administrator shall assess interest, penalties, and administrative costs on debts not paid by the due date shown on a bill for collection and collect delinquent debts or refer such debts to the Department of Justice for litigation.

§ 205.642 Fees and other charges for certification.

Fees charged by a certifying agent must be reasonable, and a certifying agent shall charge applicants for certification and certified production and handling operations only those fees and charges that it has filed with the Administrator. The certifying agent shall provide each applicant with an estimate of the total cost of certification and an estimate of the annual cost of updating the certification. The certifying agent may require applicants for certification to pay at the time of application a nonrefundable fee of no more than \$250.00, which shall be applied to the applicant's fees-for-service account. The certifying agent shall provide all persons inquiring about the application process with a copy of its fee schedule.

§§ 205.643–205.649 [Reserved]

Compliance

§ 205.660 General.

(a) The National Organic Program's Program Manager, on behalf of the Secretary, may inspect and review certified production and handling operations and accredited certifying agents for compliance with the Act or regulations in this part.

(b) The Program Manager may initiate suspension or revocation proceedings against a certified operation:

(1) When the Secretary has reason to believe that a certified operation has violated or is not in compliance with the Act or regulations in this part.

(2) When a certifying agent or a State program's governing State official fails to take appropriate action to enforce the Act or regulations in this part; or

(c) The Program Manager may initiate suspension or revocation of a certifying agent's accreditation if the certifying agent fails to meet, conduct, or maintain

accreditation requirements pursuant to the Act or this part.

§ 205.661 Investigation of certified operations.

(a) A certifying agent may investigate complaints of noncompliance with the Act or regulations of this part concerning production and handling operations certified as organic by the certifying agent. A certifying agent must notify the Program Manager of all compliance proceedings and actions taken pursuant to this part.

(b) A State program's governing State official may investigate complaints of noncompliance with the Act or regulations in this part concerning organic production or handling operations operating in the State.

§ 205.662 Noncompliance procedure for certified operations.

(a) *Notification.* When an inspection, review, or investigation of a certified operation by a certifying agent or a State program's governing State official reveals any noncompliance with the Act or regulations in this part, a written notification of noncompliance shall be sent to the certified operation. Such notification shall provide:

(1) A description of each noncompliance;

(2) The facts upon which the notification of noncompliance is based; and

(3) The date by which the certified operation must rebut or correct each noncompliance and submit supporting documentation of each such correction when correction is possible.

(b) *Resolution.* When a certified operation demonstrates that each noncompliance has been resolved, the certifying agent or the State program's governing State official, as applicable, will send the certified operation a written notification of noncompliance resolution.

(c) *Proposed suspension or revocation.* When rebuttal is unsuccessful or correction of the noncompliance is not completed within the prescribed time period or is not adequate to demonstrate that each noncompliance has been corrected, the certifying agent or State program's governing State official shall send the certified operation a written notification of proposed suspension or revocation of certification of the entire operation or a portion of the operation, as applicable to the noncompliance. When correction of a noncompliance is not possible, the notification of noncompliance and the proposed suspension or revocation of certification may be combined in one notification. The notification of

proposed suspension or revocation of certification shall state:

(1) The reasons for the proposed suspension or revocation;

(2) The proposed effective date of such suspension or revocation;

(3) The impact of a suspension or revocation on future eligibility for certification; and

(4) The right to request mediation pursuant to § 205.663 or to file an appeal pursuant to § 205.681.

(d) *Willfull violations.*

Notwithstanding paragraph (a) of this section, if a certifying agent or State program's governing State official has reason to believe that a certified operation has willfully violated the Act or regulations in this part, the certifying agent or State program's governing State official shall send the certified operation a notification of proposed suspension or revocation of certification of the entire operation, or a portion of the operation, as applicable to the noncompliance.

(e) *Suspension or revocation.*

(1) If the certified operation fails to correct the noncompliance, to resolve the issue through rebuttal or mediation, or to file an appeal of the proposed suspension or revocation of certification, the certifying agent or State program's governing State official shall send the certified operation a written notification of suspension or revocation.

(2) A certifying agent or State program's governing State official must not send a notification of suspension or revocation to a certified operation that has requested mediation pursuant to § 205.663 or filed an appeal pursuant to § 205.681.

(f) *Ineligibility.* A certified operation or a person responsibly connected with an operation whose certification has been revoked will not be eligible to receive certification for a period of not more than 5 years following the date of such revocation, as determined by the Secretary.

§ 205.663 Mediation.

Any dispute with respect to proposed suspension or revocation of certification under this part shall, at the request of the applicant for certification or certified operation, be mediated by a qualified mediator mutually agreed upon by the parties to the mediation. If a State Program is in effect, the mediation procedures established in the State Program, as approved by the Secretary, will be followed. Mediation shall be requested in writing to the applicable certifying agent. The parties to the mediation shall have no more than 30 days to reach an agreement following a mediation session. If

mediation is unsuccessful, the applicant for certification or certified operation shall have 30 days from termination of mediation to appeal the certifying agent's decision to the Administrator, pursuant to § 205.681. Any agreement reached during or as a result of the mediation process shall be in compliance with the Act and these regulations. The Secretary may review any mediated agreement for conformity to the Act and these regulations.

§ 205.664 [Reserved]

§ 205.665 Noncompliance procedure for certifying agents.

(a) *Noncompliance.* When an inspection, review, or investigation of an accredited certifying agent by the Program Manager reveals any noncompliance with the Act or regulations in this part, a written notification of noncompliance shall be sent to the certifying agent, as applicable. Such notification shall provide:

(1) A description of each noncompliance found;

(2) The facts upon which the notification of noncompliance is based; and

(3) The date by which the certifying agent must rebut or correct each noncompliance when correction is possible.

(b) *Resolution.* When each noncompliance has been resolved, the Program Manager shall send the certifying agent a written notification of noncompliance resolution.

(c) *Proposed suspension or revocation.* If rebuttal is unsuccessful or if correction of the noncompliance is not made within the prescribed time period or is not adequate to demonstrate that each noncompliance has been corrected, the Program Manager shall send a written notification of proposed suspension or revocation of accreditation to the certifying agent. The notification of proposed suspension or revocation shall state whether the certifying agent's accreditation or specified areas of accreditation are to be suspended or revoked. When correction of a noncompliance is not possible, the notification of noncompliance and the proposed suspension or revocation may be combined in one notification. The notification of proposed suspension or revocation of accreditation shall state:

(1) The reasons for the proposed suspension or revocation;

(2) The proposed effective date of the suspension or revocation;

(3) The impact of a suspension or revocation on future eligibility for accreditation; and

(4) The right to file an appeal pursuant to § 205.681.

(d) *Willfull violations.*

Notwithstanding paragraph (a) of this section, if the Program Manager has reason to believe that a certifying agent has willfully violated the Act or regulations in this part, the Program Manager shall send a written notification of proposed suspension or revocation of accreditation to the certifying agent.

(e) *Suspension or revocation.* When the accredited certifying agent fails to file an appeal of the proposed suspension or revocation of accreditation, the Program Manager shall send a written notice of suspension or revocation of accreditation to the certifying agent.

(f) *Cessation of certification activities.* A certifying agent whose accreditation is suspended or revoked must:

(1) Cease all certification activities in each area of accreditation which its accreditation is suspended or revoked.

(2) Transfer to the Secretary and make available to any applicable governing State official all records concerning its certification activities that were suspended or revoked.

(g) *Eligibility.*

(1) A certifying agent whose accreditation is suspended by the Secretary under this section may at any time submit a new request for accreditation, pursuant to § 205.502. The request must be accompanied by evidence demonstrating correction of each noncompliance and corrective actions taken to comply with and remain in compliance with the Act and the regulations in this part.

(2) A certifying agent whose accreditation is revoked by the Secretary shall be ineligible to be accredited as a certifying agent under the Act and the regulations in this part for a period of not less than 3 years following the date of such revocation.

§§ 205.666 and 205.667 [Reserved]

§ 205.668 Noncompliance procedures under State organic certification programs.

(a) A State program's governing State official must promptly notify the Secretary of commencement of any enforcement proceeding against a certified operation and forward to the Secretary a copy of each notice issued.

(b) A noncompliance proceeding, brought by a State program's governing State official against a certified operation, shall be appealable pursuant to the appeal procedures of the State organic certification program. There shall be no subsequent rights of appeal to the Secretary. Final decisions of a

State may be appealed to the United States District Court for the district in which such certified operation is located.

(c) A State program's governing State official may review and investigate complaints of noncompliance with the Act or regulations concerning accreditation of certifying agents operating in the State. When such review or investigation reveals any noncompliance, the State program's governing State official shall send a written report of noncompliance to the Program Manager. The report shall provide a description of each noncompliance and the facts upon which the notification of noncompliance is based.

§ 205.669 [Reserved]

Inspection and Testing, Reporting, and Exclusion from Sale

§ 205.670 Inspection and testing of agricultural product to be sold or labeled organic.

(a) All agricultural products that are to be sold, labeled, or represented as "100 percent organic," "organic," or "made with organic (specified ingredients)" must be made accessible by certified organic production or handling operations for examination by the Administrator, the applicable State program's governing State official, or the certifying agent.

(b) The Administrator, applicable State program's governing State official, or the certifying agent may require preharvest or postharvest testing of any agricultural input used or agricultural product to be sold, labeled, or represented as "100 percent organic," "organic," or "made with organic (specified ingredients)" when there is reasonable cause to believe that the agricultural input or product has come into contact with a prohibited substance. Such tests must be conducted by the applicable State program's governing State official or the certifying agent at the official's or certifying agent's own expense.

(c) The preharvest or postharvest tissue test sample collection pursuant to paragraph (b) of this section must be performed by an inspector representing the Administrator, certifying agent, or applicable State program's governing State official. Sample integrity must be maintained in transit, and residue testing must be performed in an accredited laboratory. Chemical analysis must be made in accordance with the methods described in the 16th edition of the *Official Methods of Analysis of the AOAC International* or other applicable validated methodology determining the

presence of contaminants in agricultural products.

(d) Results of all analyses and tests performed under this section:

(1) Must be provided to the Administrator promptly upon receipt; and

(2) Will be available for public access, unless the testing is part of an ongoing compliance investigation.

§ 205.671 Exclusion from organic sale.

(a) When residue testing detects prohibited substances at levels that are greater than the estimated national mean of detected residues for specific commodity/pesticide pairs, as demonstrated by USDA's Pesticide Data Program, or unavoidable residual environmental contamination, as determined by the Administrator, the agricultural product must not be sold, labeled, or represented as organically produced. The Administrator, the applicable State program's governing State official, or the certifying agent may conduct an investigation of the certified operation to determine the cause of the prohibited substance residue.

(b) If test results indicate a specific agricultural product contains pesticide residues or environmental contaminants that exceed the Food and Drug Administration's or the Environmental Protection Agency's regulatory tolerances, the data must be reported promptly to the appropriate public health agencies.

§ 205.672 Emergency pest or disease treatment.

When a prohibited substance is applied to a certified operation due to Federal or State emergency pest eradication or disease treatment program and the certified operation otherwise meets the requirements of this part, the certification status of the operation shall not be affected as a result of the application of the prohibited synthetic substance: *Provided, That:*

(a) Any harvested crop or plant part to be harvested that has contact with a prohibited substance applied as the result of a Federal or State emergency pest eradication or disease treatment program cannot not be sold, labeled, or represented as organically produced; and

(b) Any livestock that are treated with a prohibited substance applied as the result of a Federal or State emergency pest or disease treatment program or product derived from such treated livestock cannot be sold, labeled, or represented as organically produced: *Except, That:*

(1) Milk or milk products may be sold, labeled, or represented as organically

produced beginning 12 months following the last date that the dairy animal was treated with the prohibited substance; and

(2) The offspring of gestating mammalian breeder stock treated with a prohibited substance may be considered organic: *Provided*, That, the breeder stock was not in the last third of gestation on the date that the breeder stock was treated with the prohibited substance.

§§ 205.673—205.679 [Reserved]

Adverse Action Appeal Process

§ 205.680 General.

Persons subject to the Act who believe they are adversely affected by a noncompliance proceeding decision of the National Organic Program's Program Manager or a certifying agent may appeal such decision to the Administrator.

§ 205.681 Appeals.

(a) *Certification appeals.* An applicant for certification may appeal a certifying agent's notice of denial of certification, and a certified operation may appeal a certifying agent's notification of proposed suspension or revocation of certification to the Administrator: *Except*, That, when the applicant or certified operation is subject to an approved State organic certification program and the decision to deny, suspend, or revoke a certification is made by a certifying agent or a State program's governing State official, the appeal must be made to the State program's governing State official or such official's designee who will carry out the appeal pursuant to the State program's appeal procedures approved by the Secretary.

(1) If the Administrator sustains a certification applicant's or certified operation's appeal of a certifying agent's decision, the applicant will be issued organic certification, or a certified operation will continue its certification, as applicable to the operation. The act of sustaining the appeal shall not be an adverse action subject to appeal by the affected certifying agent.

(2) If the Administrator denies an appeal, a formal administrative proceeding will be initiated to deny, suspend, or revoke the certification. Such proceeding shall be conducted pursuant to the Department's Uniform Rules of Practice.

(b) *Accreditation appeals.* An applicant for accreditation and an accredited certifying agent may appeal a Program Manager's denial of accreditation or proposed suspension or

revocation of accreditation to the Administrator.

(1) If the Administrator sustains an appeal, an applicant will be issued accreditation, or a certifying agent will continue its accreditation, as applicable to the operation.

(2) If the Administrator denies an appeal, a formal administrative proceeding to deny, suspend, or revoke the accreditation will be initiated. Such proceeding shall be conducted pursuant to the Department's Uniform Rules of Practice.

(c) An appeal of a noncompliance decision must be filed within the time period provided in the letter of notification or at least 30 days from the receipt of the notification. The appeal will be considered "filed" on the date received by the Administrator or by the State program's governing State official or such official's designee as provided in the State's approved appeal procedures. A decision to deny, suspend, or revoke certification or accreditation will become final and nonappealable unless the decision is appealed in a timely manner.

(d) All appeals to the Administrator must be filed in writing and addressed to Administrator, USDA-AMS, Room 3071-S, PO Box 96456, Washington, DC 20090-6456, and be copied to the certifying agent completely and simultaneously with submission to the Administrator. Appeals must include a copy of the adverse decision and a statement of the appellant's position that the decision was not made in accordance with applicable program regulations, policies, or procedures.

§§ 205.682—205.689 [Reserved].

Miscellaneous

§ 205.690 OMB control number.

The control number assigned to the information collection requirements by the Office of Management and Budget pursuant to the Paperwork Reduction Act of 1980, Public Law 96-511, is OMB number 0581-0181.

§§ 205.691—205.699 [Reserved]

PARTS 206–209—[RESERVED]

Dated: March 3, 2000.

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Appendices to the Preamble

Appendix A.—Regulatory Impact Assessment for Proposed Rules Implementing the Organic Foods Production Act of 1990 (Executive Order 12866)

The following regulatory assessment is provided to fulfill the requirements of Executive Order 12866. This assessment consists of a statement of the need for the proposed action, a description of the baseline for the analysis, an examination of alternative approaches, and an analysis of the benefits and costs. Much of the analysis is necessarily descriptive of the anticipated effects of the proposed rule. Because basic market data on the prices and quantities of organic goods and services and the costs of organic production are limited, it is not possible to provide quantitative estimates of all benefits and costs of the proposed rule. The cost of fees and recordkeeping proposed by U.S. Department of Agriculture (USDA) are quantified, but the anticipated benefits are not. Consequently, the analysis does not estimate the magnitude or the direction (positive or negative) of net benefits.

The Need for the Proposed Action

The Organic Foods Production Act of 1990, Title XXI of the Food, Agriculture, Conservation and Trade Act of 1990, U.S.C. Title 7, mandates that the Secretary of Agriculture develop a national organic program. The OFPA states that the Secretary shall establish an organic certification program for farmers, wild-crop harvesters, and handlers of agricultural products that have been produced using organic methods as provided for in the OFPA. In addition, section 6514 of the OFPA requires the Secretary to establish and implement a program to accredit a State program's governing State official or any private person, who meets the requirements of the Act, as a certifying agent to certify that farm, wild-crop harvesting, or handling operations are in compliance with the standards set out in the regulation. As stated by the OFPA in section 6501, the regulations are proposed for the following purposes: (1) to establish national standards governing the marketing of certain agricultural products as organically produced products; (2) to assure consumers that organically produced products meet a consistent standard; and (3) to facilitate interstate commerce in fresh and processed food that is organically produced.

The OFPA was introduced at the request of the organic community after it experienced a number of problems in the marketing of organic products. Many consumers are willing to pay price premiums for organic food; hence, producers (farmers, ranchers, and wild-crop harvesters) and handlers have an economic incentive to label their products

organic. Because organic products cannot be distinguished from conventionally produced products by sight inspection, consumers rely on verification methods, such as certification by private entities or verification by retailers to ensure that organic claims are true. Where there has been no mandatory certification, consumers have been unable to verify organic product claims on their own, and may have been vulnerable to fraud from the mislabeling of organic products.

As organic production became better established in the 1980's, new certifying agencies were formed, and some States passed laws establishing standards for organic production. However, the standards for organic production, processing, handling, and labeling were different to some degree, causing disagreements between certifying agents over whose standards would apply to ingredients used in multi-ingredient organic processed products. Disagreements about standards also created sourcing problems for handlers of these multiingredient products.

Certifying agents are able to negotiate and maintain reciprocity agreements at some cost. These reciprocity agreements specify the conditions under which certifying agents recognize each others' standards. The current system of variable standards has led the organic industry to take on costs of private accreditation or shipment-by-shipment certification, required to gain access to some foreign markets such as the European Union (EU). These costs would be avoided if a national program were in place.

Baseline

The organic industry is characterized by an array of production and handling practices, self regulation and state regulation, and consumer perceptions. However, there are commonalities throughout the industry.

Certification

The United States currently has 49 certifying agents. There are 36 private certifying agencies and 13 States which have certification programs. Private certifying agents range from small nonprofit associations that certify only a few growers to large for-profit businesses operating in numerous States and certifying hundreds of producers. Typically, certifying agents review producers' organic production plans, inspect the farm fields and facilities to be certified, periodically reinspect, and may conduct soil tests and tests for residues of prohibited substances. In some cases, certifying agents negotiate reciprocity agreements with other agents.

State laws vary widely on organic certification and registration. Some States require only that an organic producer register and make certification voluntary. California is an example. Other States require certification by the State's own agents, while others accept certification by a private certifying agent. The least stringent requirement among States with organic legislation is that products marketed as organic comply with their definition of organic but both registration and certification are voluntary. Approximately half of the States have laws which regulate organic production and processing. Thirteen States

operate programs to certify organic production. In many States producers may claim their product is organic but operate without certification or well-defined standards. On the other hand, many organic producers operate in States with no program and voluntarily secure third party certification to well-defined standards. Certification costs vary with farm size and across certifying agents. Illustrative certification costs are presented in Tables 2A and 2B.

Very few certifying agents operate with an external accreditation. There is no law which requires them to be accredited: The price may be unacceptably high in relation to expected benefits; the certifying agent may be unable to find an accrediting party willing to accredit the particular organic program the certifying agent is marketing; and State programs may believe that their status as a government entity obviates the need for external accreditation.

In 1999 USDA began verifying certifying agents to International Organization for Standardization (ISO) Guide 65. It is a valuable recognition that the certifying entity satisfies the business capacity standards of ISO Guide 65. European Union authorities have accepted verification of certifying agents to ISO Guide 65 as an interim measure to facilitate exports pending the establishment of a national organic program.

Organic Food Production

Organic production occurs in all States. An estimated 12,000 organic producers are operating in the United States. Most organic producers are small both in terms of value of sales and acreage. Small producers do not necessarily farm full-time, and may not depend solely on farm income for a livelihood. Some organic production occurs as a distinct part of a larger operation that includes conventional production practices.

Key production practices followed by certified organic producers include: abstaining from use of certain crop chemicals and animal drugs; ecologically based pest and nutrient management; segregation of organic fields and animals from nonorganic fields and animals; following an organic production plan with multiple goals, including sustainability; and record keeping to document practices and progress toward the plan's goals. Specific elements of organic production will vary, but organic systems generally share a core set of practices. For example, the certification standards of virtually all State and private U.S. certifying agents prohibit the use synthetic chemical herbicides and insecticides or animal growth hormones. And most certification standards include a three year ban on the use of prohibited substances on cropland before production can be certified as organic.

On the other hand, certification standards for organic livestock production have been more variable, for pasture, feed, and other practices. Until 1999, the USDA Food Safety and Inspection Service (FSIS) withheld approval for the use of organic labels on meat and poultry products pending the outcome of this rulemaking. However, the Secretary announced a change in policy in January 1999. Meat and poultry products may be

labeled "certified organic by (name of the certifying agent)" if processors obtain prior label approval from FSIS and the claim meets certain basic criteria. However, many private and State certifying programs have not developed standards for livestock production.

The provisions of the New Hampshire organic program are summarized below to illustrate key elements of current organic standards. The New Hampshire program provisions are not substantially different from provisions in some State programs, private programs, and mirror provisions of USDA's proposed national program. Soil tests are required for initial certification and every three years afterward. Soil testing measures the quality of the soil for agricultural production and is different from residue testing. New Hampshire requires residue testing "if the department believes that the produce or soil which certified produce was grown may have become contaminated with prohibited substances." (New Hampshire Rule AGR 906 Certification of Organically Grown Food, Agr 906.05 Laboratory Analysis) Other production standards include a written rotation plan, tillage systems that incorporate organic matter wastes into the topsoil, compliance with limits on the sources of manure and the timing of its application, prohibitions on the use of certain substances (e.g., sewage sludge, synthetic sources of nitrates, synthetic growth regulators, and anhydrous ammonia), a list of accepted and prohibited weed and pest control practices, segregation of organic and nonorganic production, record keeping regarding fertilization, cropping, and pest management histories, separate sales records for organic and nonorganic production, and records of all laboratory analyses.

The New Hampshire program requires growers to pay a \$100 annual inspection fee, and to provide a written description of their farm operation including the size of the farm, a field map, a three-year history of crop production, pest control, and fertilizer use, a crop rotation and a soil management plan, and a description of post-harvest storage and handling methods. Applicants for certification must also agree to comply with regulations controlling the use of the New Hampshire certified organic logo.

Organic Food Handling

In addition to growers, who actually produce and harvest products to be marketed as organic, there are handlers who transform and resell the organic products. Not all certifying agents have standards for handling organic products. Some have standards for parts of the food marketing system, such as retail food establishments, that are not explicitly covered by the OFPA or by the proposed regulation.

Definitions of processing and handling differ across certifying agents and State laws. Some States, such as Washington, distinguish between a processor and a handler, specifying 21 actions which constitute processing and defining a handler as anyone who sells, distributes, or packs organic products. Washington does not consider retail grocery stores and restaurants to be organic handlers or processors.

Marketing of Organic Food—Domestic and International

The marketing practices of organic producers range from roadside stands marketing directly to consumers, to marketing through wholesale markets, to direct marketing to restaurants and supermarkets. USDA does not have official national level statistics on organic retail sales. An industry trade publication reported estimates of retail sales of organic foods for a number of years in the 1990's (Table 1). The last published estimate was \$3.5 billion in 1996 (\$3.6 billion in 1998 dollars). To put this figure in context, total food expenditures by families and individuals were \$606 billion in 1996 (\$629 billion in 1998 dollars).

The United States is both an importer and an exporter of organic foods. The United States does not restrict imports of organic foods. In fact, U.S. Customs accounts do not distinguish between organic and conventional products. The largest markets for organic foods outside the United States are in Europe, Japan, and Canada. There is increasing pressure, particularly in Europe and Japan, for U.S. exports to demonstrate that they meet a national standard rather than a variety of private and State standards.

The EU is the largest market for organic food outside the United States. The organic food market in the EU was estimated to be worth \$5.2 billion in 1997 (International Trade Centre UNCTAD/WTO 1999). The largest organic retail sales markets in the EU in 1997 were Germany (\$1.8 billion), France (\$720 million), and Italy (\$750 million). Large organic markets outside the EU include Canada and Australia, with approximately \$60 million and \$68 million, respectively, in organic retail sales in 1997 (Lohr 1998). Import share of the organic food market in Europe ranged from 10 percent in France to 70 percent in the United Kingdom, was 80 percent in Canada, and varied from 0 to 13 percent in various Australian states.

Japan is another important market for U.S. organic products. Currently, Japan has voluntary labeling guidelines for 6 categories of non-conventional agricultural products: organic, transitional organic, no pesticide, reduced pesticide, no chemical fertilizer, and reduced chemical fertilizer. Total sales, including foods marketed as "no chemical," and "reduced chemical" are forecast to jump 15 percent in 1999 to almost \$3 billion. Imports of organic agricultural products were valued at \$90 million in 1998. Given Japan's limited agricultural acreage, imports will likely provide an increasingly significant share of Japan's organic food supply (USDA FAS 1999a).

Recently, these markets have adopted or are considering to adopt procedures that may impede the importing of organic food. The EU regulations establishing the basis for equivalency in organic production among EU members and for imports from outside the EU were adopted in 1991 (Council Regulation 2092/91). The EU regulations only allow imports from non-EU countries whose national standards have been recognized as equivalent to the EU standards (Commission Regulation 94/92).

The Ministry of Agriculture, Forestry, and Fisheries (MAFF) in Japan recently

announced proposed standards and third-party certification requirements. Under Japan's proposed standards, certifying agents from countries without national organic standards administered by a federal government will have to be accredited (registered) with MAFF to obtain approval to certify products destined for the Japanese market. The Japanese proposal includes provisions for country-to-country equivalency recognition of other national programs.

The Proposed Rule

The proposed rule follows the structure established in the OFPA. By adopting this alternative, the Department would follow legislative direction in the OFPA. All products marketed as organic will have to be produced and handled as provided in the OFPA and the regulations. Compared to current organic practices, the proposed rule sets a more stringent system of requirements.

Accreditation and Certification

The rule specifies the accreditation and certification process. Persons providing certification of organic production and handling must be accredited by USDA through the NOP. Applicants for accreditation must document their abilities to certify according to the national standards and to oversee their clients' compliance with the requirements of the OFPA and NOP regulations. Producers and handlers of organic products must be certified by an accredited certifying agent. Producers and handlers are required to document their organic plans and procedures to ensure compliance with the OFPA.

All certifying agents would have to be accredited, and certification by producers and handlers would not be voluntary. The exceptions are: (1) Growers and handlers with gross organic sales of \$5,000 or less would be exempt from certification; and (2) a handling operation may be exempt or excluded from certification according to provisions described in the rule's subpart B, Applicability. For example, a handling operation that is a retail food establishment or portion of a retail food establishment would be exempt if it handles organically produced agricultural products but does not process them, and would be excluded from the requirement to be certified if it processes or prepares, on the premises of the retail food establishment, raw and ready-to-eat-food from agricultural products that are previously labeled as "100 percent organic," "organic," or "made with organic (specified ingredients)." However, this exemption does not extend to other provisions of the proposed rule such as prevention of contact with prohibited substances.

USDA will charge applicants for accreditation a \$500 fee at the time of application. USDA will also charge applicants for costs over \$500 for site evaluation of the applicant's business. The applicant would be charged for travel costs, per diem expenses, and any miscellaneous costs incurred with a site evaluation. Review of documents for renewal of accreditation will be charged at an hourly rate.

Producers and handlers will not pay certification fees to USDA. Certification fees

will be established by the accredited certifying agents. USDA will not set fees. The rule requires certifying agents to submit a copy of their fee schedules to USDA, post their fees, and provide applicants estimates of the costs for initial certification and for renewal of certification.

Production and Handling

The rule establishes standards for organic production of crops and livestock and handling of organic products. These standards were developed from specific requirements in the OFPA, recommendations from the National Organic Standards Board (NOSB), review of existing organic industry practices and standards, public comments received on the 1997 proposal and subsequent issue papers, and public meetings.

The proposed rule establishes a number of requirements for producers and handlers of organic food. These requirements will affect farming operations, packaging operations, processing operations and retailers. Some of the major provisions are: (1) Land requirements; (2) crop nutrient requirements; (3) crop rotation requirements; (4) pest management requirements; (5) livestock management requirements; (6) processing and handling requirements; and (7) commingling requirements.

National List

The National List lists allowed synthetic substances and prohibited non-synthetic substances that may or may not be used in organic production and handling operations. The list identifies those synthetic substances, which would otherwise be prohibited, that may be used in organic production based on the recommendations of the NOSB. Only those substances on the National List may be used. The National List also identifies those natural substances that may not be used in organic production, as determined by the Secretary based on the NOSB recommendations.

Testing

When certifying agents have reason to believe organic products contain a prohibited substance, they may conduct residue tests. The rule incorporates the national mean of detected residues for specific commodity/pesticide pairs and clarifies how unavoidable residual environmental contamination would be used in residue testing.

Labeling

The rule also states how organic products may be labeled and permitted uses of the USDA organic seal. In addition to the USDA seal and the certifying agent's seal, information on organic food content may be displayed. It is important to note that small businesses who are certified may use the USDA seal.

Recordkeeping

The rule will require certifying agents, producers, and handlers to keep certain records. Certifying agents will be required to file periodic reports with USDA. Producers and handlers will be required to notify and submit reports to their certifying agent. While recordkeeping is a standard practice in

conventional and organic farming, the proposal adds recordkeeping and reporting requirements which do not exist for growers and handlers operating without certification. Similarly, certifying agents would face additional recordkeeping and reporting requirements, particularly those certifying agents operating without external accreditation. State and private certifying agents regulate the use of organic seals and logos. The proposed rule permits certifying agent logos and requires the name of the certifying agent on processed organic foods.

Alternatives to the Proposed Rule

As required by E.O. 12866, alternatives to the proposed rule were considered. The identified alternatives were the Status Quo and Industry-Developed Standards. The costs and benefits of each alternative were assessed to the extent possible.

Status Quo: The Organic Market in the Absence of Federal Regulation

This is the no program alternative. There would be no national standard or national program of accreditation and certification. Certification would be voluntary and certifying agents would not have third party accreditation. Some producers and handlers would operate with certification provided by private organizations or State programs. Other producers and handlers would characterize their foods as organic but would not be certified.

A mix of State and private programs may continue to operate according to varying standards. In States without organic laws or States where certification is voluntary, goods would be marketed as organic without third party certification. Even under this scenario, organic food produced in States with production standards and certification may be produced using similar practices because most State standards follow similar requirements: A 3 year transition, prohibited use of certain substances (lists of substances tend to overlap), practices which prevent commingling with conventional products, and where livestock standards exist, organic feed.

In addition, at the time the OFPA was enacted, the industry had been unable to agree on organic standards. Recently, there has been movement toward shared standards partly in response to efforts to develop national organic standards including the 1997 proposal and the public NOSB process. The Organic Trade Association (OTA) has developed "American Organic Standards" which the OTA Board recently ratified. The OTA describes itself as " * * * a national association representing the organic industry in Canada, the United States and Mexico. Members include growers, shippers, processors, certifying agents, farmer associations, brokers, consultants, distributors and retailers. Established in 1985 as the Organic Foods Production Association of North America, the Organic Trade Association works to promote organic products in the marketplace and to protect the integrity of organic standards." (OTA website). Although there is substantial consensus on the draft standards, acceptance is not unanimous.

The draft standards developed through OTA correspond closely to many elements in the proposed national organic program. OTA envisions a system of accreditation and certification of producers and handlers but not restaurants and grocery stores. The list of allowed and prohibited substances mirrors the list developed by the NOSB. Production practices for crops and livestock include the common features in most State and private programs—a 3 year transition, no commingling, use of organic feed, limits on the use of antibiotics, requirements for an organic plan and recordkeeping. Hence, even in the absence of a national program, the organic industry may be moving toward a common standard.

Under the status quo-no national program alternative, producers and handlers who chose to be certified, or who are required by State laws to be certified, would pay fees that would vary depending on the market for the particular private certifying agent's service and whether a State certification program was operating with subsidized fees.

No federal funds would be used, there would be no transfer from federal taxpayers at large to organic market participants, and there would be no federal regulatory barriers to entry into organic production and handling.

International access for domestic organic products may be very influential on development of the organic industry in the United States. A food trade publication (The Natural Foods Merchandiser) tracked organic sales for a while in the 1990s showing annual growth in retail sales of 20–25 percent between 1990 and 1996 (Table 1). This growth took place in the absence of a national program.

In the absence of national standards, U.S. organic producers have been able to access European markets only by obtaining specific product permissions granted to individual importers by organic regulatory authorities in an EU member state (Byng, p. 27–28 1994). This process has required the importer to satisfy the authorities, through documentation and possible site inspection, that the product in question has been certified to and produced under equivalent standards of production and inspection. This case-by-case process of approving imports was intended as a temporary arrangement to accommodate non-EU countries that had not yet established government systems regulating organic production and certification. Another step State and private organic certifying agencies have taken to access international markets in the absence of a national program has been a voluntary, fee-for-service program to verify that they comply with the requirements prescribed under ISO Guide 65.

Governments in foreign markets and foreign private processors and retailers are expected to insist on additional verification that goods have been produced to acceptable organic standards. This would likely lead to an increased use of private accreditation services and of USDA's ISO Guide 65 verification service. USDA's ISO Guide 65 verification services are provided on a user fee basis with full cost recovery. These private accreditations and USDA's

verifications would increase costs for certifying agents and producers and handlers. In addition, establishing reciprocity between certifying agents in the domestic organic market involves some cost and may stifle growth in trade of organic products, although the magnitude of these costs and their effects on growth is unknown.

Under the proposed national program, all applicants for accreditation will be assessed against ISO Guide 65, eliminating the need for a separate ISO Guide 65 assessment that exists for those exporting to the EU in the absence of a national program. Growth in the trade of organic products, particularly exports, may be jeopardized by a status quo program alternative because there would be no national program upon which to establish equivalency.

Industry-Developed Standards

As an alternative to the proposed national program, another national program could adopt industry-developed standards. For example, USDA could adopt the standards recently developed by the Organic Trade Association or other consensus standards and enforce those standards. Certification to these standards could be performed as it is currently, by private certifiers or by state programs. There could be variation among certifiers' standards, but producers and certifiers would not be able to prohibit use of a product meeting the national standard from the production of other "organic" products.

There are various enforcement mechanisms that are available under this alternative. The USDA could choose to enforce the adopted standards. Enforcement could be left to other federal agencies or State governments. For example, the Federal Trade Commission could regulate truth in advertising with respect to organic food; the USDA Food Safety Inspection Service could regulate labeling of organic meat and poultry products.

Adopting the industry standard as the USDA standard, the USDA could provide an acceptable national standard that would be necessary in establishing equivalency to access international organic markets, and eliminate the problems associated with establishing reciprocity in the domestic organic market.

It is important to note that it may be difficult to develop consensus industry standards. For example, while standards recently proposed by OTA were developed with significant industry input they may not represent the kind of consensus that is the result of this proposed rule.

Number of Affected Parties and Projections

In assessing the impacts of the rule, we have attempted to determine the number of certifying agents, private and State, that are currently operating, and considered the factors likely to affect the number of certifying agents after the rule is implemented. We have attempted to determine the number of currently operating producers and handlers that would be affected. And, we have considered the factors which might affect the number of producers and handlers after the program has been implemented.

For the analysis, the USDA assumes the following:

1. Forty-nine domestic certifying agents and ten foreign certifying agents will be affected by the proposed regulation.
2. Approximately 12,200 certified and non-certified organic producers will be affected by the proposed regulation. With the assumed growth rate of 14% for certified organic producers and approximately 8% for non-certified organic producers, the number of organic producers will grow to 17,150 in 2002.
3. Approximately 1,250 processors and handlers of organic food will be affected by the proposed action. This number will grow to 2,150 by 2002.
4. The number of retailers affected by the proposed action is not quantified.

Certifying Entities

We place the number of certifying agents currently operating at 49, including 13 State programs. The number of certifying agents has remained fairly stable, between 40 and 50, for some years, with entries and exits tending to offset each other. For purposes of estimating the paperwork burden described elsewhere, we assume no growth in the number of domestic certifying agents but project 10 foreign certifying agents in the first 3 years of the program.

Organic Producers

It is more difficult to establish the number of organic producers. Organic farming was not distinguished from conventional agriculture in the 1997 Census of Agriculture. Among the sources which give insight into the number of producers, the Organic Farming Research Foundation (OFRF) has conducted nationwide surveys of certified organic producers from lists provided by cooperating certifying agents (OFRF 1999). OFRF sent its 1997 survey to 4,638 organic producers.

Because OFRF did not obtain lists from all certifying organizations or their chapters (55 out of a total of 64 identified entities provided lists), its list count of 4,638 producers is likely an underestimate of the number of certified organic farms. If the average producer-to-certifying agent ratio (55 certifying agents to 4,638 producers) holds for the 9 certifying organizations that did not provide the list (9 certifying agents out of a 64 certifying agents), then the number of producer grows to 5,397 producers.

The different estimates of the number of certifying agents should be noted. The USDA estimates 49 certifying agents; the OFRF estimates 64 certifying agents. The difference stems from the USDA's not counting different chapters of certifying organizations separately.

The California Department of Food and Agriculture's organic registration program suggests that, at least for California, most organic producers are not certified. For the 1994-95 reporting period, CDFA reported that 1,372 farms registered as organic producers but only 517 of these farms were certified (Klonsky and Tourte, 1998a). Thus, one approach to projecting national totals from OFRF survey lists of certified producers would be to apply the 1994-95 ratio between

producers registered and certified in California to the OFRF 1997 list count. This would suggest the number of non-certified producers to be 8,918, resulting in the total number of organic producers to be 14,315. However, it is important to note that California's structure of organic production may not be representative of the national profile. The number of non-certified producers may be higher or lower.

CDFA also reports the number of registered and certified producers by sales class. Many producers would likely be eligible for the small farm (sales less than \$5,000) exemption provided for in the OFPA. Of 1,372 registered organic farms in California, 907 had sales of less than \$10,000. Of the 517 certified farms, 188 had sales of under \$10,000. If these ratios are applied to the number of producers calculated, then the number of certified producers with sales under \$10,000 would be 1,962, and the number of organic producers in general with sales under \$10,000 would be 9,463. Thus, there are potentially a large number of farms which could be exempt from certification requirements.

Dunn (1995a, 1995b, and 1997) has estimated the number of certified organic producers in the United States. Dunn (1995a, 1995b) estimated the number of certified producers at 4,060 in 1994. Dunn (1997) reported 4,856 certified organic farms in 1995. USDA's 1997 proposal relied on Dunn's 1995 estimate of 4,060 total certified producers. Dunn's numbers have been used because Dunn's 1995 work was an official USDA study. The methods used were reviewed by USDA and the resulting estimates are official USDA statistics. Although Dunn's 1997 estimates were not a USDA study, the 1997 study used the same approach as the 1995 study.

An adjustment is needed to account for the number of producers who are practicing organic agriculture but who are uncertified and would be affected by this proposed rule. We reject the idea of expanding by the certified-to-registered ratio reported in California for reasons previously stated. We assume that the number of organic-but-not-certified producers in 1999 is about 4,000. We adopt this figure recognizing that there may be 1,000 such farms in California, given that there were 855 in CDFA's report on 1995 registrations. The total number of organic farms for assessing the impact of the rule is 12,200 in 1999.

Data collected by AMS indicate that the number of certified organic farmers increased about 12 percent per year during the period 1990 to 1994. OFRF survey efforts indicate that growth has continued, though it is not clear whether the growth rate has changed. We use the average growth rate from Dunn's time series from 1991-1994, which was about 14 percent. The true rate of growth could be higher or lower. By applying the 14-percent growth rate to Dunn's (1995) estimate, the number of certified organic producer potentially affected in 1999 is 8,200 and 12,150 in 2002.

We have no national-level growth rates for not-certified organic farms. The limited times series from CDFA is of limited value in estimating a growth rate. We suspect it is less than the rate for certified farms because

certification has value and organic producers would be expected to take advantage of the marketing advantages of certification. Furthermore, the emergence of State certification programs that appear to have lower certification fees than private certification entities may have encouraged more organic producers to be certified. Therefore, for purposes of analyzing the impacts of the rule for the Paperwork Reduction Act, we assume growth of non-certified organic producers from 4,000 in 1999 to 5,000 non-certified farms by 2002, making the total number of farms potentially affected by the rule, 17,150 farms. However, we request comment and/or data on the number and the growth of certified and non-certified organic farms.

Organic Handlers

Little information exists on the number of handlers. They include processors such as organic soup manufacturers, organic food packaging operations, and organic food wholesalers. USDA has estimated that there were 600 entities in this category in 1994 (Dunn 1995b). AMS estimated that the growth rate was 11 percent from 1990 through 1994 (Dunn 1995b). More recent data from CDFA registration records suggest a growth rate of about 28 percent (California Department of Health Services 1999). For projection purposes, we use a growth rate of 20 percent, which makes the number of handlers for 1999 1,250 and for 2002 2,150. Reasons for growth include the general increase in organic production and growth in the market for processed organic foods, including multiingredient products. Again, these projections are based on limited data from the early 1990's, and growth may have slowed or increased. We request comment and/or data on the number and the growth rate of processors and handlers in the organic industry.

Retail Food Establishments

Retailers of organic food are grocery stores, bakeries, restaurants and other establishments that process or prepare raw and ready-to-eat food. Most are not currently subject to either voluntary practices or mandatory standards of the organic industry. Although they are excluded from the certification requirements, they are subject to other processing, handling, and other production related requirements of the proposed rule. Hence, a new stratum of the organic industry will be regulated by the proposed rule.

Dunn's (1995a) estimates the number of certified retailers to be 31 in 1995. It is not clear whether Dunn's (1995a) definition of retailers and the proposed definition stated above are consistent. Hence, the total number of retailers that may be regulated remains unknown. USDA's Economic Research Service (ERS) reports there were 161,707 grocery stores in 1997 (ERS website). Many of these stores sell organic products and may be affected by the proposed rule. The effect of the proposed regulation on the growth of retailers remains unknown. We request comment and/or data on the number and the growth rate on the retailers of organic food.

Foreign Entities

The discussion of the number of affected parties has focused on domestic certifying agents, producers, and handlers. We recognize that foreign entities may apply for accreditation and foreign producers and handlers may be certified under the NOP. Furthermore, upon request of a foreign government, a foreign certifying agent may meet the requirements for accreditation when the Administrator determines that the certifying agent meets the requirements of the NOP.

At this time, we have no information regarding the number of foreign entities which may enter the NOP. We do not know how many foreign producers and handlers are marketing goods as organic, nor do we know how many will seek to be certified under the NOP. Accredited certifying agents will be able to certify operations outside the United States and foreign certifying agents may become accredited by USDA. It is likely that the costs for accreditation will be higher for foreign applicants for accreditation. Foreign applicants will face the same costs as domestic applicants but the levels of cost would reflect generally higher costs of foreign travel and per diem expenses for site evaluation and miscellaneous costs such as for translation of documents. For purposes of estimating the paperwork burden described elsewhere, we assume 10 foreign certifying agents in the first 3 years of the program. We request comment and/or data on the number and the growth rate of foreign entities that may export to the U.S. organic market.

Benefits of the Proposed Rule

The benefits from implementation of the proposed rule are: (1) Improved protection of buyers from misleading claims and more information on organic food; (2) reduced administrative costs; and (3) improved access to international organic markets. Not all benefits that may arise from the rule are quantifiable. Where economic data are available, they may relate to costs and are generally not adequate to quantify economic benefits.

Information

Potential benefits to consumers as a result of the proposed rule include more information on organic food, and protection from false and misleading organic food claims. Consumers may be misled by labels on processed and raw products claiming to be organic. In particular, with processed food, some of the ingredients may not be organically produced, or the product may contain less organic content than the consumer assumes. The USDA organic seal will provide consumers a quick tool to verify that goods offered for sale as organic are in fact organic. To the extent that consumers view the seal as an important information too, that is, product with the seal is perceived as more desirable, they may enhance the ability of producers to realize the price premiums associated with certified products.

There is anecdotal evidence to suggest that consumer fraud involving organic food does occur (Mergentime 1997). Criminal prosecutions involving felony pleas and fines have taken place (Mergentime 1997).

However, we have no evidence to suggest that this problem is wide-spread (Mergentime 1995). Also, it is important to recognize that the organic industry's effort to police itself and the remedies provided by the judicial system may be adequate to address consumer fraud. Mergentime (1997) documents the effect of litigating fraud cases on the industry. However, we request comment and/or data on the extent and the severity of consumer fraud that may exist.

Some producers may have limited their organic livestock production because of uncertainty regarding the standards that would be used in the NOP. By removing the uncertainty, producers may increase production, thereby increasing the quantity of livestock products.

Reduced Administrative Costs

The proposed rule addresses the problem of existing certifying agents using different standards and not granting reciprocity to other certifying agents. By accrediting certifying agents, the rule would establish the requirements and enforcement mechanisms that would reduce inconsistent certification services and lack of reciprocity between certifying agents. In the current system, the certifying agent of a final product is not required to recognize the certification of an intermediate product. Both primary farmers and food handlers may face a risk of being unable to sell a certified organic product when more than one certifying agent is involved. By imposing a uniform standard of certification and production, costs associated with establishing reciprocity between certifying agents will be eliminated. However, the magnitude of this benefit cannot be gauged without quantification. In particular, with the increasing consensus within the organic industry, the benefit may not be large.

It is important to distinguish between consensus with respect to standards of production and consensus with respect to certifying agents practices. There is growing consensus regarding crop standards, livestock standards are more problematic. And, consensus is least evolved regarding standards of conduct and practice for certifying agents. There is no consensus regarding whether certifying agents should be accredited or who the accrediting body should be.

Industry-wide training costs may decrease. The proposed uniform standards of production, certification should enable organic inspectors to move more easily from one certifying agent to another than the current system.

In addition, USDA accreditation of certifying agents would present opportunities for sharing information about standards, practices, and the general requirements of the program through the NOP staff. USDA will undertake a number of outreach and education efforts in connection with the launch of the NOP. Compliance guides and other printed material will be prepared which will be more readily understood than the **Federal Register** document. NOP staff will participate at industry meetings and will likely host public information exchange meetings.

International Markets

The final national program rule is expected to lead to EU acceptance of NOP certified organic products. That is, it is anticipated that the EU would determine that the NOP is acceptable vis-a-vis EU regulation 2092/91. Article 11 of EU Reg. 2092/91 establishes the conditions under which organic products may be imported from third countries and addresses the framework for equivalency. The NOP is a national program that should be acceptable to the EU and other governments. The result would be the removal of trade restrictions, thereby possibly increasing the growth in exports of organic food products.

Currently, despite restricted access to the European market, the United States is the most important non-EU supplier of organic products to EU countries (Foreign Agriculture Service (FAS), 1995). Import authorizations have been granted for a number of raw and processed commodities, including sunflowers, buckwheat, beans, sugar, and apples. Demand is strong throughout the European market, and the organic market share was 1-2 percent of total food sales in 1997 (Collins).

Lohr (1998) cites several growth projections:

Annual growth rates of 25% to 30% have been experienced in the EU, the United States, and Japan for over five years, but growth is already slowing in some product categories (PSC, Scott) * * * Segger projects that the EU market will reach \$58 billion and the U.S. market \$47 billion by 2006. Ahmed suggests that the Australian market could grow to \$571 million by 2000, whereas LaFond projects that the value of Canadian organics will reach \$145 million by 2006. Mergentime forecasts the Japanese market will reach \$2.6 billion by 2000 (Lohr, 1126).

Lohr further states that these projected future growth rates are based on straight-line extrapolations of current sales and growth rates without understanding the underlying market mechanisms and price elasticities (Lohr 1998).

Foreign acceptance of the U.S. national standard can be expected to expand the universe of consumers for U.S. producers and reduce costs of negotiating and documenting shipment by shipment.

Costs of the Proposed Rule

The costs of the proposed regulation are the direct costs of complying with the specific standards. It is important to note that while some costs associated with accreditation and certification are quantified, costs stemming from other provisions of the proposed regulations are not. In addition, this is a short-run analysis. The analysis examines the costs that may be incurred from 1999 to 2002. It is not possible at this time to conduct a longer-run analysis because we do not know enough about the fundamental supply and demand relationships to make economically sound long run projections.

Accreditation Costs

USDA has identified 36 private certifying agents and 13 State programs providing certification. These 49 entities are considered likely applicants during the first 18 months

during which USDA will not charge application fees or hourly fees for accreditation. An unknown number of new entrants to the certifying business may also apply. However, over the last 10 years, the number of certifying agents does not appear to have grown significantly, with the net effect of entries and exits maintaining a population of certifying agents at about 40–50.

The proposed rule would allow USDA to collect fees from certifying agents for USDA accreditation. Collecting fees from certifying agents only is administratively simpler and will enable State programs that want to keep client costs low to do so.

Applicants for accreditation will be required to submit a nonrefundable fee of \$500 at the time of application, which is applied to the applicant's fees for service account. This means that the \$500 fee paid at the time of application is credited against any subsequent costs of accreditation arising from the site evaluation. The \$500 fee is the direct cost to applicants who are denied accreditation based on the initial review of the information submitted with their application. Charges for the site evaluation visit will cover travel costs from the USDA employees' duty station, per diem expenses for USDA employees performing the site evaluation, an hourly charge that we anticipate will not exceed \$95 per hour (per each employee) for services during normal working hours (higher hourly rates will be charged for overtime and for work on holidays), and other costs associated with providing service to the applicant or certifying agent.

The anticipated hourly rate is the rate that USDA will charge for services under the Quality Systems Certification Program (QSCP). A separate rulemaking will establish the precise hourly rate that will be charged. Our preliminary estimate that the fee will be no more than \$95 per hour is presented to give the public some indication of the rate that will be charged following the 18-month transition period. QSCP is an audit-based program administered by AMS, which provides meat packers, processors, producers, and other businesses in the livestock and meat trade with the opportunity to have special processes or documented quality management systems verified. The procedures for accreditation evaluation are similar to those used to certify other types of product or system certification programs under QSCP.

At present, the base per diem for places in the United States is \$80 (\$50 for lodging and \$30 for meals and incidental expenses). Per diem rates are higher than \$80 in most large cities and urbanized places. Travel costs will depend on where the certifying agent is located.

USDA estimates the costs of a site evaluation visit after the transition period will average \$3,070–\$4,850 depending on the characteristics of the applicant. This estimate is based on experience with the QSCP and more limited experience performing audits verifying that certifying agents meet ISO Guide 65. The cost of a site evaluation visit will vary with the cost of travel from the USDA reviewer's duty station to the

applicant's place of business. In general, more distant and more remote locations will involve higher travel costs.

Accreditation will include verification of adherence to ISO Guide 65. Recent experience with USDA's program to verify organic certifying agents to ISO Guide 65 indicates that roughly 32 staff hours are required. Although much of the accreditation site evaluation will involve comparisons against ISO Guide 65, additional hours will be required because USDA will be evaluating additional aspects of the applicant's operation to determine if the applicant is qualified to perform as an accredited agent for the NOP. Based on experience with ISO Guide 65 verifications, we project that small applicants with a simple business structure will require 3 days and large applicants with more complex business structure will require 5 days. Thus, the total number of hours to be charged would range from 24 to 40 hours. At the base rate of \$95.00, the charge for hours of service would be \$2,280–\$3,800.

Per diem costs would cover 3 to 5 days, totaling \$240–\$400. A review of domestic travel by USDA staff during fiscal year 1999, indicates that transportation costs ranging from \$500–\$600. Miscellaneous costs are estimated to add another \$50 to each site visit. Thus, the total site visit cost would range from \$3,070 to \$4,850.

During the 18-month transition period, USDA intends to use 2 reviewers for site evaluation visits. One reviewer will come from the QSCP audit staff and will be familiar with the ISO Guide 65 verification; the other reviewer will come from the NOP staff and will be familiar with requirements of the organic program. The two will conduct the site evaluation jointly. We anticipate only one reviewer will be required after the transition period. During the 18 month transition period, applicants will be charged for travel and per diem costs for two persons, but not application fees or hourly fees. Thus, the estimated expenditures (travel and per diem) for these initial accreditations will be \$1,530–\$2,050. Table 3 estimates the total initial costs for an applicant to become accredited.

Currently few private certifying agents are operating with third party accreditation. Fetter (1999) reports that in a sample of 18 certification programs four programs were accredited and one had accreditation pending. All of these were large, private certifying agents. Those certifying agents currently accredited by third parties will likely pay less for USDA accreditation. In its first proposal, USDA stated at FR 62:65860, "We are aware that certifiers currently may pay in excess of \$15,000 for accreditation by a private organization." Commenters thought this figure was too high. One commenter, which operates the International Federation of Organic Agriculture Movements (IFOAM) Accreditation Programme under license to IFOAM, stated "It is possible that the largest programme operating a chapter system with activities in many countries (which is included in their IFOAM evaluation) paid this amount in their first year. On the other hand the average cost to a medium sized certifier works out at around \$3000 to \$4000 per year." Another commenter stated "At the

present time IFOAM accreditation costs less than \$10,000/year for the largest certifier and \$3–5,000 for smaller certifiers."

The direct costs of accreditation, if all currently operating certifying agents become accredited during the first 18 months following the final rule, is approximately \$75,000 to \$100,000. This figure is derived from the per firm costs in Table 3. After the first 18 months, the direct cost for accrediting 49 certifying agents would be approximately \$150,000 to \$238,000.

The 18 month period affects the distribution of program costs between the organic industry and the taxpayer. Some of the costs of accreditation would be absorbed by the NOP operation budget appropriated by Congress. In effect, the taxpayers are subsidizing the organic industry. Without this subsidy, the total cost of accreditation may approach \$1 million.

Private certifying agents and state programs that do not mirror the proposed regulation may incur additional costs to change their programs to adopt the proposed national standards. The discussion on the effect of the proposed regulation on existing state programs is in "State Program Costs." The cost associated with changing existing private certifying programs is not quantified.

Also, certifying agents who have been operating without third party accreditation will face new costs. Compared to the direct costs of \$3,000–\$5,000 per year indicated by the commenters, the direct costs of USDA accreditation will be smaller. The direct costs for certifying agents obtaining accreditation during the first 18 months, when USDA will not impose an application fee or hourly charges, will be limited to travel and per diem costs. Furthermore, USDA's charges are imposed every 5 years, not annually.

A national accreditation program may shrink the market for a third-party accreditation. Certifying agents will have little incentive to maintain or seek a second accreditation by a private organization unless that accreditation sufficiently enhances the market value of the certifying agent's services. Thus, the market will determine whether other accrediting entities continue to have a U.S. market for their services.

Training programs are currently offered by the Independent Organic Inspectors Association (IOIA), an organization of approximately 165 organic certification inspectors, and by some of the larger certifying agents (IOIA, p. 1). Costs to existing certifying agents to provide additional training to other staff are difficult to measure in the absence of information on current staff skill levels or the existence of formal training other than inspector training. Some agencies rely on volunteer staff who may have had no formal training, but the extent of this practice is unknown. AMS intends to offer assistance to certifying agents, producers, and handlers by providing guide books and other printed material that would enable participants to better understand the regulations. In addition, AMS intends to continue open and frequent communication with certifying agents and inspectors to provide as much information as possible to aid them in fulfilling the requirements of the regulations.

The OFPA requires that private certifying agents furnish reasonable security, such as a bond, for the purpose of protecting the rights of participants in the organic certification program. Specific requirements regarding reasonable security have not yet been established. It is expected that there will be costs to certifying agents from these requirements.

Certification Costs

State laws vary widely on organic certification and registration. Some States require only that an organic producer register and make certification voluntary. Other States require certification by the State's own agents, while others accept certification by a private certifying agent. The least stringent requirement among States with organic legislation is that products marketed as organic comply with their definition of organic but both registration and certification are voluntary. Thirteen States operate programs to certify organic production. In many States producers may claim their product is organic but operate without certification or well-defined standards. On the other hand, many organic producers operate in States with no program and voluntarily secure third party certification to well-defined standards.

Under the proposed rule, USDA will not impose any direct fees on producers and handlers. Certifying agents will establish a fee schedule for their certification services that will be filed with the Secretary. Certifying agents will provide all persons inquiring about the application process with a copy of their fees. The certifying agent will provide each applicant with an estimate of the total cost of certification and an estimate of the annual costs of updating the certification. However, the certifying agent may require applicants to pay at the time of application a nonrefundable fee of no more than \$250 which must be applied to the applicants' fee-for-services account. The \$250 limit is proposed as a reasonable figure considering the interests of certifying agents and applicants.

The proposed maximum nonrefundable fee protects certifying agents by ensuring that they receive some payment for their work for applicants should the applicant lose interest or be found unqualified for certification. For the purposes of estimating the cost of the paperwork burden on certifying agents, USDA has valued their time at \$27 per hour. Thus, the \$250 limit, if the certifying agent chooses to require it, would cover approximately 9 hours of work. The \$250 limit protects applicants from paying large fees up front when their ultimate eligibility for certification is unknown. The \$250 limit is believed to be low enough to ensure producers and handlers can afford to take the first steps for certification but high enough to ensure certifying agents will have an incentive to initiate certification when the prospects that the applicant will qualify are unknown.

Some States charge minimal fees for certification by subsidizing operating costs from general revenues. The majority of certifying agents structure their fee schedules on a sliding scale based on a measure of size,

usually represented by the client's gross sales of organic products but sometimes based on the acres operated (Fetter 1999 and Graf and Lohr 1999). Some certifying agents charge an hourly rate for inspection and audit services.

Graf and Lohr have applied fee schedules provided by nine certifying agents to four hypothetical farms—small, medium, large, and a super farm. Tables 2A and 2B summarizes the fees that Graf and Lohr found by applying schedules of each certifying agent to hypothetical farms. Total first-year costs and subsequent (renewal) year costs for certification are shown. The average cost for each size class should be interpreted with care because the reported average is not weighted by the number of clients certified. In their study, the Texas Department of Agriculture program is the low-cost certifying agent for all-size operations. The high-cost certifying agent differs across farm sizes. None of these certification programs mentions costs for residue testing, which the NOP will require in the form of preharvest testing when there is reason to believe that agricultural products have come in contact with prohibited substances. Preharvest testing is expected to be infrequent. Some certifying agents currently require soil nutrient testing and water quality testing. The estimated total initial costs for a producer or handler to become certified are presented in Table 3.

We have not extended the average costs reported in Tables 2A and 2B to aggregate certification costs for all organic farms because the number of organic farms is not known with precision, nor is their geographic location and there are no data to distribute the population of organic farms across size classes. Like conventional agriculture, the largest percentage of farms would be expected to fall in the smallest sales class. Many of the smallest farms would qualify for the small farm exemption from certification.

In addition, organic producers and handlers would incur the costs associated with becoming familiar with the national program. We request comment and/or data on the certification costs that may be imposed on the organic producers, handlers, processors, and retailers.

Production and Handling Costs

Producers and handlers currently active in the organic industry may bear costs under the proposed national standards. We believe that while some provisions of the proposed program mirror current industry practices, others differ. In addition to the cost associated with becoming familiar with the national program, any adjustments stemming from these differences will result in costs. These costs are only qualitatively discussed. This assessment does not include a provision-by-provision analysis of possible alternatives.

Producers

Producers of organic food will face numerous provisions that will regulate their production methods. As indicated in the Baseline section, many of the requirements are currently practiced by certified organic farmers. Farming operations that are not certified, but are registered with a State

government such as California, receive copies of the State laws to which they must comply. Some organic producers are neither certified nor registered and therefore may not practice the requirements proposed. Major provisions are discussed to illustrate costs; other provisions may also impose additional costs. We request comment and/or data on the costs that may be imposed on the producers of organic products. In addition, we request comment and/or data on the similarities and differences between the current practices of private and State programs and the proposed requirements.

Land Requirement. The transition period, which would specify the time during which prohibited materials cannot be applied before a field can be certified as organic, is included in many private and State organic standards. The OFPA specifies a required transition period of 3 years before certifying a field. The effect of this provision on the currently certified organic farming operations may be minimal. Certifying agents currently enforce the 3 year transition period required by the OFPA. Producers who are registered in States requiring registration, receive copies of the State laws governing organic production which generally require a 3 year transition period.

The effect on small farming operations that are neither certified or registered may be significant. Small farming operations that have completed a 3 year transition period and can document the transition will not be affected by this requirement. To stay in the organic industry, those who have not completed the 3 year transition period must comply with the transition period requirement. They may incur the cost of organic production for a significant length of time, yet not be allowed to sell their products as organic. Hence, some small organic operations may exit the industry. We request comment and/or data on the magnitude of the cost associated with the provision. In addition, we request comment and/or data on the similarities and differences between the current practices of private and state programs and the proposed requirements.

Soil fertility and crop nutrients. Lacking information, we have not quantified the cost associated with this provision, but we assume that it may have costs Organic production historically rests on soil fertility management. Private and State certifying agents have well developed standards addressing care and treatment of the soil. The proposed rule includes requirements for the use of manure and a practice standard for composting which may impose additional costs to producers. However, not all organic farmers use manure for soil fertility and many farmers use composting practices that are consistent with the proposed rule. We believe that this requirement will have minimal impact on certified or registered organic producers. We request comment and/or data on the magnitude of the cost associated with the provision. In addition, we request comment and/or data on the similarities and differences between the current practices of private and State programs and the proposed requirements.

Materials list. Lists of approved synthetic materials, including soil amendments and

pesticides, vary from one State program to another. A detailed analysis of specific differences in the various existing materials lists shows them to be overlapping in most cases. The impact of the national program will be determined by how the national standards differ from current certification standards and from actual practice.

Farming operations, both certified and registered, may need to adjust their production methods to comply with the list. These adjustments will impose costs on these operations. However, most currently certified operations and those operating under a State program already adhere to a materials list. These lists overlap in most cases with each other and the National List in this proposal which should mitigate the costs for these operations. The magnitude of the costs resulting from these adjustments is not quantified. We request comment and/or data on the magnitude of the costs associated with the provision. In addition, we request comment and/or data on the similarities and differences between the current practices of private and state programs and the proposed requirements.

Animal drug use. Another common feature of organic standards is the restricted use of animal drugs for livestock. Where livestock standards have been adopted by existing State programs and by private certifying agents, most prohibit the use of animal drugs except for the treatment of a specific disease condition, and use of animal drugs is generally prohibited within 90 days prior to the sale of milk or eggs as organic. Some State and private certifiers allow the use of animal drugs in animals for slaughter if the producer extends the withholding period. Others prohibit the use of animal drugs. The standards in the proposed rule would prohibit the sale as organic of an edible product derived from an animal treated with antibiotics or other unapproved substances.

The proposed standards may not differ from existing State or private standards in prohibiting the use of drugs on healthy animals. However, the effect of this provision may differ among certified and registered organic farms. The effect on the certified farming operations is unknown. We assume that this provision may have costs, but the magnitude of these costs is not quantified. We request comment and/or data on the magnitude of the costs associated with the provision. In addition, we request comment and/or data on the similarities and differences between the current practices of private and state programs and the proposed requirements.

Other livestock requirements. Lacking information, we have not quantified the cost associated with this provision, but we assume that this provision may have costs due to the variability in current housing, feed and health care practices. We request comment and/or data on the magnitude of the costs associated with the provision. In addition, we request comment and/or data on the similarities and differences between the current practices of private and state programs and the proposed requirements.

Residue Testing. Lacking information, we have not quantified the cost associated with this provision, but we assume that this

provision may have costs. We request comment and/or data on the magnitude of the costs associated with the provision. In addition, we request comment and/or data on the similarities and differences between the current practices of private and state programs and the proposed requirements.

Handling requirements. These requirements prohibit a handler from using ionizing radiation for any purpose, an ingredient produced with excluded methods, or a volatile synthetic solvent in or on a processed agricultural product intended to be sold, labeled, or represented as "100 percent organic", "organic" or "made with organic (specified ingredients)." We believe, however, that the additional costs associated with compliance may be small. We base this assumption on the thousands of comments on the first proposal, including comments from the organic industry, indicating that these practices are widely considered to be inconsistent with organic production and handling. Lacking information, we have not quantified the cost associated with this provision. We request comment and/or data on the magnitude of the costs associated with the provision. In addition, we request comment and/or data on the similarities and differences between the current practices of private and state programs and the proposed requirements.

Handlers

Handlers of organic food may be defined and regulated differently across different certifying agents and States. Handlers may incur some cost associated with complying with the requirements of the proposed regulation. We request comment and/or data on the costs that may be imposed on the retailers of organic products. In particular, we request comment and/or data on costs associated with excluded methods, residue testing, and labeling. In addition, we request comment and/or data on the similarities and differences between the current practices of private and state programs and the proposed requirements.

Retail Food Establishments

Largely, retailers of organic food are not regulated. However, they are still subject to other requirements such as prevention of contamination of organic products with prohibited substances, and commingling organic with non organic products. Complying with these provisions may incur some cost. We request comment and/or data on the costs that may be imposed on the retailers of organic products.

Labeling Costs

Certified handlers will have to comply with requirements regarding the approved use of labels. The estimated annual cost for 1,977 certified handlers to determine the composition of 20 products to be reported on labels is \$948,960. This figure is based on an average of 1 hour per product and an hourly cost of \$27. Similarly, certified handlers will have to design their labels to comply with the regulation. This is expected to take 1 hour per label at \$27 per hour for a compliance cost of \$948,960. Total label costs for certified handlers are \$1.9 million.

Any producers, processors, and retailers who are not currently certified but who package organic products are also subject to the labeling requirements. Any changes to existing labels and new labels that need to conform to the proposed regulation will incur a cost. The costs associated with these activities are not quantified. Hence, the lower bound on the labeling cost is approximately \$2 million. We request comment and/or data on the extent the current labels will need to change to conform to the proposed regulation. In addition, we request comment and/or data on the similarities and differences between the current practices of private and state programs and the proposed requirements.

State Program Costs

A national program may impose additional costs on States by requiring changes in their existing programs. The proposed rule encompasses most of the principles of existing State programs. However, there are also departures.

Where State standards are below Federal standards or where elements of the Federal standards are missing from a State program, these States would be required to make changes in their programs that they might otherwise not make. Where State programs have standards in addition to the Federal standards and they are not approved by the Secretary, States also would be required to make changes in their programs. States without organic standards or whose current standards either would conform to those of the national program or would be approved by the Secretary would not incur additional costs resulting from required changes. Currently, USDA cannot predict which States may be required to adjust their existing programs.

States will be charged for accreditation, something none of them pay for now. The cost associated with this provision is discussed in the Accreditation Section.

Enforcement Costs

Enforcement costs will fall upon USDA's NOP, States operating State programs, and on certifying agents. Certifying agents will review clients' operations and will notify clients of deficiencies. Certifying agents can initiate suspension or revocation of certification. Certifying agents will be aware of these overhead costs and we assume that they will establish fee schedules that will cover these costs. Actual costs to certifying agents for enforcement activities will depend on the number of clients, how well informed clients are of their obligations, and client conduct. State programs will face the same obligations and types of costs as private certifying agents.

USDA's enforcement costs are costs associated with ensuring private certifying agents and State programs fulfill their obligations. USDA will bear costs of investigating complaints, monitoring use of the USDA organic seal and organic labeling, and taking corrective action when needed. USDA will bear costs related to reviewing an applicant's or certified operation's appeal and for administrative proceedings. We request comment on the costs of the

enforcement provisions of the proposed regulation.

Reporting and Recordkeeping Costs

The Paperwork Reduction Act of 1995 requires an estimate of the annual reporting and recordkeeping burden of the proposed NOP. Detailed descriptions of individual elements of that burden are presented in the proposal under the heading Paperwork Reduction Act of 1995. The estimated annual reporting and recordkeeping burden reported is approximately \$6.8 million. This figure should be understood within the context of the requirements of the Paperwork Reduction Act. The Paperwork Reduction Act requires the estimation of the amount of time necessary for participants to comply with the proposed regulation in addition to the burden they currently have. Information gathered by AMS in auditing activities in conjunction with ISO Guide 65 verifications, leads us to believe that the paperwork burden on current certifying agents and certified operators will be 10 to 15 percent greater than their current business practices as a result of this proposal.

Certifying Agents. The regulation will impose administrative costs on certifying agents for reporting and recordkeeping. The actual amount of the additional administrative costs that would be imposed by the proposed rule is expected to be different for those entities which would begin their activities only after the national program is implemented. Certifying agents that currently are active in the organic industry already perform most of these administrative functions; therefore, the additional costs to them would depend upon the extent to which their current practices are different from the requirements of the proposed regulation. An estimate of the cost of compliance is the annual reporting and recordkeeping burden documented in the Paperwork Reduction Act of 1995 analysis. Table 4 shows the estimated annual costs for State certifying agents and for private or foreign certifying agents. Based on the projected number of States agents (13) and private or foreign agents (46) the total reporting and recordkeeping cost, which captures much of the compliance costs of the rule, is \$1,113,192.

The following list describes several of the most significant proposed administrative requirements or optional submissions and the probable resources required for compliance. Details on the reporting and recordkeeping burdens estimated for each item are in the paperwork analysis.

1. A list of farmers, wild crop harvesters and handlers currently certified. This information can be compiled from existing records. After implementation, certifying agents will be required to submit on a quarterly basis a list of operations certified during that quarter.

2. A copy of procedures used for certification decisions, complying with recordkeeping requirements, maintaining confidentiality of clients' business-related information, preventing conflicts of interest, sampling and residue testing, training and supervising personnel, and public disclosure of prescribed information concerning

operations they have certified and laboratory analyses. These policies may have to be created or modified to conform to the regulation.

3. Documentation on the qualifications of all personnel used in the certification operation, annual performance appraisals for each inspector and personnel involved in the certification, and an annual internal program evaluation. Existing certifying agents may already perform these operations. New certifying agents will have to establish procedures to achieve these things.

4. Documentation on the financial capacity and compliance with other administrative requirements (e.g., fee structure, reasonable security to protect the rights of the certifying agents' clients as provided in the NOP, and business relationships showing absence of conflicts of interest). Some of this information can be compiled from existing records, e.g., fee schedules, and some may be generated from other sources.

5. Copies, submitted to USDA, of notices issued involving denials of certification, noncompliance, and suspension or revocation of certification. This requirement will be fulfilled simultaneously with sending notices to applicants or clients.

6. An annual report to the Administrator including an update of previously submitted business information, information supporting any requested changes in the areas of accreditation, and steps taken to respond to previously identified concerns of the Administrator regarding the certifying agent's suitability for continued accreditation. The annual report requirement will draw on records created in the normal course of business.

7. Retention of records created by the certifying agent regarding applicants and certified operations for not less than 10 years, retention of records obtained from applicants and certified operations for not less than 5 years, and retention of other records created or received for USDA accreditation for not less than 5 years. This activity requires records and database management capabilities and resources (storage space, file cabinets, electronic storage, etc.). In an informal inquiry, AMS found that most existing certifying agents currently retain records for at least 10 years and use both electronic and paper storage. We believe that this requirement will not pose an additional burden on existing certifying agents.

8. Public access to certification records, such as a list of certified farmers and handlers, their dates of certification, products produced, and the results of pesticide residue tests. This requirement will have minimal impact given the requirements for retaining records.

9. Providing program information to certification applicants. To comply with this requirement, certifying agents may need to modify existing standards and practices. The criteria for qualified personnel in the proposed rule may likely result in an increase in labor costs for some existing certifying agents and, initially, an increase in training costs. The amount of additional costs to these certifying agents would depend on the level of expertise among current certification agency staff, the extent to which

certifying agents currently rely on volunteers, and the current costs of training certification staff.

Producers and Handlers. The regulation will impose administrative costs on producers and handlers for reporting and recordkeeping. The actual amount of the additional administrative costs that would be imposed by the final rule is expected to be different for those entities that would begin their activities only after the national program is implemented. Producers and handlers who currently are active in the organic industry already perform most of these administrative functions; therefore, the additional costs to them would depend upon the extent to which their current practices are different from the requirements of the final regulation. An estimate of the cost of compliance is the annual reporting and recordkeeping burden documented in the Paperwork Reduction Act of 1995 analysis.

The following list describes several proposed administrative requirements or optional submissions and the probable resources required for compliance.

1. Establish, implement, and update annually an organic production or handling plan. Organic plans are a standard feature in the organic industry and are required by certifying agents. Thus, producers and handlers who are already involved in organics, can rely on their current plan with revisions as needed to meet elements of the national program which are new to them or differ from their current practice. Although producers and handlers are generally aware of the goals of organic plans, current practice may fall short of the rigor that will be required by the national program. New producers and handlers will have higher costs because they will have to prepare a plan from scratch.

2. Maintain records pertaining to their organic operation for at least 5 years and allow authorized representatives of the Secretary, the applicable State program's governing State official, and the certifying agent access to records. Existing organic producers and handlers maintain records. New producers and handlers will have to develop records systems. Access is expected to be infrequent, will require little time of the certified entity, and will not require buildings or equipment other than what is required for storing records.

3. Notify the certifying agent as required, e.g., when drift of a prohibited substance may have occurred, and complete a statement of compliance with the provisions of the NOP. Notifications are expected to be infrequent.

The total reporting burden includes creation and submission of documents. It covers the greatest amount of reporting burden that might occur for any single creation or submission of a document during any one of the first 3 years following program implementation, i.e., 2000, 2001, and 2002. The total estimated reporting burden reflects the average burden for each reporting activity that might occur in 1 year of this 3-year period.

The total recordkeeping burden is the amount of time needed to store and maintain records. For the purpose of measuring the recordkeeping burden, the year 2002 is used

as the reporting year for which the largest number of records might be stored and maintained. The annual reporting and recordkeeping burdens on producers, handlers, and certifying agents is summarized in Table 4.

Certified operations. The annual burden on certified producers is estimated at 10 hours and \$229. Certified handlers have an estimated burden of 50 hours valued at \$1,189. Certifying agencies have an estimated burden of 700 hours valued at roughly \$18,900.

Exempt operations. The burden on small producers and handlers, who choose to operate as exempt entities, is minimal, 0.5 hour of recordkeeping valued at \$12. Exempt operations are exempt from reporting and recordkeeping burdens. However, small producers and handlers will have to invest some time and review documents to determine whether they qualify for exemption or exclusion. Exempt operations that produce multiingredient products containing less than 50 percent organic ingredient will be required to maintain records documenting the organic ingredients purchased. Since records of purchases would be part of the normal recordkeeping for handlers, we do not consider this a recordkeeping burden.

Based on the projected number of producers (17,150) and handlers (2,150), the total reporting and recordkeeping cost, which captures much of the compliance costs of the rule for this group, is \$5,200,721. We request comment and/or data on the costs that may be imposed by the recordkeeping requirements of the proposed regulation. In addition, we request comment and/or data on the similarities and differences between the current practices of private and state programs and the proposed requirements.

Barriers to Entry—Importers of Organic Products

Currently, there are no federal restrictions on importing organic products to the United States in addition to those regulations applying to conventional products. However, some States require organic products sold within the State to be produced according to the State's standards. Thus, some State programs are barriers to importers. The proposed regulation imposes a national standard that these importers must meet, and may incur some cost. We request comment and/or data on the extent of the organic food imports and the costs that may be imposed on these importers to meet the proposed standards.

Small Business Ramifications

USDA has proposed an 18-month period during which applicants for accreditation would not be billed for hourly services. The rationale for this transition period is to reduce the costs to certifying agents and, thus, increase the prospect that certifying agents, producers, and handlers will be able to afford to participate in the national program. The choice of 18 months is intended to provide sufficient time for parties desiring accreditation to submit their application and prepare for a site evaluation.

USDA has proposed to operate the program partially with appropriated funds, in effect

sharing the cost of the program between taxpayers and the organic industry, to respond to public concerns regarding the effects of the proposed regulation on small businesses. Thousands of comments were received opposing the first proposal's fee provisions with most focusing on the substantial impact on small certifying agents.

Congress has expressed public policy concern with the impacts of regulations on small entities generally and with the impacts on the NOP regulations on small entities particularly. The Small Business Regulatory Enforcement Fairness Act of 1996 and the Regulatory Flexibility Act express Congressional concern regarding regulatory burden on small businesses. The Report from the Committee on Appropriations regarding the Agriculture, Rural Development, Food and Drug Administration, and Related Agencies Appropriations Bill, 2000, includes the following language (U.S. Senate 1999):

"The Committee continues to recognize the importance of organic markets for small farmers and fishermen. The Committee expects the Secretary to construct a national organic program that takes into consideration the needs of small farmers and fishermen. * * * Furthermore, the Committee expects that of the funding available for the National Organic Program, necessary funds should be used to offset the initial costs of accreditation services, a subsidy necessary due to the lack of expertise in the Department of Agriculture in the areas of organic accreditation and insufficient data on the industry."

Certifying agents applying for accreditation during the first 18 months following the final regulation will face lower direct costs than subsequent applicants. The cost for later applicants for accreditation will be higher because they will have to pay a \$500 application fee and hourly charges for completing their site evaluation. The requirement for accreditation was established in the OFPA in 1990 and the proposed accreditation program was part of the 1997 proposal. Because in this proposal USDA is using appropriated funds to cover some of the costs of initial accreditation during the first 18 months of the program, certifying agents may set lower fees initially benefitting the producers and handlers who are certified during this period.

It is important to note that many small organic operations may not be certified currently. In California, for example, many small farms are registered, but not certified. Even if certifying agents pass on the cost savings of the 18 month period provision to applicants for certification, the cost of certification may be higher than the cost of registration. Hence, becoming a certified operation for small organic producers and handlers may be more costly than the current practices.

The costs imposed on small operations may be mitigated by a \$5000 certification exemption to aid the smallest organic operations. However, these operations are still subject to other requirements of the proposed regulation. To the extent that these requirements differ from their current practices, complying with the national standards may be costly for exempt operations.

In addition, the certification exemption allowed under the proposed regulation includes limits on what an exempt operation may do. Without the certification, small organic operations may not display the USDA seal and may not use a certifying agent's seal. However, we are asking for public comment on whether exempt operations should have the marketing option of selling their products to handlers who can claim the products as organic in multi-ingredient products. If the consumers of organic food view the seals as important information tools on organic food, that is, if consumers of organic products insist on only certified organic products, the inability of small operations to display these seals may prevent them from realizing the price premiums associated with certified organic products.

Industry Composition

The imposition of the national standards may change the composition of the organic industry. Even with the small business exemptions, some small organic operations may choose to exit the industry and small organic operations may also be discouraged from entering the industry, resulting in a higher concentration of larger firms. On the other hand, it may be easier for small operations to comply with certain NOP standards, such as the livestock standards which prohibit confinement production systems and require 100 percent organic feed.

Conclusion

Ideally, the net benefits of the proposed rule would be estimated by employing a welfare analysis. In a welfare model, the quantitative assessment of benefits would be represented by net changes in consumer and producer surplus, *i.e.*, the difference between the willingness to pay (or firm cost structure in the case of producers) and the market price of organic food. These net changes would be estimated using information about the cost structure of the industry, the demand for organic food, and projected shifts in supply and demand resulting from the various factors discussed in the assessment. Although researchers have conducted numerous small-scale studies to determine consumers' willingness to pay for certain organic products (primarily fresh produce) and to identify reasons why conventional food buyers do not choose organic food products (Hammit, 1990 and 1993; Jolly; Misra *et al.*; Park and Lohr; Weaver *et al.*), the available data are insufficient to support a quantitative assessment of this type. A 1998 review of studies of consumer demand for organic foods concluded, "Attitudes, motives, and willingness to pay for organic products have been measured, but apparently no retail data have been available to estimate own-price, cross-price, and income elasticities." (Thompson 1998).

USDA has identified the entities that may be affected by the proposed rule and has analyzed the anticipated business-associated impacts on them of the rule based on our knowledge of the industry and limited data. We have drawn on industry studies, including studies completed since the 1997 proposed rule was published, and

information provided in comments on the 1997 proposed rule.

The primary benefits from implementation of the proposed rule are improved protection of buyers from a reduction in market confusion including protection from false and misleading claims, and improved access to markets from the reciprocity inherent in national standards. These benefits have not been quantified.

The costs of the proposed regulation are the direct costs for accreditation and the costs of complying with the specific standards in the proposal including the reporting and recordkeeping requirements. Other than accreditation fees, recordkeeping and reporting costs, we did not quantify the magnitude of the compliance costs or the costs of adhering to other provisions of this regulation. We have also not quantified the impact of all these provisions on small business but we believe there impact to be significant.

The direct costs of accreditation if all currently operating certifying agents become certified during the first 18 months following the final rule is approximately \$75,000 to \$100,000. After the first 18 months, the direct cost for accrediting would be approximately \$150,000 to \$238,000. During the 18-month period during which the NOP is not recovering the full costs of accreditation services, the organic industry is being subsidized with appropriated funds derived from the taxpayers. For existing certifying agents compliance costs include costs to become familiar with and adopt NOP standards. The aggregate cost of complying with reporting and recordkeeping requirements of the rule are approximately \$6.8 million. Appropriated NOP funds used to operate the National Organic Program are transfers from the taxpayers to the participants in the organic sector.

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TABLE 1.—ORGANIC FOOD SALES
[\$ billions]

Year	Sales	Sales (1998 dollars)
1990	1.000	1.25
1991	1.250	1.50
1992	1.540	1.79
1993	1.890	2.13
1994	2.310	2.54
1995	2.800	2.99
1996	3.500	3.64

Source: Mergentime and Emerich in *Natural Foods Merchandiser*.

TABLE 2A.—FIRST YEAR CERTIFICATION COSTS, FROM GRAF AND LOHR ANALYSIS
[In dollars]

Certifying agent	Small farm	Medium farm	Large farm	Super farm
CCOF	750	1,650	4,750	51,150
FVO	585	1,624	5,101	51,437
FOG	325	845	2,525	25,525
NOFA-VT	335	535	585	585
OTCO-In	608	1,766	2,517	11,518
OTCO-Out	568	1,498	2,352	11,353
OCIA-WI	315	1,590	6,090	75,090
OCIA-VA	258	320	495	1,745
TDA	90	155	200	515
WSDA	330	1,375	2,800	12,000
NC/SCS	n/a	n/a	n/a	n/a
Average cost	416	1,136	2,742	24,092

Notes:

CCOF—California Certified Organic Farmers
 FVO—Farm Verified Organic
 FOG—Florida Certified Organic Growers & Consumers
 NOFA-VT—Northeast Organic Farming Association-Vermont
 OTCO-In—Oregon Tilth Certified Organic, inside Oregon
 OTCO-Out—Oregon Tilth Certified Organic, outside Oregon
 OCIA-WI—Organic Crop Improvement Association, Wisconsin chapter
 OCIA-VA—Organic Crop Improvement Association, Virginia chapter
 TDA—Texas Department of Agriculture
 WSDA—Washington State Department of Agriculture
 NC/SCS—NutriClean/Scientific Certification Systems
 Small farm—25 acres with annual sales of \$30,000.
 Medium farm—150 acres with annual sales of \$200,000.
 Large farm—500 acres with annual sales of \$800,000.
 Super farm—3,000 acres with annual sales of \$10,000,000.

TABLE 2B.—SUBSEQUENT YEAR CERTIFICATION COSTS, FROM GRAF AND LOHR ANALYSIS
[In dollars]

Certifying agent	Small farm	Medium farm	Large farm	Super farm
CCOF	425	1,300	4,350	50,550
FVO	510	1,499	4,851	51,187
FOG	325	845	2,525	25,525
NOFA-VT	300	500	550	550
OTCO-In	454	1,611	2,362	11,363
OTCO-Out	424	1,353	2,207	11,208
OCIA-WI	290	1,565	6,065	75,065
OCIA-VA	233	295	470	1,720
TDA	90	155	200	515
WSDA	330	1,375	2,800	12,000
NC/SCS	700	900	1,000	2,000
Average cost	371	1,036	2,489	21,971

Notes:

CCOF—California Certified Organic Farmers
 FVO—Farm Verified Organic
 FOG—Florida Certified Organic Growers & Consumers
 NOFA-VT—Northeast Organic Farming Association—Vermont
 OTCO-In—Oregon Tilth Certified Organic, inside Oregon
 OTCO-Out—Oregon Tilth Certified Organic, outside Oregon
 OCIA-WI—Organic Crop Improvement Association, Wisconsin chapter
 OCIA-VA—Organic Crop Improvement Association, Virginia chapter
 TDA—Texas Department of Agriculture
 WSDA—Washington State Department of Agriculture
 NC/SCS—NutriClean/Scientific Certification Systems
 Small farm—25 acres with annual sales of \$30,000.
 Medium farm—150 acres with annual sales of \$200,000.
 Large farm—500 acres with annual sales of \$800,000.
 Super farm—3,000 acres with annual sales of \$10,000,000.

TABLE 3.—COSTS OF ACCREDITATION AND CERTIFICATION

Estimated costs to certifying agents during first 18 months	
Application fee ¹	\$0
Site evaluation costs (two person team):	
Per diem (3 to 5 days)	\$480 to \$800
Travel (domestic)	\$1,000 to \$1,200
Hourly charges (not billed)	\$0
Miscellaneous charges (copying, phone, and similar costs)	\$50
Total	\$1,530 to \$2,050
Estimated costs to certifying agents for initial accreditation after first 18 months	
Application fee ¹	\$500
Site evaluation costs (one person):	
Per diem (3 to 5 days)	\$240 to \$400
Travel (domestic)	\$500 to \$600
Hourly charges (24 to 40 hours at \$95/hour)	\$2,280 to \$3,800

TABLE 3.—COSTS OF ACCREDITATION AND CERTIFICATION—Continued

Miscellaneous charges (copying, phone, and similar costs)	\$50
Total	\$3,070 to \$4,850
Annual review fees for certifying agents (2 to 8 hours at \$95/hour) ²	\$190 to \$760
Estimated costs to producers for certification ³	
Certification fee (initial certification)	\$800
Certification fee (renewals)	\$730
Estimated costs to handlers for certification ⁴	
Certification fee (initial certification)	\$1,825
Certification fee (renewals)	\$1,665

¹ Nonrefundable fee that will be applied to the applicant's fee for service account.

² Certifying agents are required to submit annual reports to USDA. Review of these reports is expected to range from 2 to 8 hours at an approximate rate of \$95 per hour.

³ Estimated certification fees are calculated from Graf and Lohr 1999 which, for a selection of certification agents, provides certification costs for four hypothetical farm sizes: (1) Small Farm ("Family Farm"): 25 acres, \$30,000 annual sales, 5 hours to certify; (2) Medium Farm ("Cottage Industry"): 150 acres, \$200,000 annual sales, 6 hours to certify; (3) Large Farm ("Commercial Farm"): 500 acres, \$800,000 annual sales, 8 hours to certify; and (4) Super Farm: 3,000 acres, \$10,000,000 annual sales, 16 hours to certify. Our estimated certification fees only include those charged for small and medium farms, because most organic producers fall into these categories as defined by Graf and Lohr. In the 1997 OFRF survey, 90 percent of respondents had gross organic farming income less than \$250,000, with 82 percent less than \$100,000.

The average current certification cost for most organic producers is about \$775 for the first year of certification (\$416 for small and \$1,136 for medium farms) and about \$705 for subsequent years (\$371 for small and \$1,036 for medium farms). Approximately \$25 is added to cover the costs associated with the National Organic Program for an estimated first year certification fee of \$800 and subsequent year certification fee of \$730 for producers. Larger producers could expect higher fees.

⁴ Because Graf and Lohr do not estimate certification fees for handlers, we estimate these fees by applying a ratio of handler-to-producer certification fees from the regulatory impact assessment from 1997. The ratio is 2.28 results in estimated fees of \$1,825 and \$1,665, respectively.

TABLE 4.—ESTIMATED ANNUAL REPORTING AND RECORDKEEPING BURDEN

Type of respondent	Annual hours per respondent	Hourly rate	Annual cost
Certified producer	10	\$24	\$229
Exempt producer	0.5	24	12
Certified handler	50	24	1,189
Exempt handler	0.5	24	12
State certifying agency	696	27	18,778
Private or foreign certifying agency	700	27	18,893

Note: Estimates derived from Paperwork Reduction Act of 1995 analysis.

Appendix B.—Unfunded Mandates Reform Act

This proposed rule has been reviewed under the Unfunded Mandates Reform Act (P.L.104-4). The Act requires that agencies prepare a qualitative and quantitative assessment of the anticipated costs and benefits before proposing any rule that may result in annual expenditures by State, local, and tribal governments, in the aggregate, or by the private sector, of \$100 million (adjusted annually for inflation) in any one year. According to the Act, the term *Federal mandate* means any provision in legislation, statute, or regulation that would impose an enforceable duty upon State, local, or tribal governments, or the private sector, except a duty arising from participation in a voluntary Federal program.

The National Organic Foods Production Act (OFPA) of 1990 mandates that the Secretary develop a National Organic Program (NOP) to accredit eligible governing

State officials or private persons as certifying agents who would certify producers or handlers of agricultural products that have been produced using organic methods as provided for in the OFPA. The OFPA also permits a governing State official to voluntarily establish a State organic certification program if the program is approved by the Secretary and meets the requirements of the OFPA. The OFPA does not require that States establish their own organic certification programs or that State, local or tribal governments, or the private sector, become accredited; therefore, the OFPA is not subject to the Unfunded Mandates Reform Act because it is a voluntary program.

Although USDA has determined that this proposed rule is not subject to the Unfunded Mandates Reform Act, USDA has sought to consider the rule's impact on various entities. USDA prepared a Regulatory Impact Assessment (RIA) that is discussed in the section titled "Executive Order 12866" (also

attached as an appendix to this proposed regulation). The RIA consists of a statement of the need for the proposed action, an examination of alternative approaches, and an analysis of the benefits and costs. Much of the analysis is necessarily descriptive of the anticipated impacts of the proposed rule. Because basic market data on the prices and quantities of organic goods and services and the costs of organic production is limited, it is not possible to provide quantitative estimates of all benefits and costs of the proposed rule. The cost of fees and recordkeeping proposed by the USDA are quantified, but the anticipated benefits are not. Consequently, the analysis does not contain an estimate of net benefits.

The analysis employed in reaching a determination that this proposed rule is the least costly and least burdensome to the regulated parties is discussed in the sections titled "The Regulatory Flexibility Act and the Effects on Small Businesses" and "Paperwork Reduction Act of 1995." The

proposed rule has been designed to be as consistent as possible with existing industry practices, while satisfying the specific requirements of the OFPA.

We have had numerous occasions to communicate with various entities during the development of the proposed rule; States, for example. Currently there are 27 States with some standards governing the production or handling of organic food and 13 States with organic certifying programs. Representatives of State governments have participated in public meetings with the NOSB, while the NOP staff has made presentations, received comments, and consulted with States and local and regional organic conferences, workshops, and trade shows. States have been actively involved in training sessions for organic inspectors; public hearings concerning standards for livestock products during 1994; a national Organic Certifiers meeting on July 21, 1995; a USDA-hosted meeting on February 26, 1996; a State certifiers meeting in February 1999; and an ISO 65 assessment training session for certifiers in April-May 1999. It is unknown at this time how many States, if any, might voluntarily establish their own organic certification programs pursuant to the OFPA and the regulations.

Appendix C.—The Regulatory Flexibility Act and the Effects on Small Businesses

The Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*) (Act) requires agencies to consider the economic impact of each proposed rule on small entities and evaluate alternatives that would accomplish the objectives of the rule without unduly burdening small entities or erecting barriers that would restrict their ability to compete in the market. The purpose is to fit regulatory actions to the scale of businesses subject to the action.

In the first proposal published in December 1997, the initial Regulatory Flexibility Analysis (RFA), describing the impact of the National Organic Program and evaluating the alternatives, was written with guidance from the U.S. Small Business Administration (SBA). The RFA of this proposal was written following consideration of comments received in response to the first proposal, other information that has become available since the first proposal, the Regulatory Impact Assessment (RIA) that is discussed in the section entitled "Executive Order 12866" (also attached as an appendix to this proposal), and the information collection burden discussed in the section entitled "Paperwork Reduction Act of 1995" (PRA).

Reasons for Proposal

Currently, organic certification is voluntary and self-imposed. Members of organic industries across the U.S. have experienced numerous problems marketing their organically produced and handled agricultural products. Inconsistent and conflicting organic production standards may have been an obstacle to the effective marketing of organic products. There are currently 36 private and 13 State organic certification agencies (certifying agents) in the United States, each with its own standards and identifying marks.

Some existing private certifying agents are concerned that States might impose registration or licensing fees which would limit or prevent private certification activities in those States. Labeling problems have confronted manufacturers of multi ingredient organic food products containing ingredients certified by different certifying agents because reciprocity agreements have to be negotiated between certifying agents. Consumer confusion may exist because of the variety of seals, labels, and logos used by certifying agents and State programs. Also, there is no industry wide agreement on an accepted list of substances that should be permitted or prohibited for use in organic production and handling. Finally, a lack of national organic standards may inhibit organic producers and handlers in taking full advantage of international organic markets and may reduce consumer choices in the variety of organic products available in the marketplace.

To address these problems in the late 1980's, the organic industry attempted to establish a national voluntary organic certification program. At that time, the industry could not develop consensus on the standards that should be adopted, so Congress was petitioned by the Organic Trade Association to establish national standards for organic food and fiber products.

Recently, the Organic Trade Association published American Organic Standards, Guidelines for the Organic Industry (AOS). However, not all participants in the organic industry elected to participate in developing the AOS. Many certifying agents preferred to wait for implementation of the National standards, and some certifying agents disagree with portions of the AOS. For these reasons, the USDA is proposing a regulation for the National Organic Program.

Legal Basis for and Objectives of Proposal

In 1990, Congress enacted the Organic Foods Production Act of 1990, as amended (7 U.S.C. 6501 *et seq.*) (OFPA). The OFPA requires all agricultural products labeled as "organically produced" to originate from farms or handling operations certified by a State or private agency that has been accredited by USDA.

The purposes of the OFPA, set forth in section 2102 (7 U.S.C. 6501), are to: (1) Establish national standards governing the marketing of certain agricultural products as organically produced products; (2) assure consumers that organically produced products meet a consistent standard; and (3) facilitate commerce in fresh and processed food that is organically produced. The National Organic Program, which this rule proposes, is the result of the OFPA.

Applicability of Proposal

This proposal will directly affect three sectors of the organic industry: certifying agents, producers, and handlers. The OFPA provides for the collection of reasonable fees by USDA from producers, handlers, and certifying agents who participate in the national program. This proposal will impose direct costs on certifying agents in the form of a fee paid to the Federal Government for USDA accreditation. This proposal does not

impose direct costs in the form of fees on producers and handlers. Certifying agents will establish a fee schedule for their certification services for producers and handlers. All three sectors are subject to indirect costs of compliance.

The term, "certifying agent," means the chief executive officer of a State or, in the case of a State that provides for the statewide election of an official to be responsible solely for the administration of the agricultural operations of a State, such official and any person (including private entities) who is accredited by the Secretary as a certifying agent for the purpose of certifying a farm or handling operation as a certified organic farm or handling operation. The term, "producer," means a person who engages in the business of growing or producing food or feed. The term, "handler," means any person engaged in the business of handling agricultural products, excluding final retailers of agricultural products that do not process agricultural products. Subpart B, section 205.101 in the proposed regulation provides information about exemptions and exclusions from certification.

According to the most complete data available to USDA's Agricultural Marketing Service (AMS), there are 49 certifying agents (36 private and 13 State) in the U.S. Over half of the private and State certifying agents certify both producers and handlers, while the others certify only producers. Over three-fourths of private and State certifying agents each certify fewer than 150 producers and 20 handlers. The number of certifying agents has remained fairly stable between 40 and 50 for some years, with entries and exits tending to offset each other. The National Organic Program staff anticipates that, in addition to the 49 domestic certifying agents, 10 foreign certifying agents may seek accreditation during the initial phase of the program.

It is more difficult to establish the number of organic producers. Organic farming was not distinguished from conventional agriculture in the 1997 Census of Agriculture. There are sources which give insight into the number of producers. The Organic Farming Research Foundation (OFRF), a California-based nonprofit organization, has conducted three nationwide surveys of certified organic producers from lists provided by cooperating certifying agents. The most recent survey applies to the 1997 production year.¹ OFRF sent its 1997 survey to 4,638 names and received 1,192 responses. Because OFRF did not obtain lists from all certifying organizations or their chapters (55 out of a total of 64 identified entities provided lists), their list count is likely an understatement of the number of certified organic producers. Note that the estimated number of organic producers includes only certified organic farms. Comments filed in response to the first proposal and studies indicate that the total number of organic farms is higher.

¹ Organic Farming Research Foundation. 1999. Final Results of the Third Biennial National Organic Farmers' Survey. Santa Cruz, CA.

Dunn has estimated the number of certified organic producers in the U.S.^{2,3} Dunn's 1995 work, a USDA study, estimated the number of certified producers at 4,060 in 1994; this estimate was used in the first proposal. Dunn's 1997 work reported 4,060 certified organic farms in 1994 and 4,856 in 1995.

Data collected by AMS indicate that the number of organic farmers increased about 12 percent per year and the number of organic handlers increased at about 11 percent per year during the period 1990 to 1994. OFRF survey efforts indicate that growth has continued, although it is not clear whether the growth rate has changed. Similarly, growth in retail sales, the addition of meat and poultry to organic production, and the possibility of increased exports suggest that the number of operations has continued to increase. Lacking an alternative estimate of the growth rate for the number of certified organic producers, we use the average growth rate of about 14 percent from Dunn's 1997 study. The true rate of growth could be higher or lower. Applying the 14-percent growth rate to Dunn's estimate of certified producers in 1995 gives an estimate of 8,200 organic producers for 1999.

An adjustment is needed to account for the number of producers who are practicing organic agriculture but who are not certified and who would be affected by this proposal. We assume that the number of organic but not certified producers in 1999 is about 4,000. This assumption is based on very limited information about the number of registered but not certified organic producers in California in 1995. Thus, the total number of organic producers used in assessing the impact of the rule is 12,176 in 1999.

Little information exists on the numbers of handlers and processors. USDA has estimated that there were 600 entities in this category in 1994. In California, there were 208 registered organic processed food firms in 1995 and 376 in 1999, a growth rate of 20 percent.⁴ We assume that this growth rate is applicable to the U.S. and project 1,250 handlers in 1999. Again, the rate of growth could be higher or lower.

SBA Definitions of Small Entities

Small business size standards, Standard Industrial Code (SIC) (13 CFR part 121), are developed by an inter-agency group, published by the Office of Management and Budget, and used by SBA to identify small

businesses. These standards represent the number of employees or annual receipts constituting the largest size that a for-profit enterprise (together with its affiliates) may be and remain eligible as a small business for various SBA and other Federal Government programs.

Small businesses in the agricultural services sector, such as certifying agents, include firms with average annual revenues of less than \$5 million (SIC Division A Major Group 7). Producers with crop production (SIC Division A Major Group 1) and annual average revenues under \$500,000 are small businesses. Producers with livestock or animal specialties are also considered small if annual average revenues are under \$500,000 (SIC Division A Major Group 2), with the exception of custom beef cattle feedlots and chicken eggs, which are considered small if annual average revenues are under \$1,500,000. In handling operations, a small business has fewer than 500 employees (SIC Division D Major Group 20).

Based on SBA's small business size standards for the agricultural services sector, it is not likely that many, if any, of the 49 domestic certifying agents have annual revenue greater than \$5 million. Based on anecdotal information, only a few private, for-profit, certifying agents might be categorized as a large business. All private, non profit, and State certifying agents would be considered small by SBA's standards. Even if State certifying agents do not exceed the revenue threshold, they would not be considered to be small entities under the Act if the agents are an arm of state government. Only government jurisdictions with populations under 50,000 are considered to be small entities under section 601(5) of the Act.

Based on SBA's small business size standards for producers, it is likely that almost all organic producers would be considered small. The OFRF survey asked for the producer's total gross organic farming income during 1997. Only 35 (less than 3 percent) of the survey respondents reported gross income greater than \$500,000, the SBA's cutoff between small and large businesses. Over 70 percent reported gross income of less than \$50,000. The OFRF survey does caution readers about potential survey "errors." It is particularly important to emphasize potential "non-response error," that is, it is unknown if those who responded

to the survey accurately represent the entire population of certified organic growers. Also, some producers combine organic and conventional production on the same operation, some with total sales that may exceed \$500,000. However, it is likely that a majority of organic producers would be considered small.

It is also likely that the vast majority of handlers would be considered small, based on SBA's small business size standards for handlers. Based on informal conversations with organic certifying agents, about 25 (about 2 percent) of the estimated 1,250 organic handlers have more than 500 employees. This includes firms that handle or process both organic and conventional foods.

Costs of This Proposal

Several requirements to complete this RFA overlap with the RIA and the PRA. In order to avoid duplication, we combine some analyses as allowed in section 605(b) of the Act. This RFA provides information specific to small entities, while the RIA or PRA should be referred to for more detail. For example, the RFA requires an analysis of the proposed rule's costs to small entities. The RIA provides an analysis of the benefits and costs of this proposal. This RFA uses the RIA information to estimate the impact on small entities. Likewise, the RFA requires a description of the projected reporting, recordkeeping, and other compliance requirements of the proposed rule. The PRA section estimates the reporting and recordkeeping (information collection) requirements that would be required by this proposal from individuals, businesses, other private institutions, and State and local governments. The burden of these requirements is measured in terms of the amount of time required of program participants and its cost. This RFA uses the PRA information to estimate the burden on small entities.

The estimated direct costs of accreditation for certifying agents and certification for producers and handlers under the first proposal issued in December 1997 and this proposal are shown in table 1 and discussed in the following sections. More specific details regarding these costs are found in the RIA.

TABLE 1.—ESTIMATED DIRECT COSTS OF ACCREDITATION AND CERTIFICATION

	First proposal		This proposal	
	1st year cost	2nd year cost	1st year cost	2nd year cost
Certifying Agents:				
Accreditation application fee	\$640	\$640	\$0	\$0
USDA administrative fee	2,000	2,000	0	0
Estimated site evaluation fee	3,500	¹	1,530 to ³ 2,050	¹
Annual review fee		²		² 190 to 760

²Dunn, Julie Anton. 1995. Organic Food and Fiber: An Analysis of 1994 Certified Production in the United States. U.S. Department of Agriculture, Agricultural Marketing Service.

³Dunn, Julie Anton. 1997. AgriSystems International Reports Certified Organic Production in the United States: Half a Decade of Growth. AgriSystems International: Wind Gap, PA.

⁴California Department of Health Services (DHS). 1995. Report on the Registration of California Organic Processed Food Firms. Sacramento: State of California. September 1999 figures obtained via personal communication with California DHS.

TABLE 1.—ESTIMATED DIRECT COSTS OF ACCREDITATION AND CERTIFICATION—Continued

	First proposal		This proposal	
	1st year cost	2nd year cost	1st year cost	2nd year cost
Total Fees	6,140	min. 2,640	min. 1,530	min. 190
Producers:				
Estimated certification fee ⁴	413	413	800	730
USDA fee	50	50	0	0
Total Fees	463	463	800	730
Handlers:				
Estimated certification fee ⁴	943	943	1,825	1,665
USDA fee	500	500	0	0
Total Fees	1,443	1,443	1,825	1,665

¹ Should certifying agents wish to become accredited in additional areas for which they have not been accredited previously, site evaluation fees will be charged.

² First proposal: Included in application and administrative fees. This proposal: Certifying agents are required to submit annual reports to USDA. Review of these reports is expected to range from 2 to 8 hours at an approximate rate of \$95 per hour.

³ During the first 18 months, site evaluation for initial accreditation will involve two reviewers. One reviewer would come from the Quality Systems Certification Program audit staff and would be familiar with ISO Guide 65 verification; the other reviewer would come from the National Organic Program staff and would be familiar with requirements of the organic program. The two would conduct the site evaluation jointly. We anticipate only one reviewer would be required after the 18-month transition period. The estimated site evaluation fee shown here includes per diem and travel costs for two reviewers plus miscellaneous charges related to accreditation. Site evaluations for smaller certifying agents are estimated to take 3 days, with 5 days for larger certifying agents.

For the first 18 months after implementation of the NOP, hourly rates will not be charged to certifying agents for accreditation. The estimated fee shown here includes only travel and per diem expenses. At an approximate rate of \$95 per hour, hourly charges would add an estimated \$4,560 to \$7,600 for 2 reviewers during the first 18 months, and \$2,280 to \$3,800 for 1 reviewer after the first 18 months or for renewal of accreditation.

⁴ First proposal: Estimated certification fees at that time were based on the average of fees charged by a representative group of certifying agents (private non-profit, private for-profit and a State agency).

This proposal: Estimated certification fees are calculated from a 1999 study by Graf and Lohr⁵ which, for a selection of certification agents, provides certification costs for four hypothetical farm sizes: (1) Small Farm ("Family Farm"): 25 acres, \$30,000 annual sales, 5 hours to certify; (2) Medium Farm ("Cottage Industry"): 150 acres, \$200,000 annual sales, 6 hours to certify; (3) Large Farm ("Commercial Farm"): 500 acres, \$800,000 annual sales, 8 hours to certify; and (4) Super Farm: 3,000 acres, \$10,000,000 annual sales, 16 hours to certify. Our estimated certification fees only include those charged for small and medium farms, because most organic producers fall into these categories as defined by Graf and Lohr. In the 1997 OFRF survey, 90 percent of respondents had gross organic farming income less than \$250,000, with 82 percent less than \$100,000.

The average current certification cost for most organic producers is about \$775 for the first year of certification (\$416 for small and \$1,136 for medium farms) and about \$705 for subsequent years (\$371 for small and \$1,036 for medium farms). An estimated \$25 is added to cover the costs associated with the National Organic Program for an estimated first year certification fee of \$800 and subsequent year certification fee of \$730 for producers. Larger producers could expect higher fees.

Because Graf and Lohr do not estimate certification fees for handlers, we estimate these fees by applying the December 1997 ratio of handler-to-producer certification fees, 2.28, to the estimated first and subsequent year certification fees for producers, resulting in fees of \$1,825 and \$1,665, respectively.

Direct Costs to Certifying Agents

We have identified 36 private certifying agents and 13 State programs providing certification. These 49 domestic entities are considered likely applicants during the first 12 months, as are an estimated 10 foreign certifying agents. An unknown number of new entrants to the certifying business may also apply. However, over the last 10 years, the number of certifying agents does not appear to have grown significantly, with the net effect of entries and exits maintaining a population of U.S.-based certifying agents at about 40 to 50. Of the 49 domestic certifying agents, based on information discussed previously, we estimate that the 36 private certifying agents are small.

In order to identify the certifying agents that might be expected to face more significant impacts as a result of this proposal, we analyzed the amount of revenues from certification fees received by

certifying agents. Total certification fees collected by the certifying agents in 1994 ranged from about \$2,500 to about \$400,000, with most certifying agents clustered around the low or high end of this range. This amount is based on information collected by AMS from a sample of 16 private and State certifying agents for certification fees collected in 1994. To determine a cutoff point for small certifying agents, the State certifying agents were eliminated from the sample because these agents are an arm of State government and are not considered small entities. Of the remaining 11 private certifying agents, 6 (or 55 percent) collected less than \$25,000 each in total certification fees, and the other 5 (45 percent) each collected more than \$200,000. Based on this information and knowledge of the organic industry, for purposes of analyzing the cost of accreditation, we estimate that about 55 percent of private certifying agents are small with total annual revenue from certification of less than \$25,000.

Certification fees probably do not constitute total income for most private certifying agents and, thus, are not a complete measure of economic size. Some

certifying agents also earn revenue from a number of other sources, such as sale of publications, membership dues, training workshop and conference fees, farmers markets, grants, or donations.

Certifying agents will be assessed for the actual time and travel expenses necessary for the National Organic Program to perform accreditation services. The National Organic Program will charge the same hourly fees as are charged for the voluntary, fee-for-service program provided by AMS to certification bodies requesting conformity assessment to the International Organization for Standardization (ISO) Guide 65, "General Requirements for Bodies Operating Product Certification Systems." We expect that at the time the National Organic Program's final rule is implemented, the fees will be approximately \$95 per hour, with higher overtime and holiday rates. Certifying agents will be charged for travel, per diem, and other related costs associated with accreditation. Applicants for accreditation will be required to pay at the time of application a nonrefundable fee of \$500, which is applied to the applicant's fee for services account. This fee is credited against

⁵ Graf, Anita and Luanne Lohr. 1999. Analysis of certification program costs. Working Paper, Fund for Rural America project, Market Development for Organic Agriculture Projects, Grant No. 97-36200-5.

any subsequent costs of accreditation arising from the site evaluation.

During the first 18 months after the National Organic Program has been implemented, USDA will not impose hourly charges on certifying agents. The direct costs for certifying agents to obtain accreditation will be limited to per diem and transportation costs for the site evaluation, which is required every 5 years. We estimate these costs to be \$1,530 for a small certifying agent and \$2,050 for a larger certifying agent. These estimates are based on, for small and larger certifying agents, two reviewers with 3 and 5 days of per diem, \$500 to \$600 in transportation costs, and \$50 in miscellaneous charges related to accreditation.⁶ In subsequent years, certifying agents will be required to submit an annual report. Review of this report is anticipated to range from 2 to 8 hours at the ISO Guide 65 hourly rate. If certifying agents wish to become accredited in additional areas for which they were not accredited previously, site evaluation fees will be charged.

After the first 18 months of the National Organic Program, USDA estimates that the costs of a site evaluation visit, required every 5 years, could be \$3,070 for small certifying agents and \$4,850 for larger certifying agents. These estimates are based on, for small and larger certifying agents, one reviewer with 3 and 5 days of per diem, \$500 to \$600 in transportation costs, \$50 in miscellaneous charges related to accreditation, and 24 to 40 hours (3 to 5 work days) at an anticipated maximum hourly rate under ISO Guide 65 of \$95. Higher hourly rates will be charged for overtime and for work on holidays.

The cost of a site evaluation will vary with the cost of travel from the auditor's work station to the applicant's place of business. Auditors live in different parts of the country, and travel costs might be reduced when the distance traveled is reduced. The lowest cost airfare would be used whenever possible. In some cases, site evaluations might be grouped geographically in order to reduce travel expenses. The per diem rate will also vary depending on the rate set for the certifying agent's location as established by the General Services Administration.

Several factors will influence the amount of time needed to complete an accreditation audit. An operation in which documents are well organized and that has few nonconformities within the quality system

will require less time for an audit than an organization in which documents are scattered and there are many nonconformities.⁷ Similarly, in a follow up audit, operations that lack organization in their documents and that had a large number of nonconformities during previous audits will require a greater amount of time. The scope of a follow up audit is to verify the correction of nonconformities and to evaluate the effectiveness of the corrections. Certifying agents are able to control these cost factors by making certain that documents are well organized and by educating themselves about quality systems.

The complexity of a certification agency's organization also will affect the time needed to complete an audit. An agency with a central office in which all certification activities take place will require less time for document review and site evaluation than a chapter organization or a business structured so that responsibility for making certification decisions is delegated outside of the central office. In the latter cases, the auditors' document review would require additional time and site evaluation that would extend from the central office to one or more of the chapters or to the site to which the certification decision making is delegated.

Other factors determine the amount of time needed to complete an accreditation audit. For an agency with numerous clients, auditors may need to spend more time reviewing client files or examining business operations than they would have to spend for a smaller agency. Audit of an agency with a large number of processor clients may require an extended amount of time to follow audit trails, confirm that organic ingredients remain segregated from nonorganic ingredients, and establish that foreign-produced ingredients originate from approved entities. Finally, the complexity of the agricultural practices certified could influence the amount of time necessary to complete an accreditation audit. An agency whose certification covers only producers who grow and harvest one crop per field per year, such as wheat or sugar beets, could quickly be audited. An agency whose producers grow several different crops per field per year or an agency that certifies handlers of crops and livestock as well as handlers would require a greater amount of time.

All of these factors will impact both small and large certifying agents. A small certifying agent could be assumed to have a less complex organization or have fewer clients, and, thus, potentially less time would be necessary for review. However, other factors, such as the degree of paperwork organization or the complexity of the agricultural practices certified, may influence the time needed for review for any size of business.

Comments from the first proposal indicate that the average accreditation cost for a certifying agent may range from \$3,000 to \$5,000 per year for small to medium-size certifying agents to less than \$10,000 per year for the largest certifying agents.

Currently, relatively few certifying agents have third party accreditation because accreditation of certifying agents is voluntary. Fetter reports that in a sample of 18 certification programs, selected to include six large, private programs, six smaller private programs, and six State programs, four programs were accredited and one had accreditation pending.⁸ All of these were large private certifying agents. Three of the certifying agents identified by Fetter as accredited requested ISO Guide 65 assessments by USDA and have been approved for selling organic products into the international market. Those certifying agents currently accredited by third parties will likely pay less for USDA accreditation because their documents are organized and they have fewer nonconformities.

Those certifying agents who have been operating without third party accreditation will face new costs—the costs of accreditation—under this proposal. Compared to the direct costs of \$3,000 to \$5,000 per year indicated by the commenters, the direct costs of USDA accreditation will be smaller, with estimated site evaluation fees (covering 5 years) ranging from \$3,070 to \$4,850 for the first year and an annual review fee ranging from \$190 to \$760 for subsequent years. Furthermore, the direct costs would be substantially less for those certifying agents obtaining accreditation during the first 18 months while USDA does not impose an application fee or hourly charges and limits direct costs to travel and per diem costs.

It is expected that all certifying agents will set their fee schedule to recover costs for their certification services, including the costs of accreditation. The larger the number of clients per certifying agent, the more fixed costs can be spread out. It is possible, however, that small certifying agents could be significantly impacted by this proposal and may not be able to continue in business from a financial standpoint.

Projected Reporting, Recordkeeping, and Other Compliance Requirements of Certifying Agents

In addition to the direct costs, the regulation will impose administrative costs on certifying agents for reporting, recordkeeping, residue testing, and other compliance requirements. The actual amount of the additional administrative costs that would be imposed by the final rule is expected to be different for those entities that would begin their activities only after the national program is implemented. Certifying agents that currently are active in the organic industry already perform most of these administrative functions; therefore, the additional costs to them would depend upon the extent to which their current practices are different from the requirements of the final regulation. Projected reporting, recordkeeping, and other compliance requirements of certifying agents are discussed in greater detail in the PRA and the RIA.

⁶During the first 18 months, site evaluation for initial accreditation will be conducted jointly by two reviewers. Two reviewers offers: (1) anticipated faster turn-around; (2) different areas of expertise—one reviewer would come from the Quality Systems Certification Program audit staff and would be familiar with ISO Guide 65 verification, while the other reviewer would come from the National Organic Program staff and would be familiar with the requirements of the program; and (3) consistency with the organic industry's desire to have reviewers from both areas of expertise during ISO Guide 65 assessments. AMS would consider sending one reviewer, rather than two, for the site evaluation of small certification agents if an individual possessing both reviewing skill and knowledge of the NOP is available. We anticipate only one reviewer would be required after the 18-month transition period.

⁷Adequate advance notice will be given to certifying agents to allow them the opportunity to organize their records prior to the audit and minimize the costs of accreditation.

⁸Fetter, Robert T. 1999. Economic Impacts of Alternative Scenarios of Organic Products Regulation. Senior Honors Thesis. University of Massachusetts, Amherst, MA.

Costs to Producers and Handlers

Under this proposal, USDA will not impose any direct fees on producers and handlers. Certifying agents will establish a fee schedule for their certification services that will be filed with the Secretary and posted in a place accessible to the public. Certifying agents will provide all persons inquiring about the application process with a copy of their fees. The certifying agent may only charge those fees that it has filed with the Secretary. Furthermore, the certifying agent will provide each applicant with an estimate of the total cost of certification and an estimate of the annual costs of updating

the certification. However, the certifying agent may require applicants to pay at the time of application a nonrefundable fee of no more than \$250 which must be applied to the applicant's fee for services account.

Currently, supply and demand for certification services determine the fees charged in most areas. Some States charge minimal fees for certification and instead subsidize operating costs from general revenues. According to separate studies by Fetter, and Graf and Lohr, the majority of certifying agents structure their fee schedules on a sliding scale based on a measure of size, usually represented by the client's gross sales

of organic products but sometimes based on the acres operated. Some certifying agents charge an hourly rate for inspection and audit services.

Graf and Lohr have applied fee schedules provided by nine certifying agents to four hypothetical farms—small, medium, large, and a super farm. They define "small" as a 25-acre farm with annual sales of \$30,000 that would take 5 hours to certify. Note that our alternative definition of small (under \$5,000) is different. Table 2 shows the total first-year cost and subsequent-year cost for certification for small farms; the RIA shows detail on other size farms.

TABLE 2.—CERTIFICATION COSTS AMONG A SELECTION OF CERTIFYING AGENTS
[For a small farm: 25 acres, \$30,000 annual sales, 5 hours to certify]

Certifying agent	Total cost to certify in first year	Total cost to certify in subsequent years
California Certified Organic Farmers	\$750	\$425
Farm Verified Organic	585	510
Florida Certified Organic Growers and Consumers	325	325
Northeast Organic Farming Association—Vermont	335	300
Oregon Tilth Certified Organic:		
—Inside Oregon	608	454
—Outside Oregon	568	424
Organic Crop Improvement Association:		
—Wisconsin chapter	315	290
—Virginia chapter	258	233
Texas Department of Agriculture	90	90
Washington State Department of Agriculture	330	330
NutriClean/Scientific Certification Systems	n/a	700
Average cost	416	371

The Texas Department of Agriculture program is the low-cost certifying agent. The high-cost certifying agent differs from first-year to subsequent-year certification. Graf and Lohr's study indicates that even small farms require significant time for the certification process and this time does not increase proportionately as farm size increases. None of these certification programs mentions costs for residue testing which the National Organic Program will require in the form of preharvest testing when there is reason to believe that agricultural products have come in contact with prohibited substances. Preharvest testing is expected to be infrequent. Certifiers will recover the costs of preharvest testing through explicit charges to the producer whose crop is tested, or through a generally higher fee structure that spreads the expected costs of tests over all clients.

Certifying agents will continue to set their own fee schedules under the organic program. Certifying agents will have to set fees to cover any net additional costs of doing business under the National Organic Program. Accreditation and administrative costs are incremental costs to existing certifying agents' businesses. Some certifying agents might drop their third party accreditation saving perhaps \$3,000 to \$5,000 per year, but most certifying agents are not currently paying for accreditation.

This proposal imposes no requirements that would cause certifying agents that are presently using a sliding scale type fee

schedule to abandon their current fee system. Certifying agents could recover their net additional costs by increasing their flat fee component, their incremental charges, or both. Because accreditations are renewed only every 5 years, certifying agents will have 5 years to recover their net new costs. Certifying agents who become accredited during the first year of the program would have fewer direct costs to recover, because they will not be charged the application fee and hourly charges for accreditation services.

The OFPA established a small farmer exemption from certification and submission of organic plans for small producers with a maximum of \$5,000 in gross sales of organic products. For purposes of the exemption, the OFPA defines a "small farmer" as those who sell no more than \$5,000 annually in value of agricultural products. In this proposal, we have clarified that the exemption applies to those who sell no more than \$5,000 annually in value of organic products.⁹ According to

⁹ We asked for comments on the first proposal as to whether the current statutory limitation of \$5,000 for exemption from certification should be raised to \$10,000 or to another amount and why such an increased monetary limitation for exemption from certification would be appropriate. Few commenters offered recommendations as to a maximum sales volume to exempt producers. Amounts ranged from \$2,000 to \$50,000, with a few suggesting \$10,000 and \$20,000 exemptions. These proposed exemption levels and justifications in comments received are not sufficiently consistent enough for us to recommend changing the statute

the OFRF survey, 27 percent of currently certified farms that responded to the survey would fall under this exemption. This percentage does not take into account those organic farms that are not currently certified by a private or State certifying agent. A study of California organic farms found that, of all organic farms¹⁰ in 1994–95, about 66 percent have revenues less than \$10,000.¹¹ If California is representative and the distribution within the sub-\$10,000 category is uniform, then a third of the farms would be classified as small for purposes of the statutory exemption with annual sales less than \$5,000. Based on the California study and the OFRF survey results, we estimate that between 25 and 33 percent of organic producers are small and would qualify for exemption from the certification requirements.

We have estimated that there are between 3,000 and 4,000 small organic producers that will be exempt from certification. These producers would be required to comply with

requirement of the \$5,000 maximum sales volume exemption.

¹⁰ California State law requires organic farmers to register with the State. Certification is voluntary at the current time.

¹¹ Klonsky, Karen, and Laura Tourte. 1998. Statistical Review of California's Organic Agriculture, 1992–95. Report prepared for the California Department of Food and Agriculture Organic Program. Cooperative Extension, Department of Agricultural Economics, University of California, Davis.

the production and handling standards and labeling requirements set forth under the National Organic Program. We anticipate that this exemption will be used primarily by small market gardeners and hobbyists who sell produce and other agricultural products at farmers markets and roadside stands to consumers within their communities. By being exempt from certification, the current certification costs (table 2) estimated at an average \$416 for the first year and an average \$370 for subsequent years have been eliminated.

Exempt producers will be allowed to market their products as organically produced without being certified by a certifying agent. Products marketed by exempt producers cannot be represented as certified organic or display the USDA organic seal. Products produced or handled on an exempt operation may be identified as organic ingredients in a multiingredient product produced by the exempt operation, but they may not be identified as organic in a product processed by others. These limitations may discourage some small producers from seeking exemption, who instead may choose to become certified. In this case, the costs of certification would apply. The value associated with having organic certification may outweigh the costs of certification.

Those currently receiving voluntary certification will likely see a modest increase as the certifying agent passes on its cost incurred under the National Organic Program. Those not currently receiving certification and producing over \$5,000 annually in organic products will be required to become certified, and they will incur the actual costs of certification.

We have estimated that there about 98 percent of the 1,250 organic handlers are small. A handling operation or a portion of a handling operation is exempt from certification requirements if it has annual gross sales of less than \$5,000; is a retail food establishment that handles organically produced agricultural products but does not process them; handles agricultural products that contain less than 50 percent organic ingredients by weight of finished product; or does not use the word, "organic," on any package panel other than the information panel if the agricultural product contains at least 50 percent organic ingredients by weight of finished product. A handling operation or specific portion of a handling operation is excluded from certification if it handles packaged certified organic products that were enclosed in their packages or containers prior to being acquired and remain in the same package and are not otherwise processed by the handler, or it is a retail food establishment that processes or prepares on its own premises raw and ready-to-eat food from certified organic products. Otherwise, to be certified organic, handlers must pay for certification fees estimated at \$1,800 per year and fulfill recordkeeping requirements.

In order to identify handlers that might be expected to face more significant impacts as a result of this proposal, we attempted to analyze handlers' revenue from organic sales. Sales data indicate that gross sales of organic

production total less than \$500,000 per firm for most certified handlers. Information from the California DHS, where State law requires organic processors to register, gives some indication of the size distribution. Of the 208 processors registered with the State in 1995, 80 firms (38 percent) reported gross sales of \$50,000 or less, and 50 firms (24 percent) had gross sales exceeding \$500,000. In mid-September 1999, 376 processors were registered with the State, with 107 firms (28 percent) reporting gross sales of \$50,000 or less and 112 firms (30 percent) reporting gross sales exceeding \$500,000. We use this California information to estimate that 25 to 30 percent of handlers have gross sales of \$50,000 or less and could be significantly impacted by this proposal. Information needed to estimate the number of exempt or excluded handlers is not available.

Some States, such as Texas and Washington, charge producers and handlers nominal fees for certification, and it is possible that more States might provide certification services as the National Organic Program is implemented. Other States, such as Minnesota, have cost-share programs to help offset costs for organic producers.

Projected Reporting, Recordkeeping, and Other Compliance Requirements for Producers and Handlers

In addition to the fees for certification, the regulation will impose administrative costs on producers and handlers for reporting, recordkeeping, residue testing, and other compliance requirements. The actual amount of the additional administrative costs that would be imposed by the final rule is expected to be different for those entities that would begin their activities only after the national program is implemented. Producers and handlers who currently are active in the organic industry already perform most of these administrative functions; therefore, the additional costs to them would depend upon the extent to which their current practices are different from the requirements of the final regulation. Projected reporting, recordkeeping, and other compliance requirements of certifying agents are discussed in greater detail in the PRA and the RIA.

Federal Rules

No other burdens are expected to fall upon the organic industry as a result of overlapping Federal rules. This proposed regulation would not duplicate, overlap or conflict with any existing Federal rules. In preparing this proposed regulation, AMS consulted other Federal agencies such as the Food and Drug Administration (FDA), the Environmental Protection Agency (EPA), the Bureau of Alcohol, Tobacco and Firearms (ATF), and the USDA's Food Safety and Inspection Service (FSIS) to ensure that this proposed regulation would complement existing regulations.

Alternatives to This Proposal

We believe that our proposed regulation could have a significant impact on a substantial number of small businesses. However, we have considered several options with the intention of mitigating negative economic impacts of the fees. We did not

consider alternatives, beyond the previously discussed exemptions, that would mitigate the indirect costs of this rule on small entities. The following options were considered by AMS prior to and during the development of this proposal:

Option 1: First Proposal Issued December 1997

The first proposal suggested a fee for direct services model which combined a fixed fee for all farmers, handlers, and certifying agents, with a variable fee for certain direct services provided by AMS in the accreditation of certifying agents.

Table 1 includes estimated direct costs of accreditation and certification for the first proposal and this proposal; the fees in this proposal are discussed in prior sections of this RFA. The fee provisions in this proposal have been changed significantly, due in large part to comments received regarding the first proposal.

In overall design, the first proposal is similar to this proposal. USDA would accredit certifying agents who would in turn certify producers and handlers. USDA proposed to charge certifying agents a \$640 application fee, costs for a site evaluation fee that were estimated at \$3,500, and a \$2,000 administrative fee. Producers would be charged a \$50 USDA fee in addition to the fees imposed by the certifying agent. Handlers would be charged a \$500 USDA fee on top of the certifying agent's fees. The fee structure was intended to recover the full costs of operating the National Organic Program, which was estimated at \$1 million annually. Producers with \$5,000 or less in annual gross sales of agricultural products and handlers with annual gross sales of less than \$5,000 were exempt from certification as provided for in the OFPA.

The OFPA permitted but did not obligate USDA to charge fees. The first proposal sought to set fees to recover the full costs of the National Organic Program. Public comment generally stressed that the fees were too high. Most certifying agents have operated without third party accreditation. Thus, USDA fees were a substantial increase in the costs of doing business for most certifiers. For producers the direct fee of \$50 was a 12 percent increase over the estimated average fee paid for certification. For certifying agents the \$500 fee would have been a 53 percent increase over estimated average certification fees. To the extent the program raised certifying agent costs, these costs would have been passed through to producers and handlers. Commenters stated that many certifying agents had few clients and to pass through the estimated direct costs of accreditation (\$6,140) would make the costs of certification higher than producers could afford.

Comments were received opposing fee provisions in the first proposal. Most of these commenters expressed the belief that the proposed fees would price small farmers, handlers, and certifying agents out of the organic industry. Many commenters stated that the proposed fees favored large farming operations and suggested a sliding scale fee system, rather than the flat fee system discussed in the first proposal, to

accommodate the economic needs of small farmers, handlers, and certifying agents. Most suggested that small farmers and processors be exempt from the payment of fees. A more comprehensive review of the comments appears in subpart G entitled "Administrative" of this proposal.

Additional comments were received that specifically referred to the section entitled "Regulatory Flexibility Act and Effects on Small Businesses" in the first proposal. Most of these commenters expressed the belief that costs were understated and benefits were overstated. Commenters thought the proposed fees were excessive, unacceptable, and burdensome and would price many small farmers, handlers, and certifying agents out of the organic industry. Some thought that this appeared to be the actual intent of the first proposal. They also supported a sliding scale fee system, rather than the flat fee system originally proposed. Some stated that the \$5,000 exemption level was much too low. Producers objected to having to pay the certification and inspection fees prior to knowing whether they would actually set a crop, if the crop would grow, or what percentage of the crop might be harvested.

Compared to this proposal, the first proposal would have been more costly to the organic industry in terms of direct costs for accreditation, and to producers and handlers in terms of direct fees and the costs which certifying agents would have attempted to pass through. However, the current proposal has not set fees at levels to recover all program costs and during an 18 month transition period will not require application fees or charge for hourly services. Costs that are not recovered through fees will be covered by appropriated funds, meaning that taxpayers at large will bear some of the costs of the proposed organic program. Thus, in terms of fees and other direct costs, the first proposal was more burdensome on the organic industry.

The first proposal also contained new information collection requirements, a description of those requirements, and an estimate of the annual economic burden on the organic industry. We received responses specifically referring to the information collection requirements of the first proposal. Among the comments made were that the requirements would be unaffordable by small businesses and that paperwork requirements should be kept small, simple, and to a bare minimum, especially for small producers.

Recordkeeping requirements for certifying agents in the first proposal that required certifying agents to maintain all records concerning their activities for 10 years have been changed to reduce the burden. Commenters expressed concern that this requirement was excessive and unnecessary. We agree and are instead proposing that there be three categories of records with retention periods: (1) Records created by certifying agents regarding applicants for certification and certified operations to be maintained 10 years, consistent with OFPA requirement for maintaining all records concerning activities of certifying agents; (2) records obtained from applicants for certification and certified operations to be maintained 5 years, the same as OFPA requirement for the retention of

records by certified operations; and (3) other records created or received by certifying agents to be maintained for five years.

Option 2: Fee per Certification Model

A fee per certification model was considered but not used. This model would have based accreditation fees on the numbers of farmers and handlers certified. Specifically, certifying agents would pay a fee to USDA for each certification performed. The smallest one-half of certifying agents, who certify about 10 percent of organic operations, would pay about 10 percent of the estimated costs associated with accreditation. The largest 10 percent of certifying agents, who certify about 45 percent of organic operations, would pay about 45 percent of accreditation costs. The remaining 40 percent of certifying agents in the middle would pay 45 percent of the costs. The fee per certification would be fixed, regardless of the size of the operation being certified. This feature has the potential to create a barrier to market access for the smaller operations. Certifying agents who charge farmers and handlers for certification based on size and scope of the operation would maximize their profits by certifying only the larger farmers and handlers from whom they would realize a higher return. If certifying agents were to discriminate in this manner in favor of larger operations, smaller farmers and handlers would find the certification services available to them to be relatively limited and possibly more expensive than under the fee for direct services model that includes a variable fee for site visits. A fixed fee per certification also would not take into account, in the distribution of costs, the large difference in size between processors and primary producers. Processors are generally much larger than primary producers in terms of both total output and total revenue.

Option 3: Exemption of Small Certifying Agents From Accreditation

Small certifying agents (those with annual revenues of \$25,000 or less) may not have the resources to meet all of the requirements of the rule, such as accreditation fees, administrative and personnel requirements, and conflict of interest restrictions, based on their current structure and revenues. Therefore, exempting the smallest certifying agents from the accreditation requirement, similar to small producers being exempt from certification requirements, could mitigate any potential adverse impact of the rule on this group. This option, however, would require a legislative amendment to the OFPA.

The exemption of the smaller certifying agents from accreditation would carry with it many of the limitations resulting from the absence of Federal oversight. International trade would likely be limited to products certified by accredited certifying agents. Protecting domestic consumers from inappropriate organic claims on the labels of products certified by exempt certifying agents would likely lead to greater confusion over labels in the marketplace. Federal enforcement agencies such as the FDA, the ATF, and FSIS might wish to distinguish accredited certifying agents from those

certifying agents who are exempt, perhaps by requiring accredited certifying agents' clients to include the USDA seal on their product labels.

One of the purposes of the OFPA described in the statute is to assure consumers that organically produced products meet a consistent standard. Without Federal oversight of certifying agents, it would be difficult to ensure that one national standard of production and handling for agricultural products would be employed. The result could be the continuation of reciprocity agreements between small, exempt certifying agents and large accredited ones. This could result in a cost for small entities, while providing less benefit to certified producers and handlers than would be provided them by accreditation of all certifying agents.

We request comments from all interested parties, particularly small businesses, as to whether a small certifier exemption would be beneficial or practical given the constraints explained in this option.

Option 4: This Proposal

The new proposal includes provisions that will mitigate the impact of the National Organic Program, especially for small businesses. Fixed administration fees for producers, handlers and certification agents have been eliminated. The fixed application fee for accreditation also has been eliminated. This will positively affect small producers and handlers because fixed fees expend a larger percentage of a smaller operation's total revenue.

As indicated earlier in this discussion, certifying agent evaluation fees would reflect actual costs for the time and travel required to do the evaluation. It is anticipated that smaller certification agents would benefit because they are small and less complex than larger certification agents. The proposed accreditation costs would be proportional to the actual time required to perform the service. Several small operations could be grouped by area to reduce travel expenses of the evaluators.

The new labeling requirements that allow the use of a certification agent's seal on the principal display panel and on the information panel of processed product labels also may benefit small operations. Certification agents that have an established consumer base may benefit by displaying their identifying seal. Small certification agents, whose clients more likely produce ingredients for processed products, could also be identified and thus share in this benefit. Certification agents also may wish to expand their operation by offering verification of truthful labeling claims which will be allowed under this proposal.

This proposal has three elements of flexibility that are advantageous to small entities: performance-based production and handling standards and certifying agent requirements; production and handling standards that contain a range of allowable practices; and temporary variances.

The standards in this proposal are performance standards based on the results of a management system, rather than prescriptive or design standards that prescribe specific technology or a precise

procedure for compliance. Performance standards allow for flexibility in compliance, which is especially important to organic farmers, handlers and certifying agents with limited resources. Performance standards promote innovation and the development of new technologies which would help the industry as a whole be more efficient. Finally, they provide a less costly means of compliance than design standards. Small entities, in particular, benefit because compliance with performance standards allows for the adaptation of existing systems without costly capital investment.

This proposal allows for flexibility by providing a range of production and handling practices that can be used to maintain the organic integrity of the operation. The use of an allowed practice or substance must be described in the organic plan as a record for consideration by the certifying agent during a certification review. The proposal provides temporary variances in the case of natural disasters, damage from wind, floods and the like, and for research trials. The benefit of variances is that a producer or handler would not lose its investment in an organic operation because of certain conditions that are beyond the producer or handler's control. Variances also enhance performance standards by allowing additional innovation and experimentation. This is especially important to producers and handlers who depend on the organic price premium.

Conclusion

USDA has identified the entities that may be affected by this proposal and has analyzed the anticipated impacts of the proposal on them based on our knowledge of the industry and limited data. We have drawn on industry studies, including studies completed since the first proposal was published in 1997, as well as information provided in comments on the first proposal. However, we lack data to thoroughly and quantitatively describe the existing organic industry and quantitatively analyze the effects of this proposal.

Whether using SBA's small business size standards by SIC or the alternative definitions created for this analysis, we believe that this proposal could have a significant impact on a substantial number of small businesses. Even with the flexibility proposed in the regulation and the expanded market opportunities brought about by implementation of the National Organic Program, some small certifying agents may choose not to become accredited to provide certifying services, and some small producers and handlers may choose not to continue being certified organic because the proposed fees would be passed down to them as certification fees. We invite comments about the expected benefits and costs to small entities as presented in this analysis. Specifically, we invite comments regarding the impact of the proposed National Organic Program on small certifying agents, producers, and handlers so that we might uncover potential unintended negative impacts on small entities.

The proposed structure of user fees outlined in this proposal attempts to minimize the burden of administrative costs which will be assumed by small-scale

organic certifying agents and the producers and handlers who use these certification services. Certifying agents already performing organic certification services in a State or private capacity on the date that the proposed national accreditation program for organic certification is implemented will not be required to pay the administrative costs of applying for initial national accreditation status; the administrative costs involved in evaluating the accreditation status of these agents will be absorbed by a portion of the National Organic Program operating budget appropriated by Congress. They will be required to pay travel expenses for the reviewers. New applicants seeking national accreditation for organic certification services will be charged a fee to cover the administrative costs of evaluating their suitability for accreditation, their application fees will be structured to reflect the actual hourly costs of having an AMS evaluator conduct a site visit (including travel time to and from the evaluator's duty station and per diem travel expenses). The departures from the first proposal—which would have imposed a uniform flat fee on all applicants for national accreditation—along with the adoption of an application fee structure which attempts to relate the imposition of fees to the actual costs involved in administering the national accreditation program, should contribute to a less burdensome and more equitable distribution of administrative costs across all segments of the organic industry.

Appendix D—Paperwork Reduction Act of 1995

The Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3506 and 3507) is designed to minimize the burden of reporting and recordkeeping (information collection requirements) required by Federal regulations on individuals, businesses, other private institutions, and State and local governments. The burden is an estimate of the amount of time and the cost required of program participants to fulfill the information collection requirements.

Information collection requirements must have Office of Management and Budget (OMB) review and approval before they can become effective. They must also be made available for public comment, and the comments become part of the public record. This notice requests comments on the proposed information collection requirements of this proposal.

Title: National Organic Program.

OMB Number: New collection.

Expiration Date of Approval: Three years from date of approval.

Type of Request: New.

Abstract: The Organic Foods Production Act (OFPA) of 1990 mandates that the Secretary develop a National Organic Program (NOP) to accredit eligible State program's governing State officials or private persons as certifying agents who would certify producers or handlers of agricultural products that have been produced using organic methods as provided for in the OFPA. This regulation is proposed: (1) To establish national standards governing the marketing of certain agricultural products as

organically produced products; (2) to assure consumers that organically produced products meet a consistent standard; and (3) to facilitate interstate commerce in fresh and processed food that is organically produced.

The OFPA was requested by the organic community because of problems encountered in the marketing of organic products. First, there was fraudulent use of the term, "organic," resulting in the mislabeling of products, caused in part because many consumers are willing to pay premium prices for organic foods. Second, there was a lack of uniformity in standards defining organic production, causing trade disruption and confusion among buyers, sellers, and users of organic products. Third, there was constraint on market growth due to the prohibition on labeling meat and poultry products as organic. After implementation of the NOP, any agricultural product labeled "organic" will have to be from a production or handling operation that is certified by a certifying agent who is accredited by the U.S. Department of Agriculture (USDA).

A proposed rule to implement the OFPA was published in December 1997. It contained information collection requirements, an estimate of the annual economic burden on the organic industry, and a request for comments about the burden. A few general comments were received about the burden and they were considered when this proposal was prepared. Also taken into account was other information about existing industry practices and documents, the Initial Regulatory Flexibility Analysis that is discussed in the section entitled "Regulatory Flexibility Act and the Effects on Small Businesses," and the Regulatory Impact Assessment (RIA) that is discussed in the section entitled "Executive Order 12866." The numbers of entities affected by this proposal are estimated in the RIA. The RIA is attached as an appendix to this proposal.

Reporting and recordkeeping are essential to the integrity of the organic certification system. They create a paper trail that is a critical element in carrying out the mandate of the OFPA. They serve the Agency mission, program objectives, and management needs by providing information on the efficiency and effectiveness of the program. The information affects decisions because it is the basis for evaluating compliance with the OFPA and the regulations, for administering the program, for management decisions and planning, and for establishing the cost of the program. It supports administrative and regulatory actions in response to noncompliance with the OFPA and the regulations.

In general, the information collected will be used by USDA, State program's governing State officials, and certifying agents. It will be created and submitted by State and foreign program officials, peer review panel members, accredited certifying agents, organic inspectors, certified organic producers and handlers, those seeking accreditation or certification, and parties interested in changing the National List. Additionally, it will necessitate that all of these entities have procedures and space for recordkeeping.

The burden on each entity is discussed below. One major estimate made about each entity is the number of entities likely to participate in the NOP. The information collection burden attempts to incorporate the burden that will be in addition to the burden that current organic marketers have with the burden required of new entrants into the field.

USDA. USDA will be the accrediting authority. USDA will accredit domestic and foreign certifying agents who will certify domestic and foreign organic producers and handlers, using information from the agents documenting their business operations and program expertise. USDA will also permit State program's governing State officials to establish their own organic certification programs after the programs are approved by the Secretary, using information from the States documenting their ability to operate such programs and showing that such programs meet the requirements of the OFPA and the regulations.

States. State program's governing State officials may operate their own organic certification programs. State officials will obtain the Secretary's approval of their programs by submitting information to USDA documenting their ability to operate such programs and showing that such programs meet the requirements of the OFPA and the regulations. More than half of the States currently have some standards governing the production, handling, or labeling of organic food and 13 States have organic certifying programs. These programs require reporting and recordkeeping burdens similar to those required by the NOP. It is unknown at this time how many States, if any, will establish their own organic certification programs pursuant to the OFPA and the regulations. *Estimates:* 13 States will operate their own certification programs. The annual burden for each State will be an average of 52,308 hours or if calculated at a rate of \$27 per hour, (rounded up to the next dollar), it would be \$1,413.

Peer review panels. Panels will assist the Agricultural Marketing Service (AMS) Administrator in evaluating applicants for accreditation as certifying agents. Individuals will apply to USDA for membership in a pool from which the panels are selected, submitting to USDA information documenting their qualifications to conduct such reviews. This will be a new burden for those serving on the panels. *Estimates:* 40 people will participate in peer review panels. The annual burden for each panel member will be an average of 10 hours or if calculated at and \$27 per hour, it would be \$270.

Certifying agents. Certifying agents may be State program's governing State officials, private entities, or foreign entities who are accredited by USDA to certify domestic and foreign producers and handlers as organic in accordance with the OFPA and the regulations. Each entity wanting to be an agent will seek accreditation from USDA, submitting information documenting its business operations and program expertise. Accredited agents will determine if a producer or handler meets organic requirements, using detailed information from the operation documenting its specific

practices and on-site inspection reports from organic inspectors. *Estimates:* 59 entities are expected to apply for certification (13 State programs, 36 private entities, 10 foreign entities). The annual burden for each State program will be an average of 695,428 hours or if calculated at \$18,778. The annual burden for each private or foreign entity will be 699,678 hours or \$27 per hour (rounded up to the next dollar) it would be \$18,893.

Administrative costs for reporting, disclosure of information, and recordkeeping are expected to vary among certifying agents. Entities which begin their activities only after the national program is implemented would be expected to incur the greatest cost as they set up an operation that conforms to the OFPA and the regulations. For agents who are currently active in the organic industry, follow ISO guidelines, and already perform many of these administrative functions, costs will vary depending upon the extent to which their current practices are different from requirements in the OFPA and the regulations. Agents will be expected to provide the public with information concerning their clients. Efforts were made to incorporate existing industry practices and documents into this proposal. A list of several proposed administrative requirements and the probable resources required for compliance is included in the Regulatory Impact Assessment.

When an entity applies for accreditation as a certifying agent, it must provide a copy of its procedures for complying with recordkeeping requirements (§ 205.504(b)(3)). Once certified, agents will have to make their records available for inspection and copying by authorized representatives of the Secretary (§ 205.501(a)(9)). USDA will charge certifying agents for the time required to do these document reviews. Audits will require less time if the documents are well organized and centrally located, than if they are in disarray and in several locations. Certifying agents will have control over these conditions, but making documents accessible to the public may bring about a substantial change in the way some agents currently operate.

Recordkeeping requirements for certifying agents in the first proposal were changed to reduce the burden. They required certifying agents to maintain all records concerning their activities for 10 years. Commenters expressed concern that this requirement was excessive and unnecessary. We agree and are instead proposing three categories of records with varying retention periods: (1) records created by certifying agents regarding applicants for certification and certified operations, maintain 10 years, consistent with OFPA's requirement for maintaining all records concerning activities of certifying agents; (2) records obtained from applicants for certification and certified operations, maintain 5 years, the same as OFPA's requirement for the retention of records by certified operations; and (3) records created or received by certifying agents regarding accreditation, maintain 5 years, consistent with OFPA's requirement for renewal of agent's accreditation (§ 205.510(b)).

Residue testing requirements in the first proposal were changed to reduce the burden. They required certifying agents to undertake

residue testing every 5 years to determine if products from certified operations contained a detectable residue level of a prohibited substance and to report such findings to appropriate authorities. Commenters expressed concern that the requirement was too costly. We agree and are instead proposing that the State program's governing State officials or certifying agents may conduct testing at their own expense only if they suspect a crop has come into contact with a prohibited substance. Test results must be submitted to the Administrator (§ 205.672(b)).

Organic inspectors. Inspectors will conduct on-site inspections for the certifying agents of each applicant for certification and annually of each certified operation. They will determine whether or not certification should continue and will report this finding to the certifying agent. Inspectors will be the agents themselves, employees of the agents, or individual contractors. We estimate that about half will be certifying agents and their employees and half will be individual contractors. Individuals who apply for positions as inspectors will submit to the agents information documenting their qualifications to conduct such inspections. *Estimates:* 293 inspectors (147 certifying agents and their employees, 146 individual contractors) will be used. The annual burden for each inspector will be an average of 48,304 hours or if calculated at \$27 per hour (rounded up to the next dollar), it would be \$1,305.

Producers and handlers. Producers and handlers, domestic and foreign, will apply to certifying agents for organic certification, to renew their certification, or to report changes in their practices, submitting to the agents detailed information documenting their specific practices. Producers include farmers, livestock and poultry producers, and wild crop harvesters. Handlers include those who transport or transform food and may include millers, bulk distributors, food manufacturers, processors, repackagers, or packers. Some handlers may be part of a retail operation that processes organic products in a location other than the premises of the retail outlet.

The OFPA requires certified operators to maintain their records for 5 years. *Estimates:* 19,300 total operators (14,153 certified and 5,147 exempt), including 17,150 producers (12,176 certified and 4,974 exempt) and 2,150 handlers (1,977 certified and 173 exempt). We do not have an estimate of the number of foreign producers and handlers that will apply for organic certification. The annual burden for each domestic operator will be: certified producer—average of 9,521 hours or if calculated at \$24 per hour, it would be \$229; certified handler—average of 49,521 hours or if calculated at \$24 per hour, it would be \$1,189; exempt/excluded operator—average of 0.5 hour or if calculated at \$24. per hour, it would be \$12.

The proposed regulation exempts certain operations from certification: (1) Producers and handlers whose gross agricultural income from organic sales totals \$5,000 or less annually; (2) handlers selling only agricultural products that contain less than 50 percent organic ingredients by total

weight of the finished product; (3) handlers that handle agricultural products that contain at least 50 percent organic ingredients and choose to use the word "organic" only on the information panel of a packaged product; and (4) handlers that are retail food establishments that handler organic food but do not process it. The proposed regulation also excludes certain operations from certification: (1) Handlers selling only agricultural products labeled as organic or made with organic ingredients that are enclosed in a container prior to being received, remain in the same container, and are not otherwise processed while in the control of the operation; and (2) handlers that are retail food establishments that process or prepare, on the premises, raw and ready-to-eat food from organic agricultural products.

Administrative costs for reporting and recordkeeping are expected to vary among certified operators. Entities which begin their activities only after the national program is implemented would be expected to incur the greatest cost as they set up an operation that conforms to the OFPA and the regulations. For operators who are currently active in the organic industry and already perform many

of these administrative functions, costs would vary depending upon the extent to which their current practices are different from requirements in the OFPA and the regulations. Efforts were made to incorporate existing industry practices and documents into this proposal. A list of several proposed administrative requirements and the probable resources required for compliance is included in the Regulatory Impact Assessment.

Research studies have indicated that operations using product labels containing the term "organic" handle an average of 19.5 labels annually, that there are about 16,000 products with the term organic on the label, and that the number of such products increased by 250 annually from 1994 through 1996. We estimate that by the year 2001, 17,000 products will be marketed with the term "organic" on the label. This proposal includes an estimate of the time needed to develop labels for products sold, labeled, or represented as "100 percent organic," "organic," "made with organic (specified ingredients)," or which use the term organic to modify an ingredient in the ingredients statement. Also included is the time spent

deciding about use of the USDA seal, a State emblem, or the seal, logo, or other identifying marks of a private certifying agent (§ 205.300–§ 205.310). Because the labeling requirements in this proposal are in addition to FDA and FSIS requirements, the burden measurement does not include the hours necessary to develop the entire label. For purposes of calculating the burden, it was estimated that each handler will develop 20 labels annually.

Interested parties. Any interested party may petition the NOSB for the purpose of having a substance evaluated for recommendation to the Secretary for inclusion on or deletion from the National List. *Estimates:* 25 interested parties may petition the NOSB. The annual burden for each interested party will be an average of 104 hours and \$2,496 (\$24 per hour).

Cost. The following table shows the salary rates used to calculate the cost of the burden. We believe the increased rates for this proposal over the first proposal are more realistic in terms of the responsibilities and requirements of each entity.

Estimated hourly rates	First proposal	This proposal
Certified and exempt operators, interested parties	\$10	\$24
State program's governing State officials, peer review panel members, certifying agents, organic inspectors	20	27

Annual Reporting and Recordkeeping Burden:

Estimated Number of Respondents: 19,730.

Total Annual Hours: 269,622.

Total Cost: \$6,780,348.

Comments. Comments are requested on these proposed information collection requirements. Comments are specifically invited on: (1) Whether the proposed collection of information is necessary for the proper performance of the functions of USDA, including whether the information would have practical utility; (2) the accuracy of USDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on those who are to respond, including the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

Comments should be submitted by the date stated in the section entitled **DATES** at the beginning of this proposal. However, they should be sent to (1) Office of Management and Budget, New Executive Office Building, 725 17th Street, NW, Room 725, Washington, D. C. 20503, Attention: Desk Officer, and to (2) Clearance Officer, USDA–OCIO, Room 404W, Jamie Whitten Building, STOP 7602, 1400 Independence Avenue, SW, Washington, D.C. 20250–7602. Additionally, comments may be sent by fax to (202) 690–4632 or submitted via the Internet through the National Organic Program's homepage at <http://www.ams.usda.gov/nop>.

Appendix E.—Executive Order 12988, Civil Justice Reform

Executive Order 12988, Civil Justice Reform, instructs each executive agency to adhere to certain requirements in the development of new and revised regulations in order to avoid unduly burdening the court system. The first proposal was reviewed under this Executive Order. No comments were received on that review and no additional related information has been obtained since then. This rule is not intended to have retroactive effect.

States and local jurisdictions are preempted under section 2115 of the OFPA (7 U.S.C. 6514) from creating programs of accreditation for private persons or State officials who want to become certifying agents of organic farms or handling operations. A governing State official would have to apply to the USDA to be accredited as a certifying agent, as described in section 2115(b) of the OFPA (7 U.S.C. 6514(b)). States also are preempted under sections 2104 through 2108 of the OFPA (7 U.S.C. 6503 through 6507) from creating certification programs to certify organic farms or handling operations unless the State programs have been submitted to, and approved by, the Secretary as meeting the requirements of the OFPA.

Pursuant to section 2108(b)(2) of the OFPA (7 U.S.C. 6507(b)(2)), a State organic certification program may contain additional requirements for the production and handling of organically produced agricultural products that are produced in the State, and for the certification of organic farm and handling operations located within the State, under certain circumstances. Such additional

requirements must: (a) Further the purposes of the OFPA; (b) not be inconsistent with the OFPA; (c) not be discriminatory towards agricultural commodities organically produced in other States; and (d) not be effective until approved by the Secretary.

Pursuant to section 2120(f) of the OFPA (7 U.S.C. 6519(f)), this proposal would not alter the authority of the Secretary under the Federal Meat Inspection Act (21 U.S.C. 601 *et seq.*), the Poultry Products Inspections Act (21 U.S.C. 451 *et seq.*) or the Egg Products Inspection Act (21 U.S.C. 1031 *et seq.*), concerning meat, poultry, and egg products, nor any of the authorities of the Secretary of Health and Human Services under the Federal Food, Drug and Cosmetic Act (21 U.S.C. 301 *et seq.*), nor the authority of the Administrator of the Environmental Protection Agency (EPA) under the Federal Insecticide, Fungicide and Rodenticide Act (7 U.S.C. 136 *et seq.*).

Section 2121 of the OFPA (7 U.S.C. 6520) provides for the Secretary to establish an expedited administrative appeals procedure under which persons may appeal an action of the Secretary, the applicable governing State official, or a certifying agent under this title that adversely affects such person or is inconsistent with the organic certification program established under this title. The Act also provides that the U.S. District Court for the district in which a person is located has jurisdiction to review the Secretary's decision.

Appendix—Executive Order 13132, Federalism

This proposal has been reviewed under Executive Order 13132, Federalism. This

Order requires that regulations that have federalism implications provide a federalism impact statement that: (1) Demonstrates the Agency consulted with the State and local officials before developing the proposed regulation, (2) summarizes State concerns, (3) provides the Agency's position supporting the need for the regulation, and, (4) describes how the concerns of State officials have been met. The Order indicates that where National standards are required by Federal statutes, Agencies shall consult with appropriate State and local officials in developing those standards. Further, Agencies are required to interpret Federal statutes to preempt State law only where the statute contains an express preemption provision. In such a case, any regulatory preemption of State law shall be restricted to the minimum necessary to meet the objectives of the statute.

The Organic Foods Production Act (OFPA) of 1990 (7 U.S.C. 6514) establishes national standards regarding the marketing of agricultural products as organically produced, assures consumers that organically produced products meet a consistent standard, and facilitates interstate commerce in fresh and processed food that is organically produced. In carrying out these purposes, the Act contemplates a significant role for the States and, in fact, envisions a partnership between the States and the Federal Government in meeting the requirements of the Statute. The Act specifies the State role and gives States recognition for their activities in organic agriculture in several ways. First, 7 CFR 6507 provides that States may establish a State organic certification program consistent with the national program. Second, these programs may contain more restrictive requirements than the National Organic Program established by the Secretary of Agriculture. To be more restrictive, State Organic programs are required to: further the purposes of the Act, be consistent with the Act, not discriminate against organic products of another State, and be approved by the Secretary. Third, States can choose to be accredited as certifying agents under the Act and carry out a State organic program. Fourth, the Act allows the States to determine the manner in which they choose to be involved in the organic program. States may choose to carry out the requirements of the Act by establishing a State program and becoming accredited as certifying agents, they may establish a State program and utilize private certifying agents to implement the program, or they may choose to utilize the national organic program as implemented by the Secretary.

In recognition of their role in carrying out the provisions of OFPA, the Department has reached out to States and actively sought their input throughout the entire process of developing the proposed organic rule. The Department drew extensively on the organic expertise of States and the organic industry by working closely with the National Organic Standards Board. The National Organic Standards Board, established under Section 2119 of the OFPA (7 CFR 6518), has provided a broad and inclusive forum for public participation in developing the recommendations and concepts that

underpin the proposed organic rule. Section 2104(c) of the OFPA (7 CFR 6503(c)) requires the Secretary to consult with the National Organic Standards Board in developing the organic program and the National List set forth in Section 2118 of the OFPA (7 CFR 6517).

The Secretary has received extensive input from the Board, interested persons, and the States regarding the establishment of the National Organic Program and this reproposal. The Board met 12 times before publication of the proposed rule on December 16, 1997, and has met five times during 1998 and 1999. States were invited to attend each of these meetings, and official State certifier representatives participated in Board deliberations in meetings held in July 1998 and July 1999. Public input sessions were held at each meeting to gather information from all interested persons, including State and local jurisdictions.

Section 2110(g) of the OFPA (7 U.S.C. 6509(g)) requires the Secretary to hold public hearings to gather information to guide development of standards for livestock products. Four hearings were held during 1994 in Washington, D.C.; Rosemont, IL; Denver, CO; and, Sacramento, CA. States were invited to participate in each of these hearings.

National Organic Program staff also received comments and consulted with States at public events. They made presentations, received comments, and consulted with States at local and regional organic conferences and workshops and at national and international organic and natural food shows.

Further, States were provided the opportunity to comment specifically on State issues at a National Organic Certifiers meeting held on July 21, 1995, to discuss accreditation issues; a meeting held on February 26, 1996, to discuss the role of States in the National Organic Program; and a February 1999 State Certifiers meeting to discuss State issues. Further, States were consulted in training sessions held for organic inspectors, as well as numerous question and answer sessions at speaking engagements of the Agricultural Marketing Service Administrator, the National Organic Program Manager, and the staff.

On publication of the first proposal on December 16, 1997, an announcement and information packet summarizing the first proposal were sent to over 1,000 interested parties, including State governors and State department of agriculture secretaries, commissioners, or directors. Subsequent to publication of the first proposal, State and local jurisdictions had the opportunity to provide input at four listening sessions held in February–March 1998 on the first proposal in Austin, TX; Ames, IA; Seattle, WA; and New Brunswick, NJ.

Finally, States had the opportunity to comment on the first proposal. More than 275,000 comments were received on the first proposal, including State commenters.

Through this extensive outreach and consultation process, States identified a number of issues with the first proposal. States expressed several specific concerns regarding accreditation requirements as they

affect State programs. These issues are described below, along with the Department's response in the reproposal.

(1) Under OPFA 2108 (7 CFR 6507), States may establish additional standards, approved by the Secretary. First, State commenters objected to the provision in the first proposal that would have prohibited States from requiring compliance with these additional standards as a condition for use of the organically produced State logo on products within the borders of such State. We agree with the commenters, as we did not intend to prohibit States from requiring that these more restrictive standards be met as a requirement to the State's logo on organically produced products. Accordingly, this proposal will permit States with more restrictive requirements approved by the Secretary and private certifiers certifying production and handling operations within these States to require that the State's more restrictive standards be met in order to use the State logo.

(2) The first proposal required annual organic inspector performance appraisal and annual program evaluations for certifying agents. State commenters objected that these requirements would duplicate State requirements. We do not intend for States to develop dual performance appraisal and program evaluation systems because we believe that programs already conducted by the States will meet the requirements of this proposal. These programs would be expected to conform with good management practices appropriate to an organization's size and structure. The questioned provisions have not been changed, but this proposal has been revised to clarify that the annual program evaluation can be conducted by the certifying agency staff, an auditing entity, or a consultant with appropriate expertise.

(3) The first proposal set forth confidentiality requirements for certifying agents. Commenters stated that these confidentiality requirements might conflict with State requirements for "open records." While we recognize this potential for conflicting requirements, records collected under the National Organic Program would be subject to the requirements of the Act. Where the Act and State requirements conflict, the Act would take precedence. There is no change to the confidentiality provision.

To clarify that authorized representatives of the Secretary or the applicable State program's governing State official may act on their behalf and must be given access to the records, this proposal adds the phrase "and their authorized representatives."

(4) This proposal will require that accredited certifying agents accept certification decisions made by another USDA-accredited certifying agent as equivalent. State commenters said that States should be able to control which certifying agents operate within their State.

The first proposal provided that accredited certifying agents accept the certification decisions made by another USDA-accredited certifying agent as equivalent to their own. Commenters representing State programs said that States should be able to control which certifying agents operate within their

State. Several commenters asked whether States with more restrictive standards could challenge certification decisions made by other accredited certifying agents. Under the Act, no organic product may be produced or handled to organic standards lower than the standards of the National Organic Program. A State Government may not prevent the marketing or sale within a given State of organic product produced in another State according to this proposal. While States may, with the approval of the Secretary, set more restrictive standards than the national organic standards for product produced or handled within their State, these requirements do not apply to products produced or handled in another State.

State programs approved by the Secretary will be required to treat all accredited certifying agents equally, and accredited certifying agents in one State cannot refuse to recognize another State's product certified to national standards. Accordingly, the requirement remains unchanged that a certifying agent accept certification decisions by another USDA-accredited certifying agent as equivalent.

(5) The first proposal required all certifying agents to submit documents and information on personnel, administrative, and financial policies and procedures to demonstrate organic expertise and ability to implement the National Organic Program. States commented that State certifying agents should not be required to submit such information, stating that these requirements should not apply to States with established personnel, administrative, and financial procedures. They also indicated that the review should be limited to organic program administration only, not to agencywide policies and procedures. We recognize that States have established personnel, administrative, and financial procedures and that these procedures would apply to State certifying agents. However, a stated purpose of the Act is establishment of national standards. Such standards should extend to uniform requirements for State and private certifying agents unless otherwise provided in the Act. Further, such information is necessary for the Administrator to make a determination on approval of an application for accreditation. Accordingly, the requirements for demonstrating organic expertise and ability to implement the National Organic Program remain the same for private and State certifying agents.

(6) The first proposal required a certifying agent to provide a description of procedures to prevent conflicts of interest and the identification of any food or agriculture-related business interests of all personnel intended to be used in the certifying operation. Commenters stated that existing State policies should be sufficient to prevent conflicts of interest for a State certifying agent and that lists of the business interests of all inspectors, program staff, and their families are not necessary.

We agree that existing State policies should be sufficient to prevent conflicts of interest but disagree that lists of the business interests of all inspectors, program staff, and their families are unnecessary. The Act (CFR 6515(h)) places responsibility for the

prevention of conflicts of interest with the certifying agent. However, the Department is responsible for ensuring that the certifying agent complies with that responsibility. The requirement to provide such a listing provides the Administrator information essential to identifying conflicts of interest. In addition, a stated purpose of the Act is to establish uniform national standards. These uniform standards should extend to uniform conflict of interest requirements for State and private certifying agents. The commenters have said that most States already have established conflict of interest policies and procedures so that the required information should be easily available for submission to the Administrator. Accordingly, no change has been made in this proposal.

Certification, the process of qualifying a producer or handler to sell agricultural products labeled as organic, raised several issues for States.

(1) The first proposal required an applicant for certification to supply required documentation to provide information necessary to allow a certifying agent to evaluate the application. State commenters suggested a provision be added to allow a certifying agent to require documentation from applicants in addition to that required by the first proposal.

A certifying agent can, if necessary, follow up on an initial application with requests for additional information, provided that information is needed to evaluate the application and determine compliance with the Act and regulations. We did not make the suggested change, as the existing language already allows the certifying agent to request additional information necessary to determine compliance with the Act and regulations.

(2) The first proposal laid out a certification program that provided for updates to a continuous organic certification. To meet continuation of certification requirements, the first proposal required an on-site inspection after receipt of the update to the application. A State certifying agent objected, saying that an on-site inspection after receipt of a renewal application is not consistent with current practice. Currently, on-site inspections conducted during the prior year are used to determine compliance with certification requirements at the time of renewal, along with a review of information submitted by the certified operation. The State certifying agent stated that an additional inspection at renewal time would not be useful if it was not an appropriate time to observe the certified unit in operation.

We disagree with the commenters, since certifiers are required to schedule on-site inspections when the certified operation can be observed for its compliance or ability to comply with the provisions of the National Organic Program. The initial certification, therefore, should have been granted when the on-site inspection verified compliance with certification requirements. The certified operation should be fulfilling its annual continuation of certification at a time when it can demonstrate its compliance with the Act.

States commented on several compliance issues included in the first proposal.

(1) The Administrator had sole authority to suspend or revoke the accreditation of certifying agents in the first proposal. Commenters indicated that State program's governing State officials should have the authority to suspend or revoke the accreditation of private certifying agents.

We agree that in a State with a program approved by the Secretary, the State program's governing State official should be authorized to suspend or revoke an accreditation granted by the Secretary to certifying agents operating within the State. We concur because of the Department's role in providing oversight to the State program, including its enforcement procedures, and have made that change in this proposal.

(2) Many commenters stated that the first proposal lacked adequate enforcement provisions, including enforcement by States with an approved State program.

We agree with the commenters that additional enforcement provisions are necessary for the National Organic Program. The following changes have been made in this proposal.

(a) As noted above, the State program's governing State official will now be authorized to suspend or revoke accreditation granted by the Secretary to certifying agents operating in the State.

(b) An enforcement proceeding brought by a State program's governing State official against a certified operation or certifying agent shall be appealable pursuant to the appeal procedures of the State program with no subsequent appeal rights to the Secretary.

States commented on several fees provisions in the first proposal.

(1) The first proposal required that payment of fees and charges to the Department be by certified check or money order. State commenters objected, saying it was insulting for USDA to require a State government agency to pay for its accreditation with a certified check.

Accordingly, we have removed this requirement, simply requiring that payments for fees and other charges for accreditation must be made payable to the Agricultural Marketing Service.

(2) Several State agencies objected to the fee provisions in the first proposal, expressing the belief that the proposed fees would price small producers and handlers out of the organic industry. Some State agencies commented that those small organic producers conducting their own on-farm handling would be forced out of the organic industry by the excessive handler fee and reporting burdens.

After review of the comments, we acknowledge that the fees charged in the first proposal may have discouraged industry growth and may not have facilitated interstate commerce of organic product. We have thus, modified the fee structure to reduce costs to all organic sectors and have removed the requirement that provided for payment of fees to the Department by certified production and handling operations. Instead, the Department will charge certifying agents only for fees and charges related to accreditation, with the balance of the costs of the program to be funded through appropriations.

(3) Some State certifying agents commented that State certifying agents should not be assessed accreditation fees. They stated that most State certifying agents could face large accreditation costs because they have many county or regional offices which would be considered subsidiaries, adding that these costs would be passed on to producers and handlers or paid with supplemental State funds. A few State certifying agents asserted that USDA should pay the States because of the State's contribution to the national program. One

State representative said that accreditation fees for State certifying agents should be less than for private certifying agents, as State certifying agents should involve less AMS review and oversight.

We disagree with those commenters who say that State certifying agents should not be assessed accreditation charges, be charged less, or be paid to certify production and handling operations. These actions would constitute unacceptable preferential treatment of State certifying agents to the detriment of private certifying agents. This

proposal will assess State certifying agents the same fees for accreditation under the same fee structure as private certifying agents.

We invite States and local jurisdictions to comment on the issues raised in this Federalism impact statement. We also encourage States and local jurisdictions to review and comment on this proposal as it relates to the operation of State organic programs.

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