

PN-ADC-529

**Supporting
Egypt's
Processed
Foods
Export
Industry**

**Findings of a Phase II
Rapid Industry
Analysis (IRA)
Of Trade,
Market Trends
And
Opportunities in the
United States of
America**

**NATIONAL
ORGANIC
PROGRAM
Volume IV of IV**

**Prepared By
Agriculture-Led
Export
Businesses
(ALEB)**

March 2001

**Funded by the
U.S. Agency for
International
Development**

**USAID/Egypt
RP 0264
Under Contract No:
263-C-00-99-00011-00**

**USAID Cognizant
Technical Office:
USAID/Egypt/EG/ED
CTO: Mr. Tarek Shata**

**Researched and Written by
Hilton P. Settle
Charles J. Stathacos**

ALEB Short Term Technical Advisors

For Abt Associates Inc.

Under the Direction of

**Douglas A. Anderson, MBA - Director/Business Development Services
Manal Karim, Ph.D. - Co-Director/ Business Development Services**

**Formatted and Edited
By
Douglas A. Anderson**

Foreword

By

Hilton P. Settle and Douglas A. Anderson

U.S. Market for Natural and Organic Foods

On December 20, 2000, the USDA established the final ruling and standards regarding the new National Organic Program (NOP). In a press release, Secretary of Agriculture, Dan Glickman, stated, "This is the strongest and most comprehensive organic standard in the world. For consumers who want to buy organic foods, the standards ensure that they can be confident in knowing what they are buying. For farmers, these standards create clear guidelines on how to take advantage of the exploding demand for organic products. And for the organic industry, these standards provide an important marketing tool to help boost exports since trading partners will now deal with only one national standard rather than multiple state and private standards. I have said all along that we would create national organic standards that farmers, consumers and the organic industry will embrace, and I think we have done just that."

Essentially, the new organic standard offers a national definition for the term "organic." It details the methods, practices and substances that can be used in producing and handling organic crops and livestock, as well as processed products. It establishes clear organic labeling criteria, and specifically prohibits the use of genetic engineering methods, ionizing radiation, and sewage sludge for fertilization. All agricultural products labeled organic must originate from farms or handling operations certified by a state or private agency accredited by USDA.

The final USDA standard for the new National Organic Program includes several changes from the proposed rule issued in March 2000:

- For a product to be labeled "Made With Organic Ingredients", its ingredients must now be 70 percent organic, as opposed to the 50 percent minimum proposed in the March version of the rule. This change will be an important step in facilitating international trade, as the 70 percent threshold is consistent with the standard used in the European Union, our top organic export market.
- "Commercial availability provisions" have been added, which require handlers to use organic ingredients in organic products whenever possible. In other words, it's no longer enough for a product labeled "Organic" to have at least 95 percent organic ingredients. Now, on top of that, its remaining ingredients must also be organic, if that's possible given what's available in the marketplace.
- Handlers are now allowed to post their products' exact percentage of organic content on the primary display label. The idea here is that the ability to boast a specific number will encourage more folks to use more organic ingredients.

Consumers will begin to see new organic labeling on products in their local grocery stores by the summer of 2001, with full implementation by mid-2002.

This final rule establishes the National Organic Program (NOP or program) under the direction of the Agricultural Marketing Service (AMS), an arm of the United States Department of Agriculture (USDA). This national program will facilitate domestic and international marketing of fresh and processed food that is organically produced and assure consumers that such products meet consistent, uniform standards. This program establishes national standards for the production and handling of organically produced products, including a National List of substances approved for and prohibited from use in organic production and handling. This final rule establishes a national-level accreditation program to

November 1998 by the Organic Trade Association (OTA). The remaining 7 percent was divided between club/discount and foodservice outlets.

The aforementioned survey by OTA was its first-ever "Manufacturers Market Survey", and used data collected from 56 manufacturers of organic products. The study showed impressive double-digit progress in nearly every product category.

In addition, the healthy growth in this sector is prompting several large food corporations to introduce and heavily promote new organic food products. A recent example of this is the launch by General Mills of its new Sunrise Organic Cereal in March 1999, accompanied by its largest-ever sampling, advertising and marketing budget of \$15-20 million. This rising U.S. demand for organic foods was also reflected in numerous inquiries received from U.S. importers for various organic food products from Egypt.

This new National Organic Program (NOP) administered by USDA is also a marketing opportunity for Egyptian producers and exporters of certified organic foods. Our contacts with the U.S. trade have produced a strong interest in organic olives, olive oil, frozen vegetables, herbs and spices, and ALEB should provide assistance to Egyptian exporters in receiving the required certification in order to effectively promote their organic products in the U.S. market.

It is highly recommended that ALEB work with qualified Egyptian institution(s) to receive the appropriate accreditation of certifying agent(s) in Egypt. This would then enable these Egyptian producers and exporters to label and market their food products in the U.S. as organic products, as specified in the NOP standards and regulations. The full text of this new ruling and standards, including six (6) short 1-2 page AMS Fact Sheets summarizing key points of the new National Organic Program appear in this volume of the United States Industry Rapid Analysis. An Application for Accreditation to USDA's National Organic Program is also included as Appendix 10 in this publication (page 273).

TABLE of CONTENTS
Technical Appendix
(Volume IV)

Appendix	Heading	Page
1.	AMS Fact Sheet – National Organic Program Overview	1
2.	AMS Fact Sheet – Organic Production and Handling Standards	3
3.	AMS Fact Sheet – Certification	5
4.	AMS Fact Sheet – Certifying Agent Accreditation and Equivalency of Imported Products	7
5.	AMS Fact Sheet – Labeling and Marketing Information	9
6.	AMS Fact Sheet – State Organic Programs	11
7.	Final Ruling and Standards Regarding USDA's National Organic Program (NOP) Heading	13
	National Organic Program Overview	15
Subparts	Subpart A – Description & Clarification (Response to Hearings)	15
	Terms Defined	20
	Subpart B – Applicability	28
	Enforcement	40
	Subpart C – Organic Crop, Wild crop, Livestock & Handling Requirements (Description & Clarification)	43
	Subpart C – Organic Production & Handling Requirements (Enforcement)	75
	Subpart D – Labels, Labeling & Marketing (Description & Clarification)	84
	Categories of Organic Content	85
	100% Organic	86
	Organic	
	Made With Organic Content	
	Product With Less Than 70% Organic Ingredients	87
	Livestock Feed	
	Prohibited Practices	
Table 1	Prohibited Production & Handling Practices for Labeling Categories	88
	Labeling "100% Organic" & "Organic" Products	89
	Labeling Products "Made with Organic (specified ingredients or food group(s))"	90
	Labeling Products with Less Than 70% Organic Ingredients	91
Table 2	Labeling Consumer Product Packages	92
	Labeling of Products Shipped In International Markets	93
Subparts	Subpart D – Labels, Labeling & Market Information (Enforcement)	107
	Subpart E – Certification (General Requirements for Certification)	114

Appendix	Heading	Page
Subparts	Subpart G – Accreditation of Certifying Agents (Description & Clarification)	120
	Subpart G – Accreditation of Certifying Agents (Enforcement)	148
	Subpart G – Administrative The National List of Allowed & Prohibited Substances	158
	Subpart G – Administrative (Enforcement) State Organic Program	167 174
	Subpart G – Fees	181
	Compliance (Description & Clarification)	187
	Compliance (Enforcement)	200
	Subpart G – Inspection & Testing, Reporting & Exclusion from Sale	204
	Adverse Action Appeal Process (Description & Clarification)	217
	Adverse Action Appeal Process (Enforcement)	222
A	Regulatory Impact Assessment for Final Rule Implementing the Organic Foods Production Act of 1990	224
	References	249
Table 3	US Organic Product Sales 1990 – 1999	252
Table 4	First Year Certification Costs	253
Table 5	Subsequent Years Certification Costs	253
Table 6	Costs of Accreditation & Certification	255
Table 7	Estimated Annual Reporting & Recording Burden	256
B	Unfunded Mandates Reform Act	257
C	Final Regulatory Flexibility Analysis	258
D	Executive Order 12988, Civil Justice Reform	268
E	Executive Order 13132, Federalism	269
10.	Application for Accreditation to USDA's National Organic Program (NOP)	273

Appendix 1

AMS Fact Sheet

National Organic Program Overview

The Organic Foods Production Act (OFPA) of 1990, adopted as part of the 1990 Farm Bill, requires USDA to develop national standards for organically produced agricultural products to assure consumers that agricultural products marketed as organic meet consistent, uniform standards. The OFPA and the National Organic Program (NOP) require that agricultural products labeled as organic originate from farms or handling operations certified by a State or private agency that has been accredited by the U.S. Department of Agriculture (USDA).

The NOP is a marketing program housed within the USDA Agricultural Marketing Service, the agency that sets marketing standards. Neither the OFPA nor these final regulations address food safety or nutrition.

How the National Organic Program was developed

The OFPA requires USDA to develop national organic standards and establish an organic certification program based on recommendations of a 15-member National Organic Standards Board (NOSB).

In addition to NOSB recommendations, USDA reviewed State, private and foreign organic certification programs to help formulate these regulations. The final regulations are similar to most of the standards organic producers and handlers currently use, and are intended to be flexible enough to accommodate the wide range of operations and products grown and raised in every region of the United States.

In December 1997, USDA published a proposed rule and received 275,603 public comments, explaining why and how the rule should be rewritten. A revised proposal was published in March 2000. An additional 40,774 comments were received, many of which were incorporated into the final rule.

What's in the final rule?

The final regulation prohibits the use of genetic engineering (included in excluded methods), ionizing radiation, and sewage sludge. The rule includes the following:

Production and handling requirements, which address organic crop production, wild crop harvesting, organic livestock management, and processing and handling of organic agricultural products. The National List of Allowed Synthetic and Prohibited Non-Synthetic Substances is also included. Labeling requirements for organic products, along with compliance, testing, fee, and State program approval requirements, including certification and record keeping requirements, accreditation requirements for receiving and maintaining accreditation, as well as requirements for foreign accreditation. Other administrative functions of the NOP, which include evaluation of foreign organic certification programs, are also included.

What's changed in the final regulation?

- We increased the minimum percentage of organic ingredients in products labeled "Made with Organic Ingredients" from 50 percent to 70 percent.
- We adopted 5 percent of the Environmental Protection Agency's pesticide residue tolerance as the pesticide residue compliance threshold.
- We allowed wine containing sulfites to be labeled "Made with Organic Grapes."

- We adjusted the organic feed requirements for dairy herds when a producer converts the entire herd to organic production as a single, one-time event.
- We minimized the burden on small farmers through a change in the composting standards.
- We redesigned the USDA Organic Seal to minimize consumer confusion.
- We made clear that use of ionizing radiation, sewage sludge, and excluded methods are prohibited throughout organic production and handling. The rule does allow one potential exception for use of animal vaccines produced using excluded methods, but only if they are first specifically recommended by the NOSB and approved by the Secretary, subject to notice and comment rulemaking.
- We established a peer review process, which will annually evaluate the NOP's accreditation decisions and adherence to accreditation procedures.
- We added commercial availability provisions that require handlers to use organic ingredients in "organic" products whenever possible.
- We established new requirements for the labeling of organic livestock feed products.
- We allowed handlers to designate on the principal display panel the exact percentage of organic content of their product.

This final rule becomes effective 60 days after its publication in the Federal Register and will be fully implemented 18 months after its effective date. Eighteen months after the effective date, all agricultural products that are sold, labeled, or represented as organic must be in compliance with these regulations. The USDA Seal may not be affixed to any "100 percent organic," or "organic," product until 18 months after the final rule's effective date. Farms and handling operations that sell less than \$5,000 annually of organic agricultural products are exempt from certification. These producers and handlers, while exempt from certification and the preparation of an organic plan, must comply with all other national standards for organic products and may label their products as organic.

December 2000

Appendix 2

AMS Fact Sheet

Organic Production and Handling Standards

The National Organic Program (NOP) final rule contains regulations that will ensure that organically labeled products meet consistent national standards.

What agricultural operations are affected by the standards?

Any farm, wild crop harvesting, or handling operation that wants to sell an agricultural product as organically produced must adhere to the national organic standards. Handling operations include processors, manufacturers, and repackers of organic products. These requirements include operating under an organic system plan approved by an accredited certifying agent and using materials in accordance with the National List of Allowed Synthetic and Prohibited Non-Synthetic Substances. Operations that sell less than \$5,000 a year in organic agricultural products are exempted from certification and preparing an organic system plan, but they must operate in compliance with these regulations and may label products as organic. Retail food establishments that sell organically produced agricultural products but do not process them are also exempt from certification.

Standards apply to production process

The national organic standards address the methods, practices, and substances used in producing and handling crops, livestock, and processed agricultural products. The requirements apply to the way the product is created, not to measurable properties of the product itself. Although specific practices and materials used by organic operations may vary, the standards require every aspect of organic production and handling to comply with the provisions of the Organic Foods Production Act (OFPA). Organically produced food cannot be produced using excluded methods, sewage sludge, or ionizing radiation.

Crop standards

The organic crop production standards say that:

Land will have no prohibited substances applied to it for at least 3 years before the harvest of an organic crop. The use of genetic engineering (included in excluded methods), ionizing radiation and sewage sludge is prohibited. Soil fertility and crop nutrients will be managed through tillage and cultivation practices, crop rotations, and cover crops, supplemented with animal and crop waste materials and allowed synthetic materials.

Preference will be given to the use of organic seeds and other planting stock, but a farmer may use non-organic seeds and planting stock under specified conditions. Crop pests, weeds, and diseases will be controlled primarily through management practices including physical, mechanical, and biological controls. When these practices are not sufficient, a biological, botanical, or synthetic substance approved for use on the National List may be used.

Livestock standards

These standards apply to animals used for meat, milk, eggs, and other animal products represented as organically produced.

The livestock standards say that:

Animals for slaughter must be raised under organic management from the last third of gestation, or no later than the second day of life for poultry. Producers are required to feed livestock agricultural feed products that are 100 percent organic, but may also provide allowed vitamin and mineral supplements. Producers may convert an entire, distinct dairy herd to organic production by providing 80 percent organically produced feed for 9

months, followed by 3 months of 100 percent organically produced feed. Organically raised animals may not be given hormones to promote growth, or antibiotics for any reason. Preventive management practices, including the use of vaccines, will be used to keep animals healthy. Producers are prohibited from withholding treatment from a sick or injured animal; however, animals treated with a prohibited medication may not be sold as organic. All organically raised animals must have access to the outdoors, including access to pasture for ruminants. They may be temporarily confined only for reasons of health, safety, and the animal's stage of production, or to protect soil or water quality.

Handling standards

The handling standards say that:

All non-agricultural ingredients, whether synthetic or non-synthetic, must be included on the National List of Allowed Synthetic and Prohibited Non-Synthetic Substances. Handlers must prevent the commingling of organic with non-organic products and protect organic products from contact with prohibited substances. In a processed product labeled as "organic," all agricultural ingredients must be organically produced, unless the ingredient(s) is not commercially available in organic form.

December 2000

Appendix 3
AMS Fact Sheet
Certification

The U.S. Department of Agriculture (USDA) will accredit State, private, and foreign organizations or persons to become "certifying agents." Certifying agents will certify that production and handling practices meet the national standards.

Who needs to be certified?

Operations or portions of operations that produce or handle agricultural products that are intended to be sold, labeled, or represented as "100 percent organic," "organic," or "made with organic ingredients" or food group(s).

Who does NOT need to be certified?

1) Farms and handling operations that sell less than \$5,000 a year in organic agricultural products: although exempt from certification, these producers and handlers must abide by the national standards for organic products and may label their products as organic. 2) Handlers, including final retailers that do not process or repackage products; 3) Handlers that only handle products with less than 70 percent organic ingredients: a handling operation or portion of an operation that is a retail food establishment that processes or prepares, on the premises of the establishment, raw and ready-to-eat food labeled organic; 4) A handling operation that chooses to use the word organic only on the information panel; 5) A handling operation that handles products that are packaged or otherwise enclosed in a container prior to being received by the operation and remain in the same package.

How will farmers and handlers become certified?

An applicant will submit specific information to an accredited certifying agent. Information will include:

- Type of operation. History of substances applied to land for the previous 3 years. Organic products being grown, raised, or processed. Applicant's organic plan, which includes practices and substances used in production. The organic plan also must describe the monitoring practices to be performed to verify that the plan is effectively implemented, the record-keeping system, and the practices to prevent commingling of organic and non-organic products and to prevent contact of products with prohibited substances.
- Applicants for certification will have to keep accurate post-certification records for 5 years concerning the production, harvesting, and handling of agricultural products that are to be sold as organic.

These records should document that the operation is in compliance with the regulations and verify the information provided to the certifying agent. Access to these records must be provided to authorized representatives of USDA, including the certifying agent.

Inspection and certification process

Certifying agents will review applications for certification eligibility. A qualified inspector will conduct an on-site inspection of the applicant's operation. Inspections will be scheduled when the inspector can observe the practices used to produce or handle organic products and talk to someone knowledgeable about the operation.

The certifying agent will review the information submitted by the applicant and the inspector's report. If this information shows that the applicant is complying with the relevant standards and requirements, the certifying agent will grant certification and issue a certificate. Certification will remain in effect until terminated, either voluntarily or through the enforcement process.

Annual inspections will be conducted of each certified operation, and updates of information will be provided annually to the certifying agent in advance of conducting these inspections. Certifying agents must be notified by a producer immediately of any changes affecting an operation's compliance with the regulations, such as application of a prohibited pesticide to a field.

Compliance review and enforcement measures

The rule will permit USDA or the certifying agent to conduct unannounced inspections at any time to adequately enforce the regulations. The Organic Foods Production Act also requires that residue tests be performed to help in enforcement of the regulations. Certifying agents and USDA will conduct residue tests of organically produced products when there is reason to believe that they have been contaminated with prohibited substances. If any detectable residues are present an investigation will be conducted to determine their source.

December 2000

Appendix 4

AMS Fact Sheet

Certifying Agent Accreditation and Equivalency of Imported Products

The Organic Foods Production Act of 1990 (OFPA) directs the U.S. Department of Agriculture (USDA) to accredit certifying agents so they can certify that producers and handlers representing their products as organic have complied with USDA regulations.

USDA's accreditation program establishes requirements an applicant must meet in order to become an accredited organic certifying agent, and procedures and requirements to maintain accreditation. The program is designed to ensure that all organic certifying agents act consistently and impartially. There are nearly 50 private and State organic certification programs in the United States, some of which have existed for 20 years or more. Most are expected to apply for USDA accreditation.

Applicants for accreditation must:

- Employ personnel, including inspectors, who have sufficient experience and training in organic production and handling to carry out certification activities.
- Demonstrate their ability to certify organic producers and/or handlers; maintain proper records; adequately communicate with producers, handlers, and the public; and communicate with USDA about decisions made.
- Prevent conflicts of interest and maintain strict confidentiality.
- Applicants granted accreditation must conduct annual performance appraisals of their inspectors and other personnel involved in the certification process, and have an annual program evaluation of their certification activities.

Accreditation process

Certifying agents will apply for accreditation to the Administrator of the Agricultural Marketing Service. Applicants will sign and return a statement of agreement prepared by the Administrator. USDA will evaluate the application to ensure that the certifying agent can comply with the NOP requirements, including a site evaluation at the applicant's place of business. The site evaluator's report will be reviewed by USDA staff. A peer review panel will annually evaluate the NOP's accreditation decisions and adherence to accreditation procedures. Accreditation will be for 5 years. Applications for renewal of accreditation are due 6 months prior to expiration of the accreditation. Certifying agents will submit to USDA annual updates on their certification activities. USDA will conduct one or more site evaluations during the period of accreditation to determine compliance with the OFPA and NOP regulations.

Equivalency of imported products

The OFPA requires USDA to review the certification programs under which imported organic products are produced to ensure that they meet the requirements of the National Organic Program (NOP). Certifying agents operating in foreign countries may apply for USDA accreditation. Foreign applicants will be evaluated based on the same criteria as domestic certifying agents.

In lieu of USDA accreditation, a foreign certifying agent may:

- Receive recognition when USDA has determined, upon the request of a foreign government, that the foreign certifying agent's government authority is able to assess and accredit certifying agents as meeting the requirements of the NOP; or

- Receive recognition as meeting requirements equivalent to the requirements of the NOP under an equivalency agreement negotiated between the United States and the foreign government.

Once accreditation or recognition is granted, organic product produced under the oversight of the certifying agent or foreign government will be eligible to be imported into this country and labeled as organic.

December 2000

Appendix 5

AMS Fact Sheet

Labeling and Marketing Information

The Organic Foods Production Act and the National Organic Program (NOP) are intended to assure consumers that the organic foods they purchase are produced, processed, and certified to consistent national organic standards. The labeling requirements of the new program apply to raw, fresh products and processed foods that contain organic ingredients. Foods that are sold, labeled, or represented as organic will have to be produced and processed in accordance with the NOP standards.

Except for operations whose gross agricultural income from organic sales totals \$5,000 or less, farm and processing operations that grow and process organic foods must be certified by USDA-accredited certifying agents. A certified operation may label its products or ingredients as organic and may use the "USDA Organic" seal.

Labeling requirements are based on the percentage of organic ingredients in a product.

- Foods labeled "100 percent organic" and "organic"
- Products labeled as "100 percent organic" must contain (excluding water and salt) only organically produced ingredients.
- Products labeled "organic" must consist of at least 95 percent organically produced ingredients (excluding water and salt). Any remaining product ingredients must consist of nonagricultural substances approved on the National List or non-organically produced agricultural products that are not commercially available in organic form.
- Products meeting the requirements for "100 percent organic" and "organic" may display these terms and the percentage of organic content on their principal display panel.
- The USDA seal and the seal or mark of involved certifying agents may appear on product packages and in advertisements.
- Foods labeled "100 percent organic" and "organic" cannot be produced using excluded methods, sewage sludge, or ionizing radiation.
- Processed products labeled "made with organic ingredients"
- Processed products that contain at least 70 percent organic ingredients can use the phrase "made with organic ingredients" and list up to three of the organic ingredients or food groups on the principal display panel. For example, soup made with at least 70 percent organic ingredients and only organic vegetables may be labeled either "soup made with organic peas, potatoes, and carrots," or "soup made with organic vegetables."
- Processed products labeled "made with organic ingredients" cannot be produced using excluded methods, sewage sludge, or ionizing radiation.
- The percentage of organic content and the certifying agent seal or mark may be used on the principal display panel. However, the USDA seal cannot be used anywhere on the package.
- Processed products that contain less than 70 percent organic ingredients
- These products cannot use the term organic anywhere on the principal display panel. However, they may identify the specific ingredients that are organically produced on the ingredients statement on the information panel.

Other labeling provisions

- Any product labeled as organic must identify each organically produced ingredient in the ingredient statement on the information panel.
- The name and address of the certifying agent of the final product must be displayed on the information panel.

- There are no restrictions in this final rule on use of other truthful labeling claims such as "no drugs or growth hormones used," "free range," or "sustainably harvested."

Penalties for misuse of labels

A civil penalty of up to \$10,000 can be levied on any person who knowingly sells or labels as organic a product that is not produced and handled in accordance with the National Organic Program's regulations.

When the new regulations become effective, organic farmers and handlers will have 18 months to adjust their growing and processing operations and revise their product labels to conform to the new standards.

December 2000

Appendix 6

AMS Fact Sheet

State Organic Programs

The Organic Foods Production Act of 1990 (OFPA) authorizes the Secretary of Agriculture to approve State organic programs that are consistent with the national organic standards and regulations established under the OFPA. Under USDA's National Organic Program (NOP), a State government may request the Secretary to approve its State organic program. Once a State's requested organic requirements are approved by the Secretary, those requirements become the NOP requirements for organic producers, handlers, and certifying agents operating in the State.

What criteria must a State organic program meet to be approved by the Secretary?

Under the NOP final rule, a State's organic requirements cannot be less restrictive than NOP requirements. State organic programs can have more restrictive requirements than the NOP. These more restrictive organic requirements will be approved by the Secretary only if those requirements are found to be necessary in light of a particular environmental condition or unique production or handling practice in the State or a particular area of the State. For instance, a State may request approval of additional restrictions to protect a sensitive watershed. A State's more restrictive standards cannot be applied to production and handling activities outside its jurisdiction. Finally, a State's more restrictive requirements cannot be used to discriminate against organic products produced in other States.

Must a State assume responsibilities for administration of its State organic program?

Yes. The governing State official of a State organic program must agree to administer the NOP program, including any approved more restrictive State requirements. The State's organic program will oversee certified organic producers and handlers in the State to assure that they are operating in compliance with the NOP. Working with certifying agents, the State organic program will administer enforcement and appeal procedures to make sure all certified organic operations are in compliance with NOP and State requirements. However, only the NOP will exercise compliance authority over accredited certifying agents operating in the State.

States may also administer other organic programs outside the jurisdiction of the OFPA, such as research and promotion programs, tax incentives, or transition assistance for organic producers within the State. Such projects will not be subject to the Secretary's approval, provided they do not conflict with the general requirements of the Act.

What happens if a State doesn't have a State organic program?

In States with no approved State organic program, USDA will administer and enforce the requirements of the NOP. USDA will monitor any State, private, and foreign certifying agents operating within the State to assure compliance with the national program.

What steps are followed to implement a State organic program?

States with established organic programs and States that intend to establish a new organic program must submit an application to the Secretary for the approval of their State organic program. The request for approval must describe the State organic program and provide justification statements on any more restrictive requirements requested by the State. Once approved, the State organic program, including any additional requirements, becomes the NOP for that State. The State also must agree to administer the State's additional requirements and NOP requirements in the State. Existing and new State organic programs should be approved and operating when the NOP is implemented, 18 months after the final

rule becomes effective. The Secretary will review requests to amend an approved State program, and will review the State organic program at least once every 5 years.

December 2000

Appendix 7

Final Ruling and Standards Regarding USDA's National Organic Program (NOP)

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

ACTION: Final Rule with request for comments.

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

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

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

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

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

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

SUPPLEMENTARY INFORMATION:

Prior Documents in this Proceeding

This final rule is issued pursuant to the Organic Food Production Act of 1990 (Act or OFPA), as amended (7 U.S.C. 6501 et seq.). This final rule replaces the proposed rule published in the Federal Register March 13, 2000. The public submitted 40,774 comments on the proposed rule. Comments to the proposed rule were considered in the preparation of this final rule.

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

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

Approval of Paperwork Reduction Act Requirements for this Final Rule

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

National Organic Program Overview

Subpart A - Definitions

Description of Regulations

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

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

Definitions - Changes Based on Comments

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

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

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

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

We have also rejected comments requesting that we include the prohibition on excluded methods in the definition and, likewise, those requesting that we refer to "intentional use" of excluded methods. The final rule maintains and clarifies the prohibition on the use of excluded methods in organic production systems. The prohibition is most properly addressed in the appropriate provisions of the regulations, particularly in Section 205.105, and not in the definition. Similarly, although we recognize that a distinction between intentional and unintentional use of excluded methods may be meaningful, particularly as it pertains to issues of drift, this is an issue that is best handled in the sections of the regulation governing use of excluded methods, not in the definition. The definition for "excluded methods" now reads:

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Definitions - Changes Requested But Not Made

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

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

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

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

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

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

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

Definitions - Clarifications

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

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

Subpart A - Definitions

§ 205.1 Meaning of words.

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

§ 205.2 Terms defined.

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

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

Action level. The limit at or above which the Food and Drug Administration will take legal action against a product to remove it from the market. Action levels are based on unavailability of the poisonous or deleterious substances and do not represent permissible levels of contamination where it is avoidable.

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

Agricultural inputs. All substances or materials used in the production or handling of organic agricultural products.

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

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 or handling, or any combination thereof that a certifying agent may be accredited to certify under this part.

Audit trail. Documentation that is sufficient to determine the source, transfer of ownership, and transportation of any agricultural product labeled as "100 percent organic," the organic ingredients of any agricultural product labeled as "organic" or "made with organic (specified ingredients)" or the organic ingredients of any agricultural product containing less than 70 percent organic ingredients identified as organic in an ingredients statement.

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

Biologics. All viruses, serums, toxins, and analogous products of natural or synthetic origin, such as diagnostics, antitoxins, vaccines, live microorganisms, killed microorganisms, and

the antigenic or immunizing components of microorganisms intended for use in the diagnosis, treatment, or prevention of diseases of animals.

Breeder stock. Female livestock whose offspring may be incorporated into an organic operation at the time of their birth.

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

Bulk. The presentation to consumers at retail sale of an agricultural product in unpackaged, loose form, enabling the consumer to determine the individual pieces, amount, or volume of the product purchased.

Certification or certified. A determination made by a certifying agent that a production or handling operation is in compliance with the Act and the regulations in this part, which is documented by a certificate of organic operation.

Certified operation. A crop or livestock production, wild-crop harvesting or handling operation, or portion of such operation that is certified by an accredited certifying agent as utilizing a system of organic production or handling as described by the Act and the regulations in this part.

Certifying agent. Any entity accredited by the Secretary as a certifying agent for the purpose of certifying a production or handling operation as a certified production or handling operation.

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

Claims. Oral, written, implied, or symbolic representations, statements, or advertising or other forms of communication presented to the public or buyers of agricultural products that relate to the organic certification process or the term, "100 percent organic," "organic," or "made with organic (specified ingredients or food group(s))," or, in the case of agricultural products containing less than 70 percent organic ingredients, the term, "organic," on the ingredients panel.

Commercially available. The ability to obtain a production input in an appropriate form, quality, or quantity to fulfill an essential function in a system of organic production or handling, as determined by the certifying agent in the course of reviewing the organic plan.

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

Compost. The product of a managed process through which microorganisms break down plant and animal materials into more available forms suitable for application to the soil. Compost must be produced through a process that combines plant and animal materials with an initial C: N ratio of between 25:1 and 40:1. Producers using an in-vessel or static aerated pile system must maintain the composting materials at a temperature between 131F and 170F for 3 days. Producers using a windrow system must maintain the composting

materials at a temperature between 131 F and 170 F for 15 days, during which time, the materials must be turned a minimum of five times.

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

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

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

Crop rotation. The practice of alternating the annual crops grown on a specific field in a planned pattern or sequence in successive crop years so that crops of the same species or family are not grown repeatedly without interruption on the same field. Perennial cropping systems employ means such as alley cropping, intercropping, and hedgerows to introduce biological diversity in lieu of crop rotation.

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

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

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

Detectable residue. The amount or presence of chemical residue or sample component that can be reliably observed or found in the sample matrix by current approved analytical methodology.

Disease vectors. Plants or animals that harbor or transmit disease organisms or pathogens which may attack crops or livestock.

Drift. The physical movement of prohibited substances from the intended target site onto an organic operation or portion thereof.

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

Employee. Any person providing paid or volunteer services for a certifying agent.

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

Feed. Edible materials which are consumed by livestock for their nutritional value. Feed may be concentrates (grains) or roughages (hay, silage, fodder). The term, "feed," encompasses all agricultural commodities, including pasture ingested by livestock for nutritional purposes.

Feed additive. A substance added to feed in micro quantities to fulfill a specific nutritional need; i.e., essential nutrients in the form of amino acids, vitamins, and minerals.

Feed Supplement. A combination of feed nutrients added to livestock feed to improve the nutrient balance or performance of the total ration and intended to be:

- (1) Diluted with other feeds when fed to livestock;
- (2) Offered free choice with other parts of the ration if separately available; or
- (3) Further diluted and mixed to produce a complete feed.

Fertilizer. A single or blended substance containing one or more recognized plant nutrient(s) which is used primarily for its plant nutrient content and which is designed for use or claimed to have value in promoting plant growth.

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

Forage. Vegetative material in a fresh, dried, or ensiled state (pasture, hay, or silage), which is fed to livestock.

Governmental entity. Any domestic government, tribal government, or foreign governmental subdivision providing certification services.

Handle. To sell, process, or package agricultural products, except such term shall not include the sale, transportation, or delivery of crops or livestock by the producer thereof to a handler.

Handler. Any person engaged in the business of handling agricultural products, including producers who handle crops or livestock of their own production, except such term shall not include final retailers of agricultural products that do not process agricultural products.

Handling operation. Any operation or portion of an operation (except final retailers of agricultural products that do not process agricultural products) that receives or otherwise acquires agricultural products and processes, packages, or stores such products.

Immediate family. The spouse, minor children, or blood relatives who reside in the immediate household of a certifying agent or an employee, inspector, contractor, or other personnel of the certifying agent. For the purpose of this part, the interest of a spouse, minor child, or blood relative who is a resident of the immediate household of a certifying agent or an employee, inspector, contractor, or other personnel of the certifying agent shall be considered to be an interest of the certifying agent or an employee, inspector, contractor, or other personnel of the certifying agent.

Inert ingredient. Any substance (or group of substances with similar chemical structures if designated by the Environmental Protection Agency) other than an active ingredient which is intentionally included in any pesticide product (40 CFR 152.3(m)).

Information panel. That part of the label of a packaged product that is immediately contiguous to and to the right of the principal display panel as observed by an individual facing the principal display panel, unless another section of the label is designated as the information panel because of package size or other package attributes (e.g., irregular shape with one usable surface).

Ingredient. Any substance used in the preparation of an agricultural product that is still present in the final commercial product as consumed.

Ingredients statement. The list of ingredients contained in a product shown in their common and usual names in the descending order of predominance.

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.

Manure. Feces, urine, other excrement, and bedding produced by livestock that has not been composted.

Market information. Any written, printed, audiovisual, or graphic information, including advertising, pamphlets, flyers, catalogues, posters, and signs, distributed, broadcast, or made available outside of retail outlets that are used to assist in the sale or promotion of a product.

Mulch. Any non-synthetic material, such as wood chips, leaves, or straw, or any synthetic material included on the National List for such use, such as newspaper or plastic that serves to suppress weed growth, moderate soil temperature, or conserve soil moisture.

Narrow range oils. Petroleum derivatives, predominately of paraffinic and naphthenic fractions with 50 percent boiling point (10 mm Hg) between 415F and 440F.

National List. A list of allowed and prohibited substances as provided for in the Act.

National Organic Program (NOP). The program authorized by the Act for the purpose of implementing its provisions.

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

Natural resources of the operation. The physical, hydrological, and biological features of a production operation, including soil, water, wetlands, woodlands, and wildlife.

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

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

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 production. A production system that is managed in accordance with the Act and regulations in this part to respond to site-specific conditions by integrating cultural, biological, and mechanical practices that foster cycling of resources, promote ecological balance, and conserve biodiversity.

Organic system plan. A plan of management of an organic production or handling operation that has been agreed to by the producer or handler and the certifying agent and that includes written plans concerning all aspects of agricultural production or handling described in the Act and the regulations in subpart C of this part.

Pasture. Land used for livestock grazing that is managed to provide feed value and maintain or improve soil, water, and vegetative resources.

Peer review panel. A panel of individuals who have expertise in organic production and handling methods and certification procedures and who are appointed by the Administrator to assist in evaluating applicants for accreditation as certifying agents.

Person. An individual, partnership, corporation, association, cooperative, or other entity.

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

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

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

Practice standard. The guidelines and requirements through which a production or handling operation implements a required component of its production or handling organic system plan. A practice standard includes a series of allowed and prohibited actions, materials, and conditions to establish a minimum level performance for planning, conducting, and maintaining a function, such as livestock health care or facility pest management, essential to an organic operation.

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

Private entity. Any domestic or foreign nongovernmental for-profit or not-for-profit organization providing certification services.

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

Processing aid. (a) substance that is added to a food during the processing of such food but is removed in some manner from the food before it is packaged in its finished form; (b) a substance that is added to a food during processing, is converted into constituents normally present in the food, and does not significantly increase the amount of the constituents naturally found in the food; and (c) a substance that is added to a food for its technical or functional effect in the processing but is present in the finished food at insignificant levels and does not have any technical or functional effect in that food.

Producer. A person who engages in the business of growing or producing food, fiber, feed, and other agricultural-based consumer products.

Production lot number/identifier. Identification of a product based on the production sequence of the product showing the date, time, and place of production used for quality control purposes.

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

Records. Any information in written, visual, or electronic form that documents the activities undertaken by a producer, handler, or certifying agent to comply with the Act and regulations in this part.

Residue testing. An official or validated analytical procedure that detects, identifies, and measures the presence of chemical substances, their metabolites, or degradation 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.

Split operation. An operation that produces or handles both organic and non-organic agricultural products.

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 organic program (SOP). A State program that meets the requirements of section 6506 of the Act, is approved by the Secretary, and is designed to ensure that a product that is sold or labeled as organically produced under the Act is produced and handled using organic methods.

State organic program's governing State official. The chief executive official of a State or, in the case of a State that provides for the statewide election of an official to be responsible solely for the administration of the agricultural operations of the State, such official who administers a State organic certification program.

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

Tolerance. The maximum legal level of a pesticide chemical residue in or on a raw or processed agricultural commodity or processed food.

Transplant. A seedling which has been removed from its original place of production, transported, and replanted.

Unavoidable residual environmental contamination (UREC). Background levels of naturally occurring or synthetic chemicals that are present in the soil or present in organically produced agricultural products that are below established tolerances.

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

Subpart B - Applicability

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

Description of Regulations

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

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

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

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

Exempt and Excluded Operations

This regulation establishes several categories of exempt or excluded operations. An exempt or excluded operation does not need to be certified. However, operations that qualify as exempt or excluded operations can voluntarily choose to be certified. A production or handling operation that is exempt or excluded from obtaining certification still must meet other regulatory requirements contained in this rule as explained below.

Exempt Operations

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

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

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

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

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

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

Excluded Operations

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

prohibited substances in section 205.272. The requirements for the prevention of commingling and contact with prohibited substances protect the integrity of organically produced products.

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

(2) A retail food establishment or portion of a retail food establishment that processes on the premises of the retail food establishment raw and ready-to-eat food from certified agricultural products labeled as "100 percent organic," "organic," or "made with..." is excluded from the requirements in these regulations, except for the provisions for prevention of contact of organic products with prohibited substances as provided in section 205.272 and the labeling regulations in section 205.310. The prevention of commingling and contact with prohibited substances and labeling requirements protect the integrity of organically produced products. Excluded retail food establishments include restaurants; delicatessens; bakeries; grocery stores; or any retail outlet with an in-store restaurant, delicatessen, bakery, salad bar, or other eat-in or carry-out service of processed or prepared raw and ready-to-eat food.

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

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

Recordkeeping Requirements for Certified Operations

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

Examples of Records

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

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

Allowed and Prohibited Substances

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

Applicability - Changes Based on Comments

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

(1) Violations of the Act or Regulations. We have amended section 205.100 by adding a new paragraph (c), which addresses violations of the Act and these regulations. A number of commenters advocated for provisions within the final rule describing what legal proceedings USDA would conduct against operations or persons that violate the NOP. We agree that this rule should include provisions addressing violations of the Act and these regulations. Accordingly, we have added at section 205.100 the misuse of label provisions and false statement provisions of section 2120 (7 U.S.C. 6519) of the Act. Specifically, section 205.100(c) provides that persons not in compliance with the labeling requirements of the Act or these regulations are subject to a civil penalty of not more than \$10,000 per violation and that persons making false statements under the Act to the Secretary, a governing State official, or an accredited certifying agent shall be subject to the provisions of section 1001 of Title 18, United States Code. The provisions of the Act and these regulations apply to all operations or persons that sell, label, or represent their agricultural product as organic.

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

redesignated as section 205.105, includes all of the provisions covered under old section 205.600.

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

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

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

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

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

Based on comments received and because the potential impact of the prohibition on use of excluded methods is still uncertain, we have created the possibility at section 205.105(e) for

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

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

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

Applicability - Changes Requested But Not Made

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

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

(2) Retailer Exclusion from Certification. Many commenters objected to the provisions of section 205.101(b)(2) which exclude retail food establishments from certification. These commenters assert that only final retailers that do not process agricultural products should be excluded from certification. There is clearly a great deal of public concern regarding the handling of organic products by retail food establishments. We have not required certification of retail food establishments at this time because of a lack of consensus as to whether retail

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

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

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

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

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

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

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

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

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

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

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

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

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

(10) Fair Labor Practices on Organic Farms. Many commenters asked the NOP to develop fair labor practice standards as a part of the final rule. We have not adopted these comments. Other statutes cover labor and worker safety standards. The Act does not provide the authority to include them in these regulations. However, these regulations do not prohibit certifying agents from developing a voluntary certification program, separate from organic certification, that address fair labor and worker safety standards.

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

Applicability - Clarifications

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

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

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

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

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

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

excluded methods as detailed in their approved organic system plan, the unintentional presence of the products of excluded methods should not affect the status of an organic product or operation.

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

(2) Additional NOP Standards for Specific Production Categories. Many commenters asked that the NOP include in the final rule certification standards for apiculture, greenhouses, mushrooms, aquatic species, culinary herbs, pet food, and minor animal species (e.g., rabbits) food. The NOP intends to provide standards for categories where the Act provides the authority to promulgate standards. During the 18-month implementation period, the NOP intends to publish for comment certification standards for apiculture, mushrooms, greenhouses and aquatic animals. These standards will build upon the existing final rule and will address only the unique requirements necessary to certify these specialized operations. Some of the other questions raised by commenters are already addressed in the final rule. For example, feed for minor species is covered by livestock feed provisions within subpart C and the livestock feed labeling provisions within subpart D. The production and utilization of culinary herbs, including herbal teas, is covered by the provisions of the final rule. We do not envision needing to do additional rulemaking on these two categories.

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

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

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

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

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

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

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

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

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

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

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

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

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

Subpart B - Applicability

§ 205.100 What has to be certified.

(a) Except for operations exempt or excluded in § 205.101, each production or handling operation or specified portion of a production or handling operation that produces or handles crops, livestock, livestock products, or other agricultural products that are intended to be sold, labeled, or represented as "100 percent organic," "organic," or "made with organic (specified ingredients or food group(s))" must be certified according to the provisions of subpart E of this part and must meet all other applicable requirements of this part.

(b) Any production or handling operation or specified portion of a production or handling operation that has been already certified by a certifying agent on the date that the certifying agent receives its accreditation under this part shall be deemed to be certified under the Act until the operation's next anniversary date of certification. Such recognition shall only be available to those operations certified by a certifying agent that receives its accreditation within 18 months from the effective date of this final rule.

(c) Any operation that:

- (1) Knowingly sells or labels a product as organic, except in accordance with the Act, shall be subject to a civil penalty of not more than \$10,000 per violation.
- (2) Makes a false statement under the Act to the Secretary, a governing State official, or an accredited certifying agent shall be subject to the provisions of section 1001 of title 18, United States Code.

§ 205.101 Exemptions and exclusions from certification.

(a) Exemptions.

(1) A production or handling operation that sells agricultural products as "organic" but whose gross agricultural income from organic sales totals \$5,000 or less annually is exempt from certification under subpart E of this part and from submitting an organic system plan for acceptance or approval under § 205.201 but must comply with the applicable organic production and handling requirements of subpart C of this part and the labeling requirements of § 205.310. The products from such operations shall not be used as ingredients identified as organic in processed products produced by another handling operation.

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

(3) A handling operation or portion of a handling operation that only handles agricultural products that contain less than 70 percent organic ingredients by total weight of the finished product (excluding water and salt) is exempt from the requirements in this part, except:

(i) The provisions for prevention of contact of organic products with prohibited substances set forth in § 205.272 with respect to any organically produced ingredients used in an agricultural product;

(ii) The labeling provisions of §§ 205.305 and 205.310; and

(iii) The recordkeeping provisions in paragraph (c) of this section.

(4) A handling operation or portion of a handling operation that only identifies organic ingredients on the information panel is exempt from the requirements in this part, except:

(i) The provisions for prevention of contact of organic products with prohibited substances set forth in § 205.272 with respect to any organically produced ingredients used in an agricultural product;

(ii) The labeling provisions of §§ 205.305 and 205.310; and

(iii) The recordkeeping provisions in paragraph (c) of this section.

(b) Exclusions.

(1) A handling operation or portion of a handling operation is excluded from the requirements of this part, except for the requirements for the prevention of commingling and contact with prohibited substances as set forth in § 205.272 with respect to any organically produced products, if such operation or portion of the operation only sells organic agricultural products labeled as "100 percent organic," "organic," or "made with organic (specified ingredients or food group(s))" that:

- (i) Are packaged or otherwise enclosed in a container prior to being received or acquired by the operation; and
- (ii) Remain in the same package or container and are not otherwise processed while in the control of the handling operation.

(2) A handling operation that is a retail food establishment or portion of a retail food establishment that processes, on the premises of the retail food establishment, raw and ready-to-eat food from agricultural products that were previously labeled as "100 percent organic," "organic," or "made with organic (specified ingredients or food group(s))" is excluded from the requirements in this part, except:

- (i) The requirements for the prevention of contact with prohibited substances as set forth in § 205.272; and
- (ii) The labeling provisions of § 205.310.

(c) Records to be maintained by exempt operations.

(1) Any handling operation exempt from certification pursuant to paragraph (a)(3) or (a)(4) of this section must maintain records sufficient to:

- (i) Prove that ingredients identified as organic were organically produced and handled; and
- (ii) Verify quantities produced from such ingredients.

(2) Records must be maintained for no less than 3 years beyond their creation and the operations must allow representatives of the Secretary and the applicable State organic programs' governing State official access to these records for inspection and copying during normal business hours to determine compliance with the applicable regulations set forth in this part.

§ 205.102 Use of the term, "organic."

Any agricultural product that is sold, labeled, or represented as "100 percent organic," "organic," or "made with organic (specified ingredients or food group(s))" must be:

(a) Produced in accordance with the requirements specified in § 205.101 or §§ 205.202 through 205.207 or §§ 205.236 through 205.239 and all other applicable requirements of part 205; and

(b) Handled in accordance with the requirements specified in § 205.101 or §§ 205.270 through 205.272 and all other applicable requirements of this part 205.

§ 205.103 Recordkeeping by certified operations.

(a) A certified operation must maintain records concerning the production, harvesting, and handling of agricultural products that are or that are intended to be sold, labeled, or represented as "100 percent organic," "organic," or "made with organic (specified ingredients or food group(s))."

(b) Such records must:

- (1) Be adapted to the particular business that the certified operation is conducting;
- (2) Fully disclose all activities and transactions of the certified operation in sufficient detail as to be readily understood and audited;
- (3) Be maintained for not less than 5 years beyond their creation; and
- (4) Be sufficient to demonstrate compliance with the Act and the regulations in this part.

(c) The certified operation must make such records available for inspection and copying during normal business hours by authorized representatives of the Secretary, the applicable State program's governing State official, and the certifying agent.

§ 205.104 [Reserved]

§ 205.105 Allowed and prohibited substances, methods, and ingredients in organic production and handling.

To be sold or labeled as "100 percent organic," "organic," or "made with organic (specified ingredients or food group(s))," the product must be produced and handled without the use of:

- (a) Synthetic substances and ingredients, except as provided in § 205.601 or § 205.603;
- (b) Non-synthetic substances prohibited in § 205.602 or § 205.604;
- (c) Nonagricultural substances used in or on processed products, except as otherwise provided in § 205.605;
- (d) Non-organic agricultural substances used in or on processed products, except as otherwise provided in § 205.606;
- (e) Excluded methods, except for vaccines, Provided, That, the vaccines are approved in accordance with § 205.600(a);
- (f) Ionizing radiation, as described in Food and Drug Administration regulation, 21 CFR 179.26; and
- (g) Sewage sludge.

§§ 205.106-205.199 [Reserved]

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

Description of Regulations

General Requirements

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

Production and Handling (General)

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

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

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

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

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

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

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

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

The fifth element that 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 non-organic products to describe the management practices and physical barriers established to prevent commingling of organic and non-organic products. This requirement addresses contact of organic products, including livestock, organic field units, storage areas, and packaging to be used for organic products, with prohibited substances.

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

Crop Production

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

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

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

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

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

The producer must use preventive practices to manage crop pests, weeds, and diseases, including but not limited to crop rotation, soil and crop nutrient management, sanitation measures, and cultural practices that enhance crop health. Such cultural practices include the selection of plant species and varieties with regard to suitability to site-specific conditions and resistance to prevalent pests, weeds, and diseases. Mechanical and biological methods that do not entail application of synthetic substances may be used as needed to control pest, weed, and disease problems that may occur. Pest control practices include augmentation or introduction of pest predators or parasites; development of habitat for natural enemies; and non-synthetic 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 that suppress the spread of disease organisms and the application of non-synthetic biological, botanical, or mineral inputs. When these practices are insufficient to prevent or control crop pests, weeds, and diseases, a biological or botanical substance or a synthetic substance that is allowed on the National List may be used provided that the conditions for using the substance are documented in the organic system plan. The producer must not use lumber treated with arsenate or other prohibited materials for new installations or replacement purposes that comes into contact with soil or livestock.

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

Livestock Production

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

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

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

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

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

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

produced. Every use of a synthetic medication or parasiticide must be incorporated into the livestock operation's organic system plan subject to approval by the certifying agent.

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

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

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

Handling

Mechanical or biological methods can be used to process an agricultural product intended to be sold, labeled, or represented as "100 percent organic," "organic," or "made with organic ingredients" for the purpose of retarding spoilage or otherwise preparing the agricultural product for market. Processed multi-ingredient products labeled "100 percent organic," may only use wholly organic ingredients, pursuant to paragraph (a) of section 205.301. Nonagricultural substances that are allowed for use on the National List and non-organically produced agricultural products may be used in or on "organic" and "made with..." products pursuant to paragraphs (b) and (c) of section 205.301, respectively. Documentation of

commercial availability of each substance to be used as a non-organic ingredient in products labeled "organic" must be listed in the organic handling system plan in accordance with section 205.201.

Handlers are prohibited from using: (1) ionizing radiation for the treatment or processing of foods; (2) ingredients produced using excluded methods; or (3) volatile synthetic solvents in or on a processed product or any ingredient which is sold, labeled, or represented as organic. The prohibition on ionizing radiation for the treatment or processing of foods is discussed under Applicability, section 205.105. This rule does not prohibit an organic handling operation from using Food and Drug Administration (FDA)-approved X-rays for inspecting packaged foods for foreign objects that may be inadvertently commingled in the packaged product.

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

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

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

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

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

Section 205.272 provides additional practice standards that must be followed by an organic handling operation to prevent the commingling of organic and non-organic products and to

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

Temporary Variances

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

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

Upon notification by the Administrator that a temporary variance has been established, the certifying agent must inform each production and handling operation it certifies that may be affected by the temporary variance. For example, if a drought causes a severe shortage of organically produced hay, a dairy operation may be permitted to substitute some non-organic 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 non-organic hay used and the timeframe needed to restore the total feed ration to organic sources. The certifying agent may require that the next organic plan include contingency measures to avoid the need to resort to non-organic feed in case of a future shortage.

General - Changes Based on Comments

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

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

(2) Management Practices and Physical Barriers to Prevent Commingling. Many commenters, including numerous certifying agents, stated that the proposed provisions for an organic system plan were not adequate for the task of certifying an operation that produces both organic and non-organic products. The commenters requested that the final rule incorporate the provisions established in the OFPA for certifying these split operations. These provisions include separate recordkeeping for the organic and non-organic operations

and the implementation of protective practices to prevent the commingling of product and the unintentional contact of organic product with prohibited substances. We have amended the provisions for an organic system plan in section 205.201(a)(5) to require greater accountability regarding the segregation of organic and non-organic products in a split operation. The changes we made incorporate language from the OFPA ("physical facilities, management practices") to provide clear criteria for producers, handlers and certifying agents to agree upon an organic system plan that protects the integrity of organic product.

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

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

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

certifying agents regarding when and under what circumstances an ingredient is commercially available would undermine our intent to create an equitable and enforceable standard.

AMS is soliciting additional comment and information on a number of issues concerning the development of standards for the commercial availability of organically produced agricultural commodities used in processed products labeled as "organic." On the basis of these comments and information and additional recommendations that the NOSB may develop, AMS will develop a commercial availability standard for use in implementing the final rule. AMS intends to develop the commercial availability standard and incorporate it within the final rule prior to the commencement of certification activities by accredited certifying agents. This approach will provide organic handlers and certifying agents the standard necessary to incorporate the consideration of commercial availability of ingredients in an organic system plan at the time that the USDA organic standard comes into use. Specifically, AMS requests comments and information addressing the following questions:

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

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

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

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

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

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

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

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

(4) Conservation of Biodiversity. Many commenters recommended amending the definition of organic production to include the requirement that an organic production system must promote or enhance biological diversity (biodiversity). Commenters stated that the definitions for organic production developed by the NOSB and the Codex Commission include this requirement. We agree with these commenters and have amended the definition of organic production to require that a producer must conserve biodiversity on his or her operation. The use of "conserve" establishes that the producer must initiate practices to support biodiversity

and avoid, to the extent practicable, any activities that would diminish it. Compliance with the requirement to conserve biodiversity requires that a producer incorporate practices in his or her organic system plan that are beneficial to biodiversity on his or her operation.

General - Changes Requested But Not Made

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

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

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

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

Crop Production - Changes Based on Comments

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

(1) **Crop nutrient management.** The fundamental requirement of the soil fertility and crop nutrient management practice standard, that tillage, cultivation, and nutrient management practices maintain or improve the physical, chemical, and biological condition of the soil and minimize erosion, remains unaltered. The proposed rule required that a producer budget crop nutrients by properly utilizing manure or other animal and plant materials, mined

substances of low or high solubility, and allowed synthetic amendments. Many commenters disagreed with using the term, "budget," which they considered too limiting to characterize nutrient management in organic systems. These commenters recommended that the practice standard instead emphasize the diverse practices used in organic systems to cycle nutrients over extended periods of time.

We agree with these commenters and have amended the final rule to require that producers manage crop nutrients and soil fertility through the use of crop rotations and cover crops in addition to plant and animal materials. Additionally, we clarified that producers may manage crop nutrients and soil fertility by applying mined substances if they are used in compliance with the conditions established in the National List. Finally, we removed the word "waste," from our description of animal and plant materials in the proposed rule to emphasize the importance of these resources in organic soil fertility management.

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

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

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

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

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

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

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

whether these materials should be prohibited in organic production or whether restrictions on their use are appropriate.

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

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

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

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

(4) Burning crop residues. The proposed rule prohibited burning as a means of crop disposal, except for burning prunings from perennial crops to suppress the spread of disease. Many commenters supported the principle behind the prohibition but maintained that the proposed language was too restrictive and would preclude certain beneficial agronomic practices. Several producers stated that the proposed rule would prevent them from collecting and burning residues from diseased annual crops, which they felt was an effective and beneficial practice. Other producers cited their use of prescriptive burning as a management practice for certain native or wild crops. As evidenced by the allowance for burning to suppress disease with perennial crops, the proposed rule was not designed to preclude the selective use of fire in organic production. We agree with the commenters that a more flexible allowance for the practice is warranted, and we have amended the provision to allow burning of annual and perennial crop residues for the suppression of disease and to

stimulate seed germination. Producers must establish their need and procedures for burning in their organic system plan, and the practice cannot be used solely to remove crop debris from fields. (5) Requirement for Organic Seed in Sprout Production. The proposed rule allowed non-organically produced seeds for all purposes, including sprout production, when the certifying agent concurred with the producer that organically produced seeds were not commercially available. While commenters predominately supported this approach with seed used for planting, they were virtually unanimous in stating that it is never appropriate to allow non-organically produced and handled seeds in organic sprout production. Commenters cited the NOSB's June 1994 recommendation that seed used for the production of edible sprouts shall be organically produced and stated that existing certification standards do not provide an exemption based on commercial availability. We agree with these commenters and have modified the final rule to require that organic seed must be used for the production of edible sprouts.

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

(7) Prohibition on Use of Treated Lumber. The proposed rule did not specifically address the use of lumber that had been treated with a prohibited substance, such as arsenic, in organic production. Citing the explicit prohibition on these substances in existing organic standards, many commenters felt that treated lumber should be excluded in the final rule. Commenters also cited the NOSB's recommendation to prohibit the use of lumber treated with a prohibited substance for new construction and replacement purposes effective upon publication of the final rule. We have included a modified version of the NOSB's recommendation within the crop pest, weed, and disease management practice standard. This provision prohibits the use of lumber treated with arsenate or other prohibited materials for new installations or replacement purposes in contact with an organic production site. We included this modification to clarify that the prohibition applies to lumber used in direct contact with organically produced and handled crops and livestock and does not include uses, such as lumber for fence posts or building materials, that are isolated from production. The prohibition applies to lumber used in crop production, such as the frames of a planting bed, and for raising livestock, such as the boards used to build a farrowing house.

(8) Greater Rigor in the Wild Harvest Production Organic System Plan. A number of commenters stated that the wild-crop harvesting practice standard was insufficiently descriptive and that the proposed rule failed to apply the same oversight to wild harvest operations as it did to those producing crops and livestock. Some commenters maintained that the proposed rule did not require a wild harvest producer to operate under an approved organic system plan. These commenters proposed specific items, including maps of the production area that should be required in a wild harvest operation's organic system plan. One commenter recommended that the definition for "wild crop" be modified to allow the harvest of plants from aquatic environments.

We amended the practice standard for wild-crop harvesting to express the compliance requirements more clearly. Wild-crop producers must comply with the same organic system

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

Crop Production - Changes Requested But Not Made

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

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

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

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

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

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

Neither the identification of food safety as a consideration in the OFPA or the inclusion of this practice standard in the final rule should be construed to suggest that organically produced agricultural products are any safer than non-organically produced ones. USDA has consistently stated that certification is a process claim, not a product claim, and, as such, cannot be used to differentiate organic from non-organic commodities with regard to food safety. National organic standards for manure use cannot be used to establish a food safety standard for certified commodities in the absence of as uniform Federal regulation to ensure the safety of all human food crops to which raw manure has been applied. The OFPA was designed to certify a process for informational marketing purposes.

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

(2) No Prohibition on Manure from Non-organic Operations. The proposed rule identified animal and plant waste materials as important components in soil fertility and crop nutrient management without providing criteria for distinguishing allowed and prohibited sources. A large number of commenters objected to this provision and stated that manure from non-organic sources may contain residues from prohibited substances, including animal

medications. These commenters maintained that some of these residues, such as antibiotics, may remain active for extended intervals, and others, such as heavy metals, could accumulate on the organic operation. Commenters stated that if either or both conditions prevailed, the integrity of the organic operation would be jeopardized. Many producers and certifying agents emphasized that the proposed rule conflicted with the Codex guidelines that prohibit the use of manure from factory farms. These commenters were concerned that failure to restrict the use of manure from non-organic operations would put their products at a competitive disadvantage, particularly in European markets. When raising this issue, most commenters requested that the final rule either prohibit the use of manure from factory farms or state that certifying agents could regulate the practice by requiring residue testing and restrictions on application.

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

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

We have not amended the final rule to prohibit the rotation of a field on an operation in and out of organic production. The statutory prohibition on the application of a prohibited substance is 3 years, and this requirement is contained in section 205.202(b). This prohibition restricts the application of a prohibited substance, not its residual activity. If AMS receives evidence that the rotation of fields in this manner threatens to compromise organic production, the NOP and NOSB will collaborate on developing standards to remedy it.

(4) Use of Seed Treatments on the National List. The seed and planting stock practice standard in the proposed rule generated a very diverse array of responses that, while largely favorable, highlighted a potentially disruptive impact on organic producers. The practice standard favored organic seed and planting stock over non-organically produced but untreated varieties and non-organically produced, untreated seed and planting stock over non-organically produced seeds and planting stock treated with an allowed synthetic substance. Producers could use the less preferable seed or planting stock variety if they demonstrated to their certifying agent that an equivalent variety in the preferred form was not commercially available. Most commenters endorsed the principle of requiring organic seed and planting stock and agreed that the proposed provisions were a workable approach to enforcement. They stated that the provisions created an incentive for seed and planting stock providers to develop supplies for organic markets, yet enabled producers who made a

good faith effort but failed to locate seed or planting stock in the preferred form the ability to continue producing organically. Most commenters indicated that this approach would support the existing market for organic seed and planting stock while fostering its continued development.

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

We have not changed the seed and planting stock practice standard in response to these commenters because the prohibition on using synthetic materials not on the National List is a requirement of the OFPA. The final rule cannot allow producers to use synthetic seed treatments that have not been reviewed, favorably recommended by the NOSB, and added to the National List by the Secretary. The practice standard creates incentives for producers to seek out seed and planting stock inputs that are the most compatible with organic production, yet includes allowances when preferred forms are not commercially available. While no seed treatments are included on the National List in the final rule, individuals may petition the NOSB for review of such substances. Additionally, the practice standard creates an incentive for seed and planting stock producers and suppliers to develop natural treatments suitable for organic systems that would not need to appear on the National List. The objectives of spurring production of organically grown seed and promoting research in natural seed treatments are compatible with the OFPA's purpose of facilitating commerce in organically produced and processed food. We designed the practice standard to pursue these objectives while preventing the disruption that an ironclad requirement for organically produced seed and planting stock may have caused.

(5) Practice Standard for Maple Syrup. Many commenters stated that the proposed rule lacked production and handling standards for operations that produce maple syrup. Commenters stated that maple syrup production is a significant enterprise for many organic producers and that the absence of a practice standard in the final rule would adversely affect existing markets for organic products. Many commenters recommended that the final rule incorporate the maple syrup practice standard from an existing certification program or the American Organic Standards.

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

Crop Production - Clarifications

Clarification is given on the following issues raised by commenters:

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

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

(2) Excluding Annual Seedlings from Planting Stock. The proposed rule allowed a producer to use non-organically produced seeds and planting stock if organically produced equivalent varieties were not commercially available. Several commenters, including the NOSB, were concerned that the definition of planting stock as "any plant or plant tissue, including rhizomes, shoots, leaf or stem cuttings, roots, or tubers, used in plant production or propagation" was sufficiently broad to be applied to annual seedlings. While many commenters, including the NOSB, supported the commercial availability exemption in the case of seeds and planting stock, they objected to extending it to annual seedlings. The proposed rule did not intend to include annual seedling within the definition of planting stock and included a separate definition of "annual seedling" as "a plant grown from seed that will complete its life cycle or produce a harvestable crop yield within the same crop year or season in which it is planted." The proposed rule addressed annual seedlings as a distinct category within the seed and planting stock practice standard. There was no allowance for using non-organically produced annual seedlings based on commercial availability, and such seedlings can only be used when a temporary variance has been issued due to a catastrophic business interruption. The growth of markets for organically produced annual seedlings, unlike those for seeds and planting stock, obviates the need for the commercial availability provision. We have retained this approach in the final rule.

Livestock Production - Changes Based on Comments

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

(1) Whole Herd Conversion. The proposed rule required that livestock receive 1 year of continuous organic management prior to the milk or milk products they produce being

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

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

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

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

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

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

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

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

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

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

Commenters questioned whether non-synthetic but nonagricultural substances, such as ground oyster shells and diatomaceous earth, would be allowed in agricultural feed. In 1994, the NOSB recommended that natural feed additives can be from any source, provided that the additive is not classified as a prohibited natural on the National List. We agree with this recommendation and have amended the final rule to allow such materials as feed additives and supplements. The only additional constraint on these materials is that every feed, feed additive, and feed supplement be used in compliance with the Federal Food, Drug, and Cosmetic Act, as stated in section 205.237(b)(6).

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

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

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

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

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

Numerous commenters requested clarification on species-specific living conditions, such as the use of cages for poultry and confinement systems for veal production. The use of continuous confinement systems including cages for poultry and veal production is incompatible with the requirement that organically raised livestock receive access to the outdoors and the ability to engage in physical activity appropriate to their needs. There will be times when producers must temporarily confine livestock under their care, but these instances must be supported by the exemptions to the outdoor access requirement included in the final rule. Other commenters requested additional guidance on whether confinement for the purpose of finishing slaughter stock would be allowed, and, if so, how long that confinement could last. Commenters who supported an allowance for finishing most often recommended that, in the case of cattle, confinement should not exceed 90 days. The final rule does not include a specific length of time that cattle or other species may be confined prior to slaughter. We will seek additional input from the NOSB and public comment before developing such standards.

Several commenters questioned whether a Federal, State, or local regulation that required confinement would supersede the requirement for outdoor access. These commenters were

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

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

Livestock Production - Changes Requested But Not Made

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

(1) Prohibition on Factory Farms. Many commenters requested that the final rule prohibit the certification of "factory farms." These commenters stated that factory farms are dependent upon practices and materials that are inconsistent with or expressly prohibited in the OFPA. The final rule does not contain such a prohibition because commenters did not provide a clear, enforceable definition of "factory farm" for use in the final rule. All organic operations, regardless of their size or other characteristics, must develop and adhere to an approved organic system plan that complies with these regulations in order to be certified.

(2) Non-organic Feed Protocol. The proposed rule required that, except for nonagricultural products and synthetic substances included on the National List, a producer must provide livestock with a total feed ration composed of agricultural feed products, including pasture and forage, that is organically produced and, if applicable, handled. It also included provisions for temporary variances that, under very limited circumstances and with the approval of the certifying agent and the Administrator, would provide an exemption from specific production and handling standards. The preamble of the proposed rule described an emergency resulting in the unavailability of organic agricultural feed products as an example of a situation in which a temporary variance could be issued. Many commenters recommended that the final rule require a producer who received a temporary variance for a feed emergency to follow the order of preference for noncertified organic feed developed by the NOSB. This order of preference requires a producer to procure agricultural feed products from sources that are as close to complying with the standards for organic certification as possible. Commenters stated that adherence to the order of preference would most closely conform with the expectation of consumers that organically raised livestock received organic feed and would create an incentive for livestock feed producers to pursue certification.

We have not included the NOSB's feed emergency order of preference in the final rule because it would be too prescriptive and difficult to enforce during an emergency. Receiving a temporary variance categorically exempts a producer from the provision for which it was issued, although that producer may not substitute any practice, material, or procedure that is otherwise prohibited, although that producer may not substitute any practice, material, or

procedure that is otherwise prohibited under section 205.105. Additionally, certified organic feed is far more available in terms of quantity and affordability than when the NOSB developed its order of preference in 1994. We anticipate that producers whose original supply of organic agricultural feed products is interrupted will be able to fill the shortfall through the marketplace.

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

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

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

We have retained the proposed provision for physical alterations without taking any further position on whether specific practices are allowed or prohibited. We did not receive substantial new guidance on techniques to measure stress in animals due to physical alterations and have made no revisions in that regard. The final rule establishes that, when appropriately performed and within the context of an overall management system, specific physical alterations are allowed. It also mandates that, as an element of a preventative health care program, physical alterations must benefit the ultimate physical and psychological welfare of the affected animal.

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

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

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

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

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

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

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

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

Handling - Changes Based on Comments

The following changes are made based on comments received.

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

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

(2) Prohibited Practices. Commenters were unclear about the extent of the prohibition on use of excluded methods and ionizing radiation. To make that prohibition clear, we have moved the handling prohibitions in proposed rule sections 205.270 (c) to 205.105, Applicability, subpart B. Paragraphs (c)(1) and (c)(2) which listed excluded methods and ionizing radiation in the proposed rule are combined into paragraph (c)(1) that cross-references new section 205.105.

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

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

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

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

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

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

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

This regulation does not preempt Federal, State, or local health and sanitation requirements. We recognize that inspectors who monitor compliance with those regulations may require immediate intervention and use of synthetic substances, not on the National List, before or at the same time as the methods specified in paragraphs (b) and (c). Therefore, to make this

clear, we have added a new paragraph (f). To ensure that the use of the substances does not destroy a product's organic integrity, we are requiring that the handler take appropriate measures to prevent contact of the product with the pest control substance used.

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

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

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

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

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

Handling - Changes Requested But Not Made

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

(2) Allowed Synthetics Used in Packaging Materials and Storage Containers. A State department of agriculture commented that section 205.272(b)(1) prohibits use of synthetic

fungicides, preservatives, or fumigants in packaging materials and storage containers or bins. The comment stated that it is inconsistent to permit use of allowed substances as ingredients in processed products but prohibit their use as a preservative or fumigant in the packaging materials and storage containers and bins. The commenter suggested that paragraph (b)(1) be amended to permit use of National List-allowed substances in section 205.605, particularly carbon dioxide and ozone, in packaging materials and storage containers or bins.

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

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

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

Handling - Clarifications

Clarification is given on the following issues raised by commenters.

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

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

Temporary Variances - Changes Based on Comments

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

We agree and have added drought to the regulatory text in paragraph (a)(2) of section 205.290. We have also added "hail" as a natural disaster warranting a temporary variance. Both drought and hail were mentioned in the preamble of the proposed rule but were unintentionally left out of the regulatory text.

Temporary Variances - Changes Requested But Not Made

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

Subpart C - Organic Production and Handling Requirements

§ 205.200 General. The producer or handler of a production or handling operation intending to sell, label, or represent agricultural products as "100 percent organic," "organic," or "made with organic (specified ingredients or food group(s))" must comply with the applicable provisions of this subpart. Production practices implemented in accordance with this subpart must maintain or improve the natural resources of the operation, including soil and water quality.

§ 205.201 Organic production and handling system plan.

(a) The producer or handler of a production or handling operation, except as exempt or excluded under § 205.101, intending to sell, label, or represent agricultural products as "100 percent organic," "organic," or "made with organic (specified ingredients or food group(s))" must develop an organic production or handling system plan that is agreed to by the producer or handler and an accredited certifying agent. An organic system plan must meet the requirements set forth in this section for organic production or handling. An organic production or handling system plan must include:

- (1) A description of practices and procedures to be performed and maintained, including the frequency with which they will be performed;
- (2) A list of each substance to be used as a production or handling input, indicating its composition, source, location(s) where it will be used, and documentation of commercial availability, as applicable;
- (3) A description of the monitoring practices and procedures to be performed and maintained, including the frequency with which they will be performed, to verify that the plan is effectively implemented;
- (4) A description of the recordkeeping system implemented to comply with the requirements established in § 205.103;
- (5) A description of the management practices and physical barriers established to prevent commingling of organic and non-organic products on a split operation and to prevent contact of organic production and handling operations and products with prohibited substances; and
- (6) Additional information deemed necessary by the certifying agent to evaluate compliance with the regulations.

(b) A producer may substitute a plan prepared to meet the requirements of another Federal, State, or local government regulatory program for the organic system plan: Provided, That, the submitted plan meets all the requirements of this subpart.

§ 205.202 Land requirements.

Any field or farm parcel from which harvested crops are intended to be sold, labeled, or represented as "organic," must:

- (a) Have been managed in accordance with the provisions of §§ 205.203 through 205.206;
- (b) Have had no prohibited substances, as listed in § 205.105, applied to it for a period of 3 years immediately preceding harvest of the crop; and
- (c) Have distinct, defined boundaries and buffer zones such as runoff diversions to prevent the unintended application of a prohibited substance to the crop or contact with a prohibited substance applied to adjoining land that is not under organic management.

§ 205.203 Soil fertility and crop nutrient management practice standard.

(a) The producer must select and implement tillage and cultivation practices that maintain or improve the physical, chemical, and biological condition of soil and minimize soil erosion.

(b) The producer must manage crop nutrients and soil fertility through rotations, cover crops, and the application of plant and animal materials.

(c) The producer must manage plant and animal materials to maintain or improve soil organic matter content in a manner that does not contribute to contamination of crops, soil, or water by plant nutrients, pathogenic organisms, heavy metals, or residues of prohibited substances. Animal and plant materials include:

(1) Raw animal manure, which must be composted unless it is:

(i) Applied to land used for a crop not intended for human consumption;

(ii) Incorporated into the soil not less than 120 days prior to the harvest of a product whose edible portion has direct contact with the soil surface or soil particles; or

(iii) Incorporated into the soil not less than 90 days prior to the harvest of a product whose edible portion does not have direct contact with the soil surface or soil particles;

(2) Composted plant and animal materials produced through a process that

(i) established an initial C:N ratio of between 25:1 and 40:1; and

(ii) maintained a temperature of between 131 F and 170 F for 3 days using an in-vessel or static aerated pile system; or

(iii) maintained a temperature of between 131F and 170F for 15 days using a windrow composting system, during which period, the materials must be turned a minimum of five times.

(3) Un-composted plant materials.

(d) A producer may manage crop nutrients and soil fertility to maintain or improve soil organic matter content in a manner that does not contribute to contamination of crops, soil, or water by plant nutrients, pathogenic organisms, heavy metals, or residues of prohibited substances by applying:

(1) A crop nutrient or soil amendment included on the National List of synthetic substances allowed for use in organic crop production;

(2) A mined substance of low solubility;

(3) A mined substance of high solubility, Provided, That, the substance is used in compliance with the conditions established on the National List of non-synthetic materials prohibited for crop production;

(4) Ash obtained from the burning of a plant or animal material, except as prohibited in paragraph (e) of this section: Provided, That, the material burned has not been treated or combined with a prohibited substance or the ash is not included on the National List of non-synthetic substances prohibited for use in organic crop production; and

(5) A plant or animal material that has been chemically altered by a manufacturing process: Provided, That, the material is included on the National List of synthetic substances allowed for use in organic crop production established in § 205.601.

(e) The producer must not use:

(1) Any fertilizer or composted plant and animal material that contains a synthetic substance not included on the National List of synthetic substances allowed for use in organic crop production;

(2) Sewage sludge (biosolids) as defined in 40 CFR Part 503; and

(3) Burning as a means of disposal for crop residues produced on the operation: Except, That, burning may be used to suppress the spread of disease or to stimulate seed germination.

§ 205.204 Seeds and planting stock practice standard.

(a) The producer must use organically grown seeds, annual seedlings, and planting stock: Except, That,

(1) Non-organically produced, untreated seeds and planting stock may be used to produce an organic crop when an equivalent organically produced variety is not commercially available, Except, That, organically produced seed must be used for the production of edible sprouts;

(2) Non-organically 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) Non-organically 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) Non-organically 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.

§ 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) Non-synthetic 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 non-synthetic biological, botanical, or mineral inputs.

(e) When the practices provided for in paragraphs (a) through (d) of this section are insufficient to prevent or control crop pests, weeds, and diseases, a biological or botanical substance or a substance included on the National List of synthetic substances allowed for use in organic crop production may be applied to prevent, suppress, or control pests, weeds, or diseases: Provided, That, the conditions for using the substance are documented in the organic system plan.

(f) The producer must not use lumber treated with arsenate or other prohibited materials for new installations or replacement purposes in contact with soil or livestock.

§ 205.207 Wild-crop harvesting practice standard.

(a) A wild crop that is intended to be sold, labeled, or represented as organic must be harvested from a designated area that has had no prohibited substance, as set forth in § 205.105, applied to it for a period of 3 years immediately preceding the harvest of the wild crop.

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

§§ 205.208 - 205.235 [Reserved]

§ 205.236 Origin of livestock.

(a) Livestock products that are to be sold, labeled, or represented as organic must be from livestock under continuous organic management from the last third of gestation or hatching: Except, That,

(1) Poultry. Poultry or edible poultry products must be from poultry that has been under continuous organic management beginning no later than the second day of life;

(2) Dairy animals. Milk or milk products must be from animals that have been under continuous organic management beginning no later than 1 year prior to the production of the milk or milk products that are to be sold, labeled, or represented as organic, Except, That, when an entire, distinct herd is converted to organic production, the producer may:

(i) For the first 9 months of the year, provide a minimum of 80-percent feed that is either organic or raised from land included in the organic system plan and managed in compliance with organic crop requirements; and

(ii) provide feed in compliance with § 205.237 for the final 3 months.

(iii) Once an entire, distinct herd has been converted to organic production, all dairy animals shall be under organic management from the last third of gestation.

(3) Breeder stock. Livestock used as breeder stock may be brought from a non-organic operation onto an organic operation at any time: Provided, That, if such livestock are gestating and the offspring are to be raised as organic livestock, the breeder stock must be brought onto the facility no later than the last third of gestation.

(b) The following are prohibited:

(1) Livestock or edible livestock products that are removed from an organic operation and subsequently managed on a non-organic operation may be not sold, labeled, or represented as organically produced.

(2) Breeder or dairy stock that has not been under continuous organic management since the last third of gestation may not be sold, labeled, or represented as organic slaughter stock.

(c) The producer of an organic livestock operation must maintain records sufficient to preserve the identity of all organically managed animals and edible and non-edible animal products produced on the operation.

§ 205.237 Livestock feed.

(a) The producer of an organic livestock operation must provide livestock with a total feed ration composed of agricultural products, including pasture and forage, that are organically produced and, if applicable, organically handled: Except, That, non-synthetic substances and synthetic substances allowed under § 205.603 may be used as feed additives and supplements.

(b) The producer of an organic operation must not:

(1) Use animal drugs, including hormones, to promote growth;

(2) Provide feed supplements or additives in amounts above those needed for adequate nutrition and health maintenance for the species at its specific stage of life;

(3) Feed plastic pellets for roughage;

(4) Feed formulas containing urea or manure;

(5) Feed mammalian or poultry slaughter by-products to mammals or poultry; or

(6) Use feed, feed additives, and feed supplements in violation of the Federal Food, Drug, and Cosmetic Act.

§ 205.238 Livestock health care practice standard.

(a) The producer must establish and maintain preventive livestock health care practices, including:

(1) Selection of species and types of livestock with regard to suitability for site-specific conditions and resistance to prevalent diseases and parasites;

(2) Provision of a feed ration sufficient to meet nutritional requirements, including vitamins, minerals, protein and/or amino acids, fatty acids, energy sources, and fiber (ruminants);

(3) Establishment of appropriate housing, pasture conditions, and sanitation practices to minimize the occurrence and spread of diseases and parasites;

(4) Provision of conditions that allow for exercise, freedom of movement, and reduction of stress appropriate to the species;

(5) Performance of physical alterations as needed to promote the animal's welfare and in a manner that minimizes pain and stress; and

(6) Administration of vaccines and other veterinary biologics.

(b) When preventive practices and veterinary biologics are inadequate to prevent sickness, a producer may administer synthetic medications: Provided, That, such medications are allowed under § 205.603. Parasiticides allowed under § 205.603 may be used on

(1) Breeder stock, when used prior to the last third of gestation but not during lactation for progeny that are to be sold, labeled, or represented as organically produced; and

(2) Dairy stock, when used a minimum of 90 days prior to the production of milk or milk products that are to be sold, labeled, or represented as organic.

(c) The producer of an organic livestock operation must not:

(1) Sell, label, or represent as organic any animal or edible product derived from any animal treated with antibiotics, any substance that contains a synthetic substance not allowed under § 205.603, or any substance that contains a non-synthetic substance prohibited in § 205.604.

(2) Administer any animal drug, other than vaccinations, in the absence of illness;

(3) Administer hormones for growth promotion;

(4) Administer synthetic parasiticides on a routine basis;

(5) Administer synthetic parasiticides to slaughter stock;

(6) Administer animal drugs in violation of the Federal Food, Drug, and Cosmetic Act; or

(7) Withhold medical treatment from a sick animal in an effort to preserve its organic status. All appropriate medications must be used to restore an animal to health when methods acceptable to organic production fail. Livestock treated with a prohibited

substance must be clearly identified and shall not be sold, labeled, or represented as organically produced.

§ 205.239 Livestock living conditions.

(a) The producer of an organic livestock operation must establish and maintain livestock living conditions that accommodate the health and natural behavior of animals, including:

(1) Access to the outdoors, shade, shelter, exercise areas, fresh air, and direct sunlight suitable to the species, its stage of production, the climate, and the environment;

(2) Access to pasture for ruminants;

(3) Appropriate clean, dry bedding. If the bedding is typically consumed by the animal species, it must comply with the feed requirements of § 205.237;

(4) Shelter designed to allow for:

(i) Natural maintenance, comfort behaviors, and opportunity to exercise;

(ii) Temperature level, ventilation, and air circulation suitable to the species; and

(iii) Reduction of potential for livestock injury;

(b) The producer of an organic livestock operation may provide temporary confinement for an animal because of:

(1) Inclement weather;

(2) The animal's stage of production;

(3) Conditions under which the health, safety, or well being of the animal could be jeopardized; or

(4) Risk to soil or water quality.

(c) The producer of an organic livestock operation must manage manure in a manner that does not contribute to contamination of crops, soil, or water by plant nutrients, heavy metals, or pathogenic organisms and optimizes recycling of nutrients.

§§ 205.240 - 205.269 [Reserved]

§ 205.270 Organic handling requirements.

(a) Mechanical or biological methods, including but not limited to cooking, baking, curing, heating, drying, mixing, grinding, churning, separating, distilling, extracting, slaughtering, cutting, fermenting, eviscerating, preserving, dehydrating, freezing, chilling, or otherwise manufacturing, and the packaging, canning, jarring, or otherwise enclosing food in a container may be used to process an organically produced agricultural product for the purpose of retarding spoilage or otherwise preparing the agricultural product for market.

(b) Nonagricultural substances allowed under § 205.605 and non-organically produced agricultural products allowed under § 205.606 may be used:

(1) In or on a processed agricultural product intended to be sold, labeled, or represented as "organic," pursuant to § 205.301(b), if not commercially available in organic form.

(2) In or on a processed agricultural product intended to be sold, labeled, or represented as "made with organic (specified ingredients or food group(s))," pursuant to § 205.301(c).

(c) The handler of an organic handling operation must not use in or on agricultural products intended to be sold, labeled, or represented as "100 percent organic," "organic," or "made with organic (specified ingredients or food group(s))," or in or on any ingredients labeled as organic:

(1) Practices prohibited under paragraphs (e) and (f) of § 205.105.

(2) A volatile synthetic solvent or other synthetic processing aid not allowed under § 205.605, Except, That, non-organic ingredients in products labeled "made with organic (specified ingredients or food group(s))" are not subject to this requirement.

§ 205.271 Facility pest management practice standard.

(a) The producer or handler of an organic facility must use management practices to prevent pests, including but not limited to:

(1) Removal of pest habitat, food sources, and breeding areas;

(2) Prevention of access to handling facilities; and

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

(b) Pests may be controlled through:

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

(2) Lures and repellents using non-synthetic or synthetic substances consistent with the National List.

(c) If the practices provided for in paragraphs (a) and (b) of this section are not effective to prevent or control pests, a non-synthetic or synthetic substance consistent with the National List may be applied.

(d) If the practices provided for in paragraphs (a), (b), and © of this section are not effective to prevent or control facility pests, a synthetic substance not on the National List may be applied, Provided, That, the handler and certifying agent agree on the substance, method of application, and measures to be taken to prevent contact of the organically produced products or ingredients with the substance used.

(e) The handler of an organic handling operation who applies a non-synthetic or synthetic substance to prevent or control pests must update the operation's organic handling plan to reflect the use of such substances and methods of application. The updated organic plan must include a list of all measures taken to prevent contact of the organically produced products or ingredients with the substance used.

(f) Notwithstanding the practices provided for in paragraphs (a), (b), (c), and (d) of this section, a handler may otherwise use substances to prevent or control pests as required by Federal, State, or local laws and regulations, Provided, That, measures are taken to prevent contact of the organically produced products or ingredients with the substance used.

§ 205.272 Commingling and contact with prohibited substance prevention practice standard.

(a) The handler of an organic handling operation must implement measures necessary to prevent the commingling of organic and non-organic products and protect organic products from contact with prohibited substances.

(b) The following are prohibited for use in the handling of any organically produced agricultural product or ingredient labeled in accordance with subpart D of this part:

(1) Packaging materials, and storage containers, or bins that contain a synthetic fungicide, preservative, or fumigant;

(2) The use or reuse of any bag or container that has been in contact with any substance in such a manner as to compromise the organic integrity of any organically produced product or ingredient placed in those containers, unless such reusable bag or container has been thoroughly cleaned and poses no risk of contact of the organically produced product or ingredient with the substance used.

§§ 205.273 - 205.289 [Reserved]

§ 205.290 Temporary variances.

(a) Temporary variances from the requirements in §§ 205.203 through 205.207, 205.236 through 205.239, and 205.270 through 205.272 may be established by the Administrator for the following reasons:

(1) Natural disasters declared by the Secretary;

(2) Damage caused by drought, wind, flood, excessive moisture, hail, tornado, earthquake, fire, or other business interruption; and

(3) Practices used for the purpose of conducting research or trials of techniques, varieties, or ingredients used in organic production or handling.

(b) A State organic program's governing State official or certifying agent may recommend in writing to the Administrator that a temporary variance from a standard set forth in subpart C of this part for organic production or handling operations be established: Provided, That, such variance is based on one or more of the reasons listed in paragraph (a) of this section.

(c) The Administrator will provide written notification to certifying agents upon establishment of a temporary variance applicable to the certifying agent's certified production or handling operations and specify the period of time it shall remain in effect, subject to extension as the Administrator deems necessary.

(d) A certifying agent, upon notification from the Administrator of the establishment of a temporary variance, must notify each production or handling operation it certifies to which the temporary variance applies.

(e) Temporary variances will not be granted for any practice, material, or procedure prohibited under § 205.105.

§§ 205.291-205.299 [Reserved]

Subpart D - Labels, Labeling, and Market Information

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

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

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

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

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

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

Description of Regulations

General Requirements

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

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

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

Categories of Organic Content

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

organic; 95 percent or more organic; 70 to 95 percent organic; and less than 70 percent organic.

100 Percent Organic

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

Organic

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

Made with Organic Ingredients

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

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

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

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

Product With Less Than 70 Percent Organic Ingredients

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

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

Livestock feed

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

Prohibited Practices

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

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

TABLE 1: PROHIBITED PRODUCTION AND HANDLING PRACTICES FOR LABELING CATEGORIES

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

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

Calculating the Percentage of Organic Ingredients

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

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

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

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

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

Labeling "100 Percent Organic" and "Organic" Products

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

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

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

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

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

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

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

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

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

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

The USDA seal may not be displayed on the pdp of products labeled "made with organic ingredients." However, at the handler's option and consistent with any contract agreement between the organic producer or handler and the certifying agent, the certifying agent's seal or logo may be displayed on the pdp and other package panels.

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

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

The handler may include the business address, Internet address, or telephone number of the certifying agent which certified the handler of the finished product.

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

Labeling Products with Less Than 70 Percent Organic Ingredients

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

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

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

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

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

TABLE 2: LABELING CONSUMER PRODUCT PACKAGES

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

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

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

imply that products labeled in this manner are different from other organic products that are not so labeled.

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

Labeling Organically Produced Livestock Feed Products

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

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

Labeling of Products Shipped in International Markets

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

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

Labeling Nonretail Containers

Section 205.307 provides for labeling nonretail containers used to ship or store raw or processed organic agricultural products that are labeled "100 percent organic," "organic," and "made with organic..." Labeling nonretail containers as containing organically produced product should provide for easy identification of the product to help prevent commingling with

non-organic product or handling of the product which would destroy the organic nature of the product (fumigation, etc.). These labeling provisions are not intended for shipping or storage containers that also are used in displays at the point of retail sale. Retail containers must meet labeling provisions specified in section 205.307.

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

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

Labeling Products at the Point of Retail Sale

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

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

Section 205.309 addresses "made with..." products that are not packaged prior to sale and are presented in a manner which allows the consumer to select the quantity of the product purchased. These products include, but are not limited to, multi-ingredient products containing between 70 and 95 percent organic ingredients. The "made with..." label may be used to modify the name of the product in retail displays, labeling, and market information. Up to three organic ingredients or food groups may be identified in the statement. If such statement is declared in market information at the point of retail sale, the ingredient statement and market information must identify the organic ingredients. Retail display and market information of bulk products cannot display the USDA seal but may, if the product is prepared in a certified facility, display the seal or logo of the certifying agent which certified the finished product. The certifying agent's seal or logo may be displayed at the option of the retail food establishment.

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

Labeling Products Produced in Exempt or Excluded Operations

Section 205.310 provides limited organic labeling provisions for organic product produced or handled on exempt and excluded operations. Such operations would include retail food establishments, certain manufacturing facilities, and production and handling operations with

annual organic sales of less than \$5,000. These operations are discussed more thoroughly in subpart B, Applicability.

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

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

USDA Organic Seal

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

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

Labeling - Changes Based on Comments

The following changes are made based on comments received.

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

We agree with commenters that such product names can be misleading and would be a violation of section 205.300(a). In the examples, the word, "organic," precedes the words, "chocolate" and "cherry," and clearly implies that those ingredients are organically produced. The chocolate and cherry flavorings must be organically produced to be used in this way. If the product is at least 95 percent organically produced but the flavoring is non-organic, the word sequence must be reversed or the word, "flavored," must be added to the name; e.g.,

"chocolate organic ice cream" or "chocolate flavored organic ice cream." A sentence has been added to section 205.300(a) to specify that the term, "organic," may not be used in a product name to identify an ingredient that is not organically produced.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Comments to the first (1997) proposal and to the revised proposed rule suggested that the minimum organic content for labeling purposes should be increased. All comments received, including comments from certifying agents, a leading organic association, the EU and other international commenters recommended that the minimum organic content to qualify for pdp labeling should be raised to 70 percent, which is the EU's minimum. All comments stated that the increase is necessary to make the NOP standards consistent with international organic standards. Commenters also pointed to advances in organic production and processing technologies and to increases in the availability of organically produced products and processed ingredients. These factors should make it easier for handlers to assemble food products with higher organic content.

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

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

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

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

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

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

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

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

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

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

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

Labeling - Changes Requested But Not Made

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

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

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

Regarding the first comment, the term is not specifically provided for in the Act. However, the Secretary has the authority under section 6506(a)(11) to require other terms and conditions as may be necessary to develop a national organic program. When a product is wholly organic, pursuant to the production and handling requirements of the NOP, we believe the handler should have the option to differentiate it from products which, by necessity, are less than 100 percent organic. We believe the label meets the purposes of the Act.

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

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

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

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

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

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

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

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

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

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

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

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

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

A few commenters contended that the statement "made with organic (specified ingredients)" is unclear and "open ended" and that consumers may assume the entire product is organically produced. The "made with..." labeling claim refers only to the organic ingredients and not to the whole product. We do not believe that consumers will be confused by the label.

(7) Use of Other Terms as Synonymous for "Organic". A few commenters representing international organic standards suggested that use of the terms, "biologic" and "ecologic," which are synonymous with "organic" in other countries, should be allowed under the NOP. Commenters claimed these terms are approved by Codex and their inclusion in this regulation would facilitate international trade and equivalency agreements.

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

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

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

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

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

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

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

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

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

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

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

We do not believe the suggested change is necessary. We assume that any use of a certifying agent's seal on a product means that the certifying agent has checked and

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

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

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

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

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

Labeling - Clarifications

Clarification is given on the following issues raised by commenters:

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

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

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

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

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

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

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

Minor ingredients and processing aids must be treated as any other ingredient or substance which is used as an ingredient in or in the processing of an organically produced product. To be added as an ingredient or used in the processing of a product labeled "100 percent organic," a minor ingredient must be extracted from a certified organic source without the use of chemicals or solvents. To be added as an ingredient or used in the processing of a product labeled "organic," a minor ingredient must be from an organic agricultural source, if commercially available. If not commercially available, the ingredient must be an agricultural product or a substance consistent with the National List.

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

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

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

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

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

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

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

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

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

Subpart D - Labels, Labeling, and Market Information

§ 205.300 Use of the term, "organic."

(a) The term, "organic," may only be used on labels and in labeling of raw or processed agricultural products, including ingredients, that have been produced and handled in accordance with the regulations in this part. The term, "organic," may not be used in a product name to modify a non-organic ingredient in the product.

(b) Products for export, produced and certified to foreign national organic standards or foreign contract buyer requirements, may be labeled in accordance with the organic labeling requirements of the receiving country or contract buyer. Provided, That, the shipping containers and shipping documents meet the labeling requirements specified in § 205.307(c).

(c) Products produced in a foreign country and exported for sale in the United States must be certified pursuant to subpart E of this part and labeled pursuant to this subpart D.

(d) Livestock feeds produced in accordance with the requirements of this part must be labeled in accordance with the requirements of § 205.306.

§ 205.301 Product composition.

(a) Products sold, labeled, or represented as "100 percent organic." A raw or processed agricultural product sold, labeled, or represented as "100 percent organic" must contain (by weight or fluid volume, excluding water and salt) 100 percent organically produced ingredients. If labeled as organically produced, such product must be labeled pursuant to § 205.303.

(b) Products sold, labeled, or represented as "organic." A raw or processed agricultural product sold, labeled, or represented as "organic" must contain (by weight or fluid volume, excluding water and salt) not less than 95 percent organically produced raw or processed agricultural products. Any remaining product ingredients must be organically produced, unless not commercially available in organic form, or must be nonagricultural substances or non-organically produced agricultural products produced consistent with the National List in subpart G of this part. If labeled as organically produced, such product must be labeled pursuant to § 205.303.

(c) Products sold, labeled, or represented as "made with organic (specified ingredients or food group(s))." Multi-ingredient agricultural product sold, labeled, or represented as "made with organic (specified ingredients or food group(s))" must contain (by weight or fluid volume, excluding water and salt) at least 70 percent organically produced ingredients which are produced and handled pursuant to requirements in subpart C of this part. No ingredients may be produced using prohibited practices specified in paragraphs (1), (2), and (3) of § 205.301(f). Non-organic ingredients may be produced without regard to paragraphs (4), (5), (6), and (7) of § 205.301(f). If labeled as containing organically produced ingredients or food groups, such product must be labeled pursuant to § 205.304.

(d) Products with less than 70 percent organically produced ingredients. The organic ingredients in multi-ingredient agricultural product containing less than 70 percent organically produced ingredients (by weight or fluid volume, excluding water and salt) must be produced and handled pursuant to requirements in subpart C of this part. The non-organic ingredients may be produced and handled without regard to the requirements of this part. Multi-ingredient agricultural product containing less than 70 percent organically produced ingredients may represent the organic nature of the product only as provided in § 205.305.

(e) Livestock feed:

(1) A raw or processed livestock feed product sold, labeled, or represented as "100 percent organic" must contain (by weight or fluid volume, excluding water and salt) not less than 100 percent organically produced raw or processed agricultural product.

(2) A raw or processed livestock feed product sold, labeled, or represented as "organic" must be produced in conformance with § 205.237.

(f) All products labeled as "100 percent organic" or "organic" and all ingredients identified as "organic" in the ingredient statement of any product must not:

(1) Be produced using excluded methods, pursuant to § 201.105(e);

(2) Be produced using sewage sludge, pursuant to § 201.105(f);

(3) Be processed using ionizing radiation, pursuant to § 201.105(g);

(4) Be processed using processing aids not approved on the National List of Allowed and Prohibited Substances in subpart G of this part: Except, That, products labeled as "100 percent organic," if processed, must be processed using organically produced processing aids;

(5) Contain sulfites, nitrates, or nitrites added during the production or handling process, Except, That, wine containing added sulfites may be labeled "made with organic grapes";

(6) Be produced using non-organic ingredients when organic ingredients are available; or

(7) Include organic and non-organic forms of the same ingredient.

§ 205.302 Calculating the percentage of organically produced ingredients.

(a) The percentage of all organically produced ingredients in an agricultural product sold, labeled, or represented as "100 percent organic," "organic," or "made with organic (specified ingredients or food group(s))," or that include organic ingredients must be calculated by:

(1) Dividing the total net weight (excluding water and salt) of combined organic ingredients at formulation by the total weight (excluding water and salt) of the finished product.

(2) Dividing the fluid volume of all organic ingredients (excluding water and salt) by the fluid volume of the finished product (excluding water and salt) if the product and ingredients are liquid. If the liquid product is identified on the principal display panel or information panel as being reconstituted from concentrates, the calculation should be made on the basis of single-strength concentrations of the ingredients and finished product.

(3) For products containing organically produced ingredients in both solid and liquid form, dividing the combined weight of the solid ingredients and the weight of the liquid ingredients (excluding water and salt) by the total weight (excluding water and salt) of the finished product.

(b) The percentage of all organically produced ingredients in an agricultural product must be rounded down to the nearest whole number.

(c) The percentage must be determined by the handler who affixes the label on the consumer package and verified by the certifying agent of the handler. The handler may use information provided by the certified operation in determining the percentage.

§ 205.303 Packaged products labeled "100 percent organic" or "organic."

(a) Agricultural products in packages described in § 205.301(a) and (b) may display, on the principal display panel, information panel, and any other panel of the package and on any labeling or market information concerning the product, the following:

(1) The term, "100 percent organic" or "organic," as applicable, to modify the name of the product;

(2) For products labeled "organic," the percentage of organic ingredients in the product; (The size of the percentage statement must not exceed one-half the size of the largest type size on the panel on which the statement is displayed and must appear in its entirety in the same type size, style, and color without highlighting.)

(3) The term, "organic," to identify the organic ingredients in multi-ingredient products labeled "100 percent organic";

(4) The USDA seal; and/or

(5) The seal, logo, or other identifying mark of the certifying agent which certified the production or handling operation producing the finished product and any other certifying agent which certified production or handling operations producing raw organic product or organic ingredients used in the finished product: Provided, That, the handler producing the finished product maintain records, pursuant to this part, verifying organic certification of the operations producing such ingredients, and: Provided further, That, such seals or marks are not individually displayed more prominently than the USDA seal.

(b) Agricultural products in packages described in § 205.301(a) and (b) must:

(1) For products labeled "organic," identify each organic ingredient in the ingredient statement with the word, "organic," or with an asterisk or other reference mark which is defined below the ingredient statement to indicate the ingredient is organically produced. Water or salt included as ingredients cannot be identified as organic.

(2) On the information panel, below the information identifying the handler or distributor of the product and preceded by the statement, "Certified organic by....," or similar phrase, identify the name of the certifying agent that certified the handler of the finished product and may display the business address, Internet address, or telephone number of the certifying agent in such label.

§ 205.304 Packaged products labeled "made with organic (specified ingredients or food group(s))."

(a) Agricultural products in packages described in § 205.301(c) may display on the principal display panel, information panel, and any other panel and on any labeling or market information concerning the product:

(1) The statement:

(i) "Made with organic (specified ingredients)": Provided, That, the statement does not list more than three organically produced ingredients; or

(ii) "Made with organic (specified food groups)": Provided, That, the statement does not list more than three of the following food groups: beans, fish, fruits, grains, herbs, meats, nuts, oils, poultry, seeds, spices, sweeteners, and vegetables or processed milk products; and, Provided Further, That, all

ingredients of each listed food group in the product must be organically produced; and

(iii) Which appears in letters that do not exceed one-half the size of the largest type size on the panel and which appears in its entirety in the same type size, style, and color without highlighting.

(2) The percentage of organic ingredients in the product. The size of the percentage statement must not exceed one-half the size of the largest type size on the panel on which the statement is displayed and must appear in its entirety in the same type size, style, and color without highlighting.

(3) The seal, logo, or other identifying mark of the certifying agent that certified the handler of the finished product.

(b) Agricultural products in packages described in § 205.301(c) must:

(1) In the ingredient statement, identify each organic ingredient with the word, "organic," or with an asterisk or other reference mark which is defined below the ingredient statement to indicate the ingredient is organically produced. Water or salt included as ingredients cannot be identified as organic.

(2) On the information panel, below the information identifying the handler or distributor of the product and preceded by the statement, "Certified organic by..." or similar phrase, identify the name of the certifying agent that certified the handler of the finished product: Except, That, the business address, Internet address, or telephone number of the certifying agent may be included in such label.

(c) Agricultural products in packages described in § 205.301(c) must not display the USDA seal.

§ 205.305 Multi-ingredient packaged products with less than 70 percent organically produced ingredients.

(a) An agricultural product with less than 70 percent organically produced ingredients may only identify the organic content of the product by:

(1) Identifying each organically produced ingredient in the ingredient statement with the word, "organic," or with an asterisk or other reference mark which is defined below the ingredient statement to indicate the ingredient is organically produced, and

(2) If the organically produced ingredients are identified in the ingredient statement, displaying the product's percentage of organic contents on the information panel.

(b) Agricultural products with less than 70 percent organically produced ingredients must not display:

(1) The USDA seal; and

(2) Any certifying agent seal, logo, or other identifying mark which represents organic certification of a product or product ingredients.

§ 205.306 Labeling of livestock feed.

(a) Livestock feed products described in § 205.301(e)(1) and (e)(2) may display on any package panel the following terms:

(1) The statement, "100 percent organic" or "organic," as applicable, to modify the name of the feed product;

(2) The USDA seal;

(3) The seal, logo, or other identifying mark of the certifying agent which certified the production or handling operation producing the raw or processed organic ingredients used in the finished product, Provided, That, such seals or marks are not displayed more prominently than the USDA seal;

(4) The word, "organic," or an asterisk or other reference mark which is defined on the package to identify ingredients that are organically produced. Water or salt included as ingredients cannot be identified as organic.

(b) Livestock feed products described in § 205.301(e)(1) and (e)(2) must:

(i) On the information panel, below the information identifying the handler or distributor of the product and preceded by the statement, "Certified organic by....," or similar phrase, display the name of the certifying agent that certified the handler of the finished product. The business address, Internet address, or telephone number of the certifying agent may be included in such label.

(ii) Comply with other Federal agency or State feed labeling requirements as applicable.

§ 205.307 Labeling of nonretail containers used for only shipping or storage of raw or processed agricultural products labeled as "100 percent organic," "organic," or "made with organic (specified ingredients or food group(s))."

(a) Nonretail containers used only to ship or store raw or processed agricultural product labeled as containing organic ingredients may display the following terms or marks:

(1) The name and contact information of the certifying agent which certified the handler which assembled the final product;

(2) Identification of the product as organic;

(3) Special handling instructions needed to maintain the organic integrity of the product;

(4) The USDA seal;

(5) The seal, logo, or other identifying mark of the certifying agent that certified the organic production or handling operation that produced or handled the finished product.

(b) Nonretail containers used to ship or store raw or processed agricultural product labeled as containing organic ingredients must display the production lot number of the product if applicable.

(c) Shipping containers of domestically produced product labeled as organic intended for export to international markets may be labeled in accordance with any shipping container labeling requirements of the foreign country of destination or the container labeling specifications of a foreign contract buyer. Provided, That, the shipping containers and shipping documents accompanying such organic products are clearly marked "For Export Only" and: Provided further, That, proof of such container marking and export must be maintained by the handler in accordance with recordkeeping requirements for exempt and excluded operations under § 205.101.

§ 205.308 Agricultural products in other than packaged form at the point of retail sale that are sold, labeled, or represented as "100 percent organic" or "organic."

(a) Agricultural products in other than packaged form may use the term, "100 percent organic" or "organic," as applicable, to modify the name of the product in retail display,

labeling, and display containers: Provided, That, the term, "organic," is used to identify the organic ingredients listed in the ingredient statement.

(b) If the product is prepared in a certified facility, the retail display, labeling, and display containers may use:

(1) The USDA seal; and

(2) The seal, logo, or other identifying mark of the certifying agent that certified the production or handling operation producing the finished product and any other certifying agent which certified operations producing raw organic product or organic ingredients used in the finished product: Provided, That, such seals or marks are not individually displayed more prominently than the USDA seal.

§ 205.309 Agricultural products in other than packaged form at the point of retail sale that are sold, labeled, or represented as "made with organic (specified ingredients or food group(s))."

(a) Agricultural products in other than packaged form containing between 70 and 95 percent organically produced ingredients may use the phrase, "made with organic (specified ingredients or food group(s))," to modify the name of the product in retail display, labeling, and display containers.

(1) Such statement must not list more than three organic ingredients or food groups, and

(2) In any such display of the product's ingredient statement, the organic ingredients are identified as "organic."

(b) If prepared in a certified facility, such agricultural products labeled as "made with organic (specified ingredients or food group(s))" in retail displays, display containers, and market information may display the certifying agent's seal, logo, or other identifying mark.

§ 205.310 Agricultural products produced on an exempt or excluded operation.

(a) An agricultural product organically produced or handled on an exempt or excluded operation must not:

(1) Display the USDA seal or any certifying agent's seal or other identifying mark which represents the exempt or excluded operation as a certified organic operation, or

(2) Be represented as a certified organic product or certified organic ingredient to any buyer.

(b) An agricultural product organically produced or handled on an exempt or excluded operation may be identified as an organic product or organic ingredient in a multi-ingredient product produced by the exempt or excluded operation. Such product or ingredient must not be identified or represented as "organic" in a product processed by others.

(c) Such product is subject to requirements specified in paragraph (a) of § 205.300, and paragraphs (f)(1) through (f)(7) of § 205.301.

§ 205.311 USDA Seal.

(a) The USDA seal described in paragraphs (b) and (c) of this section may be used only for raw or processed agricultural products described in paragraphs (a), (b), (e)(1), and (e)(2) of § 205.301.

(b) The USDA seal must replicate the form and design of the example in figure 1 and must be printed legibly and conspicuously:

(1) On a white background with a brown outer circle and with the term, "USDA," in green overlaying a white upper semicircle and with the term, "organic," in white overlaying the green lower half circle; or

(2) On a white or transparent background with black outer circle and black "USDA" on a white or transparent upper half of the circle with a contrasting white or transparent "organic" on the black lower half circle.

(3) The green or black lower half circle may have four light lines running from left to right and disappearing at the point on the right horizon to resemble a cultivated field.

§§ 205.312-205.399 [Reserved]

Subpart E - Certification

§ 205.400 General requirements for certification.

A person seeking to receive or maintain organic certification under the regulations in this part must:

- (a) Comply with the Act and applicable organic production and handling regulations of this part;
- (b) Establish, implement, and update annually an organic production or handling system plan that is submitted to an accredited certifying agent as provided for in § 205.200;
- (c) Permit on-site inspections with complete access to the production or handling operation, including noncertified production and handling areas, structures, and offices by the certifying agent as provided for in § 205.403;
- (d) Maintain all records applicable to the organic operation for not less than 5 years beyond their creation and allow authorized representatives of the Secretary, the applicable State organic program's governing State official, and the certifying agent access to such records during normal business hours for review and copying to determine compliance with the Act and the regulations in this part, as provided for in § 205.104;
- (e) Submit the applicable fees charged by the certifying agent; and
- (f) Immediately notify the certifying agent concerning any:
 - (1) Application, including drift, of a prohibited substance to any field, production unit, site, facility, livestock, or product that is part of an operation; and
 - (2) Change in a certified operation or any portion of a certified operation that may affect its compliance with the Act and the regulations in this part.

§ 205.401 Application for Certification.

A person seeking certification of a production or handling operation under this subpart must submit an application for certification to a certifying agent. The application must include the following information:

- (a) An organic production or handling system plan, as required in § 205.200;
- (b) The name of the person completing the application; the applicant's business name, address, and telephone number; and, when the applicant is a corporation, the name, address, and telephone number of the person authorized to act on the applicant's behalf;
- (c) The name(s) of any organic certifying agent(s) to which application has previously been made; the year(s) of application; the outcome of the application(s) submission, including, when available, a copy of any notification of noncompliance or denial of certification issued to the applicant for certification; and a description of the actions taken by the applicant to correct the noncompliances noted in the notification of noncompliance, including evidence of such correction; and
- (d) Other information necessary to determine compliance with the Act and the regulations in this part.

§ 205.402 Review of application.

- (a) Upon acceptance of an application for certification, a certifying agent must:
 - (1) Review the application to ensure completeness pursuant to § 205.401;

(2) Determine by a review of the application materials whether the applicant appears to comply or may be able to comply with the applicable requirements of subpart C of this part;

(3) Verify that an applicant who previously applied to another certifying agent and received a notification of noncompliance or denial of certification, pursuant to § 205.405, has submitted documentation to support the correction of any noncompliances identified in the notification of noncompliance or denial of certification, as required in § 205.405(e); and

(4) Schedule an on-site inspection of the operation to determine whether the applicant qualifies for certification if the review of application materials reveals that the production or handling operation may be in compliance with the applicable requirements of subpart C of this part.

(b) The certifying agent shall within a reasonable time:

(1) Review the application materials received and communicate its findings to the applicant;

(2) Provide the applicant with a copy of the on-site inspection report, as approved by the certifying agent, for any on-site inspection performed; and

(3) Provide the applicant with a copy of the test results for any samples taken by an inspector.

(c) The applicant may withdraw its application at any time. An applicant who withdraws its application shall be liable for the costs of services provided up to the time of withdrawal of its application. An applicant that voluntarily withdrew its application prior to the issuance of a notice of noncompliance will not be issued a notice of noncompliance. Similarly, an applicant that voluntarily withdrew its application prior to the issuance of a notice of certification denial will not be issued a notice of certification denial.

§ 205.403 On-site inspections.

(a) On-site inspections. (1) A certifying agent must conduct an initial on-site inspection of each production unit, facility, and site that produces or handles organic products and that is included in an operation for which certification is requested. An on-site inspection shall be conducted annually thereafter for each certified operation that produces or handles organic products for the purpose of determining whether to approve the request for certification or whether the certification of the operation should continue.

(2) (i) A certifying agent may conduct additional on-site inspections of applicants for certification and certified operations to determine compliance with the Act and the regulations in this part.

(ii) The Administrator or State organic program's governing State official may require that additional inspections be performed by the certifying agent for the purpose of determining compliance with the Act and the regulations in this part.

(iii) Additional inspections may be announced or unannounced at the discretion of the certifying agent or as required by the Administrator or State organic program's governing State official.

(b) Scheduling. (1) The initial on-site inspection must be conducted within a reasonable time following a determination that the applicant appears to comply or may be able to comply with the requirements of subpart C of this part: Except, That, the initial inspection may be delayed for up to 6 months to comply with the requirement that the inspection be conducted when the

land, facilities, and activities that demonstrate compliance or capacity to comply can be observed.

(2) All on-site inspections must be conducted when an authorized representative of the operation who is knowledgeable about the operation is present and at a time when land, facilities, and activities that demonstrate the operation's compliance with or capability to comply with the applicable provisions of subpart C of this part can be observed, except that this requirement does not apply to unannounced on-site inspections.

(c) Verification of information. The on-site inspection of an operation must verify:

(1) The operation's compliance or capability to comply with the Act and the regulations in this part;

(2) That the information, including the organic production or handling system plan, provided in accordance with §§ 205.401, 205.406, and 205.200, accurately reflects the practices used or to be used by the applicant for certification or by the certified operation;

(3) That prohibited substances have not been and are not being applied to the operation through means which, at the discretion of the certifying agent, may include the collection and testing of soil; water; waste; seeds; plant tissue; and plant, animal, and processed products samples.

(d) Exit interview. The inspector must conduct an exit interview with an authorized representative of the operation who is knowledgeable about the inspected operation to confirm the accuracy and completeness of inspection observations and information gathered during the on-site inspection. The inspector must also address the need for any additional information as well as any issues of concern.

(e) Documents to the inspected operation. (1) At the time of the inspection, the inspector shall provide the operation's authorized representative with a receipt for any samples taken by the inspector. There shall be no charge to the inspector for the samples taken.

(2) A copy of the on-site inspection report and any test results will be sent to the inspected operation by the certifying agent.

§ 205.404 Granting certification.

(a) Within a reasonable time after completion of the initial on-site inspection, a certifying agent must review the on-site inspection report, the results of any analyses for substances conducted, and any additional information requested from or supplied by the applicant. If the certifying agent determines that the organic system plan and all procedures and activities of the applicant's operation are in compliance with the requirements of this part and that the applicant is able to conduct operations in accordance with the plan, the agent shall grant certification. The certification may include requirements for the correction of minor noncompliances within a specified time period as a condition of continued certification.

(b) The certifying agent must issue a certificate of organic operation which specifies the:

(1) Name and address of the certified operation;

(2) Effective date of certification;

(3) Categories of organic operation, including crops, wild crops, livestock, or processed products produced by the certified operation; and

(4) Name, address, and telephone number of the certifying agent.

(c) Once certified, a production or handling operation's organic certification continues in effect until surrendered by the organic operation or suspended or revoked by the certifying agent, the State organic program's governing State official, or the Administrator.

§ 205.405 Denial of certification.

(a) When the certifying agent has reason to believe, based on a review of the information specified in § 205.402 or § 205.404, that an applicant for certification is not able to comply or is not in compliance with the requirements of this part, the certifying agent must provide a written notification of noncompliance to the applicant. When correction of a noncompliance is not possible, a notification of noncompliance and a notification of denial of certification may be combined in one notification. The notification of noncompliance shall provide:

(1) A description of each noncompliance;

(2) The facts upon which the notification of noncompliance is based; and

(3) The date by which the applicant must rebut or correct each noncompliance and submit supporting documentation of each such correction when correction is possible.

(b) Upon receipt of such notification of noncompliance, the applicant may:

(1) Correct noncompliances and submit a description of the corrective actions taken with supporting documentation to the certifying agent;

(2) Correct noncompliances and submit a new application to another certifying agent. Provided, That, the applicant must include a complete application, the notification of noncompliance received from the first certifying agent, and a description of the corrective actions taken with supporting documentation; or

(3) Submit written information to the issuing certifying agent to rebut the noncompliance described in the notification of noncompliance.

(c) After issuance of a notification of noncompliance, the certifying agent must:

(1) Evaluate the applicant's corrective actions taken and supporting documentation submitted or the written rebuttal, conduct an on-site inspection if necessary, and

(i) When the corrective action or rebuttal is sufficient for the applicant to qualify for certification, issue the applicant an approval of certification pursuant to § 205.404; or

(ii) When the corrective action or rebuttal is not sufficient for the applicant to qualify for certification, issue the applicant a written notice of denial of certification.

(2) Issue a written notice of denial of certification to an applicant who fails to respond to the notification of noncompliance.

(3) Provide notice of approval or denial to the Administrator, pursuant to § 205.501(a)(14).

(d) A notice of denial of certification must state the reason(s) for denial and the applicant's right to:

(1) Reapply for certification pursuant to §§ 205.401 and 205.405(e);

(2) Request mediation pursuant to § 205.663 or, if applicable, pursuant to a State organic program; or

(3) File an appeal of the denial of certification pursuant to § 205.681 or, if applicable, pursuant to a State organic program.

(e) An applicant for certification who has received a written notification of noncompliance or a written notice of denial of certification may apply for certification again at any time with any certifying agent, in accordance with §§ 205.401 and 205.405(e). When such applicant submits a new application to a certifying agent other than the agent who issued the notification of noncompliance or notice of denial of certification, the applicant for certification must include a copy of the notification of noncompliance or notice of denial of certification and a description of the actions taken, with supporting documentation, to correct the noncompliances noted in the notification of noncompliance.

(f) A certifying agent who receives a new application for certification, which includes a notification of noncompliance or a notice of denial of certification, must treat the application as a new application and begin a new application process pursuant to § 205.402.

(g) Notwithstanding paragraph (a) of this section, if a certifying agent has reason to believe that an applicant for certification has willfully made a false statement or otherwise purposefully misrepresented the applicant's operation or its compliance with the certification requirements pursuant to this part, the certifying agent may deny certification pursuant to paragraph (c)(1)(ii) of this section without first issuing a notification of noncompliance.

§ 205.406 Continuation of certification.

(a) To continue certification, a certified operation must annually pay the certification fees and submit the following information, as applicable, to the certifying agent:

(1) An updated organic production or handling system plan which includes:

- (i) A summary statement, supported by documentation, detailing any deviations from, changes to, modifications to, or other amendments made to the previous year's organic system plan during the previous year; and
- (ii) Any additions or deletions to the previous year's organic system plan, intended to be undertaken in the coming year, detailed pursuant to § 205.200;

(2) Any additions to or deletions from the information required pursuant to § 205.401(b);

(3) An update on the correction of minor noncompliances previously identified by the certifying agent as requiring correction for continued certification; and

(4) Other information as deemed necessary by the certifying agent to determine compliance with the Act and the regulations in this part.

(b) Following the receipt of the information specified in paragraph (a) of this section, the certifying agent shall within a reasonable time arrange and conduct an on-site inspection of the certified operation pursuant to § 205.403: Except. That, when it is impossible for the certifying agent to conduct the annual on-site inspection following receipt of the certified operation's annual update of information, the certifying agent may allow continuation of certification and issue an updated certificate of organic operation on the basis of the information submitted and the most recent on-site inspection conducted during the previous 12 months: Provided. That, the annual on-site inspection, required pursuant to § 205.403, is conducted within the first 6 months following the certified operation's scheduled date of annual update.

(c) If the certifying agent has reason to believe, based on the on-site inspection and a review of the information specified in § 205.404, that a certified operation is not complying with the requirements of the Act and the regulations in this part, the certifying agent shall provide a written notification of noncompliance to the operation in accordance with § 205.662.

(d) If the certifying agent determines that the certified operation is complying with the Act and the regulations in this part and that any of the information specified on the certificate of organic operation has changed, the certifying agent must issue an updated certificate of organic operation pursuant to § 205.404(b).

§§ 205.407-205.499 [Reserved]

Subpart F - Accreditation of Certifying Agents

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

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

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

Description of Regulations

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

Application Process

Certifying agents will apply to the Administrator for accreditation to certify production or handling operations operating under the NOP. The certifying agent's application must include basic business information, must identify each area of operation for which accreditation is requested and the estimated number of each type of operation to be certified annually, and must include a list of each State or foreign country where it currently certifies production or handling operations and where it intends to certify such operations. Certifying agents must also submit personnel, administrative, conflict of interest, current certification, and other documents and information to demonstrate their expertise in organic production or handling techniques, their ability to comply with and implement the organic certification program, and their ability to comply with the requirements for accreditation. Certifying agents

planning to certify production or handling operations within a State with an approved State organic program (SOP) must demonstrate their ability to comply with the requirements of the SOP.

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

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

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

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

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

Statement of Agreement.

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

The statement of agreement will include the applicant's agreement to accept the certification decisions made by another certifying agent accredited or accepted by USDA pursuant to

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

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

Granting Accreditation.

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

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

Once accredited, a certifying agent may establish a seal, logo, or other identifying mark to be used by certified production and handling operations. However, the certifying agent may not

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

Site Evaluations.

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

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

Peer Review Panels.

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

Continuing Accreditation.

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

specified in the most recent notification of accreditation or notice of renewal of accreditation; (4) the results of the most recent performance evaluations and annual program review and a description of adjustments to the certifying agent's operation and procedures implemented or to be implemented in response to the performance evaluations and program review; and (5) the required AMS fees.

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

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

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

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

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

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

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

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

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

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

Renewal of Accreditation.

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

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

Amending accreditation.

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

Accreditation - Changes Based on Comments

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

(1) Advice and Consultancy Services. We have amended section 205.501(a)(11)(iv) to clarify that certifying agents are to prevent conflicts of interest by not giving advice or providing consultancy services to applicants for certification and certified operations for overcoming identified barriers to certification. This amendment has been made in response to a commenter who stated that the provisions of section 205.501(a)(11)(iv), as proposed, seemed to preclude the providing of advice and educational workshops and training programs. It was not our intent to prevent certifying agents from sponsoring in-house

publications, conferences, workshops, informational meetings, and field days for which participation is voluntary and open to the general public. The provisions as originally proposed and as amended are intended to prohibit certifying agents from telling applicants and certified operations how to overcome barriers to certification identified by the certifying agent. It would be a conflict of interest for a certifying agent to tell an operation how to comply inasmuch as the certifying agents impartiality and objectivity will be lost should the advice or consultancy prove ineffective in resolving the noncompliance. The provisions of section 205.501(a)(11)(iv) are consistent with ISO Guide 61.

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

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

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

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

(5) Acceptance of Applications. We have added a new section 205.501(a)(19) requiring the certifying agent to accept all production or handling applications for certification that fall within the certifying agent's areas of accreditation and to certify all qualified applicants, to the extent of their administrative capacity to do so, without regard to size or membership in any

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

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

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

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

and 205.510(a)(4) have been amended to make their language consistent with the changes to section 205.501(a)(7).

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

(18) Correction of Minor Noncompliances. We have added a new section 205.506(b)(3) providing that the notification granting accreditation will state any terms and conditions for the correction of minor noncompliances. Commenters requested the addition of language to section 205.506(b) which would clarify that the Administrator may accredit with required corrective actions for minor noncompliances. In the proposed rule, we addressed

accreditation subject to the correction of minor noncompliances at section 205.510(a)(3). We agree with commenters that, for the purposes of clarity, this issue should also be addressed in section 205.506 on the granting of accreditation. Accordingly, we have added new section 205.506(b)(3) as noted above. We have also retained the provisions of section 205.510(a)(3), which requires certifying agents to annually report on actions taken to satisfy any terms and conditions addressed in the most recent notification of accreditation or notice of renewal of accreditation. Section 205.506(b)(3) has been redesignated as section 205.506(b)(4).

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

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

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

(22) Peer Review. We have amended section 205.509. As amended, the section requires that the Administrator establish a peer review panel pursuant to FACA (5 U.S.C. App. 2 et seq.). The peer review panel will be composed of not less than 3 members who will annually evaluate the NOP's adherence to the accreditation procedures in subpart F of these regulations and ISO/IEC Guide 61, General requirements for assessment and accreditation of certification/registration bodies, and the NOP's accreditation decisions. This will be

accomplished through the review of accreditation procedures, document review and site evaluation reports, and accreditation decision documents and documentation. The peer review panel will report its finding, in writing, to the NOP's Program Manager. We developed this approach to peer review as a means of addressing the suggestions of the commenters and the need for administration of an effective and timely accreditation program.

Many commenters wanted the opening language in the first sentence of section 205.509 changed from "The Administrator may" to the "The Administrator shall" establish a peer review panel to assist in evaluating applicants for accreditation, amendment to an accreditation, and renewal of accreditation as certifying agents. One of the most frequent comments, including a comment by the NOSB, was that peer reviewers should be compensated for their time and expenses. Many commenters believe also that the peer review process should be collaborative. Some commenters who wanted this change recognized that a collaborative process where confidential information was shared could run into problems because FACA (P.L. 92-463, 5 U.S.C. App.) meetings are open to the public. They advised creating a FACA panel but restricting public access during discussion of confidential business information based on 5 U.S.C. Section 522b(c)(4) of the Government in the Sunshine Act.

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

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

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

(24) Amendments to Accreditation. We have added a new section 205.510(f) to provide that an amendment to an accreditation may be requested at any time. The application for amendment must be sent to the Administrator and must contain information applicable to the requested change in accreditation. The application for amendment must also contain a complete and accurate update of the information submitted in accordance with section 205.503, Applicant information; and section 205.504, Evidence of expertise and ability. The applicant must also submit the applicable fees required in section 205.640. We have added this new section because we agree with the commenter who expressed concern that the

regulations were not clear regarding amendments to accreditation. This addition is consistent with section 205.510(a)(2) which allows certifying agents to request amendment of their accreditation as part of their annual report to the Administrator.

Accreditation - Changes Requested But Not Made

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

(1) Accreditation by USDA. A commenter stated that ISO/IEC Guide 61 specifies, but the proposed rule did not specify, the requirements for USDA to assess and accredit certifying agents. The commenter questioned USDA's acceptance internationally as a competent accreditation body. A few commenters requested that USDA provide certifying agents with assurance of international trade acceptance of the USDA's accreditation program prior to implementation of the final rule. We do not believe that it is necessary to include in these regulations detailed procedures by which USDA will operate its accreditation program. USDA has developed its accreditation and certification programs with the intent that they meet or exceed international guidelines. Every country will make its own decision regarding acceptance of this accreditation program. Accordingly, while we do not anticipate problems with acceptance of our accreditation program, we cannot provide assurance against problems as requested by the commenters.

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

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

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

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

(5) Requirements for Accreditation. Some commenters requested more specificity in the requirements for accreditation. For example, one recommended that section 205.501(a)(1) should include the requirement that inspectors demonstrate completion of a specified training program or internship or ongoing education and/or licensing. Another commenter wanted baseline criteria for denying an application due to expertise. Still others wanted a definition for (1) "experience and training pertaining to organic/sustainable agricultural methods and their implementation on farm or in processing facilities," (2) "trained certifying agent personnel," and (3) "reasonable time." Finally, one wanted recordkeeping and evaluative parameters. AMS does not believe that it is necessary to present the requirements for accreditation to the extent of detail requested by the commenters. The intent is to provide flexibility to the certifying agents such that they can tailor their policies and procedures to the nature and scope of their operation. The NOP is available to respond to questions and to assist certifying agents in complying with the requirements for accreditation.

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

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

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

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

making that would assist them personally. This commenter proposed the amendment for the purpose of creating a firewall between those persons involved in certification decision-making and the volunteer board members.

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

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

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

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

We disagree with the recommendations calling for a longer precertification conflict of interest prohibition period. We continue to believe that 12 months is a sufficient period to ensure that any previous commercial interest would not create a conflict of interest situation for two reasons. First, this time period is consistent with similar provisions governing conflicts of interest for government employees. Second, section 205.501(a)(11)(v) requires the completion of an annual conflict of interest disclosure report by all personnel designated to be used in the certification operation, including administrative staff, certification inspectors,

members of any certification review and program evaluation committees, contractors, and all parties responsibly connected to the certification operation. This requirement will assist certifying agents in complying with the requirements to prevent conflicts of interest. We also continue to believe that a longer prohibition period would have the effect of severely curtailing most certifying agents' ability to comply with the Act's requirement that they employ persons with sufficient expertise to implement the applicable certification program. Accordingly, we have not made the recommended change.

The change recommended by the commenters who requested that the conflict of interest determination period extend for 2 years after certification is unnecessary. Certifying agents and their responsibly connected parties, employees, inspectors, contractors, and other personnel are prohibited from engaging in activities or associations at any time during their affiliation with the certifying agent which would result in a conflict of interest. While associated with the certifying agent, all employees, inspectors, contractors, and other personnel are expected to disclose to the certifying agent any offer of employment they have received and not immediately refused. They are also expected to disclose any employment they are seeking and any arrangement they have concerning future employment with an applicant for certification or a certified operation. The certifying agent would then have to exclude that person from work, discussions, and decisions in all stages of the certification or monitoring of the operation making the employment offer. If a certifying agent or a responsibly connected party of the certifying agent has received and not immediately refused an offer of employment, is seeking employment, or has an arrangement concerning future employment with an applicant for certification, the certifying agent may not accept or process the application. Further, certifying agents and responsibly connected parties may not seek employment or have an arrangement concerning future employment with an operation certified by the certifying agent while associated with that certifying agent. Certifying agents and responsibly connected parties must sever their association with the certifying agent when such person does not immediately refuse an offer of employment from a certified operation. Accordingly, we have decided not to include a postcertification prohibition period in this final rule.

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

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

(14) Certifying Agent Compliance With Terms and Conditions Deemed Necessary. A commenter recommended that we remove section 205.501(a)(17). This section requires that certifying agents comply with and implement other terms and conditions deemed necessary by the Secretary. This requirement is consistent with section 6515(d)(2) of the Act, which

requires a certifying agent to enter into an agreement with the Secretary under which such agent shall agree to such other terms and conditions as the Secretary determines appropriate. Accordingly, we have not accepted the commenter's recommendation. This requirement is located at current section 205.501(a)(21).

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

We believe the positions advocated by the commenters are inconsistent with section 6501(2) of the Act, which provides that a stated purpose of the Act is to assure consumers that organically produced products meet a consistent national standard. We believe that, to accomplish the goal of establishing a consistent standard and to facilitate trade, it is vital that an accredited certifying agent accept the certification decisions made by another certifying agent accredited or accepted by USDA pursuant to section 205.500. All organic production and handling operations, unless exempted or excluded under section 205.101 or not regulated under the NOP (i.e., a producer of dog food), must be certified to these national standards and, when applicable, any State standards approved by the Secretary. All certified operations must be certified by a certifying agent accredited by the Administrator. No accredited certifying agent may establish or require compliance with its own organic standards. Accredited certifying agents may establish other standards outside of the NOP. They may not, however, refer to them as organic standards nor require that applicants for certification under the NOP or operations certified under the NOP comply with such standards as a requirement for certification under the NOP. Use of the certifying agent's identifying mark must be voluntary and available to all of its clients certified under the NOP. However, a certifying agent may withdraw a certified operation's authority to use its identifying mark during a compliance process. The certifying agent, however, accepts full liability for any such action.

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

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

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

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

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

We do not concur with the commenters. These regulations provide for assessment of the applicant's qualifications and capabilities through a rigorous review of the application and supporting documentation. Following this review, an initial site evaluation shall be conducted before or within a reasonable period of time after issuance of the applicant's "notification of accreditation." In cases where the document review raises concerns regarding the applicant's qualifications and capabilities and the Administrator deems it necessary, a preapproval site evaluation will be conducted. We have further provided that a site evaluation shall be conducted after application for renewal of accreditation but prior to renewal of accreditation.

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

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

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

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

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

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

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

(24) Notice of Renewal of Accreditation. A commenter recommended that section 205.510(d) be amended to include a timeframe within which the Administrator must notify an applicant of its renewal of accreditation. We believe that a mandated timeframe for notifying the applicant of renewal of accreditation is inappropriate. We plan to process all applications for renewal of accreditation in the order in which they are received, to confirm the receipt of each application, and to establish a dialog with the applicant upon confirmation of receipt of an application for renewal of accreditation. The length of the renewal process will depend in large part on the nature of the operation seeking renewal of accreditation. To minimize the

chances that an accreditation will expire during the renewal process, we have: (1) provided that the Administrator shall send the accredited certifying agent a notice of pending expiration of accreditation approximately 1 year before the date of expiration of the certifying agent's accreditation, (2) required that an application for renewal of accreditation must be received at least 6 months prior to expiration of the certifying agent's accreditation, and (3) provided that the accreditation of a certifying agent who makes timely application for renewal of accreditation will not expire during the renewal process. Accordingly, we have not made the recommended amendment.

Accreditation - Clarifications

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

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

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

(2) State Approval of Product From Foreign Countries. A commenter stated that any product making claims of organic agricultural ingredients to be sold in California shall fall under the jurisdiction of the California Organic Program for enforcement, inspection, and certification direction. The commenter further stated that, should any foreign certifying agents be accepted, they too shall be subject to the sovereign rights of the State of California to protect and enforce the laws of the State of California and to protect agricultural claims in this State. Any organic program administered by a State will have to be approved by the Secretary. Approval of an SOP will be contingent upon the State's agreeing to accept the certification decisions made by certifying agents accredited or accepted by USDA pursuant to section 205.500.

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

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

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

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

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

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

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

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

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

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

(8) Nondiscriminatory Services. A commenter wanted the addition of a provision in section 205.501(a) requiring certifying agents to provide nondiscriminatory services. We have not

included the suggested addition in this final rule because the provision already exists in section 205.501(d).

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

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

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

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

(12) Self-evaluation of Ability to Comply. A commenter requested that section 205.504 be amended to provide clarity on the baseline requirements that would allow a certifying agent to conduct a self-evaluation to determine its ability to comply. The commenter stated that there should be some type of baseline acceptance of expertise and ability. The commenter wants details regarding the "training" or "experience" requirements necessary to qualify for accreditation. This commenter also stated that criteria for inspector and reviewer training should be added and enlarged.

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

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

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

be considered in granting or denying accreditation. We believe these requirements meet or exceed the ISO Guide 65 guidelines.

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

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

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

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

(17) Response to Accreditation Applicant. A commenter requested that section 205.506(a)(3) be amended to provide a timeframe within which the Administrator has to respond to the accreditation application. While section 205.506(a)(3) identifies the information to be reviewed by the Administrator prior to the granting of accreditation, we assume the commenter is seeking a specific time limit by which the Administrator will acknowledge receipt of an application for accreditation. In the alternative, the commenter may have been seeking a specific time limit by which the Administrator must grant or deny accreditation. We believe that a regulation-mandated timeframe for notifying the applicant of receipt of an application or for granting or denying accreditation is unnecessary. We plan to process all applications in the order in which they are received, to confirm the receipt of each application upon receipt, and to establish a dialog with the applicant upon confirmation of receipt of an application for accreditation. We will work with each applicant to complete the accreditation process as expeditiously as possible. A firm timeframe, however, cannot be set for granting or denying accreditation due to the anticipated uniqueness of each applicant and its application for accreditation.

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

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

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

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

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

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

(23) Update and Review of Inspector Lists. In commenting on section 205.510(c)(1) (current section 205.510(c)(2)) several commenters stated that updating and review of inspector lists must occur more frequently than every 5 years. They cited ISO Guide 61, section 3.5.1. Section 205.510(a)(1) requires that the certifying agent annually update the information required in section 205.504. This includes the inspector information required by paragraphs 205.504(a)(2) and 205.504(a)(3)(i).

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

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

Subpart F - Accreditation of Certifying Agents

§ 205.500 Areas and duration of accreditation.

(a) The Administrator shall accredit a qualified domestic or foreign applicant in the areas of crops, livestock, wild crops, or handling or any combination thereof to certify a domestic or foreign production or handling operation as a certified operation.

(b) Accreditation shall be for a period of 5 years from the date of approval of accreditation pursuant to § 205.506.

(c) In lieu of accreditation under paragraph (a) of this section, USDA will accept a foreign certifying agent's accreditation to certify organic production or handling operations if:

(1) USDA determines, upon the request of a foreign government, that the standards under which the foreign government authority accredited the foreign certifying agent meet the requirements of this part; or

(2) The foreign government authority that accredited the foreign certifying agent acted under an equivalency agreement negotiated between the United States and the foreign government.

§ 205.501 General requirements for accreditation.

(a) A private or governmental entity accredited as a certifying agent under this subpart must:

(1) Have sufficient expertise in organic production or handling techniques to fully comply with and implement the terms and conditions of the organic certification program established under the Act and the regulations in this part;

(2) Demonstrate the ability to fully comply with the requirements for accreditation set forth in this subpart;

(3) Carry out the provisions of the Act and the regulations in this part, including the provisions of §§ 205.402 through 205.406 and § 205.670;

(4) Use a sufficient number of adequately trained personnel, including inspectors and certification review personnel, to comply with and implement the organic certification program established under the Act and the regulations in subpart E of this part;

(5) Ensure that its responsibly connected persons, employees, and contractors with inspection, analysis, and decision-making responsibilities have sufficient expertise in organic production or handling techniques to successfully perform the duties assigned.

(6) Conduct an annual performance evaluation of all persons who review applications for certification, perform on-site inspections, review certification documents, evaluate qualifications for certification, make recommendations concerning certification, or make certification decisions and implement measures to correct any deficiencies in certification services;

(7) Have an annual program review of its certification activities conducted by the certifying agent's staff, an outside auditor, or a consultant who has expertise to conduct such reviews and implement measures to correct any noncompliances with the Act and the regulations in this part that are identified in the evaluation;

(8) Provide sufficient information to persons seeking certification to enable them to comply with the applicable requirements of the Act and the regulations in this part;

(9) Maintain all records pursuant to § 205.510(b) and make all such records available for inspection and copying during normal business hours by authorized representatives of the Secretary and the applicable State organic program's governing State official;

(10) Maintain strict confidentiality with respect to its clients under the applicable organic certification program and not disclose to third parties (with the exception of the Secretary or the applicable State organic program's governing State official or their authorized representatives) any business-related information concerning any client obtained while implementing the regulations in this part, except as provided for in § 205.504(b)(5);

(11) Prevent conflicts of interest by: (i) Not certifying a production or handling operation if the certifying agent or a responsibly connected party of such certifying agent has or has held a commercial interest in the production or handling operation, including an immediate family interest or the provision of consulting services, within the 12-month period prior to the application for certification;

(ii) Excluding any person, including contractors, with conflicts of interest from work, discussions, and decisions in all stages of the certification process and the monitoring of certified production or handling operations for all entities in which such person has or has held a commercial interest, including an immediate family interest or the provision of consulting services, within the 12-month period prior to the application for certification;

(iii) Not permitting any employee, inspector, contractor, or other personnel to accept payment, gifts, or favors of any kind, other than prescribed fees, from any business inspected, Except. That, a certifying agent that is a not-for-profit organization with an Internal Revenue Code tax exemption or, in the case of a foreign certifying agent, a comparable recognition of not-for-profit status from its government, may accept voluntary labor from certified operations;

(iv) Not giving advice or providing consultancy services, to certification applicants or certified operations, for overcoming identified barriers to certification;

(v) Requiring all persons who review applications for certification, perform on-site inspections, review certification documents, evaluate qualifications for certification, make recommendations concerning certification, or make certification decisions and all parties responsibly connected to the certifying agent to complete an annual conflict of interest disclosure report; and

(vi) Ensuring that the decision to certify an operation is made by a person different from those who conducted the review of documents and on-site inspection.

(12) (i) Reconsider a certified operation's application for certification and, if necessary, perform a new on-site inspection when it is determined, within 12 months of certifying the operation, that any person participating in the certification process and covered under § 205.501(a)(11)(ii) has or had a conflict of interest involving the applicant. All costs associated with a reconsideration of application, including onsite inspection costs, shall be borne by the certifying agent.

(ii) Refer a certified operation to a different accredited certifying agent for recertification and reimburse the operation for the cost of the recertification when it is determined that any person covered under § 205.501(a)(11)(i) at the time of certification of the applicant had a conflict of interest involving the applicant.

(13) Accept the certification decisions made by another certifying agent accredited or accepted by USDA pursuant to § 205.500;

(14) Refrain from making false or misleading claims about its accreditation status, the USDA accreditation program for certifying agents, or the nature or qualities of products labeled as organically produced;

(15) Submit to the Administrator a copy of: (i) Any notice of denial of certification issued pursuant to § 205.405, notification of noncompliance, notification of noncompliance correction, notification of proposed suspension or revocation, and notification of suspension or revocation sent pursuant to § 205.662 simultaneously with its issuance and

(ii) A list, on January 2 of each year, including the name, address, and telephone number of each operation granted certification during the preceding year;

(16) Charge applicants for certification and certified production and handling operations only those fees and charges for certification activities that it has filed with the Administrator;

(17) Pay and submit fees to AMS in accordance with § 205.640;

(18) Provide the inspector, prior to each on-site inspection, with previous on-site inspection reports and notify the inspector of its decision regarding certification of the production or handling operation site inspected by the inspector and of any requirements for the correction of minor noncompliances;

(19) Accept all production or handling applications that fall within its area(s) of accreditation and certify all qualified applicants, to the extent of its administrative capacity to do so without regard to size or membership in any association or group; and

(20) Demonstrate its ability to comply with a State's organic program to certify organic production or handling operations within the State.

(21) Comply with, implement, and carry out any other terms and conditions determined by the Administrator to be necessary.

(b) A private or governmental entity accredited as a certifying agent under this subpart may establish a seal, logo, or other identifying mark to be used by production and handling operations certified by the certifying agent to indicate affiliation with the certifying agent: Provided, That, the certifying agent:

(1) Does not require use of its seal, logo, or other identifying mark on any product sold, labeled, or represented as organically produced as a condition of certification and

(2) Does not require compliance with any production or handling practices other than those provided for in the Act and the regulations in this part as a condition of use of its identifying mark: Provided, That, certifying agents certifying production or handling operations within a State with more restrictive requirements, approved by the Secretary, shall require compliance with such requirements as a condition of use of their identifying mark by such operations.

(c) A private entity accredited as a certifying agent must:

(1) Hold the Secretary harmless for any failure on the part of the certifying agent to carry out the provisions of the Act and the regulations in this part;

(2) Furnish reasonable security, in an amount and according to such terms as the Administrator may by regulation prescribe, for the purpose of protecting the rights of production and handling operations certified by such certifying agent under the Act and the regulations in this part; and

(3) Transfer to the Administrator and make available to any applicable State organic program's governing State official all records or copies of records concerning the person's certification activities in the event that the certifying agent dissolves or loses its accreditation; Provided, That, such transfer shall not apply to a merger, sale, or other transfer of ownership of a certifying agent.

(d) No private or governmental entity accredited as a certifying agent under this subpart shall exclude from participation in or deny the benefits of the National Organic Program to any person due to discrimination because of race, color, national origin, gender, religion, age, disability, political beliefs, sexual orientation, or marital or family status.

§ 205.502 Applying for accreditation.

(a) A private or governmental entity seeking accreditation as a certifying agent under this subpart must submit an application for accreditation which contains the applicable information and documents set forth in §§ 205.503 through 205.505 and the fees required in § 205.640 to: Program Manager, USDA-AMS-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 governmental entity seeking accreditation as a certifying agent must submit the following information:

(a) The business name, primary office location, mailing address, name of the person(s) responsible for the certifying agent's day-to-day operations, contact numbers (telephone, facsimile, and Internet address) of the applicant, and, for an applicant who is a private person, the entity's taxpayer identification number;

(b) The name, office location, mailing address, and contact numbers (telephone, facsimile, and Internet address) for each of its organizational units, such as chapters or subsidiary offices, and the name of a contact person for each unit;

(c) Each area of operation (crops, wild crops, livestock, or handling) for which accreditation is requested and the estimated number of each type of operation anticipated to be certified annually by the applicant along with a copy of the applicant's schedule of fees for all services to be provided under these regulations by the applicant;

(d) The type of entity the applicant is (e.g., government agricultural office, for-profit business, not-for-profit membership association) and for:

(1) A governmental entity, a copy of the official's authority to conduct certification activities under the Act and the regulations in this part,

(2) A private entity, documentation showing the entity's status and organizational purpose, such as articles of incorporation and by-laws or ownership or membership provisions, and its date of establishment; and

(e) A list of each State or foreign country in which the applicant currently certifies production and handling operations and a list of each State or foreign country in which the applicant intends to certify production or handling operations.

§ 205.504 Evidence of expertise and ability.

A private or governmental entity seeking accreditation as a certifying agent must submit the following documents and information to demonstrate its expertise in organic production or handling techniques; its ability to fully comply with and implement the organic certification program established in §§ 205.100 and 205.101, §§ 205.201 through 205.203, §§ 205.300 through 205.303, §§ 205.400 through 205.406, and §§ 205.661 and 205.662; and its ability to comply with the requirements for accreditation set forth in § 205.501:

(a) Personnel. (1) A copy of the applicant's policies and procedures for training, evaluating, and supervising personnel;

(2) The name and position description of all personnel to be used in the certification operation, including administrative staff, certification inspectors, members of any certification review and evaluation committees, contractors, and all parties responsibly connected to the certifying agent;

(3) A description of the qualifications, including experience, training, and education in agriculture, organic production, and organic handling, for:

(i) Each inspector to be used by the applicant and

(ii) Each person to be designated by the applicant to review or evaluate applications for certification; and

(4) A description of any training that the applicant has provided or intends to provide to personnel to ensure that they comply with and implement the requirements of the Act and the regulations in this part.

(b) Administrative policies and procedures. (1) A copy of the procedures to be used to evaluate certification applicants, make certification decisions, and issue certification certificates;

(2) A copy of the procedures to be used for reviewing and investigating certified operation compliance with the Act and the regulations in this part and the reporting of violations of the Act and the regulations in this part to the Administrator;

(3) A copy of the procedures to be used for complying with the recordkeeping requirements set forth in § 205.501(a)(9);

(4) A copy of the procedures to be used for maintaining the confidentiality of any business-related information as set forth in § 205.501(a)(10);

(5) A copy of the procedures to be used, including any fees to be assessed, for making the following information available to any member of the public upon request:

(i) Certification certificates issued during the current and 3 preceding calendar years;

(ii) A list of producers and handlers whose operations it has certified, including for each the name of the operation, type(s) of operation, products produced, and the effective date of the certification, during the current and 3 preceding calendar years;

(iii) The results of laboratory analyses for residues of pesticides and other prohibited substances conducted during the current and 3 preceding calendar years; and

(iv) Other business information as permitted in writing by the producer or handler; and

(6) A copy of the procedures to be used for sampling and residue testing pursuant to § 205.670.

(c) Conflicts of interest. (1) A copy of procedures intended to be implemented to prevent the occurrence of conflicts of interest, as described in § 205.501(a)(11).

(2) For all persons who review applications for certification, perform on-site inspections, review certification documents, evaluate qualifications for certification, make recommendations concerning certification, or make certification decisions and all parties responsibly connected to the certifying agent, a conflict of interest disclosure report, identifying any food- or agriculture-related business interests, including business interests of immediate family members, that cause a conflict of interest.

(d) Current certification activities. An applicant who currently certifies production or handling operations must submit: (1) a list of all production and handling operations currently certified by the applicant;

(2) Copies of at least 3 different inspection reports and certification evaluation documents for production or handling operations certified by the applicant during the previous year for each area of operation for which accreditation is requested; and

(3) The results of any accreditation process of the applicant's operation by an accrediting body during the previous year for the purpose of evaluating its certification activities.

(e) Other information. Any other information the applicant believes may assist in the Administrator's evaluation of the applicant's expertise and ability.

§ 205.505 Statement of agreement.

(a) A private or governmental entity seeking accreditation under this subpart must sign and return a statement of agreement prepared by the Administrator which affirms that, if granted accreditation as a certifying agent under this subpart, the applicant will carry out the provisions of the Act and the regulations in this part, including:

(1) Accept the certification decisions made by another certifying agent accredited or accepted by USDA pursuant to section 205.500;

(2) Refrain from making false or misleading claims about its accreditation status, the USDA accreditation program for certifying agents, or the nature or qualities of products labeled as organically produced;

(3) Conduct an annual performance evaluation of all persons who review applications for certification, perform on-site inspections, review certification documents, evaluate qualifications for certification, make recommendations concerning certification, or make certification decisions and implement measures to correct any deficiencies in certification services;

(4) Have an annual internal program review conducted of its certification activities by certifying agent staff, an outside auditor, or a consultant who has the expertise to conduct such reviews and implement measures to correct any noncompliances with the Act and the regulations in this part;

(5) Pay and submit fees to AMS in accordance with § 205.640; and

(6) Comply with, implement, and carry out any other terms and conditions determined by the Administrator to be necessary.

(b) A private entity seeking accreditation as a certifying agent under this subpart must additionally agree to:

(1) Hold the Secretary harmless for any failure on the part of the certifying agent to carry out the provisions of the Act and the regulations in this part;

(2) Furnish reasonable security, in an amount and according to such terms as the Administrator may by regulation prescribe, for the purpose of protecting the rights of production and handling operations certified by such certifying agent under the Act and the regulations in this part; and

(3) Transfer to the Administrator and make available to the applicable State organic program's governing State official all records or copies of records concerning the certifying agent's certification activities in the event that the certifying agent dissolves or loses its accreditation; Provided, That such transfer shall not apply to a merger, sale, or other transfer of ownership of a certifying agent.

§ 205.506 Granting accreditation.

(a) Accreditation will be granted when: (1) The accreditation applicant has submitted the information required by §§ 205.503 through 205.505;

(2) The accreditation applicant pays the required fee in accordance with § 205.640(c); and

(3) The Administrator determines that the applicant for accreditation meets the requirements for accreditation as stated in § 205.501, as determined by a review of the information submitted in accordance with §§ 205.503 through 205.505 and, if necessary, a review of the information obtained from a site evaluation as provided for in § 205.508.

(b) On making a determination to approve an application for accreditation, the Administrator will notify the applicant of the granting of accreditation in writing, stating:

(1) The area(s) for which accreditation is given;

(2) The effective date of the accreditation;

(3) Any terms and conditions for the correction of minor noncompliances; and

(4) For a certifying agent who is a private entity, the amount and type of security that must be established to protect the rights of production and handling operations certified by such certifying agent.

(c) The accreditation of a certifying agent shall continue in effect until such time as the certifying agent fails to renew accreditation as provided in § 205.510(c), the certifying agent voluntarily ceases its certification activities, or accreditation is suspended or revoked pursuant to § 205.665.

§ 205.507 Denial of accreditation.

(a) If the Program Manager has reason to believe, based on a review of the information specified in §§ 205.503 through 205.505 or after a site evaluation as specified in § 205.508, that an applicant for accreditation is not able to comply or is not in compliance with the requirements of the Act and the regulations in this part, the Program Manager shall provide a written notification of noncompliance to the applicant. Such notification shall provide:

(1) A description of each noncompliance;

(2) The facts upon which the notification of noncompliance is based; and

(3) The date by which the applicant must rebut or correct each noncompliance and submit supporting documentation of each such correction when correction is possible.

(b) When each noncompliance has been resolved, the Program Manager will send the applicant a written notification of noncompliance resolution and proceed with further processing of the application.

(c) If an applicant fails to correct the noncompliances, fails to report the corrections by the date specified in the notification of noncompliance, fails to file a rebuttal of the notification of noncompliance by the date specified, or is unsuccessful in its rebuttal, the Program Manager will provide the applicant with written notification of accreditation denial. An applicant who has received written notification of accreditation denial may apply for accreditation again at any time in accordance with § 205.502, or appeal the denial of accreditation in accordance with § 205.681 by the date specified in the notification of accreditation denial.

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

§ 205.508 Site evaluations.

(a) Site evaluations of accredited certifying agents shall be conducted for the purpose of examining the certifying agent's operations and evaluating its compliance with the Act and the regulations of this part. Site evaluations shall include an on-site review of the certifying agent's certification procedures, decisions, facilities, administrative and management systems, and production or handling operations certified by the certifying agent. Site evaluations shall be conducted by a representative(s) of the Administrator.

(b) An initial site evaluation of an accreditation applicant shall be conducted before or within a reasonable period of time after issuance of the applicant's "notification of accreditation." A site evaluation shall be conducted after application for renewal of accreditation but prior to the issuance of a notice of renewal of accreditation. One or more site evaluations will be conducted during the period of accreditation to determine whether an accredited certifying agent is complying with the general requirements set forth in § 205.501.

§ 205.509 Peer review panel.

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

§ 205.510 Annual report, recordkeeping, and renewal of accreditation.

(a) Annual report and fees. An accredited certifying agent must submit annually to the Administrator, on or before the anniversary date of the issuance of the notification of accreditation, the following reports and fees:

(1) A complete and accurate update of information submitted pursuant to §§ 205.503 and 205.504;

(2) Information supporting any changes being requested in the areas of accreditation described in § 205.500;

(3) A description of the measures implemented in the previous year and any measures to be implemented in the coming year to satisfy any terms and conditions determined by the Administrator to be necessary, as specified in the most recent notification of accreditation or notice of renewal of accreditation;

(4) The results of the most recent performance evaluations and annual program review and a description of adjustments to the certifying agent's operation and procedures implemented or to be implemented in response to the performance evaluations and program review; and

(5) The fees required in § 205.640(a).

(b) Recordkeeping. Certifying agents must maintain records according to the following schedule:

(1) Records obtained from applicants for certification and certified operations must be maintained for not less than 5 years beyond their receipt;

(2) Records created by the certifying agent regarding applicants for certification and certified operations must be maintained for not less than 10 years beyond their creation; and

(3) Records created or received by the certifying agent pursuant to the accreditation requirements of this subpart F, excluding any records covered by §§ 205.510(b)(2), must be maintained for not less than 5 years beyond their creation or receipt.

(c) Renewal of accreditation. (1) The Administrator shall send the accredited certifying agent a notice of pending expiration of accreditation approximately 1 year prior to the scheduled date of expiration.

(2) An accredited certifying agent's application for accreditation renewal must be received at least 6 months prior to the fifth anniversary of issuance of the notification of accreditation and each subsequent renewal of accreditation. The accreditation of certifying agents who make timely application for renewal of accreditation will not expire during the renewal process. The accreditation of certifying agents who fail to make timely application for renewal of accreditation will expire as scheduled unless renewed prior to the scheduled expiration date. Certifying agents with an expired accreditation must not perform certification activities under the Act and these regulations.

(3) Following receipt of the information submitted by the certifying agent in accordance with paragraph (a) of this section and the results of a site evaluation, the Administrator will determine whether the certifying agent remains in compliance with the Act and the regulations of this part and should have its accreditation renewed.

(d) Notice of renewal of accreditation. Upon a determination that the certifying agent is in compliance with the Act and the regulations of this part, the Administrator will issue a notice

of renewal of accreditation. The notice of renewal will specify any terms and conditions that must be addressed by the certifying agent and the time within which those terms and conditions must be satisfied.

(e) Noncompliance. Upon a determination that the certifying agent is not in compliance with the Act and the regulations of this part, the Administrator will initiate proceedings to suspend or revoke the certifying agent's accreditation.

(f) Amending accreditation. Amendment to scope of an accreditation may be requested at any time. The application for amendment shall be sent to the Administrator and shall contain information applicable to the requested change in accreditation, a complete and accurate update of the information submitted pursuant to §§ 205.503 and 205.504, and the applicable fees required in § 205.640.

§§ 205.511-205.599 [Reserved]

Subpart G Administrative
The National List of Allowed and Prohibited Substances
Description of Regulations
General Requirements

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

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

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

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

The NOSB is responsible for making the recommendation of whether a substance is suitable for use in organic production and handling. The OFPA allows the NOSB to develop substance recommendations and annotations and forward to the Secretary a Proposed National List and any subsequent proposed amendments. We have made every effort to ensure the National List in this final rule corresponds to the recommendations on allowed and prohibited substances made by the NOSB. In developing their recommendations, the NOSB evaluates synthetic substances for the National List utilizing the criteria stipulated by the Act. Additionally, criteria for evaluating synthetic processing ingredients have been implemented by the NOSB. These criteria are an interpretation and application of the general evaluation criteria for synthetic substances contained in the OFPA that the NOSB will apply to processing aids and adjuvants. The NOSB adopted these criteria as internal guidelines for evaluating processing aids and adjuvants. The adopted criteria do not supersede the criteria contained in the OFPA or replace the Food and Drug Administration's (FDA) regulations related to food additives and generally recognized as safe (GRAS) substances. The NOSB has also provided recommendations for the use of synthetic inert ingredients in formulated pesticide products used as production inputs in organic crop or livestock operations. The Environmental Protection Agency (EPA) regulates and maintains the EPA Lists of Inert ingredients used for pesticide. In this final rule, EPA Inerts List 1 and 2 are prohibited, EPA List 3 is also prohibited unless specifically recommended as allowed by the NOSB, and EPA List 4 Inerts are allowed unless specifically prohibited.

In this final rule, only EPA List 4 Inerts are allowed as ingredients in formulated pesticide products used in organic crop and livestock production. The allowance for EPA List 4 Inerts

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

We expect the maintenance of the National List to be a dynamic process. We anticipate that decisions on substance petitions for the inclusion on or deletion from the National List will be made on an annual basis. Any person seeking a change in the National List should request a copy of the petition procedures that were published in the Federal Register (65 Fed Reg 43259 - 43261) on July 13, 2000, from the NOP. The National List petition process contact information is: Program Manager, National Organic Program, USDA/AMS/TMP/NOP, Room 2945-S, Ag Stop 0268, P.O. Box 96456, Washington, DC 20090-8456 or visit the NOP website: www.ams.usda.gov/nop. Substances petitioned for inclusion on the National List will be reviewed by the NOSB, which will forward a recommendation to the Secretary. Any amendments to the National List will require rulemaking and must be published for comment in the Federal Register.

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

Under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), EPA regulates the use of all pesticide products, including those that may be approved for use in the NOP. In registering a pesticide under FIFRA, EPA approves the uses of each pesticide product. It is a violation of FIFRA to use a registered product in a manner inconsistent with its labeling.

The fact that a substance is on the National List does not authorize use of a pesticide product for that use if the pesticide product label does not include that use. If the National List and the pesticide labeling conflict, the pesticide labeling takes precedence and may prohibit a practice allowed on the National List.

National List - Changes Based On Comments

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

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

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

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

Crop Production:

- Lime sulfur as a plant disease control substance
- Elemental sulfur as a plant or soil amendment
- Copper as a plant or soil micronutrient
- Streptomycin sulfate as plant disease control substances with the annotation "for fire blight control in apples and pears only"
- Terramycin (oxytetracycline calcium complex) as a plant disease control substance with the annotation "for fire blight control only"
- Magnesium sulfate as a plant or soil amendment with the annotation "allowed with a documented soil deficiency"
- Ethylene as a plant growth regulator, with the annotation "for regulation of pineapple flowering"

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

Livestock Production:

- Oxytocin with the annotation "for use in postparturition therapeutic applications"
- EPA List 4 inert ingredients as synthetic inert ingredients for use with non-synthetic substances or synthetic substances allowed in organic livestock production.

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

Organic Handling (Processing):

- Tribasic calcium phosphate
- Non-synthetic colors
- Flavors, with the annotation "non-synthetic sources only and must not be produced using synthetic solvents and carrier systems or any artificial preservatives"
- Non-synthetic waxes, carnauba wax, wood resin
- Comstarch (native), gums, kelp, lecithin and pectin were moved from section 205.605 to section 205.606

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

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

- The annotation for hydrated lime as a plant disease control substance now states, "must be used in a manner that minimizes accumulation of copper in the soil."
- The annotation for horticultural oils as an insecticide substance and as a plant disease control substance now states, "Narrow range oils as dormant, suffocating, and summer oils."
- The annotation for hydrated lime in livestock production now states, "not permitted for soil application or to cauterize physical alterations or deodorize animal wastes."
- The annotation for the allowed synthetic parasiticide Ivermectin has been modified to state that the substance may not be used during the lactation period of breeding stock.
- The annotation for trace minerals and vitamins allowed as feed additives has been modified and now states, "used for enrichment or fortification when FDA approved."
- The annotation for magnesium sulfate in organic handling now states, "non-synthetic sources only."
- The annotation for EPA List 4 Inerts allowed in crop and livestock production has been modified to state, "...for use with non-synthetic substances or synthetic substances listed in this section..."

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

National List - Changes Requested But Not Made

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

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

(2) Use of EPA List 4 Inerts. The proposed rule allowed EPA List 4 Inerts to be used as synthetic inert ingredients with allowed synthetic active ingredients in crop production. Some commenters stated that certain substances among the EPA List 4 inerts should not be allowed in organic production. Some commenters went further and recommended that the allowance for synthetic inert ingredients should be limited to the subset of materials that the EPA designates as List 4A. We do not agree with these commenters and have retained the allowance for all inerts included on EPA List 4. List 4 inerts are classified by EPA as those of "minimal concern" and, after continuing consultation with EPA, we believe there is no justification for a further restriction to List 4A. If commenters believe that a particular List 4 inert should not be allowed in formulated products used in organic production, they can petition the NOSB to have that substance prohibited.

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

(4) Adding Amino Acids to the National List. Some commenters recommended that amino acids should be added to the National List as allowed synthetic substances for livestock

production. We have not added amino acids to the National List because the NOSB has not recommended that they should be allowed. This subject is discussed further in item 4, Livestock - Changes Based on Comments, subpart C.

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

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

(7) Remove Categories for Feed Supplements. A commenter stated that it was inappropriate for the National List of synthetic substances allowed in livestock production to contain categories for feed supplements and feed additives because they are not authorized in the OFPA. We disagree with this commenter because the identification of categories on the National List does not mean that all substances within that category are allowed. The categories help to clarify which types of materials may be included on the National List. The substances included under the categories of feed supplements and feed additives were recommended by the NOSB and added to the National List with the Secretary's approval.

(8) Neurotoxic Substances on the National List. Many commenters requested that the NOP remove particular substances from section 205.605 of the National List. They stated these substances were sources of neurotoxic compounds that negatively effect human health. The substances cited were yeast (autolysate and brewers), carrageenan, and enzymes. Moreover, these commenters argued against including on the National List some amino acids or their derivatives which the commenters claim have neurotoxic side effects. These commenters requested that amino acids should be prohibited from the National List due to the possibility that neurotoxic substances could be utilized for either organic agricultural production or handling.

We do not agree with the requests of the commenters and we have not made the requested changes. There are no amino acids currently on the National List; therefore, synthetic sources of amino acids are prohibited. Unless recommended for use by the NOSB, synthetic amino acids will not be included on the National List. The NOP has established a petition process for substances to be evaluated for inclusion on or removal from the National List of Allowed and Prohibited Substances in organic production and handling. Anyone seeking to have a particular substance removed from the National List may file a substance petition to amend the National List.

(9) EPA List 4 Inerts for Organic Processing. A few commenters recommended that substances in EPA List 4 inerts that are allowed for use in crop production also be allowed for use as processing materials. We do not agree, and we have not included EPA List 4 inerts on the National List for organic handling. Inerts listed on EPA List 4 have been

evaluated and approved for use in pesticide formulations, not for use as processing materials. Inerts that are included on EPA List 4 would have to be further evaluated to determine whether such materials meet the criteria for inclusion on the National List.

(10) Modifying Annotations of Organic Processing Substances. One commenter requested that the Department modify the annotation for phosphoric acid to include its use as a processing aid. We have not made the suggested change. Any change in the annotation of a substance can only occur through an NOSB recommendation. Individuals or groups can use the petition process to submit substance petitions to the NOSB for the evaluation to be included on or removed from the National List.

(11) Nutritional Supplementation of Organic Foods. Some commenters asserted that 21 CFR 104.20 is not an adequate stand-alone reference for nutritional supplementation of organic foods. As a result, these commenters recommended that the final rule include as additional cites 21 CFR 101.9(c)(8) for FDA-regulated foods and 9 CFR 317.30(c), 318.409(c)(8) for foods regulated by FSIS to support 21 CFR 104.20. We did not implement the suggested changes of the commenters. Section 205.605(b)(20) in the proposed rule allowed the use of synthetic nutrient vitamins and minerals to be used in accordance with 21 CFR 104.20, Nutritional Quality Guidelines For Foods, as ingredients in processed products to be sold as "organic" or "made with..." The commenters recommended cites, 21 CFR 101.9(c)(8) for FDA-regulated foods and 9 CFR 317.30(c); section 318.409(c)(8) did not provide provisions for nutritional supplementation of foods. Instead, these suggested cites were particularly aimed toward: (1) the declaration of nutrition information on the label and in labeling of a food; (2) labeling, marking devices, and containers; (3) entry into official establishments; and (4) reinspection and preparation of products. The NOP, in consultation with FDA, considers 21 CFR 104.20 to be the most appropriate reference regarding nutritional supplementation for organic foods.

(12) National List Petition Process as Part of the Final Rule.

Commenters have requested that the National List Petition Process, approved by the NOSB at its June 2000 meeting (and published in the Federal Register on July 13, 2000), be included in the final rule. We do not agree with the commenters, and we have retained the National List Petition Process regulation language from the proposed rule. We have separated the specific petition process from the regulation to provide for maximum flexibility to change and clarify the petition process to accommodate new considerations developed during the NOP implementation. If this process were part of this final rule, updates to the petition process would require notice and comment rulemaking. Any changes in the National List that may be a result of the petition process, however, would require notice and comment rulemaking.

(13) Nonapproved Substance Amendments to the National List. Commenters also requested to have many substances that are not on the National List and that have not been recommended by the NOSB for use in organic production and handling be added to the National List. We do not agree. Amendments to the National List must be petitioned for NOSB consideration, must have an NOSB recommendation, and must be published for public comment in the Federal Register.

National List - Clarifications

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

(1) Inerts Use in Botanical or Microbial Pesticides. Commenters expressed concern that the prohibition on the use of EPA List 3 inerts would prevent organic producers from using certain botanical or microbial formulated products that are currently allowed under some certification programs. These commenters requested that the NOP and the NOSB expedite the evaluation of List 3 inerts used in non-synthetic formulated products to prevent the loss of certain formulated products. The prohibition of List 3 inerts was based on the

recommendation of the NOSB to add only those substances from List 4 to the National List. The NOSB also recommended that individual inert substances included on List 3 could be petitioned for addition to the National List. The NOP has requested that the NOSB identify for expedited review those List 3 inerts that are most important in formulated products used in organic production. Individuals may petition to have these inerts considered for inclusion on the National List. Additionally, the NOP will work with the EPA and the registrants of formulated products to expedite review of List 3 inerts currently included in formulated products used in organic production. Unless List 3 inerts are moved to List 4 or individually added to the National List, they are prohibited for use in organic production.

(2) Prohibiting Ash, Grit, and Screenings Derived from Sewage Sludge. Many commenters recommended that the ash, grit, and screenings derived from the production of sewage sludge should be added to the National List as non-synthetic materials prohibited for use in crop production. While the use of sewage sludge, including ash, grit, and screenings, is prohibited in organic production, we did not add them to the National List as prohibited non-synthetic substances. This subject is discussed further under subpart A, Definitions - Changes Requested But Not Made.

(3) Allowed Uses for Pheromones. Some commenters were concerned that the annotation for using pheromones as "insect attractants" was too limiting and would not include uses such as mating disruption, trapping, and monitoring. The annotation for pheromones does not preclude any use for a pheromone that is otherwise allowed by Federal, State, or local regulation.

(4) Nonagricultural Products as Livestock Feed Ingredients. Some commenters questioned whether non-synthetic, nonagricultural substances such as fishmeal and crushed oyster shell needed to be added to the National List to be used in livestock feed. Non-synthetic substances do not have to appear on the National List and may be used in organic livestock feed, provided that they are used in compliance with the FFDCFA. This subject is discussed further under item 4, Livestock - Changes Based on Comments, subpart C.

(5) Chlorine Disinfectant Limit Annotation for Organic Production and Handling. Some commenters requested clarification on the annotation for using chlorine materials as an allowed synthetic substance in crop and handling operations. The annotation in the proposed rule, which has been retained in the final rule, stated that "residual chlorine levels in the water shall not exceed the maximum residual disinfectant limit under the Safe Water Drinking Act." With this annotation, the residual chlorine levels at the point where the wastewater stream leaves the production or handling operation must meet limits under the Safe Drinking Water Act.

(6) Tobacco Use in Organic Production. One commenter questioned whether forms of tobacco other than tobacco dust, such as water extracts or smoke, were prohibited non-synthetic substances. The technical advisory panel (TAP) review on which the NOSB based its recommendation to prohibit tobacco dust identified nicotine sulfate as the active ingredient. Therefore, any substance containing nicotine sulfate as an active ingredient is prohibited in crop production.

(7) Non-synthetic Agricultural Processing Aids on the National List. A commenter requested clarification from the NOP on whether processing aids (e.g., defoaming agents), which are non-synthetic and non-organic agricultural substances (e.g., soybean oil), must appear on the National List when used in processing. In this regulation, a non-synthetic and non-organic agricultural product, such as soybean oil, used as a processing aid does not have to appear on the National List. Such products are included in the provision in section 205.606 that non-organically produced agricultural products may be used in accordance with any applicable restrictions when the substance is not commercially available in organic form.

(8) Transparency of the National List Petition Process. Some commenters stated the petition process for amending the National List appears to have limited public access and should be more transparent. These commenters advocate that any amendments to the National List should be subject to notice and comment. They also requested clarity on how petitions are prioritized and reviewed and the timeframes for review. Additionally, these commenters asked the NOP to expedite the review of materials for the National List. On July 13, 2000, AMS published in the Federal Register (Vol. 65, 43259-43261) guidelines for submitting petitions for the evaluations of substances for the addition to or removal from the National List. In this notice, the NOP stated that most petition information is available for public inspection with the exception of information considered to be "confidential business information." The notice also specified that any changes to the National List must be published in the Federal Register for public comment. The published petition notice has also provided an indication to the industry about the urgency of the need for substance review and that the industry should provide pertinent information to the NOSB to expedite the review of materials not on the National List.

Subpart G - Administrative
The National List of Allowed and Prohibited Substances

§ 205.600 Evaluation criteria for allowed and prohibited substances, methods, and ingredients.

The following criteria will be utilized in the evaluation of substances or ingredients for the organic production and handling sections of the National List:

(a) Synthetic and non-synthetic substances considered for inclusion on or deletion from the National List of allowed and prohibited substances will be evaluated using the criteria specified in the Act (7 U.S.C. 6517 and 6518).

(b) In addition to the criteria set forth in the Act, any synthetic substance used as a processing aid or adjuvant will be evaluated against the following criteria:

(1) The substance cannot be produced from a natural source and there are no organic substitutes;

(2) The substance's manufacture, use, and disposal do not have adverse effects on the environment and are done in a manner compatible with organic handling;

(3) The nutritional quality of the food is maintained when the substance is used, and the substance, itself, or its breakdown products do not have an adverse effect on human health as defined by applicable Federal regulations;

(4) The substance's primary use is not as a preservative or to recreate or improve flavors, colors, textures, or nutritive value lost during processing, except where the replacement of nutrients is required by law;

(5) The substance is listed as generally recognized as safe (GRAS) by Food and Drug Administration (FDA) when used in accordance with FDA's good manufacturing practices (GMP) and contains no residues of heavy metals or other contaminants in excess of tolerances set by FDA; and

(6) The substance is essential for the handling of organically produced agricultural products.

(c) Non-synthetics used in organic processing will be evaluated using the criteria specified in the Act (7 U.S.C. 6517 and 6518).

§ 205.601 Synthetic substances allowed for use in organic crop production.

In accordance with restrictions specified in this section, the following synthetic substances may be used in organic crop production:

(a) As algaecide, disinfectants, and sanitizer, including irrigation system cleaning systems

(1) Alcohols

(i) Ethanol

(ii) Isopropanol

(2) Chlorine materials - Except. That, residual chlorine levels in the water shall not exceed the maximum residual disinfectant limit under the Safe Drinking Water Act.

(i) Calcium hypochlorite

(ii) Chlorine dioxide

(iii) Sodium hypochlorite

(3) Hydrogen peroxide

(4) Soap-based algaecide/demisters

- (b) As herbicides, weed barriers, as applicable.
 - (1) Herbicides, soap-based - for use in farmstead maintenance (roadways, ditches, right of ways, building perimeters) and ornamental crops
 - (2) Mulches
 - (i) Newspaper or other recycled paper, without glossy or colored inks.
 - (ii) Plastic mulch and covers (petroleum-based other than polyvinyl chloride (PVC))
- (c) As compost feedstocks
 - Newspapers or other recycled paper, without glossy or colored inks
- (d) As animal repellents
 - Soaps, ammonium - for use as a large animal repellent only, no contact with soil or edible portion of crop
- (e) As insecticides (including acaricides or mite control)
 - (1) Ammonium carbonate - for use as bait in insect traps only, no direct contact with crop or soil
 - (2) Boric acid - structural pest control, no direct contact with organic food or crops
 - (3) Elemental sulfur
 - (4) Lime sulfur - including calcium polysulfide
 - (5) Oils, horticultural - narrow range oils as dormant, suffocating, and summer oils.
 - (6) Soaps, insecticidal
 - (7) Sticky traps/barriers
- (f) As insect attractants
 - Pheromones
- (g) As rodenticides
 - (1) Sulfur dioxide - underground rodent control only (smoke bombs)
 - (2) Vitamin D3
- (h) As slug or snail bait
 - <None>
- (i) As plant disease control
 - (1) Coppers, fixed - copper hydroxide, copper oxide, copper oxychloride, includes products exempted from EPA tolerance, Provided, That, copper-based materials must be used in a manner that minimizes accumulation in the soil and shall not be used as herbicides.
 - (2) Copper sulfate - Substance must be used in a manner that minimizes accumulation of copper in the soil.
 - (3) Hydrated lime - must be used in a manner that minimizes copper accumulation in the soil.
 - (4) Hydrogen peroxide
 - (5) Lime sulfur
 - (6) Oils, horticultural, narrow range oils as dormant, suffocating, and summer oils.
 - (7) Potassium bicarbonate
 - (8) Elemental sulfur
 - (9) Streptomycin, for fire blight control in apples and pears only
 - (10) Tetracycline (oxytetracycline calcium complex), for fire blight control only
- (j) As plant or soil amendments.
 - (1) Aquatic plant extracts (other than hydrolyzed) - Extraction process is limited to the use of potassium hydroxide or sodium hydroxide; solvent amount used is limited to that amount necessary for extraction.
 - (2) Elemental sulfur

- (3) Humic acids - naturally occurring deposits, water and alkali extracts only
- (4) Lignin sulfonate - chelating agent, dust suppressant, floatation agent
- (5) Magnesium sulfate - allowed with a documented soil deficiency
- (6) Micronutrients - not to be used as a defoliant, herbicide, or desiccant. Those made from nitrates or chlorides are not allowed. Soil deficiency must be documented by testing.

- (i) Soluble boron products

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

- (7) Liquid fish products - can be pH adjusted with sulfuric, citric or phosphoric acid. The amount of acid used shall not exceed the minimum needed to lower the pH to 3.5

- (8) Vitamins, B1, C, and E

(k) As plant growth regulators

- Ethylene - for regulation of pineapple flowering

(l) As floating agents in postharvest handling

- (1) Lignin sulfonate

- (2) Sodium silicate - for tree fruit and fiber processing

(m) As synthetic inert ingredients as classified by the Environmental Protection Agency (EPA), for use with non-synthetic substances or synthetic substances listed in this section and used as an active pesticide ingredient in accordance with any limitations on the use of such substances.

- (1) EPA List 4 - Inerts of Minimal Concern

(n)-(z) [Reserved]

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

The following non-synthetic substances may not be used in organic crop production:

- (a) Ash from manure burning

- (b) Arsenic

- (c) Lead salts

- (d) Sodium fluoaluminate (mined)

- (e) Strychnine

- (f) Tobacco dust (nicotine sulfate)

- (g) Potassium chloride - unless derived from a mined source and applied in a manner that minimizes chloride accumulation in the soil.

- (h) Sodium nitrate - unless use is restricted to no more than 20% of the crop's total nitrogen requirement.

- (i)-(z) [Reserved]

§ 205.603 Synthetic substances allowed for use in organic livestock production.

In accordance with restrictions specified in this section the following synthetic substances may be used in organic livestock production:

- (a) As disinfectants, sanitizer, and medical treatments as applicable

- (1) Alcohols

- (i) Ethanol - disinfectant and sanitizer only, prohibited as a feed additive

- (ii) Isopropanol - disinfectant only

- (2) Aspirin - approved for health care use to reduce inflammation

- (3) Chlorine materials - disinfecting and sanitizing facilities and equipment. Residual chlorine levels in the water shall not exceed the maximum residual disinfectant limit under the Safe Drinking Water Act

- (i) Calcium hypochlorite

(ii) Chlorine dioxide

(iii) Sodium hypochlorite

(4) Chlorohexidine - Allowed for surgical procedures conducted by a veterinarian. Allowed for use as a teat dip when alternative germicidal agents and/or physical barriers have lost their effectiveness

(5) Electrolytes - without antibiotics

(6) Glucose

(7) Glycerin - Allowed as a livestock teat dip, must be produced through the hydrolysis of fats or oils

(8) Iodine

(9) Hydrogen peroxide

(10) Magnesium sulfate

(11) Oxytocin - use in postparturition therapeutic applications

(12) Parasiticides

- Ivermectin - prohibited in slaughter stock, allowed in emergency treatment for dairy and breeder stock when organic system plan-approved preventive management does not prevent infestation. Milk or milk products from a treated animal cannot be labeled as provided for in subpart D of this part for 90 days following treatment. In breeder stock, treatment cannot occur during the last third of gestation if the progeny will be sold as organic and must not be used during the lactation period of breeding stock.

(13) Phosphoric acid - allowed as an equipment cleaner, Provided, That, no direct contact with organically managed livestock or land occurs.

(14) Biologics

Vaccines

(b) As topical treatment, external parasiticide or local anesthetic as applicable.

(1) Iodine

(2) Lidocaine - as a local anesthetic. Use requires a withdrawal period of 90 days after administering to livestock intended for slaughter and 7 days after administering to dairy animals

(3) Lime, hydrated - (bordeaux mixes), not permitted to cauterize physical alterations or deodorize animal wastes.

(4) Mineral oil - for topical use and as a lubricant

(5) Procaine - as a local anesthetic, use requires a withdrawal period of 90 days after administering to livestock intended for slaughter and 7 days after administering to dairy animals

(6) Copper sulfate

(c) As feed supplements

Milk replacers - without antibiotics, as emergency use only, no non-milk products or products from BST treated animals

(d) As feed additives

(1) Trace minerals, used for enrichment or fortification when FDA approved, including:

(i) Copper sulfate

(ii) Magnesium sulfate

(2) Vitamins, used for enrichment or fortification when FDA approved

(e) As synthetic inert ingredients as classified by the Environmental Protection Agency (EPA), for use with non-synthetic substances or a synthetic substances listed in this section and used as an active pesticide ingredient in accordance with any limitations on the use of such substances.

EPA List 4 - Inerts of Minimal Concern.

(f)-(z) [Reserved]

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

The following non-synthetic substances may not be used in organic livestock production:

(a) Strychnine

(b)-(z) [Reserved]

§ 205.605 Nonagricultural (non-organic) substances allowed as ingredients in or on processed products labeled as "organic" or "made with organic (specified ingredients or food group(s))."

The following nonagricultural substances may be used as ingredients in or on processed products labeled as "organic" or "made with organic (specified ingredients or food group(s))" only in accordance with any restrictions specified in this section.

(a) Non-synthetics allowed:

(1) Acids

(i) Alginic

(ii) Citric - produced by microbial fermentation of carbohydrate substances

(iii) Lactic

(2) Bentonite

(3) Calcium carbonate

(4) Calcium chloride

(5) Colors, non-synthetic sources only

(6) Dairy cultures

(7) Diatomaceous earth - food filtering aid only

(8) Enzymes - must be derived from edible, nontoxic plants, nonpathogenic fungi, or nonpathogenic bacteria

(9) Flavors, non-synthetic sources only and must not be produced using synthetic solvents and carrier systems or any artificial preservative.

(10) Kaolin

(11) Magnesium sulfate, non-synthetic sources only

(12) Nitrogen - oil-free grades

(13) Oxygen - oil-free grades

(14) Perlite - for use only as a filter aid in food processing

(15) Potassium chloride

(16) Potassium iodide

(17) Sodium bicarbonate

(18) Sodium carbonate

(19) Waxes - non-synthetic

(i) Carnauba wax

(ii) Wood resin

(20) Yeast - non-synthetic, growth on petrochemical substrate and sulfite waste liquor is prohibited

(i) Autolysate

(ii) Bakers

(iii) Brewers

(iv) Nutritional

(v) Smoked - non-synthetic smoke flavoring process must be documented.

(b) Synthetics allowed:

(1) Alginates

(2) Ammonium bicarbonate - for use only as a leavening agent

(3) Ammonium carbonate - for use only as a leavening agent

(4) Ascorbic acid

- (5) Calcium citrate
- (6) Calcium hydroxide
- (7) Calcium phosphates (monobasic, dibasic, and tribasic)
- (8) Carbon dioxide
- (9) Chlorine materials - disinfecting and sanitizing food contact surfaces, Except, That, residual chlorine levels in the water shall not exceed the maximum residual disinfectant limit under the Safe Drinking Water Act.
 - (i) Calcium hypochlorite
 - (ii) Chlorine dioxide
 - (iii) Sodium hypochlorite
- (10) Ethylene - allowed for postharvest ripening of tropical fruit
- (11) Ferrous sulfate - for iron enrichment or fortification of foods when required by regulation or recommended (independent organization)
- (12) Glycerides (mono and di) - for use only in drum drying of food
- (13) Glycerin - produced by hydrolysis of fats and oils
- (14) Hydrogen peroxide
- (15) Lecithin - bleached
- (16) Magnesium carbonate - for use only in agricultural products labeled "made with organic (specified ingredients or food group(s))," prohibited in agricultural products labeled "organic"
- (17) Magnesium chloride - derived from sea water
- (18) Magnesium stearate - for use only in agricultural products labeled "made with organic (specified ingredients or food group(s))," prohibited in agricultural products labeled "organic"
- (19) Nutrient vitamins and minerals, in accordance with 21 CFR 104.20, Nutritional Quality Guidelines For Foods
- (20) Ozone
- (21) Pectin (low-methoxy)
- (22) Phosphoric acid - cleaning of food-contact surfaces and equipment only
- (23) Potassium acid tartrate
- (24) Potassium tartrate made from tartaric acid
- (25) Potassium carbonate
- (26) Potassium citrate
- (27) Potassium hydroxide - prohibited for use in lye peeling of fruits and vegetables
- (28) Potassium iodide - for use only in agricultural products labeled "made with organic (specified ingredients or food group(s))," prohibited in agricultural products labeled "organic"
- (29) Potassium phosphate - for use only in agricultural products labeled "made with organic (specific ingredients or food group(s))," prohibited in agricultural products labeled "organic"
- (30) Silicon dioxide
- (31) Sodium citrate
- (32) Sodium hydroxide - prohibited for use in lye peeling of fruits and vegetables
- (33) Sodium phosphates - for use only in dairy foods
- (34) Sulfur dioxide - for use only in wine labeled "made with organic grapes," Provided, That, total sulfite concentration does not exceed 100 ppm.
- (35) Tocopherols - derived from vegetable oil when rosemary extracts are not a suitable alternative
- (36) Xanthan gum

(c)-(z) [Reserved]

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

The following non-organically produced agricultural products may be used as ingredients in or on processed products labeled as "organic" or "made with organic (specified ingredients or food group(s))" only in accordance with any restrictions specified in this section.

Any non-organically produced agricultural product may be used in accordance with the restrictions specified in this section and when the product is not commercially available in organic form.

- (a) Cornstarch (native)
- (b) Gums - water extracted only (arabic, guar, locust bean, carob bean)
- (c) Kelp - for use only as a thickener and dietary supplement
- (d) Lecithin - unbleached
- (e) Pectin (high-methoxy)

§ 205.607 Amending the National List.

(a) Any person may petition the National Organic Standard Board for the purpose of having a substance evaluated by the Board for recommendation to the Secretary for inclusion on or deletion from the National List in accordance with the Act.

(b) A person petitioning for amendment of the National List should request a copy of the petition procedures from the USDA at the address in § 205.607(c).

(c) A petition to amend the National List must be submitted to: Program Manager, USDA/AMS/TMP/NOP, Room 2945, South Building, P.O. Box 96456, Washington, DC 20090-6456.

State Organic Programs

The Act provides that each State may implement an organic program for agricultural products that have been produced and handled within the State, using organic methods that meet the requirements of the Act and these regulations. The Act further provides that a State organic program (SOP) may contain more restrictive requirements for organic products produced and handled within the State than are contained in the National Organic Program (NOP). All SOP's and subsequent amendments thereto must be approved by the Secretary.

A State may have an SOP but not have a State certifying agent. A State may have a State certifying agent but no SOP. Finally, a State may have an SOP and a State certifying agent. In all cases, the SOP's must be approved by the Secretary. In all cases, the State certifying agent must apply for and receive accreditation to certify organic production or handling operations pursuant to subpart F.

In States with an approved SOP, the SOP's governing State official is responsible for administering a compliance program for enforcement of the NOP and any more restrictive requirements contained in the SOP. The SOP governing State officials may review and investigate complaints of noncompliance involving organic production or handling operations operating within their State and, when appropriate, initiate suspension or revocation of certification. The SOP governing State officials may also review and investigate complaints of noncompliance involving accredited certifying agents operating within their State. They must report the findings of any review and investigation of a certifying agent to the NOP Program Manager along with any recommendations for appropriate action. States that do not have an SOP will not be responsible for compliance under the NOP, except that an accredited State certifying agent operating within such State will have compliance responsibilities under the NOP as a condition of its accreditation.

The sections covering SOP's, beginning with section 205.620, establish: (1) the requirements for an SOP and amending such a program and (2) the process for approval of an SOP and amendments to the SOP's. Review and approval of an SOP will occur not less than once during each 5-year period. Review related to compliance matters may occur at any time.

Description of Regulations

State Organic Program Requirements

A State may establish an SOP for production and handling operations within the State that produces and handles organic agricultural products. The SOP and supporting documentation must demonstrate that the SOP meets the requirements for organic programs specified in the Act.

An SOP may contain more restrictive requirements governing the production and handling of organic products within the State. Such requirements must be based on environmental conditions or specific production or handling practices particular to the State or region of the United States, which necessitates the more restrictive requirement. More restrictive requirements must be justified and shown to be consistent with and to further the purposes of the Act and the regulations in this part. Requirements necessitated by an environmental condition that is limited to a specific geographic area of the State should only be required of organic production and handling operations operating within the applicable geographic area. If approved by the Secretary, the more restrictive requirements will become the NOP regulations for organic producers and handlers in the State or applicable geographical area of the State. All USDA-accredited certifying agents planning to operate within a State with an SOP will be required to demonstrate their ability to comply with the SOP's more restrictive requirements.

No provision of an SOP shall discriminate against organic agricultural products produced by production or handling operations certified by certifying agents accredited or accepted by USDA pursuant to section 205.500. Specifically, an SOP may not discriminate against agricultural commodities organically produced in other States in accordance with the Act and the regulations in this part. Further, an SOP may not discriminate against agricultural commodities organically produced by production or handling operations certified by foreign certifying agents operating under: (1) standards determined by USDA to meet the requirements of this part or (2) an equivalency agreement negotiated between the United States and a foreign government.

To receive approval of its SOP, a State must assume enforcement obligations in the State for the requirements of this part and any more restrictive requirements included in the SOP and approved by the Secretary. Specifically, the State must ensure compliance with the Act, the regulations in this part, and the provisions of the SOP by certified production and handling operations operating within the State. The SOP must include compliance and appeals procedures equivalent to those provided for under the NOP.

An SOP and any amendments thereto must be approved by the Secretary prior to implementation by the State.

State Organic Program Approval Process

An SOP and subsequent amendments thereto must be submitted to the Secretary by the SOP's governing State official for approval prior to implementation. A request for approval of an SOP must contain supporting materials that include statutory authorities, program descriptions, documentation of environmental or ecological conditions or specific production and handling practices particular to the State which necessitate more restrictive requirements than the requirements of this part, and other information as may be required by the Secretary. A request for amendment of an approved SOP must contain supporting materials that include an explanation and documentation of the environmental or ecological conditions or specific production practices particular to the State or region, which necessitate the proposed amendment. Supporting material also must explain how the proposed amendment furthers and is consistent with the purposes of the Act and the regulations in this part.

Each request for approval of an SOP or amendment to an SOP and its supporting materials and documentation will be reviewed for compliance with the Act and these regulations. Within 6 months of receiving the request for approval, the Secretary will notify the SOP's governing State official of approval or disapproval. A disapproval will include the reasons for disapproval. A State receiving a notice of disapproval of its SOP or amendment to its SOP may submit a revised SOP or amendment to its SOP at any time.

Review of State Organic Programs

SOP's will be reviewed at least once every 5 years by the Secretary as required by section 6507(c)(1) of the Act. The Secretary will notify the SOP's governing State official of approval or disapproval of the program within 6 months after initiation of the review.

State Organic Programs - Changes Based on Comments

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

(1) Publication of SOP's and Consideration of Public Comments. Some commenters assert that the USDA should not publish SOP provisions for public comment in the Federal Register. These commenters argued that it is not appropriate for the NOP to have nonresidents commenting on a particular State program as nearly all States have a mechanism to ensure full public participation in their regulation promulgation. They believe the comment process set forth in the proposed rule is a redundant and unacceptable intrusion on State sovereignty.

We will not publish for public comment the provisions of SOP's under review by the Secretary in the Federal Register. We have removed the provision from this final rule, described in section 205.621(b), requiring the Secretary to publish in the Federal Register for public comment a summary of the SOP and a summary of any amendment to such a program. Alternatively, we will announce which SOP's are being reviewed through the NOP website. The NOP will issue public information notices that will announce each approved SOP and any approved amendments to an existing State program. The notices will identify the characteristics of the approved State program that warranted the more restrictive organic production or handling requirements. We also will include a summary of the new program on the NOP website.

(2) NOP Oversight of SOP's. Several commenters stated that, in the proposed rule, the provisions did not provide a comprehensive description of organic programs operated by States that would be under NOP authority. Some commenters implied that the proposed rule would only include States with organic certification programs, while other commenters inquired whether the sections 205.620 to 205.622 included other SOP activities beyond certification.

To address the commenters' concerns, we have modified the section heading by adding the term, "organic," and removing the term, "certification," from the description and definition of SOP's. We have taken this action to clarify that, while certification is one component of the requirements, it does not define the extent of evaluation of State programs that will be conducted by the NOP. SOP's can choose not to conduct certification activities under their existing organic program. State programs whose provisions fall within the scope of the eleven general provisions described in the Act (7 U.S.C. 6506) will require Departmental review.

States may conduct other kinds of organic programs that will not need review and approval by the NOP. Examples of these other programs may include: organic promotion and research projects, marketing; transition assistance or cost share programs, registration of State organic production and handling operations, registration of certifying agents operating within the State, or a consumer referral program. The NOP will not regulate such State activities. Such programs may not advertise, promote, or otherwise infer that the State's organic products are more organic or better than organic product produced in other States. Such programs and projects would be beyond the scope of this national program and will not be subject to the Secretary's review.

State Organic Programs - Changes Requested But Not Made

(1) Limitations on SOP More Restrictive Requirements. Commenters expressed concern that limiting a State's ability to craft a regulation designated as a more restrictive requirement to environmental conditions or specific production and handling practices would hinder the ongoing development of SOP's. They were concerned that any State legislation modifying the SOP would need to be preapproved by the Secretary.

We have retained the provision limiting the scope of more restrictive requirements States can include in their organic program as described in section 205.620(c). We believe the language contained in the provision is broad enough to facilitate the development of SOP's without hindering development or State program implementation and enforcement. Section 6507(b)(1) of the Act provides that States may establish more restrictive organic certification requirements; paragraph (b)(2) establishes parameters for those requirements. More restrictive SOP requirements must: further the purposes of the Act, be consistent with the Act, not discriminate against other State's agricultural commodities, and be approved by the Secretary before becoming effective. We expect that a State's more restrictive requirements are likely to cover specific organic production or handling practices to address a State's

specific environmental conditions. The Secretary will approve State's requests for more restrictive State requirements that are consistent with the purposes of the Act. However, we believe requests from States for more restrictive requirements will be rare. Although SOP's can impose additional requirements, we believe States will be reluctant to put their program participants at a competitive disadvantage when compared to producers and handlers in other States absent compelling environmental conditions or a compelling need for special production and handling practices. While preapproval of State legislation modifying an existing SOP is not required, the NOP envisions a close consultation with States with existing programs to ensure consistency with the final rule.

(2) SOP Enforcement Obligations. Some commenters expressed concern about States having adequate resources available to implement enforcement activities that they are obligated to conduct under the NOP. A few of these commenters argue that the enforcement obligation will result in their State programs being discontinued. A few commenters cited a lack of federal funding to support State enforcement obligations and suggested the NOP provide funding for enforcement activities.

The proposed rule indicated that States with organic programs must assume enforcement obligations for this regulation within their State. We have retained this enforcement obligation in section 205.620(d). Many States currently have organic programs with the kind of comprehensive enforcement and compliance mechanisms necessary for implementing any State regulatory program. Assuming those enforcement activities are consistent with the NOP, this final rule adds no additional regulatory burden to the SOP's. The costs associated with the enforcement activities of an approved SOP should be similar to the enforcement costs associated with the existing State program. Additional clarification of SOP enforcement obligations is in the Accreditation, Appeals, and Compliance preamble discussions.

(3) SOP Evaluation Notification Period. A few commenters indicated that the SOP review and decision notification period described in section 205.621(b) of the proposed rule could hinder a State's ability to develop or implement an SOP. These commenters cited potential cases in which particular States have requirements for regulatory promulgation that must occur within 6 months under a State legislative session that is held once every 2 years. These commenters suggested the NOP should reduce the notification time to 1 to 3 months. We disagree with the commenters. In the proposed rule in section 205.621(b), the Secretary is required to notify the SOP's governing State official within 6 months of receipt of submission of documents and information regarding the approval of the SOP. We have retained this time period. We will review SOP applications as quickly as possible and will endeavor to make decisions in less than 6 months whenever possible. However, some SOP's may be very complex and require more review time. The NOP envisions working closely with the States and State officials to ensure a smooth transition to the requirements of this final rule.

State Organic Programs - Clarifications

(1) Discrimination Against Organic Products. Several commenters requested the addition of a provision prohibiting an SOP from discriminating against agricultural commodities organically produced in other States. Discrimination by a State against organically produced agricultural products produced in another State is prevented in two ways. First, any organic program administered by a State must meet the requirements for organic programs specified in the Act and be approved by the Secretary. Finally, a USDA-accredited certifying agent must accept the certification decisions made by another USDA-accredited certifying agent as its own.

(2) Potential Duplication Between the Accreditation and SOP Review Process. Some commenters asked about possible duplication between the process for reviewing SOP's and the process of accreditation review. These commenters have asked the NOP to eliminate

any duplication that may exist between the two review processes. The NOP will be conducting a review process for SOP's and a separate review process for accrediting State and private certifying agents. The two reviews are different. The SOP review is the evaluation of SOP compliance with the Act and the NOP regulations. If approved, the SOP becomes the NOP standards for the particular State with which all certifying agents operating in that State must comply. Approved SOP's must be in compliance with the Act and the NOP regulations. They cannot have weaker standards than the NOP. States can have more restrictive requirements than the NOP if approved by the Secretary.

The accreditation review is an evaluation of the ability of certifying agents to carry out their responsibilities under the NOP. This review is a measure of the competency of certifying agents to evaluate compliance to national organic standards. Certifying agents will not be unilaterally establishing regulations or standards related to the certification of organic products. They will only provide an assessment of compliance.

Thus, SOP reviews and accreditation reviews are separate evaluations of different procedures. We acknowledge some of the information for the two evaluations may be similar, e.g., compliance procedures. The reviews do not duplicate the same requirements. However, the NOP envisions working with States to ensure documentation is not duplicated.

(3) Scope of Enforcement by States. A number of State commenters have requested clarification on the proposed rule provision specifying that approved SOP's must assume enforcement obligations in their State for the requirements of the NOP and any additional requirements approved by the Secretary. These commenters have indicated that they remain uncertain as to what is expected by the term, "enforcement obligation."

Approved SOP's will have to administer and provide enforcement of the requirements of the Act and the regulations of the NOP. The administrative procedures used by the State in administering the approved SOP should have the same force and effect as the procedures use by AMS in administering this program. This final rule specifies that the requirements for environmental conditions or for special production and handling practices are necessary for establishing more restrictive requirements. These factors establish our position that a State must agree to incurring increased enforcement responsibilities and obligations to be approved as an SOP under the NOP. For instance, a State with an approved organic program will oversee compliance and appeals procedures for certified organic operations in the State. Those procedures must provide due process opportunities such as rebuttal, mediation, and correction procedures. Once approved by the Secretary, the State governing official of the SOP must administer the SOP in a manner that is consistent and equitable for the certified parties involved in compliance actions.

(4) SOP's That Do not Certify and NOP Oversight. A few commenters requested that the NOP develop new provisions to include State programs that have organic regulations but do not conduct certification activities. These commenters argue that any SOP that has a regulatory impact on organic producers, regardless of whether or not the program includes certification, be approved by the Secretary. This regulation, in section 205.620(b), provides for NOP oversight of SOP's that do not conduct certification activities.

(5) State's Use of Private Certifying Agents. Some commenters have requested that the NOP provide clarification of the proposed rule sections 205.620 through 205.622 on how these sections will affect States that delegate certification activities to private certifying agents. These commenters asked how the NOP intends to oversee this type of State activity.

The NOP intends to give considerable latitude to States in choosing the most appropriate system or procedures to structure their programs. This may include a State establishing its

own certifying agent or relying on private certifying agents. However, States will not be accrediting certifying agents operating in their State. Accreditation of all certifying agents operating in the United States is the responsibility of USDA. Establishment of a single national accreditation program is an essential part of the NOP. As stated elsewhere in this final rule, any accreditation responsibilities of a State's current organic program will cease with implementation of this program. Pursuant to the Compliance provisions of this subpart, the governing State official charged with compliance oversight under the SOP may investigate and notify the NOP of possible compliance violations on the part of certifying agents operating in the State. However, the State may not pursue compliance actions or remove accreditation of any certifying agent accredited by the Secretary. That authority is the sole responsibility of the Secretary. If more restrictive State requirements are approved by the Secretary, we will review certifying agent qualifications in the State, as provided by section 205.501(a)(20), and determine whether they are able to certify to the approved, more restrictive requirements. Our accreditation responsibilities include oversight of both State and private certifying agents, including any foreign certifying agents that may operate in a State.

State Organic Programs

§ 205.620 Requirements of State organic programs.

(a) A State may establish a State organic program for production and handling operations within the State which produce and handle organic agricultural products.

(b) A State organic program must meet the requirements for organic programs specified in the Act.

(c) A State organic program may contain more restrictive requirements because of environmental conditions or the necessity of specific production or handling practices particular to the State or region of the United States.

(d) A State organic program must assume enforcement obligations in the State for the requirements of this part and any more restrictive requirements approved by the Secretary.

(e) A State organic program and any amendments to such program must be approved by the Secretary prior to being implemented by the State.

§ 205.621 Submission and determination of proposed State organic programs and amendments to approved State organic programs.

(a) A State organic program's governing State official must submit to the Secretary a proposed State organic program and any proposed amendments to such approved program.

(1) Such submission must contain supporting materials that include statutory authorities, program description, documentation of the environmental conditions or specific production and handling practices particular to the State which necessitate more restrictive requirements than the requirements of this part, and other information as may be required by the Secretary.

(2) Submission of a request for amendment of an approved State organic program must contain supporting materials that include an explanation and documentation of the environmental conditions or specific production and handling practices particular to the State or region, which necessitates the proposed amendment. Supporting material also must explain how the proposed amendment furthers and is consistent with the purposes of the Act and the regulations of this part.

(b) Within 6 months of receipt of submission, the Secretary will: Notify the State organic program's governing State official of approval or disapproval of the proposed program or amendment of an approved program and, if disapproved, the reasons for the disapproval.

(c) After receipt of a notice of disapproval, the State organic program's governing State official may submit a revised State organic program or amendment of such a program at any time.

§ 205.622 Review of approved State organic programs.

The Secretary will review a State organic program not less than once during each 5-year period following the date of the initial program approval. The Secretary will notify the State organic program's governing State official of approval or disapproval of the program within 6 months after initiation of the review.

Subpart G - Fees

This portion of subpart G sets forth the regulations on fees and other charges to be assessed for accreditation and certification services under the National Organic Program (NOP). These regulations address the kinds of fees and charges to be assessed by the U.S. Department of Agriculture (USDA) for the accreditation of certifying agents, the level of such fees and charges, and the payment of such fees and charges. These regulations also address general requirements to be met by certifying agents in assessing fees and other charges for the certification of producers and handlers as certified organic operations. Finally, these regulations address the Secretary's oversight of a certifying agent's fees and charges for certification services.

Description of Regulation

Fees and Other Charges for Accreditation

Fees and other charges will be assessed and collected from applicants for initial accreditation and accredited certifying agents submitting annual reports or seeking renewal of accreditation. Such fees will be equal as nearly as may be to the cost of the accreditation services rendered under these regulations. Fees-for-service will be based on the time required to render the service provided calculated to the nearest 15-minute period. Activities to be billed on the basis of time used include the review of applications and accompanying documents and information, evaluator travel, the conduct of on-site evaluations, review of annual reports and updated documents and information, and the preparation of reports and any other documents in connection with the performance of service. The hourly rate will be the same as that charged by the Agricultural Marketing Service (AMS), through its Quality System Certification Program, to certification bodies requesting conformity assessment to the International Organization for Standardization "General Requirements for Bodies Operating Product Certification Systems" (ISO Guide 65).

Applicants for initial accreditation and accredited certifying agents submitting annual reports or seeking renewal of accreditation during the first 18 months following the effective date of subpart F will receive service without incurring an hourly charge for such service. Applicants for initial accreditation and renewal of accreditation must pay at the time of application, effective 18 months following the effective date of subpart F, a nonrefundable fee of \$500.00. This fee will be applied to the applicant's fees-for-service account.

When service is requested at a place so distant from the evaluator's headquarters that a total of one-half hour or more is required for the evaluator(s) to travel to such a place and back to the headquarters or from a place of prior assignment on circuitous routing requiring a total of one-half hour or more to travel to the next place of assignment on the circuitous routing, the charge for such service will include all applicable travel charges. Travel charges may include a mileage charge administratively determined by USDA, travel tolls, or, when the travel is made by public transportation (including hired vehicles), a fee equal to the actual cost thereof. If the service is provided on a circuitous routing, the travel charges will be prorated among all the applicants and certifying agents furnished the service involved. Travel charges will become effective for all applicants for initial accreditation and accredited certifying agents on the effective date of subpart F. The applicant or certifying agent will not be charged a new mileage rate without notification before the service is rendered.

When service is requested at a place away from the evaluator's headquarters, the fee for such service shall include a per diem charge if the employee(s) performing the service is paid per diem in accordance with existing travel regulations. Per Diem charges to applicants and certifying agents will cover the same period of time for which the evaluator(s) receives per diem reimbursement. The per diem rate will be administratively determined by USDA. Per Diem charges shall become effective for all applicants for initial accreditation and accredited certifying agents on the effective date of subpart F. The applicant or certifying

agent will not be charged a new per diem rate without notification before the service is rendered.

When costs, other than fees-for-service, travel charges, and per diem charges, are associated with providing the services, the applicant or certifying agent will be charged for these costs. Such costs include but are not limited to equipment rental, photocopying, delivery, facsimile, telephone, or translation charges incurred in association with accreditation services. The amount of the costs charged will be determined administratively by USDA. Such costs will become effective for all applicants for initial accreditation and accredited certifying agents on the effective date of subpart F.

Payment of Fees and Other Charges

Applicants for initial accreditation and renewal of accreditation must remit the nonrefundable fee along with their application. Remittance must be made payable to the Agricultural Marketing Service, USDA, and mailed to: Program Manager, USDA-AMS-TMP-NOP, Room 2945-South Building, P.O. Box 96456, Washington, DC 20090-6456 or such other address as required by the Program Manager. All other payments for fees and other charges must be received by the due date shown on the bill for collection, made payable to the Agricultural Marketing Service, USDA, and mailed to the address provided on the bill for collection. The Administrator will assess interest, penalties, and administrative costs on debts not paid by the due date shown on a bill for collection and collect delinquent debts or refer such debts to the Department of Justice for litigation.

Fees and Other Charges for Certification

Fees charged by a certifying agent must be reasonable, and a certifying agent may charge applicants for certification and certified production and handling operations only those fees and charges that it has filed with the Administrator. The certifying agent must provide each applicant with an estimate of the total cost of certification and an estimate of the annual cost of updating the certification. The certifying agent may require applicants for certification to pay at the time of application a nonrefundable fee that must be applied to the applicant's fees-for-service account. A certifying agent may set the nonrefundable portion of certification fees; however, the nonrefundable portion of certification fees must be explained in the fee schedule submitted to the Administrator. The fee schedule must explain what fee amounts are nonrefundable and at what stage during the certification process the respective fees become nonrefundable. The certifying agent must provide all persons inquiring about the application process with a copy of its fee schedule.

Fees - Changes Based on Comments

This subpart differs from the proposal in the following respects:

Nonrefundable Portion of Certification Fees. Commenters were not satisfied with the provision in section 205.642 that stated, "The certifying agent may require applicants for certification to pay at the time of application a nonrefundable fee of no more than \$250.00, which shall be applied to the applicant's fee for service account." Some commenters believed we were requiring the certifying agents to bill fees for inspection services separately. One State agency expressed a concern that we were placing a limit on the initial fee the certifying agent could collect. As a result, the State agency commented that by not being allowed to collect the full certification fee at the time of application, the certifying agent, in effect, would be extending credit to the applicant. Commenters reported that some State agencies are prevented by statute from extending credit and are required to collect all fees at the time of application. Several commenters stated that the amount of \$250.00 was too low and would not cover the costs the certifying agents could incur during the certification process. One organization noted that we should consider prorating the amount of the fee to be refunded when an applicant for certification withdraws before the completion of the certification process. The organization recommended that the amount of the prorated fee should be based on how far along in the certification process the applicant had progressed

before withdrawal. Another commenter believed it was inappropriate for USDA to set any fees for private certification programs and that the fees should be market driven.

It was not our intent to limit the initial amount that certifying agents could collect from the applicant for certification. Our intent was to limit the portion of the fee that would be nonrefundable in order to reduce the potential liability for the small producer/handler who may need to withdraw prematurely from the certification process. However, we acknowledge that this provision could be misinterpreted. We also realize that certifying agents may incur initial costs during the preliminary stage of the certification process that may be more or less than the \$250.00 application rate proposed. As a result, we have removed the provision that stated certifying agents could collect a nonrefundable fee of not more than \$250.00 at the time of application from applicants for certification.

Certifying agents may set the nonrefundable portion of their certification fees. However, the nonrefundable portion of their certification fees must be explained in the fee schedule submitted to the Administrator. The fee schedule must explain what fee amounts are nonrefundable and at what stage during the certification process the respective fees become nonrefundable. Certifying agents will also provide all persons inquiring about the application process with a copy of its fee schedule.

Fees - Changes Requested But Not Made

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

(1) Farm Subsidy/Transition Program. Many commenters asked that USDA subsidize or develop a cost-share program for small farmers/producers who are certified or who are in transition to organic farming. Some commenters wanted these costs to be fully subsidized; a few commenters suggested that USDA pay for any extra site visit costs; and many others wanted USDA to pay premium prices to farmers for their products during the period of transition to organic production. In addition, many commenters argued that USDA should fully fund certification costs. Finally, many commenters suggested that the USDA should provide additional financial support to the organic industry because the industry is relatively young and composed of a large number of small, low-resource businesses.

We have considered the commenters requests but have not made the suggested changes. The NOP under AMS is primarily a user-fee-based Federal program. Section 2107(a)(10) of the Organic Food Production Act of 1990 (OFPA) requires that the NOP provide for the collection of reasonable fees from producers, certifying agents, and handlers who participate in activities to certify, produce, or handle agricultural products as organically produced. Therefore, under the statutory authority of OFPA, it is outside of the scope of the NOP to provide for the subsidization of producers, handlers, and certifying agents as desired by some commenters. We have, however, established provisions in this part that we believe will minimize the economic impact of the NOP on producers, handlers, and certifying agents.

(2) Small Farmer Exemption Versus Lower Certification Fees. Many commenters suggested that certification fees be lowered or based on a sliding scale rather than instituting an exemption from certification for small farmers and handlers.

We have not accepted the commenters' suggestion. We cannot remove the small farmer exemption because section 2106(d) of the Act requires that small farmers be provided an exemption from organic certification if they sell no more than \$5,000 annually in value of agricultural products. Also, certification fees cannot be lowered by USDA because NOP under AMS is primarily a user-fee-based Federal agency. It is not our goal or objective to make a profit on our accreditation activities. However, our fees associated with the accreditation process are targeted toward recovering costs incurred during the accreditation process. Commenters expressed a concern that the accreditation fees charged by USDA

would have an impact on the certification fees prescribed by certifying agents to operations seeking organic certification. We understand the commenters' concern that accreditation fees charged to certifying agents will most likely be calculated into the fees that certifiers charge their clients. However, we believe that our provision to waive the hourly service charges for accreditation during the first 18 months of implementation of the NOP should help reduce accreditation costs of the certifying agent and should, therefore, result lower certification fee charged by certifying agents. As provided by the Act and the regulations in this part, fees charged by certifying agents must be reasonable. Also, certifying agents must submit their fee schedule to the Administrator and may only charge those fees and charges filed with the Administrator. In addition, certifiers are required to provide their approved fee schedules to applicants for certification. Therefore, applicants for certification will be able to base their selection of a certifying agent on price if they choose. Moreover, there are no provisions in the regulations that preclude certifying agents from pricing their services on a sliding scale, as long as their fees are consistent and nondiscriminatory and are approved during the accreditation process.

(3) Accreditation Fees. Many industry commenters suggested that we reevaluate our accreditation fee structure. They believe the hourly accreditation rate proposed is unacceptable. Commenters were concerned that high accreditation costs would lead to high certification costs, which would have a greater impact on small operations. Some industry commenters also noted that we should be required to provide a fee schedule such as the certifiers are required to do. They stated that unless USDA provided a fee schedule that included travel costs, they would not be able to accurately budget for these costs. A few commenters wanted USDA to forgo charging travel costs or not charge travel time at the full rate. Several commenters also stated that the hourly rate stated in the proposal is much higher than what the people who actually perform the accreditations will earn. However, a large majority of the commenters favored the 18-month period in which AMS will not charge the hourly accreditation rate to applicants.

As stated in the proposal, the hourly rate will be the same as that of AMS' Quality Systems Certification Program. Due to the fact that AMS' Quality Systems Certification Program publishes one rate that is readily available to the public, it is our belief that it is unnecessary for the NOP to set up a separate fee schedule. The NOP will notify accredited certifying agents and applicants for accreditation of any proposed rate changes and final actions on such rates by AMS. We will also periodically report the status of fees to the National Organic Standards Board.

Those applicants and certifying agents who need accreditation cost estimates, including travel, for budgetary or other reasons may notify the NOP. The NOP staff will provide the applicant with a cost estimate, based on information provided by the applicant. As stated in an earlier response ((2) - Changes Requested But Not Made), the objective of the fee that is charged to accredit certifying agents is not to gain a profit for accreditation activities but to recover costs incurred during the accreditation process. As such, these costs include but are not limited to salaries, benefits, clerical help, equipment, supplies, etc.

Fees

§ 205.640 Fees and other charges for accreditation.

Fees and other charges equal as nearly as may be to the cost of the accreditation services rendered under the regulations, including initial accreditation, review of annual reports, and renewal of accreditation, shall be assessed and collected from applicants for initial accreditation and accredited certifying agents submitting annual reports or seeking renewal of accreditation in accordance with the following provisions:

(a) **Fees-for-Service.** (1) Except as otherwise provided in this section, fees-for-service shall be based on the time required to render the service provided calculated to the nearest 15-minute period, including the review of applications and accompanying documents and information, evaluator travel, the conduct of on-site evaluations, review of annual reports and updated documents and information, and the time required to prepare reports and any other documents in connection with the performance of service. The hourly rate shall be the same as that charged by the Agricultural Marketing Service, through its Quality Systems Certification Program, to certification bodies requesting conformity assessment to the International Organization for Standardization "General Requirements for Bodies Operating Product Certification Systems" (ISO Guide 65).

(2) Applicants for initial accreditation and accredited certifying agents submitting annual reports or seeking renewal of accreditation during the first 18 months following the effective date of subpart F of this part shall receive service without incurring an hourly charge for service.

(3) Applicants for initial accreditation and renewal of accreditation must pay at the time of application, effective 18 months following 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 U.S. Department of Agriculture and travel tolls, if applicable, or such travel prorated among all the applicants and certifying agents furnished the service involved on an equitable basis or, when the travel is made by public transportation (including hired vehicles), a fee equal to the actual cost thereof. Travel charges shall become effective for all applicants for initial accreditation and accredited certifying agents on 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 U.S. Department of Agriculture. 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 U.S. Department of Agriculture. 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, P.O. Box 96456, Washington, DC 20090-6456 or such other address as required by the Program Manager.

(b) Payments for fees and other charges not covered under paragraph (a) of this section must be:

- (1) Received by the due date shown on the bill for collection;
- (2) Made payable to the Agricultural Marketing Service, USDA; and
- (3) Mailed to the address provided on the bill for collection.

(c) The Administrator shall assess interest, penalties, and administrative costs on debts not paid by the due date shown on a bill for collection and collect delinquent debts or refer such debts to the Department of Justice for litigation.

§ 205.642 Fees and other charges for certification.

Fees charged by a certifying agent must be reasonable, and a certifying agent shall charge applicants for certification and certified production and handling operations only those fees and charges that it has filed with the Administrator. The certifying agent shall provide each applicant with an estimate of the total cost of certification and an estimate of the annual cost of updating the certification. The certifying agent may require applicants for certification to pay at the time of application a nonrefundable fee which shall be applied to the applicant's fees-for-service account. The certifying agent may set the nonrefundable portion of certification fees; however, the nonrefundable portion of certification fees must be explained in the fee schedule submitted to the Administrator. The fee schedule must explain what fee amounts are nonrefundable and at what stage during the certification process fees become nonrefundable. The certifying agent shall provide all persons inquiring about the application process with a copy of its fee schedule.

§§ 205.643-205.659 [Reserved]

Compliance

This portion of subpart G sets forth the enforcement procedures for the National Organic Program (NOP). These procedures describe the compliance responsibilities of the NOP Program Manager, State organic programs' (SOP) governing State officials, and State and private certifying agents. These provisions also address the rights of certified production and handling operations and accredited certifying agents operating under the NOP. The granting and denial of certification and accreditation are addressed under subparts E and F.

Description of Regulations

The Secretary is required under the Act to review the operations of SOP's, accredited certifying agents, and certified production or handling operations for compliance with the Act and these regulations. The Program Manager of the NOP may carry out compliance proceedings and provide oversight of compliance proceedings on behalf of the Secretary and the Administrator. The Program Manager will initiate proceedings to suspend or revoke a certified operation's certification if a certifying agent or SOP's governing State official fails to take appropriate enforcement action. The Program Manager may also initiate proceedings to suspend or revoke a certified operation's certification if the operation is found to have been erroneously certified by a certifying agent whose accreditation has been suspended or revoked. We anticipate, however, that most investigations, reviews, and analyses of certification noncompliance and initiation of suspension or revocation will be conducted by the certified operation's certifying agent. With regard to certifying agents, the Program Manager will, when appropriate, initiate proceedings to suspend or revoke the accreditation of a certifying agent for noncompliance with the Act and these regulations.

In States with an approved SOP, the SOP's governing State official is responsible for administering a compliance program for enforcement of the NOP/SOP. SOP's governing State officials may review and investigate complaints of noncompliance involving organic production or handling operations operating within their State and, when appropriate, initiate suspension or revocation of certification. SOP's governing State officials may also review and investigate complaints of noncompliance involving accredited certifying agents operating within their State. They must report the findings of any review and investigation of a certifying agent to the Program Manager along with any recommendations for appropriate action.

The compliance provisions of the NOP are consistent with the requirements of the Administrative Procedure Act (APA) (5 U.S.C. 553-559) in that this program provides for due process including an opportunity for hearing, appeal procedures, written notifications of noncompliance, and opportunities to demonstrate or achieve compliance before any suspension or revocation of organic certification or accreditation is invoked. A compliance action regarding certification carried out under an approved SOP's compliance procedures will have the same force and effect as a certification compliance action carried out under these NOP compliance procedures. The notification process for denying certification and accreditation is laid out in subparts E and F, respectively.

Each notification of noncompliance, rejection of mediation, noncompliance resolution, proposed suspension or revocation, and suspension or revocation issued under these regulations must be sent to the recipient's place of business via a delivery service which provides return receipts. Certified operations and certifying agents must respond to all compliance notifications via a delivery service which provides return receipts.

Noncompliance Procedure for Certified Operations

The Act provides for the enforcement of certification requirements. Statutory oversight of production and handling operations by certifying agents includes review of organic plans, on-site inspections, residue and tissue testing, authority to conduct investigations and initiate suspension or revocation actions, and responsibility to report violations.

Notification of Noncompliance

A written notification of noncompliance will be sent to the certified operation when an inspection, review, or investigation reveals any noncompliance with the Act or these regulations. A noncompliance notification may encompass the entire operation or a portion of the operation. For instance, a violation at one farm may not warrant loss of certification at other farms of the certified operation not affected by the violation. The notification of noncompliance will provide: (1) a description of each condition, action, or item of noncompliance; (2) the facts upon which the notification is based; and (3) the date by which the certified operation must rebut the notification or correct the noncompliance and submit supporting documentation of the correction. A certified operation may continue to sell its product as organic upon receiving a notification of noncompliance and throughout the compliance proceeding and any appeal procedure which might follow the compliance proceeding unless otherwise notified by a State or Federal government agency.

If a certified operation believes the notification of noncompliance is incorrect or not well-founded, the certified operation may submit a rebuttal to the certifying agent or SOP's governing State official, as applicable, providing supporting data to refute the facts stated in the notification. The opportunity for rebuttal is provided to allow certifying agents and certified operations to informally resolve noncompliance issues. The rebuttal process should be helpful in resolving differences which may be the result of misinterpretation of requirements, misunderstandings, or incomplete information. Alternatively, the certified operation may correct the identified noncompliances and submit proof of such corrections. When the certified operation demonstrates that each noncompliance has been corrected or otherwise resolved, the certifying agent or SOP's governing State official, as applicable, will send the certified operation a written notification of noncompliance resolution.

Proposed Suspension or Revocation of Certification

If the noncompliance is not resolved or is not in the process of being resolved by the date specified in the notification of noncompliance, the certifying agent or SOP's governing State official will send the certified operation a written notification of proposed suspension or revocation of certification for the entire operation or a portion of the operation affected by the noncompliance. The notification will state: (1) the reasons for the proposed suspension or revocation; (2) the proposed effective date of the suspension or revocation; (3) the impact of the suspension or revocation on the certified operation's future eligibility for certification; and (4) that the certified operation has a right to request mediation or to file an appeal. The impact of a proposed suspension or revocation may include the suspension or revocation period or whether the suspension or revocation applies to the entire operation or to a portion or portions of the operation.

If a certifying agent or SOP's governing State official determines that correction of a noncompliance is not possible, the notification of noncompliance and the proposed suspension or revocation of certification may be combined in one notification of proposed suspension or revocation. The certified operation will have an opportunity to appeal the proposed suspension or revocation.

If a certifying agent or SOP's governing State official has reason to believe that a certified operation has willfully violated the Act or regulations, a notification of proposed suspension or revocation will be sent to the certified operation. The proposed suspension or revocation will be for the entire operation or a portion of the operation. This notification, because it involves a willful violation, will be sent without first issuing a notification of noncompliance.

Mediation

A production or handling operation may request mediation of any dispute regarding denial of certification or proposed suspension or revocation of certification. Mediation is not required prior to filing an appeal but is offered as an option which may resolve the dispute more

quickly than the next step, which is filing an appeal. When mediation is requested, it must be requested in writing to the applicable certifying agent. The certifying agent will have the option of accepting or rejecting the request for mediation. If the certifying agent rejects the request for mediation, the certifying agent must provide written notification to the applicant for certification or certified operation. The written notification must advise the applicant for certification or certified operation of the right to request an appeal in accordance with section 205.681. Any such appeal must be requested within 30 days of the date of the written notification of rejection of the request for mediation. If mediation is accepted by the certifying agent, such mediation must be conducted by a qualified mediator mutually agreed upon by the parties to the mediation. If an SOP is in effect, the mediation procedures established in the SOP, as approved by the Secretary, must be followed. The parties to the mediation will have no more than 30 days to reach an agreement following a mediation session. If mediation is unsuccessful, the production or handling operation will have 30 days from termination of mediation to appeal the denial of certification or proposed suspension or revocation in accordance with the appeal procedures in section 205.681.

Any agreement reached during or as a result of the mediation process must be in compliance with the Act and these regulations. The Secretary reserves the right to review any mediated agreement for conformity to the Act and these regulations and to reject any agreement or provision not in conformance with the Act or these regulations

Suspension or Revocation

The certifying agent or SOP's governing State official will suspend or revoke the certified operation's certification when the operation fails to resolve the issue through rebuttal or mediation, fails to complete needed corrections, or does not file an appeal. The operation will be notified of the suspension or revocation by written notification. The certifying agent or SOP's governing State official must not send a notification of suspension or revocation to a certified operation that has requested mediation or filed an appeal while final resolution of either is pending.

The decision to suspend or revoke certification will be based on the seriousness of the noncompliance. Such decisions must be made on a case-by-case basis. Section 6519 of the Act establishes that willful violations include making a false statement, knowingly affixing a false label, or otherwise violating the purposes of the Act.

In addition to suspension or revocation, a certified operation that knowingly sells or labels a product as organic, except in accordance with the Act, will be subject to a civil penalty of not more than \$10,000 per violation. Further, a certified operation that makes a false statement under the Act to the Secretary, an SOP's governing State official, or a certifying agent will be subject to the provisions of section 1001 of title 18, United States Code.

A certified operation whose certification has been suspended under this section may at any time, unless otherwise stated in the notification of suspension, submit a request to the Secretary for reinstatement of its certification. The request must be accompanied by evidence demonstrating correction of each noncompliance and corrective actions taken to comply with and remain in compliance with the Act and the NOP.

A certified operation or a person responsibly connected with an operation that has had its certification revoked will be ineligible to receive certification for an operation in which such operation or person has an interest for 5 years following the date of revocation. Accordingly, an operation will be ineligible for organic certification if one of its responsibly connected parties was a responsibly connected party of an operation that had its certification revoked. The Secretary may, when in the best interest of the certification program, reduce or eliminate the period of ineligibility.

Noncompliance Procedure for Certifying Agents

The Program Manager, on behalf of the Secretary, may initiate a compliance action against an accredited certifying agent who violates the Act or these regulations. Compliance proceedings may be initiated as a result of annual reviews for continuation of accreditation, site evaluations, or investigations initiated in response to complaints of noncompliant activities. Compliance proceedings also may be initiated on recommendation of an SOP's governing State official.

A written notification of noncompliance will be sent by the Program Manager to an accredited certifying agent when an inspection, review, or investigation of such person reveals any noncompliance with the Act or these regulations. A notification of noncompliance will provide a description of each noncompliance found and the facts upon which the notification is based. Additionally, the notification will provide the date by which the certifying agent must rebut or correct each noncompliance described and submit supporting documentation of each correction.

When documentation received by the Program Manager demonstrates that each noncompliance has been resolved, the Program Manager will send the certifying agent a written notification of noncompliance resolution.

If a noncompliance is not resolved by rebuttal or correction, the Program Manager will issue a notification of proposed suspension or revocation of accreditation. The notification will state whether the suspension or revocation will be for the certifying agent's entire accreditation, that portion of the accreditation applicable to a particular field office, or a specific area of accreditation. For instance, if a certifying agent with field offices in different geographic areas is cited for a compliance violation at one field office, the Program Manager could determine that only that portion of the accreditation applicable to the noncompliant field office should be suspended or revoked.

If the Program Manager determines that the noncompliance cannot be immediately or easily corrected, the Program Manager may combine the notification of noncompliance and the proposed suspension or revocation in one notification.

The notification of proposed suspension or revocation of accreditation will state the reasons and effective date for the proposed suspension or revocation. Such notification will also state the impact of a suspension or revocation on future eligibility for accreditation and the certifying agent's right to file an appeal.

If the Program Manager has reason to believe that a certifying agent has willfully violated the Act or regulations, the Program Manager will issue a notification of proposed suspension or revocation of accreditation. The proposed suspension or revocation may be for the certifying agent's entire accreditation, that portion of the accreditation applicable to a particular field office, or a specified area of accreditation. This notification, because it involves a willful violation, will be sent without first issuing a notification of noncompliance.

The certifying agent may file an appeal of the Program Manager's determination pursuant to section 205.681. If the certifying agent fails to file an appeal of the proposed suspension or revocation, the Program Manager will suspend or revoke the certifying agent's accreditation. The certifying agent will be notified of the suspension or revocation by written notification.

A certifying agent whose accreditation is suspended or revoked must cease all certification activities in each area of accreditation and in each State for which its accreditation is suspended or revoked. Any certifying agent whose accreditation has been suspended or revoked must transfer to the Secretary all records concerning its certification activities that were suspended or revoked. The certifying agent must also make such records available to

any applicable SOP's governing State official. The records will be used to determine whether operations certified by the certifying agent may retain their organic certification.

A certifying agent whose accreditation is suspended by the Secretary may at any time, unless otherwise stated in the notification of suspension, submit a request to the Secretary for reinstatement of its accreditation. Such request must be accompanied by evidence demonstrating correction of each noncompliance and actions taken to comply with and remain in compliance with the Act and regulations. A certifying agent whose accreditation is revoked by the Secretary will be ineligible to be accredited as a certifying agent under the Act and regulations for a period of not less than 3 years following the date of revocation.

State Organic Programs' Compliance Procedures

An SOP's governing State official may initiate noncompliance proceedings against certified organic operations operating in the State. Such proceedings may be initiated for failure of a certified operation to meet the production or handling requirements of this part or the State's more restrictive requirements, as approved by the Secretary.

The SOP's governing State official must promptly notify the Program Manager of commencement of noncompliance proceedings initiated against certified operations and forward to the Program Manager a copy of each notice issued. A noncompliance proceeding, brought by an SOP's governing State official against a certified operation may be appealed in accordance with the appeal procedures of the SOP. There will be no subsequent rights of appeal to the Secretary. Final decisions of a State may be appealed to the United States District Court for the district in which such certified operation is located.

An SOP's governing State official may review and investigate complaints of noncompliance with the Act or regulations concerning accreditation of certifying agents operating in the State. When such review or investigation reveals any noncompliance, the SOP's governing State official must send a written report of noncompliance to the Program Manager. The SOP's governing State official's report must provide a description of each noncompliance and the facts upon which the noncompliance is based.

Compliance - Changes Based On Comments

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

(1) Written Notifications. We have added a new paragraph (d) to section 205.660. The preamble to the proposed rule stated that all written notifications sent by certifying agents and SOP's governing State officials, as well as rebuttals, requests for mediation, and notices of correction of noncompliances sent by certified operations, will be sent to the addressee's place of business by a delivery service which provides dated return receipts. The assurance of completed communications and timely compliance procedures was given as the reason for delivery by a service which provides dated return receipts. The addition of paragraph (d) at section 205.660 is one of the actions that we have taken in response to requests from commenters that we further clarify the compliance process. Paragraph (d) requires that each notification of noncompliance, rejection of mediation, noncompliance resolution, proposed suspension or revocation, and suspension or revocation issued in accordance with sections 205.662, 205.663, and 205.665 and each response to such notification must be sent to the recipient's place of business via a delivery service which provides return receipts. This action will facilitate the effective administration of the compliance process by assuring a verifiable time line on the issuance and receipt of compliance documents and the response given to each such document.

(2) Determination of Willful. The preamble statement that "only the Program Manager or governing State official may make the final determination that a violation is willful" was incorrect and inconsistent with the regulatory language in section 205.662(d). Section 205.662(d) provides that, "if a certifying agent or State organic program's governing State

official has reason to believe that a certified operation has willfully violated the Act or regulations in this part, the certifying agent or State organic program's governing State official shall send the certified operation a notification of proposed suspension or revocation of certification of the entire operation or a portion of the operation, as applicable to the noncompliance." Accordingly, as recommended by a commenter, the incorrect statement has been deleted from the preamble to this final rule.

(3) Proposed Suspension or Revocation. We have amended sections 205.662(c) and 205.665(c) by removing the redundant phrase "or is not adequate to demonstrate that each noncompliance has been corrected" from the first sentence of each section.

(4) Suspension or Revocation. We have amended section 205.662(e)(2) by adding "while final resolution of either is pending" to the end thereof. The language of section 205.662(e)(2) now reads: "A certifying agent or State organic program's governing State official must not send a notification of suspension or revocation to a certified operation that has requested mediation pursuant to section 205.663 or filed an appeal pursuant to section 205.681 while final resolution of either is pending." We have made this change because we agree with those commenters who expressed the belief that section 205.662(e)(2) needed to be amended to clarify the duration of the stay on the issuance of a notification of suspension or revocation when mediation is requested or an appeal is filed. Several commenters stated that section 205.662(e)(2) needed to be amended to clarify that requesting mediation or filing an appeal does not indefinitely stop the suspension or revocation process.

(5) Eligibility After Suspension or Revocation of Certification. We have amended section 205.662(f) such that it now parallels section 205.665(g) which addresses suspension and revocation of certifying agents. We have also changed the title of section 205.662(f) from "Ineligibility" to "Eligibility" to parallel section 205.665(g). A few commenters referred to the provisions in section 205.665(g), which addresses eligibility after suspension or revocation of accreditation, and requested clarification of the difference between suspension and revocation of certification. Upon reviewing section 205.662(f), we decided that amendment was needed to clarify the difference between suspension and revocation of certification relative to eligibility for certification. Accordingly, we added a new paragraph (1) which provides that a certified operation whose certification has been suspended under this section may at any time, unless otherwise stated in the notification of suspension, submit a request to the Secretary for reinstatement of its certification. The paragraph also provides that the request must be accompanied by evidence demonstrating correction of each noncompliance and corrective actions taken to comply with and remain in compliance with the Act and the regulations in this part. We also amended what is now paragraph (2) of section 205.662(f) to clarify that the period of ineligibility following revocation of certification is 5 years unless reduced or eliminated by the Secretary.

Further, we have amended section 205.665(g)(1) to clarify that a certifying agent that has had its accreditation suspended may request reinstatement of its accreditation rather than submit a new request for accreditation. The amendment also clarifies that the reinstatement may be requested at any time unless otherwise stated in the notification of suspension. This amendment makes section 205.665(g)(1) similar to new paragraph (1) of section 205.662(f). This amendment is also consistent with commenter desires that the noncompliance procedures for certified operations and accredited certifying agents be similar.

(6) Penalties for Violations of the Act. We have amended section 205.662 by adding a new paragraph (g) which incorporates therein the provisions of paragraphs (a) and (b) of section 2120, 7 U.S.C. 6519, Violations of Title, of the Act. Specifically, paragraph (g) provides that, in addition to suspension or revocation, any certified operation that knowingly sells or labels a product as organic, except in accordance with the Act, shall be subject to a civil penalty of not more than \$10,000 per violation. This paragraph also provides that any certified

operation that makes a false statement under the Act to the Secretary, an SOP's governing State official, or a certifying agent shall be subject to the provisions of section 1001 of title 18, United States Code. Commenters requested regulatory language citing section 2120, 7 USC 6519, Violations of Title, of the Act. Commenters also requested a clearer description of enforcement. Specifically, they want provisions describing how USDA will deal with operations that make false claims or do not meet the NOP requirements. Further, numerous commenters expressed concern that there are no penalties in the regulations other than suspension and revocation. The European Community stated that it did not find, in the proposal, requirements for penalties to be applied by certifying agents when irregularities or infringements are found. The European Community went on to say that the European Union requires such penalties.

The Act provides for suspension and revocation of certification and the civil and criminal penalties addressed in 7 U.S.C. 6519. Certified operations are also required through the compliance program set forth in these regulations, to correct all noncompliances with the Act or regulations as a condition of retaining their certification. Furthermore, to get a suspended certification reinstated, an operation must submit a request to the Secretary. The request must be accompanied by evidence demonstrating correction of each noncompliance and corrective actions taken to comply with and remain in compliance with the Act and the regulations in this part. An operation or a person responsibly connected with an operation whose certification has been revoked will be ineligible to receive certification for a period of not more than 5 years.

We believe adding paragraph (g) will help clarify that there are penalties which may be imposed on certified operations that violate the Act and these regulations in addition to suspension or revocation.

The provisions of the Act and these regulations apply to all persons who sell, label, or represent their agricultural product as organic. Accordingly, persons who falsely sell, label, or represent their product as organic, are subject to the provisions of paragraphs (a) and (b) of section 2120, 7 USC 6519, of the Act. To clarify this, we have added a new paragraph (c) to section 205.100 of the Applicability subpart.

Certifying agents, SOP's governing State officials, and USDA will receive complaints alleging violations of the Act or these regulations. Certifying agents will review all complaints that they receive to determine if the complaint involves one of their clients. If the complaint involves a client of the certifying agent, the agent will handle the complaint in accordance with its procedures for reviewing and investigating certified operation compliance. If the complaint involves a person who is not a client of the certifying agent, the certifying agent will refer the complaint to the SOP's governing State official, when applicable, or, in the absence of an applicable SOP's governing State official, the Administrator. SOP's governing State officials will review all complaints that they receive in accordance with their procedures for reviewing and investigating alleged violations of the NOP and SOP. The SOP's governing State official's review of the complaint could result in referral of the complaint to a certifying agent when the complaint involves a client of the certifying agent, dismissal, or investigation by the SOP's governing State official. SOP's governing State officials will, as appropriate, investigate allegations of violations of the Act by non-certified operations operating within their State. USDA will review all complaints that it receives in accordance with its procedures for reviewing and investigating alleged violations of the NOP. USDA will refer complaints alleging violations of the NOP/SOP to the applicable SOP's governing State official, who may, in turn, refer the complaint to the applicable certifying agent. In States without an approved SOP, USDA will refer complaints to the applicable certifying agent. USDA will, as appropriate, investigate allegations of violations of the Act by non-certified operations operating in States where there is no approved SOP.

(7) Mediation. We have amended section 205.663 by providing that a dispute with respect to proposed suspension or revocation of certification may, rather than shall, be mediated. We have also provided that mediation must be requested in writing to the applicable certifying agent. The certifying agent will have the option of accepting or rejecting the request for mediation. If the certifying agent rejects the request for mediation, the certifying agent must provide written notification to the applicant for certification or certified operation. The written notification must advise the applicant for certification or certified operation of the right to request an appeal within 30 days of the date of the written notification of rejection of the request for mediation. If mediation is accepted by the certifying agent, such mediation must be conducted by a qualified mediator mutually agreed upon by the parties to the mediation.

Several commenters wanted section 205.663 amended to provide that disputes "may," rather than "shall," be mediated. The commenters advocated allowing the certifying agent to determine when mediation is a productive option. Several State commenters wanted to amend the second sentence to read as follows: "If a State organic program is in effect, the mediation procedures established in the State organic program, as approved by the Secretary, will be followed for cases involving the State organic program and its applicants or certified parties." Another commenter wanted to retain the requirement that disputes "shall" be mediated but wanted disputes mediated in accordance with 7 CFR Part 11 and section 205.681 of these regulations.

We concur that certifying agents should be authorized to reject a request for mediation, especially when they believe that the noncompliance issue is not conducive to mediation. Accordingly, we amended section 205.663 as noted above. We disagree, however, with the State commenters who want to amend the second sentence. We believe that the recommended change would exclude the clients of private-sector certifying agents operating within the State. USDA approval of an SOP will require that all certified operations operating within the State have the same opportunities for mediation, regardless of whether they are certified by a private or State certifying agent. If an approved SOP provides for mediation, such mediation must be available to all certified operations operating within the State. We also disagree with the commenter who requested that disputes be mediated in accordance with 7 CFR Part 11 and section 205.681 of these regulations. First, we believe that States with an approved SOP must be allowed to establish their own mediation program and procedures. Second, the Act and its implementing regulations are subject to the APA for adjudication. The provisions of the APA generally applicable to agency adjudication are not applicable to proceedings under 7 CFR Part 11, National Appeals Division Rules of Procedure. Even if 7 CFR Part 11 were applicable, it does not address mediation procedures. Mediation is merely addressed in 7 CFR Part 11 as an available dispute resolution method along with its impact on the filing of an appeal.

(8) Noncompliance Procedure for Certifying Agents. We have amended section 205.665(a)(3) to clarify that, like certified operations, certifying agents must submit supporting documentation of each correction of a noncompliance identified in a notification of noncompliance. This amendment to section 205.665(a)(3) was made in response to commenter concerns that the noncompliance procedures for certified operations and certifying agents be similar. It had been our intent that certifying agents would have to document their correction of noncompliances and that the noncompliance procedures for certified operations and certifying agents would be similar.

Compliance - Changes Requested But Not Made

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

(1) Funding for Enforcement. Several commenters stated that USDA should provide funding to the States for the cost of performing enforcement activities. Others asked who should fund investigations and enforcement actions if certifying agents (State and private) are enforcing

compliance with a Federal law. Numerous commenters requested information on how enforcement will be funded. The National Organic Standards Board (NOSB) recommended that the NOP examine existing models for capturing enforcement fees such as the State of California's registration program for all growers, handlers, and processors who use the word, "organic," in marketing their products.

We disagree with the commenters who stated that USDA should fund enforcement activities (State and private). Costs for compliance under the NOP will be borne by USDA, States with approved SOP's, and accredited certifying agents. Each of the entities will bear the cost of their own enforcement activities under the NOP. AMS anticipates that States will consider the cost of enforcing their SOP's prior to seeking USDA approval of such programs. We also anticipate that certifying agents will factor the cost of compliance into their certification fee schedules.

We agree that there may be alternatives, such as the State of California's registration program, available to raise funds for enforcing the NOP. We will help identify existing models and potential options that may be available in the future at the Federal, State, or certifying agent level. In the interim, we believe that SOP's should explore funding options at their level and that certifying agents should factor the cost of enforcement into their certification fees structure.

(2) Stop Sale. A number of commenters requested that the regulations include the ability to stop sales or recall misbranded or fraudulently produced products. The Act does not authorize the NOP to stop sales or recall misbranded or fraudulently produced product. Accordingly, USDA cannot authorize stop sales or the recall of product. We also believe that the certified operation's right to due process precludes a stop sale or recall prior to full adjudication of the alleged noncompliance. However, the Food and Drug Administration (FDA) and the USDA's Food Safety Inspection Service (FSIS) have stop sale authority that may be used in certain organic noncompliance cases. Further, States may, at their discretion, be able to provide for stop sale or recall of misbranded or fraudulently produced products produced within their State. While the Act does not provide for stop sale or recall, it does provide at 7 U.S.C. 6519 that any person who: (1) knowingly sells or labels a product as organic, except in accordance with the Act, shall be subject to a civil penalty of not more than \$10,000 and (2) makes a false statement under the Act to the Secretary, an SOP's governing State official, or a certifying agent shall be subject to the provisions of section 1001 of title 18, United States Code.

(3) Notification of Proposed Suspension or Revocation. A commenter recommended replacing "notification of proposed suspension or revocation" in section 205.662(d) with "notification of suspension or revocation." Certification cannot be suspended or revoked without due process. Accordingly, the issuance of a written notification of proposed suspension or revocation is necessary to provide the certified operation with information regarding the alleged noncompliance(s) and its right to answer the allegations. For this reason we have not accepted the commenter's recommendation.

(4) Mediation for Certifying Agents. Several commenters recommended amending section 205.665(c)(4) to provide for mediation between a certifying agent and the Program Manager when a proposed suspension or revocation is disputed by the certifying agent. We have not accepted the recommendation. USDA uses 7 CFR Part 1, Rules of Practice Governing Formal Adjudicatory Proceedings Instituted by the Secretary Under Various Statutes, for adjudicatory proceedings involving the denial, suspension, and revocation of accreditation.

(5) Revocation of Accreditation. A commenter stated that revocation of accreditation for 3 years is excessive. The commenter stated that a period of 6 to 12 months might be reasonable. We have not amended section 205.665(g)(2) because the Act requires that the

period of revocation for certifying agents, who violate the Act and these regulations, be for not less than 3 years. Suspension is available to the Secretary to address less egregious noncompliances. A certifying agent whose accreditation is suspended may at any time, unless otherwise stated in the notification of suspension, submit a request to the Secretary for reinstatement of its accreditation. The request must be accompanied by evidence demonstrating correction of each noncompliance and corrective actions taken to comply with and remain in compliance with the Act and these regulations.

(6) Appeals Under SOP's. Several commenters recommended amending 205.668(b) by adding at the end thereof: "unless the State program's appeals procedures include judicial review through the State District Court." Another commenter wanted 205.668(b) amended by removing "of the State organic certification program. There shall be no subsequent rights of appeal to the Secretary. Final decisions of a State may be appealed to the United States District Court for the district in which such certified operation is located," and inserting in its place "at 7 CFR part 11 and 205.681 of this chapter." We have not accepted the recommendations because the Act at 7 U.S.C. 6520 provides that a final decision of the Secretary may be appealed to the United States District Court for the district in which the person is located. We consider an approved SOP to be the NOP for that State. As such, we consider the SOP's governing State official of such approved SOP to be the equivalent of a representative of the Secretary for the purposes of the appeals procedures under the NOP. Accordingly, the final decision of the SOP's governing State official of an approved SOP is considered the final decision of the Secretary and, as such, is appealable to the United States District Court for the district in which the person is located, not a State's District Court. We also disagree with the commenter who wanted all appeals to be made to the National Appeals Division under the provisions at 7 CFR Part 11 and section 205.681 of these regulations. First, we believe that States with an approved SOP must be allowed to establish their own appeal procedures. Such procedures would have to comply with the Act, be equivalent to the procedures of USDA, and be approved by the Secretary. Second, as noted elsewhere in this preamble, the Act and its implementing regulations are subject to the APA for adjudication. The provisions of the APA generally applicable to agency adjudication are not applicable to proceedings under 7 CFR Part 11.

Compliance - Clarifications

Clarification is given on the following issues raised by commenters:

(1) Complaints, Investigations, Stop Sales, and Penalties. Many commenters wanted USDA to spell out the responsibilities and authorities of States, State and private certifying agents, Federal agencies, and citizens to make complaints, investigate violations, halt the sale of products, and impose penalties. Anyone may file a complaint, with USDA, an SOP's governing State official, or certifying agent, alleging violation of the Act or these regulations. Certifying agents, SOP's governing State officials, and USDA will receive, review, and investigate complaints alleging violations of the Act or these regulations as described in item 6 above under Changes Based on Comments. Citizens have no authority under the NOP to investigate complaints alleging violation of the Act or these regulations.

As noted elsewhere in this preamble, the Act does not authorize USDA to stop the sale of product. Accordingly, USDA cannot authorize stop sales by accredited certifying agents. We also believe that the certified operation's right to due process precludes a stop sale prior to full adjudication of the alleged noncompliance. However, FDA and FSIS have stop sale authority that may be used in the event of food safety concerns. Further, States may, at their discretion, be able to provide for stop sale of product produced within their State. Citizens have no authority under the NOP to stop the sale of a product.

The Act and these regulations provide for suspension or revocation of certification by certifying agents, SOP's governing State officials, and the Secretary. Only USDA may suspend or revoke a certifying agent's accreditation. All proposals to suspend or revoke a

certification or accreditation are subject to appeal as provided in section 205.681. The Act provides at 7 U.S.C. 6519 that any person who: (1) knowingly sells or labels a product as organic, except in accordance with the Act, shall be subject to a civil penalty of not more than \$10,000 and (2) makes a false statement under the Act to the Secretary, an SOP's governing State official, or a certifying agent shall be subject to the provisions of section 1001 of title 18, United States Code. Only USDA may bring an action under 7 U.S.C. 6519.

(2) Certifying Agent's Identifying Mark. The NOSB reaffirmed its recommendation which would allow private certifying agents to prevent the use of their service mark (seal) upon written notification that: (1) certification by the private certifying agent has been terminated, and (2) the certifying agent has 30 days to appeal the certifying agent's decision to the Secretary of Agriculture. We will neither prohibit nor approve a certifying agent's actions to withdraw a certified operation's authority to use the certifying agent's identifying mark for alleged violations of the Act or regulations. We stand fast in our position that all certified operations are to be given due process prior to the suspension or revocation of their certification. The reader is also reminded that the certifying agent cannot terminate, suspend, or revoke a certification if the certified operation files an appeal with an SOP's governing State official, when applicable, or the Administrator as provided for in the notification of proposed suspension or revocation. The certifying agent accepts full liability for any action brought as a result of the withdrawal of a certified operation's authority to use the certifying agent's identifying mark.

(2) Loss of Certification. A commenter posed several questions regarding the loss of certification. The commenter's questions and our responses are as follows:

How will consumers and affected regulatory agencies know if a grower or handler loses its certification? We will provide public notification of suspensions and revocations of certified operations through means such as the NOP website.

What will the effect of a lost certification be? Suspension or revocation of a producer's or handler's certification will require that the producer or handler immediately cease its sale, labeling, and representation of agricultural products as organically produced or handled as provided in the suspension or revocation order. A production or handling operation or a person responsibly connected with an operation whose certification has been suspended may at any time, unless otherwise stated in the notification of suspension, submit a new request for certification in accordance with section 205.401. The request must be accompanied by evidence demonstrating correction of each noncompliance and corrective actions taken to comply with and remain in compliance with the Act and the regulations in this part. An operation or a person responsibly connected with an operation whose certification has been revoked will be ineligible to receive certification for a period of not more than 5 years following the date of such revocation, as determined by the Secretary. Any producer or handler who sells, labels, or represents its product as organic contrary to the provisions of the suspension or revocation order would be subject to prosecution under 7 U.S.C. 6519 of the Act.

Will the certifying agent give a future effective date for loss of certification, or could the loss of certification be immediate or even retroactive? Suspension or revocation will become effective as specified in the suspension or revocation order once it becomes final and effective. The operation, upon suspension or revocation, will be prohibited from selling, labeling, and representing its product as organic per the provisions of the suspension or revocation order.

If organic products already on the market were grown or handled by someone whose certification is revoked or suspended, would USDA require that the products be recalled and relabeled? USDA will not, unless the noncompliance involves a food safety issue under

FSIS, require the recall or relabeling of product in the channels of commerce prior to the issuance of a suspension or revocation order. First, at the time the product was produced, it may have been produced in compliance with the Act and these regulations. Second, USDA does not have the authority, under the Act, to issue a stop sale order for product sold, labeled, or represented as organic and placed in the channels of commerce prior to suspension or revocation of a certified operation's certification. The Act, however, provides at 7 U.S.C. 6519(a) for the prosecution of any person who knowingly sells or labels a product as organic, except in accordance with the Act. Such persons shall be subject to a civil penalty of not more than \$10,000 per violation.

(4) Investigations. A commenter suggested that we amend section 205.661(a) to require that all complaints must be investigated in accordance with the certifying agent's complaints policy. The commenter also stated that the Administrator should know which complaints were not investigated. We disagree that all complaints must be investigated since, upon review of the alleged noncompliance, some complaints may lack grounds for investigation. For example, a concerned citizen could allege that an organic producer was seen applying a pesticide to a specific field. Upon review of the allegation, the certifying agent could determine that the producer in question was a split operation and that the field in question was part of the conventional side of the production operation. Accordingly, there would be no need for an investigation. However, the certifying agent will be expected to: (1) take each allegation seriously, (2) review each complaint received, (3) make a determination as to whether there may be a basis for conducting an investigation, (4) investigate all allegations when it is believed that there may be a basis for conducting the investigation, and (5) maintain a detailed log of all complaints received and their disposition. The actions taken by the certifying agent must be in conformance with the certifying agent's procedures for reviewing and investigating certified operation compliance.

(5) Deadline for the Correction of a Noncompliance. Several commenters requested that 205.662(a)(3) be amended by adding: "The deadline for correction of the noncompliance may be extended at the discretion of the certifier if substantial progress has been made to correct the noncompliance." We believe that the requested amendment is unnecessary. Section 205.662(a)(3) requires that the notification of noncompliance include a date by which the certified operation must rebut or correct each noncompliance and submit supporting documentation of each correction when correction is possible. There is no prohibition preventing the certifying agent from extending the deadline specified when the certifying agent believes that the certified operation has made a good faith effort at correcting each noncompliance.

(6) Compliance with SOP. Several States requested that section 205.665 be amended to clarify how States may handle a private certifying agent found to be in noncompliance with SOP's approved by the Secretary. A majority of these commenters also asked if NOP intends to suspend or revoke the accreditation of certifying agents on a State-by-State basis. Section 205.668(c) authorizes an SOP's governing State official to review and investigate complaints of noncompliance with the Act or regulations concerning accreditation of certifying agents operating in the State. When such review or investigation reveals any noncompliance, the SOP's governing State official shall send a written report of noncompliance to the NOP Program Manager. The report shall provide a description of each noncompliance and the facts upon which the noncompliance is based. The NOP Program Manager will then employ the noncompliance procedures for certifying agents as found in section 205.665. This may include additional investigative work by AMS. Only USDA may suspend or revoke a certifying agent's accreditation.

SOP's must meet the general requirements for organic programs specified in the Act and be at least equivalent to these regulations. Accordingly, noncompliances worthy of suspension or revocation would in all probability be worthy of national suspension or revocation of

accreditation for one or more areas of accreditation. Therefore, USDA does not anticipate suspending or revoking accreditations, or areas of accreditation, on a State-by-State basis. It is possible, however, that the Secretary may decide to only suspend or revoke a certifying agent's accreditation or an area of accreditation to certify producers or handlers within a given State. Such a decision would in all probability be tied to a State's more restrictive requirements.

Compliance

§ 205.660 General.

(a) The National Organic Program's Program Manager, on behalf of the Secretary, may inspect and review certified production and handling operations and accredited certifying agents for compliance with the Act or regulations in this part.

(b) The Program Manager may initiate suspension or revocation proceedings against a certified operation:

(1) When the Program Manager has reason to believe that a certified operation has violated or is not in compliance with the Act or regulations in this part; or

(2) When a certifying agent or a State organic program's governing State official fails to take appropriate action to enforce the Act or regulations in this part.

(c) The Program Manager may initiate suspension or revocation of a certifying agent's accreditation if the certifying agent fails to meet, conduct, or maintain accreditation requirements pursuant to the Act or this part.

(d) Each notification of noncompliance, rejection of mediation, noncompliance resolution, proposed suspension or revocation, and suspension or revocation issued pursuant to § 205.662, § 205.663, and § 205.665 and each response to such notification must be sent to the recipient's place of business via a delivery service which provides dated return receipts.

§ 205.661 Investigation of certified operations.

(a) A certifying agent may investigate complaints of noncompliance with the Act or regulations of this part concerning production and handling operations certified as organic by the certifying agent. A certifying agent must notify the Program Manager of all compliance proceedings and actions taken pursuant to this part.

(b) A State organic program's governing State official may investigate complaints of noncompliance with the Act or regulations in this part concerning organic production or handling operations operating in the State.

§ 205.662 Noncompliance procedure for certified operations.

(a) Notification. When an inspection, review, or investigation of a certified operation by a certifying agent or a State organic program's governing State official reveals any noncompliance with the Act or regulations in this part, a written notification of noncompliance shall be sent to the certified operation. Such notification shall provide:

(1) A description of each noncompliance;

(2) The facts upon which the notification of noncompliance is based; and

(3) The date by which the certified operation must rebut or correct each noncompliance and submit supporting documentation of each such correction when correction is possible.

(b) Resolution. When a certified operation demonstrates that each noncompliance has been resolved, the certifying agent or the State organic program's governing State official, as applicable, shall send the certified operation a written notification of noncompliance resolution.

(c) Proposed suspension or revocation. When rebuttal is unsuccessful or correction of the noncompliance is not completed within the prescribed time period, the certifying agent or State organic program's governing State official shall send the certified operation a written notification of proposed suspension or revocation of certification of the entire operation or a portion of the operation, as applicable to the noncompliance. When correction of a noncompliance is not possible, the notification of noncompliance and the proposed

suspension or revocation of certification may be combined in one notification. The notification of proposed suspension or revocation of certification shall state:

- (1) The reasons for the proposed suspension or revocation;
- (2) The proposed effective date of such suspension or revocation;
- (3) The impact of a suspension or revocation on future eligibility for certification; and
- (4) The right to request mediation pursuant to § 205.663 or to file an appeal pursuant to § 205.681.

(d) Willful violations. Notwithstanding paragraph (a) of this section, if a certifying agent or State organic program's governing State official has reason to believe that a certified operation has willfully violated the Act or regulations in this part, the certifying agent or State organic program's governing State official shall send the certified operation a notification of proposed suspension or revocation of certification of the entire operation or a portion of the operation, as applicable to the noncompliance.

(e) Suspension or revocation. (1) If the certified operation fails to correct the noncompliance, to resolve the issue through rebuttal or mediation, or to file an appeal of the proposed suspension or revocation of certification, the certifying agent or State organic program's governing State official shall send the certified operation a written notification of suspension or revocation.

(2) A certifying agent or State organic program's governing State official must not send a notification of suspension or revocation to a certified operation that has requested mediation pursuant to § 205.663 or filed an appeal pursuant to § 205.681, while final resolution of either is pending.

(f) Eligibility. (1) A certified operation whose certification has been suspended under this section may at any time, unless otherwise stated in the notification of suspension, submit a request to the Secretary for reinstatement of its certification. The request must be accompanied by evidence demonstrating correction of each noncompliance and corrective actions taken to comply with and remain in compliance with the Act and the regulations in this part.

(2) A certified operation or a person responsibly connected with an operation whose certification has been revoked will be ineligible to receive certification for a period of 5 years following the date of such revocation, Except, That, the Secretary may, when in the best interest of the certification program, reduce or eliminate the period of ineligibility.

(g) Violations of Act. In addition to suspension or revocation, any certified operation that:

- (1) Knowingly sells or labels a product as organic, except in accordance with the Act, shall be subject to a civil penalty of not more than \$10,000 per violation.
- (2) Makes a false statement under the Act to the Secretary, a State organic program's governing State official, or a certifying agent shall be subject to the provisions of section 1001 of title 18, United States Code.

§ 205.663 Mediation.

Any dispute with respect to denial of certification or proposed suspension or revocation of certification under this part may be mediated at the request of the applicant for certification or certified operation and with acceptance by the certifying agent. Mediation shall be requested in writing to the applicable certifying agent. If the certifying agent rejects the request for mediation, the certifying agent shall provide written notification to the applicant for certification or certified operation. The written notification shall advise the applicant for certification or certified operation of the right to request an appeal, pursuant to § 205.681, within 30 days of the date of the written notification of rejection of the request for mediation. If mediation is accepted by the certifying agent, such mediation shall be conducted by a qualified mediator mutually agreed upon by the parties to the mediation. If a State organic program is in effect, the mediation procedures established in the State organic program, as

approved by the Secretary, will be followed. The parties to the mediation shall have no more than 30 days to reach an agreement following a mediation session. If mediation is unsuccessful, the applicant for certification or certified operation shall have 30 days from termination of mediation to appeal the certifying agent's decision pursuant to § 205.681. Any agreement reached during or as a result of the mediation process shall be in compliance with the Act and these regulations. The Secretary may review any mediated agreement for conformity to the Act and these regulations and may reject any agreement or provision not in conformance with the Act or these regulations.

§ 205.664 [Reserved]

§ 205.665 Noncompliance procedure for certifying agents.

(a) **Notification.** When an inspection, review, or investigation of an accredited certifying agent by the Program Manager reveals any noncompliance with the Act or regulations in this part, a written notification of noncompliance shall be sent to the certifying agent. Such notification shall provide:

- (1) A description of each noncompliance;
- (2) The facts upon which the notification of noncompliance is based; and
- (3) The date by which the certifying agent must rebut or correct each noncompliance and submit supporting documentation of each correction when correction is possible.

(b) **Resolution.** When the certifying agent demonstrates that each noncompliance has been resolved, the Program Manager shall send the certifying agent a written notification of noncompliance resolution.

(c) **Proposed suspension or revocation.** When rebuttal is unsuccessful or correction of the noncompliance is not completed within the prescribed time period, the Program Manager shall send a written notification of proposed suspension or revocation of accreditation to the certifying agent. The notification of proposed suspension or revocation shall state whether the certifying agent's accreditation or specified areas of accreditation are to be suspended or revoked. When correction of a noncompliance is not possible, the notification of noncompliance and the proposed suspension or revocation may be combined in one notification. The notification of proposed suspension or revocation of accreditation shall state:

- (1) The reasons for the proposed suspension or revocation;
- (2) The proposed effective date of the suspension or revocation;
- (3) The impact of a suspension or revocation on future eligibility for accreditation; and
- (4) The right to file an appeal pursuant to § 205.681.

(d) **Willful violations.** Notwithstanding paragraph (a) of this section, if the Program Manager has reason to believe that a certifying agent has willfully violated the Act or regulations in this part, the Program Manager shall send a written notification of proposed suspension or revocation of accreditation to the certifying agent.

(e) **Suspension or revocation.** When the accredited certifying agent fails to file an appeal of the proposed suspension or revocation of accreditation, the Program Manager shall send a written notice of suspension or revocation of accreditation to the certifying agent.

(f) **Cessation of certification activities.** A certifying agent whose accreditation is suspended or revoked must:

- (1) Cease all certification activities in each area of accreditation and in each State for which its accreditation is suspended or revoked.
- (2) Transfer to the Secretary and make available to any applicable State organic program's governing State official all records concerning its certification activities that were suspended or revoked.

(g) Eligibility. (1) A certifying agent whose accreditation is suspended by the Secretary under this section may at any time, unless otherwise stated in the notification of suspension, submit a request to the Secretary for reinstatement of its accreditation. The request must be accompanied by evidence demonstrating correction of each noncompliance and corrective actions taken to comply with and remain in compliance with the Act and the regulations in this part.

(2) A certifying agent whose accreditation is revoked by the Secretary shall be ineligible to be accredited as a certifying agent under the Act and the regulations in this part for a period of not less than 3 years following the date of such revocation.

§§ 205.666 and 205.667 [Reserved]

§ 205.668 Noncompliance procedures under State organic programs.

(a) A State organic program's governing State official must promptly notify the Secretary of commencement of any noncompliance proceeding against a certified operation and forward to the Secretary a copy of each notice issued.

(b) A noncompliance proceeding, brought by a State organic program's governing State official against a certified operation, shall be appealable pursuant to the appeal procedures of the State organic program. There shall be no subsequent rights of appeal to the Secretary. Final decisions of a State may be appealed to the United States District Court for the district in which such certified operation is located.

(c) A State organic program's governing State official may review and investigate complaints of noncompliance with the Act or regulations concerning accreditation of certifying agents operating in the State. When such review or investigation reveals any noncompliance, the State organic program's governing State official shall send a written report of noncompliance to the Program Manager. The report shall provide a description of each noncompliance and the facts upon which the noncompliance is based.

§ 205.669 [Reserved]

Inspection and Testing, Reporting, and Exclusion from Sale

This portion of subpart G sets forth the inspection and testing requirements for agricultural products that have been produced on organic production operations or handled through organic handling operations.

Residue testing plays an important role in organic certification by providing a means for monitoring compliance with the National Organic Program (NOP) and by discouraging the mislabeling of agricultural products. This testing program provides State organic programs' (SOP) governing State officials and certifying agents with a tool for ensuring compliance with three areas for testing: (1) preharvest residue testing, (2) postharvest residue testing, and (3) testing for unavoidable residual environmental contamination levels.

Description of Regulations

General Requirements

Under the residue testing requirements of the NOP, all agricultural products sold, labeled, or represented as organically produced must be available for inspection by the Administrator, SOP's governing State official, or certifying agent. Organic farms and handling operations must be made available for inspection under subpart E, Certification. In addition, products from the aforementioned organic operations may be required by the SOP's governing State official or certifying agent to undergo preharvest or postharvest testing when there is reason to believe that agricultural inputs used in organic agriculture production or agricultural products to be sold or labeled as organically produced have come into contact with prohibited substances or have been produced using excluded methods. The cost of such testing will be borne by the applicable certifying agent and is considered a cost of doing business. Accordingly, certifying agents should make provisions for the cost of preharvest or postharvest residue testing when structuring certification fees.

Preharvest and Postharvest Residue Testing

The main objectives of the residue testing program are to: (1) ensure that certified organic production and handling operations are in compliance with the requirements set forth in this final rule and (2) serve as a means for monitoring drift and unavoidable residue contamination of agricultural products to be sold or labeled as organically produced. Any detectable residues of a prohibited substance or a product produced using excluded methods found in or on samples during analysis will serve as a warning indicator to the certifying agent.

The Administrator, SOP's governing State official, or certifying agent may require preharvest or postharvest testing of any agricultural input used in organic agricultural production or any agricultural product to be sold or labeled as "100 percent organic," "organic," or "made with organic (specified ingredients or food group(s))." It is based on the Administrator's, SOP's governing State official's, or certifying agent's belief that an agricultural product or agricultural input has come into contact with one or more prohibited substances or has been produced using excluded methods. Certifying agents do not have to conduct residue tests if they do not have reason to believe that there is a need for testing. Certifying agents must ensure, however, that certified organic operations are operating in accordance with the Act and the regulations set forth in this part.

The "reason to believe" could be triggered by various situations, for example: (1) the applicable authority receiving a formal, written complaint regarding the practices of a certified organic operation; (2) an open container of a prohibited substance found on the premises of a certified organic operation; (3) the proximity of a certified organic operation to a potential source of drift; (4) suspected soil contamination by historically persistent substances; or (5) the product from a certified organic operation being unaffected when neighboring fields or crops are infested with pests. These situations do not represent all of the possible

occurrences that would trigger an investigation. Preharvest or postharvest residue testing will occur on a case-by-case basis.

In each case, an inspector representing the Administrator, SOP's governing State official, or certifying agent or will conduct sampling. According to subpart F, Accreditation, private or State entities accredited as certifying agents under the NOP must ensure that its responsibly connected persons, employees, and contractors with inspection, analysis, and decision-making responsibilities have sufficient expertise to successfully perform the duties assigned. Therefore, all inspectors employed by certifying agents to conduct sampling must have sufficient expertise in methods of chain-of-custody sampling. Moreover, testing for chemical residues must be performed in an accredited laboratory. When conducting chemical analyses, the laboratory must incorporate the analytical methods described in the most current edition of the Official Methods of Analysis of the AOAC International or other current applicable validated methodology for determining the presence of contaminants in agricultural products. Results of all analyses and tests performed under section 205.670 must be promptly provided to the Administrator, except, that, where an SOP exists, all test results and analyses should be provided to the SOP's governing State official by the applicable certifying party that requested testing. Residue test results and analyses must also be, according to section 205.403(e)(2), provided to the owner of the certified organic operation whose product was tested. All other parties desiring to obtain such information must request it from the applicable certifying agent.

OFPA requires certifying agents, to the extent of their awareness, to report violations of applicable laws relating to food safety to appropriate health agencies such as EPA and FDA. When residue testing indicates that an agricultural product contains pesticide residues or environmental contaminants that exceed either the EPA tolerance level or FDA action level, as applicable, the certifying agent must promptly report data revealing such information to the Federal agency whose regulatory tolerance or action level has been exceeded.

Residue Testing and Monitoring Tools

When testing indicates that an agricultural product to be sold or labeled as organically produced contains residues of prohibited substances, certifying agents will compare the level of detected residues with 5 percent of the Environmental Protection Agency (EPA) tolerance for the specific residue detected on the agricultural product intended to be sold as organically produced. This compliance measure, 5 percent of EPA tolerance for the detected prohibited residue, will serve as a standard for the Administrator, SOP's governing State officials, and certifying agents to assist in monitoring for illegal use violations.

In addition, we intend to establish levels of unavoidable residual environmental contamination (UREC) for crop-and site-specific agricultural commodities to be sold, labeled, or represented as "100 percent organic," "organic," or "made with..." These levels will represent limits at which USDA may take compliance action to suspend the use of a contaminated area for organic agricultural production. Currently, USDA is seeking scientifically sound principles and measures by which it can establish UREC levels to most effectively address issues of unavoidable residual environmental contamination with respect to this rule. However, in the interim, UREC will be defined as the Food and Drug Administration's (FDA) action levels for poisonous or deleterious substances in human food or animal feed. UREC levels will be initially set for persistent prohibited substances (aldrin, dieldrin, chlordane, DDE, etc.) in the environment. They may become more inclusive of prohibited residues as additional information becomes available. Unavoidable residual environmental contamination levels will be based on the unavoidability of the chemical substances and do not represent permissible levels of contamination where it is avoidable.

Analyses and test results will be available for public access unless the residue testing is part of an ongoing compliance investigation. Information relative to an ongoing compliance investigation will be confidential and restricted to the public.

Detection of Prohibited Substances or Products Derived from Excluded Methods

In the case of residue testing and the detection of prohibited substances in or on agricultural products to be sold, labeled, or represented as "100 percent organic," "organic," or "made with..." products with detectable residues of prohibited substances that exceed 5 percent of the EPA tolerance for the specific residue or UREC cannot be sold or labeled as organically produced. When such an agricultural crop is in violation of these requirements, the certification of that crop will be suspended for the period that the crop is in production. Certifying agents must follow the requirements specified in sections 205.662 and 205.663 of subpart G, Compliance.

The "5 percent of EPA tolerance" standard is considered a level above which an agricultural product cannot be sold as organic, regardless of how the product may have come into contact with a potential prohibited substance. This standard has been established to: (1) satisfy consumer expectations that organic agricultural products will contain minimal chemical residues and (2) respond to the organic industry's request to implement a standard comparable to current industry practices. However, the "5 percent of EPA tolerance" standard cannot be used to automatically qualify agricultural products as organically produced, even if the level of chemical residues detected on an agricultural product is below 5 percent of the EPA tolerance for the respective prohibited substance. This final rule is a comprehensive set of standards and regulations that determines whether a product can or cannot be considered to carry the specified organic labeling terms in subpart D, Labeling. Therefore, in addition to this section of subpart G, Administrative, all other requirements of this part must be met by certified organic operations to have an agricultural product considered "organically produced."

When residue testing detects the presence of any prohibited substance, whether above or below 5 percent of the EPA tolerance for the specific pesticide or UREC, the SOP's governing State official or certifying agent may conduct an investigation of the certified organic operation to determine the cause of the prohibited substance or product in or on the agricultural product to be sold or labeled as organically produced. The same shall occur if testing detects a product produced using excluded methods. If the investigation reveals that the presence of the prohibited substance or product produced using excluded methods in or on an agricultural product intended to be sold as organically produced is the result of an intentional application of a prohibited substance or use of excluded methods, the certified organic operation shall be subject to suspension or revocation of its organic certification. In addition, any person who knowingly sells, labels, or represents an agricultural product as organically produced in violation of the Act or these regulations shall be subject to a civil penalty of not more than \$10,000 per violation.

Emergency Pest or Disease Treatment Programs

When a prohibited substance is applied to an organic production or handling operation due to a Federal or State emergency pest or disease treatment program and the organic handling or production operation otherwise meets the requirements of this final rule, the certification status of the operation shall not be affected as a result of the application of the prohibited substance, except that: (1) any harvested crop or plant part to be harvested that has contact with a prohibited substance applied as the result of a Federal or State emergency pest or disease treatment program cannot be sold, labeled, or represented as "100 percent organic," "organic," or "made with..." and (2) any livestock that are treated with a prohibited substance applied as the result of a Federal or State emergency pest or disease treatment program or product derived from such treated livestock cannot be sold, labeled, or represented as "100 percent organic," "organic," or "made with..."

However, milk or milk products may be labeled or sold as organically produced beginning 12 months following the last date that the dairy animal was treated with the prohibited substance. Additionally, the offspring of gestating mammalian breeder stock treated with a prohibited substance may be considered organic if the breeder stock was not in the last third of gestation on the date that the breeder stock was treated with the prohibited substance.

Residue Testing - Changes Based on Comments

This portion of subpart G differs from our proposal in several respects as follows:

(1) **Reporting Requirements.** Commenters were not satisfied with the language in section 205.670(d)(1) that required results of all analyses and tests performed under section 205.670 to be provided to the Administrator promptly upon receipt. They asked that the paragraph be amended to include that: (1) results of all analyses and tests performed under section 205.670 be provided by the Administrator to the appropriate SOP's governing State official and (2) test results be made immediately available to the owner of the material sampled. They stated that since State organic certification programs are responsible for enforcement within their State, results of residue tests conducted by certifying agents must be provided to the SOP's governing State official for routine monitoring and for investigating possible violations of the Act.

We agree with the commenters and have responded to their concerns accordingly. To ensure that SOP's receive results of all tests and analyses conducted under the inspection and testing requirements of subpart G, section 205.670(d) has been amended to include that the results of all analyses and residue tests must be provided to the Administrator promptly upon receipt; Except: That where an SOP exists, all test results and analyses should be provided to the SOP's governing State official.

In regard to the commenters' request that certified organic operations be provided with a copy of test results from samples taken by an inspector, an additional paragraph, section 205.403(e)(2), has been added to subpart E, Certification, that assures that such information is provided to the owners of certified organic operations by the certifying agents.

(2) **Integrity Of Organic Samples.** We have modified language in section 205.670(c) to clarify our intent regarding the maintenance of sample integrity. The proposed rule stated that "sample integrity must be maintained in transit, and residue testing must be performed in an accredited laboratory." During the final rulemaking process, we did not believe that our intent was clear on this subject. Our intent is to ensure that sample integrity is maintained throughout the entire chain of custody during the residue testing process. Proposed language only suggests that sample integrity be maintained in transit. Therefore, we have changed the second sentence in section 205.670(c) to state that "sample integrity must be maintained throughout the chain of custody, and residue testing must be performed in an accredited laboratory."

(3) **Reporting Residue and Other Food Safety Violations to Appropriate Health Agencies.** In the proposed rule, section 205.671(b) under Exclusion from Organic Sale states, "If test results indicate a specific agricultural product contains pesticide residues or environmental contaminants that exceed the FDA's or the EPA's regulatory tolerances, the data must be reported promptly to the appropriate public health agencies." During the final rulemaking process, a group of commenters suggested that we move section 205.671(b) into section 205.670 as paragraph (e). They recommended that we move section 205.671(b) because it does not specifically address the sale of organically produced products, as indicated by the section heading. They recommended that section 205.671(b) be placed under section 205.670 as paragraph (e) because it dealt with the reporting of residues that exceed Federal regulatory tolerances. The commenters further stated that, while section 205.671(b) creates a duty to report, it is not specific as to who must report.

We have accepted the suggestions of the commenters and have responded accordingly. We have removed section 205.671(b) and relocated it under section 205.670 as paragraph (e). We have also modified the regulatory text of paragraph (e) to include language that instructs certifying agents to report, when residue testing indicates that an agricultural product contains pesticide residues or environmental contaminants that exceed either the EPA tolerance level or FDA action level, as applicable, data revealing such information to the Federal agency whose regulatory tolerance or action level has been exceeded.

(4) Exclusion from Organic Sale. We have reviewed section 205.671(a), removed the requirement to implement the Pesticide Data Program (pdp) estimated national mean as a compliance tool in monitoring for the presence of unacceptable levels of prohibited substances in agricultural products intended to be sold as organic, and added the "5 percent of EPA tolerance" standard.

Commenters voiced the opinion that the estimated national mean would be a difficult standard in organic agricultural production for several reasons. Some stated that the estimated national mean was a new concept that would confuse producers and handlers because they would not know the exact definition of "estimated national mean" and how it would be determined. Others stated that the PDP was too limited in scope to employ an estimated national mean for all commodity/pesticide combinations. Commenters reasoned that PDP data were limited in terms of the agricultural commodities that are sampled and tested.

Another group of commenters stated that PDP data would be unfair to use in the NOP's residue testing plan. They argued PDP data should not be used to set maximum residue levels for organic agricultural products because PDP samples its products as close to the point of consumption as possible. As a result, commenters believe that PDP data may not be totally reflective of residue levels of agricultural products at the farmgate level. Since most residue testing in organic agricultural production takes place at the farmgate, these commenters argued that it would be an inappropriate standard for organic agricultural production.

As a result, a large number of commenters suggested that we reconsider using the estimated national mean as a standard for the maximum allowable residues on organically produced products. Instead, commenters recommended that the NOP incorporate the National Organic Standards Board's (NOSB) recommendation and current industry practice of using 5 percent of the EPA tolerance as a maximum level of pesticide residue on organic agricultural products. Commenters argued that using 5 percent of the EPA tolerance provides a sense of confidence to the consumers of organic agricultural products.

In many respects, we agree with the commenters. We have revisited using PDP data to establish an estimated national mean for commodity/pesticide combinations and for setting a maximum level of pesticide residue that could exclude agricultural products from being sold, labeled, or represented as organic. As a result, we have concluded that such an approach may be somewhat underdeveloped to incorporate into the NOP. We have reached this conclusion based on many of the same arguments presented by commenters (i.e., limited scope of agricultural products tested under PDP, product sampling based upon market availability, testing near the point of consumption, etc.). Also, we estimated that there would be a considerable time lag between the implementation of the NOP and defining a comprehensive list of estimated national means for all commodity/pesticide combinations. Thus, we have decided not to use the estimated national mean as a tool for monitoring organic agricultural products for the presence of prohibited substances and as a standard to exclude agricultural products from being sold, labeled, or represented as organically produced.

Instead, we have decided to follow the recommendation of the commenters by replacing the estimated national mean for specific commodity/pesticide pairs with 5 percent of the EPA tolerance for the specific pesticide. Therefore, when residue testing detects prohibited substances at levels that are greater than 5 percent of the EPA tolerance for the specific pesticide detected on the particular product samples, the agricultural product must not be sold or labeled as organically produced.

We fully understand that the EPA tolerance is defined as the maximum legal level of a pesticide residue in or on a raw or processed agricultural commodity. We also acknowledge that the EPA tolerance is a health-based standard. We are not trying to employ the 5 percent standard in a manner similar to that of EPA. As mentioned in our proposal, the national organic standards, including provisions governing prohibited substances, are based on the method of production, not the content of the product. The primary purpose of the residue testing approach described in this final rule, then, is to provide an additional tool for SOP's governing State officials and certifying agents to use in monitoring and ensuring compliance with the NOP.

(5) Unavoidable Residual Environmental Contamination. We have defined, as an interim measure, UREC as the FDA action levels for poisonous or deleterious substances in human food or animal feed.

Section 205.671 proposed the use of UREC to serve as a residue-testing tool for compliance. Commenters believed UREC levels, as prescribed in section 205.671 of the proposed rule, would be problematic as a standard because they were undefined. Commenters argued that it would be impractical and very expensive to establish UREC levels for every organic crop and region in the United States. They suggested that UREC levels be managed as a practice standard or program manual issue. They also expressed the concern that inconsistent application of UREC levels could create difficulties for certifying agents and certified operations.

We agree that UREC levels should be defined. We are seeking scientifically sound principles and measures by which we can establish UREC levels to most effectively address issues of unavoidable residual contamination with respect to this rule. However, in the interim, the ability to implement an undefined standard would be difficult for certifying agents. Therefore, we have included language in the preamble that temporarily defines UREC as the FDA action levels for poisonous or deleterious substances in human food or animal feed. When residue testing detects the presence of a prohibited substance on an agricultural product greater than such levels mentioned, the agricultural product cannot be sold as organic. We have decided to use FDA action levels for UREC because they encompass many of the toxic, persistent chemicals and heavy metals that are present in the environment and may be found on food and animal feed. As mentioned earlier, the FDA action levels are being employed in this part as temporary measures for compliance. We will continue to seek scientifically sound principles and measures by which to establish UREC levels that more appropriately satisfy the purposes of this part.

Residue Testing - Changes Requested But Not Made

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

(1) Residue Testing Responsibility. Commenters petitioned that we remove the requirement in section 205.670(b) that states residue tests must be conducted by the applicable SOP's governing State official or the certifying agent at the official's or certifying agent's own expense. The commenters expressed the opinion that we were practicing "micromanagement." They also said that there was no need for the proposal to be so detailed with respect to who pays for residue testing. Based on the commenters' responses,

residue analyses are reportedly paid by producers, buyers, brokers, certifiers, and government residue testing programs.

We have not adopted the suggestion of the commenters. In the proposal, we stated that conducting residue tests was considered a cost of doing business for certifying agents. Our position has not changed. Certifying agents can factor residue testing costs into certification fees. It is not our intention to "micromanage" the way that certifying agents conduct business. Section 2107(a)(6) of the Act requires that certifying agents conduct residue testing of agricultural products that have been produced on certified organic farms and handled through certified organic handling operations. OFPA also requires, under section 2112(a) through (c), that certifying agents enforce its provisions by implementing a system of residue testing to test products sold or labeled as organically produced. In addition, subpart E, Certification, authorizes certifying agents to conduct on-site inspections, which may include residue testing, of certified organic operations to verify that the operation is complying with the provisions in the Act and the regulations in this part. Certifying agents are responsible for monitoring organic operations for the presence of prohibited substances; we view residue testing as a cost of doing business. Therefore, we believe that certifying agents should factor monitoring costs associated with implementing the provisions in the Act and Rule into their certification fees.

(2) Reporting to Federal Regulatory Agencies. Commenters disagree with section 205.671(b) of the proposed rule which states that if test results indicate a specific agricultural product contains pesticide residues or environmental contaminants that exceed the FDA action level or EPA tolerance, the data must be reported promptly to appropriate public health agencies. Commenters believe that since results of all analyses and tests must be provided to the Administrator, USDA should be responsible for communicating such test results to other Federal agencies such as FDA or EPA if regulatory tolerances or action levels are exceeded. They also suggested that section 205.671(b) be removed from the national regulations. Commenters expressed the view that such a requirement is not related to organic certification.

We do not agree with the commenters. It is not our intent to create additional responsibility for the certifying agent. Section 205.671(b), redesignated as section 205.670(e), is a statutory requirement. Section 2107(a)(6) of the Organic Food Production Act of 1990 requires certifying agents, to the extent of their awareness, to report violations of applicable laws relating to food safety to appropriate health agencies such as EPA and FDA. Therefore, due to section 2107 of the Act, section 205.670(e) has been included in the national regulations.

(3) "Threshold" for Genetic Contamination. Many commenters suggested that we establish a "threshold" for the unintended or adventitious presence of products of excluded methods in organic products. Some commenters argued that a threshold is necessary because, without the mandatory labeling of biotechnology-derived products, organic operations and certifying agents could not be assured that products of excluded methods were not being used. Others argued that, without an established threshold, the regulations would constitute a "zero tolerance" for products of excluded methods, which would be impossible to achieve.

We do not believe there is sufficient consensus upon which to establish such a standard at this time. Much of the basic, baseline information about the prevalence of genetically engineered products in the conventional agricultural marketplace that would be necessary to set such a threshold - e.g., the effects of pollen drift where it may be a factor, the extent of mixing at various points throughout the marketing chain, the adventitious presence of genetically engineered seed in non-engineered seed lots-is still largely unknown. Our understanding of how the use of biotechnology in conventional agricultural production might affect organic crop production is even less well developed.

Also, as was pointed out in some comments, the testing methodology for the presence of products of excluded methods has not yet been fully validated. Testing methods for some biotechnology traits in some commodities are becoming commercially available. Without recognized methods of testing for and quantifying of all traits in a wide range of food products, however, it would be very difficult to establish a reliable numerical tolerance.

There are publicly and privately funded research projects underway that may provide useful baseline information. Efforts of Federal agencies to clarify the marketing and labeling of biotechnology- and derived-derived crops may also help address these concerns. FDA, for example, is developing guidance for food producers who voluntarily chose to label biotechnology- and derived-derived foods. USDA is also preparing a Federal Register Notice to seek public comment on the appropriate role, if any, that it can play in facilitating the marketing of agricultural products through the development of "quality assurance" type programs that help to preserve the identity of agricultural commodities. USDA, in cooperation with the technology providers, is also working to validate testing procedures and laboratories for some commodities.

All of these efforts may help to provide information on this issue. Practices for preserving product identity, including segregating genetically engineered and non-genetically engineered products, are evolving in some conventional markets. As we discussed in the preamble to the proposed rule, we anticipate that these evolving industry best practices and standards will become the standards for implementing the provisions in this regulation relating to the use of excluded methods. As was also discussed in the proposed rule, these regulations do not establish a "zero tolerance" standard. As with other substances not approve for use in organic production systems, a positive detection of a product of excluded methods would trigger an investigation by the certifying agent to determine if a violation of organic production or handling standards occurred. The presence of a detectable residue alone does not necessarily indicate use of a product of excluded methods that would constitute a violation of the standards.

(4) Certification Status After Emergency Pest or Disease Treatment. We have not modified language in section 205.672 that would affect the certification status of a certified organic operation if the operation had been subjected to a Federal or State emergency pest or disease treatment program.

Section 205.672 states that when a prohibited substance is applied to a certified operation due to a Federal or State emergency pest or disease treatment program and the certified operation otherwise meets the requirements of this part, the certification status of the operation shall not be affected as a result of the application of the prohibited substance: Provided, That, the certified operation adheres to certain requirements prescribed by the NOP. One group of commenters informed us that they did not support maintaining the organic status of an operation that has been directly treated with prohibited substances, regardless of the reason for treatment. They believe that Federal and State emergency pest or disease treatment programs should provide alternatives for organic operations whenever feasible. If no alternative measure is feasible, the organic operation should choose between voluntary surrender of their organic status on targeted parts of the operation or destruction of the crop to eliminate pest habitat. The commenters also suggested that compensation should be provided to organic producers whose crops must be destroyed to eliminate habitat. They feel that allowing the application of prohibited materials to certified organic land without affecting the certification status violates the trust consumers place in organic certification.

We disagree with the position of the commenters. Historically, residues from emergency pest or disease treatment programs have been treated as drift cases by certifiers. In these cases, the specific crop may not be sold as organic, but the organic status of future crop years are

not affected. We intend to handle such cases in a similar manner. We understand that commenters would like us to remove the certification of an organic operation that has been treated with a prohibited substance, but organic certification is a production claim, not a content claim. We, along with the commenters, are concerned with consumers trusting organic certification. At the same time, we are concerned with the welfare of certified organic operations. We have tried to include language in section 205.672 that would address both issues. We believe that, if a certified organic grower has been a good steward of his/her land and has managed the production of his/her product(s) in accordance with all regulations in the Act and other requirements in this part, the certification status of the operation should not be affected. The application of a prohibited substance as part of a Federal or State emergency pest or disease treatment program is outside the control of the certified operation. We also believe that maintaining consumer trust is important. Thus, section 205.672 states that any harvested crop or plant part to be harvested that has been treated with a prohibited substance as part of a Federal or State emergency pest or disease treatment program cannot be sold as organically produced. Therefore, the certified organic operation can retain its certification status, and the consumer can be assured that a product from a certified organic operation that has been in contact with a prohibited substance as the result of a Federal or State pest or disease treatment program will not enter the organic marketplace. Accordingly, we have not made the change to section 205.672 as proposed by the commenters.

(5) Emergency Pest or Disease Treatment Programs. Commenters suggested that the Department add a new paragraph to section 205.672 that states "the certifying agent must monitor production operations that have been subjected to a Federal or State emergency pest or disease treatment program, and may require testing of following crops, or an extended transition period for affected production sites, if residue test results indicate the presence of a prohibited substance." Commenters said the language in the proposed rule did not clearly establish that a transition period could be needed after contamination of a certified organic operation by a government-mandated spray program. They felt that there may be a need for a case-by-case determination by the certifying agent as to when it would be best for a certified organic operation to begin selling its products as organically produced after it has been subject to a government mandated spray program.

We understand that commenters would like USDA to mandate certifying agents to monitor operations that have been subject to Federal or State emergency pest or disease treatment programs; however, we do not see a need to prescribe such a provision. Based on the responsibilities of being a USDA-accredited certifier, it is our belief that certifying agents would monitor a certified organic operation that has been subjected to a Federal or State emergency pest or disease treatment program to make sure that product being produced for organic sale is actually being produced in accordance with the Act and the regulations in this part. Certifying agents have been granted the authority to conduct additional on-site inspections of certified organic operations to determine compliance with the Act and national standards under subpart E, section 205.403. Commenters requested that we include language that would allow certifying agents to recommend an extended transition period for affected production sites if residue tests indicate the presence of a prohibited substance. Again, we understand the commenters' concern, but we are not aware of comprehensive soil residue data that could guide certifying agents in determining appropriate withdrawal intervals for operations that have been subjected to emergency pest or disease treatment programs.

Residue Testing - Clarifications

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

(1) Sampling and Testing. Commenters stated that the purpose of residue testing under the Act is to assure that organically produced agricultural products that are sold as organic do not contain pesticide residues or residues of other prohibited substances that exceed levels

as specified by the NOP. Based on language in section 205.670(b) of the proposed rule, commenters expressed the opinion that the Agricultural Marketing Service (AMS) was, not only requiring residue testing of organic agricultural products, but also of "any" agricultural input used or agricultural product intended to be sold as "100 percent organic," "organic," or "made with..." when there is reason to believe that the agricultural input or product has come into contact with a prohibited substance. Commenters believe that organic certifying agents may be required to test many non-organic agricultural inputs (such as seeds, compost, straw, sawdust, and plastic) and non-organic agricultural products and ingredients used in products labeled as "made with...". They also argued that such testing would be unnecessary, burdensome, and expensive because such materials are more likely to have come into contact with a prohibited substance. Therefore, commenters suggested that we amend section 205.670(b) by deleting "agricultural inputs" and replacing "agricultural product" with "organically produced agricultural product." They also recommended that we replace the second occurrence of "product" with "organic product." Thus section 205.670(b) would suggest that only organic agricultural products could be required to be tested by the certifying agent.

We understand the concerns of the commenters but believe that the commenters have misinterpreted the intent of section 205.670(b). It is not our intent to mandate residue testing of all inputs and ingredients used in the production of organic agricultural products. Neither is it our intent for certifying agents to abuse residue testing responsibility by conducting residue tests of certified organic operations without reason to believe that the agricultural input or product intended to be sold as organic has come into contact with prohibited substances. Our intent is to make it clear that certifying agents have the authority to test any agricultural input used or agricultural product intended to be sold as organically produced when there is reason to believe that the agricultural input or product has come into contact with a prohibited substance. Section 205.670(b) allows for testing of inputs and agricultural products, but it does not require that all inputs of a product intended to be sold as organically produced must be tested. However, certifying agents must be able to ensure that certified organic operations are operating in accordance with the Act and the regulations set forth in this part. To assure that certifying agents have established fair and effective procedures for enforcing residue testing requirements, section 205.504(b)(6) provides that they must submit to USDA a copy of the procedures to be used for sampling and residue testing pursuant to section 205.670.

(2) Chain Of Custody Training. A commenter suggested that section 205.670(c) address chain of custody training for inspectors that will be performing preharvest or postharvest tissue test sample collection on behalf of the Administrator, SOP's governing State official, or certifying agent. The commenter proposed that all inspectors should be trained to handle chain of custody samples in order to maintain the integrity of the samples.

We agree that inspectors should be appropriately trained to handle chain-of-custody samples in order to maintain the integrity of the samples taken from a certified organic operation. However, we do not believe that the language in section 205.670(c) must be modified to address such an issue. As a USDA-accredited body, a private or State entity operating as a certifying agent must ensure that its responsibly connected persons, employees, and contractors with inspection, analysis, and decision-making responsibilities have sufficient expertise in organic production or handling techniques to successfully perform the duties assigned. The certifying agent must also submit a description of the training that has been provided or intends to be provided to personnel to ensure that they comply with and implement the requirements of the Act and the regulations in this part. In addition, certifying agents must submit a copy of the procedure to be used for sampling and residue testing for approval by the Administrator. Through the accreditation process, therefore, we will be able to assess the expertise of the individuals employed by the

certifying agent and provide guidance in areas where additional training is needed to comply with the requirements of the Act and the regulations in this part.

(3) Exclusion from Organic Sale. Commenters expressed that section 205.671(a) could be easily misinterpreted. They said that section 205.671(a) did not make clear that residue testing may not be used to qualify crops to be sold as organic if a direct application of prohibited materials occurred. Commenters suggested that section 205.671(a) include: "Any crop or product to which prohibited materials have been directly applied shall not be sold, labeled, or represented as organically produced."

We do not believe this additional language is necessary. Residue testing cannot be used to qualify any agricultural crop or product to which a prohibited material has been purposefully/directly applied. The presence of any prohibited substance on an agricultural product to be sold as organic warrants an investigation as to why the detected prohibited substance is present on the agricultural product. It does not matter if the product has come into contact with a prohibited substance through means of drift or intentional application. If the outcome of the investigation reveals that the presence of the detected prohibited substance is the result of an intentional application, the certified operation will be subject to suspension or revocation of its organic certification and/or a civil penalty of not more than \$10,000 if he/she knowingly sells the product as organic. The use of prohibited substances is not allowed in the Act or this final rule. Residue testing is not a means of qualifying a crop or product as organic if a prohibited substance has been intentionally/directly applied. It is a tool for monitoring compliance with the regulations set forth in the Act and in this part.

(4) Emergency Pest or Disease Treatment Programs. Commenters requested that we make a clear distinction between crops or agricultural products that have had prohibited substances directly applied to them and those that have come into contact with prohibited substances through chemical drift. They have proposed that we amend section 205.672(a) to address this issue. Section 205.672(a) of the proposal states that any harvested crop or plant part to be harvested that has had contact with a prohibited substance applied as the result of a Federal or State emergency pest or disease treatment program cannot be sold as organically produced. Commenters did not find this language acceptable because it did not distinguish between the two types of ways that products can come into contact with prohibited substances (drift and direct/intentional application) and how each situation would be addressed with respect to the national organic standards. Commenters believed that section 205.672(a) was fairly ambiguous and open for misinterpretation.

Commenters requested that we amend language in section 205.672(a) to include that "Any harvested crop or plant part to be harvested that has contact with a prohibited substance directly applied to the crop as the result of a Federal or State emergency pest or disease treatment program cannot be sold, labeled, or represented as organically produced."

We do not accept the commenters' request and believe that the commenters have misinterpreted section 205.672 of the proposed rule. Section 205.672 specifically addresses certified organic operations that have had prohibited substances applied to them due to a Federal or State pest or disease treatment program. Section 205.672 does not include those organic operations that may have been drifted upon by prohibited substances that have been applied to a neighboring farm as a result of a Federal or State emergency pest or disease treatment program. Any potential drift from a mandatory pest and disease treatment program will be treated in the same manner as drift from any other source.

Inspection and Testing, Reporting, and Exclusion from Sale

§ 205.670 Inspection and testing of agricultural product to be sold or labeled "organic."

(a) All agricultural products that are to be sold, labeled, or represented as "100 percent organic," "organic," or "made with organic (specified ingredients or food group(s))" must be made accessible by certified organic production or handling operations for examination by the Administrator, the applicable State organic program's governing State official, or the certifying agent.

(b) The Administrator, applicable State organic program's governing State official, or the certifying agent may require preharvest or postharvest testing of any agricultural input used or agricultural product to be sold, labeled, or represented as "100 percent organic," "organic," or "made with organic (specified ingredients or food group(s))" when there is reason to believe that the agricultural input or product has come into contact with a prohibited substance or has been produced using excluded methods. Such tests must be conducted by the applicable State organic program's governing State official or the certifying agent at the official's or certifying agent's own expense.

(c) The preharvest or postharvest tissue test sample collection pursuant to paragraph (b) of this section must be performed by an inspector representing the Administrator, applicable State organic program's governing State official, or certifying agent. Sample integrity must be maintained throughout the chain of custody, and residue testing must be performed in an accredited laboratory. Chemical analysis must be made in accordance with the methods described in the most current edition of the Official Methods of Analysis of the AOAC International or other current applicable validated methodology determining the presence of contaminants in agricultural products.

(d) Results of all analyses and tests performed under this section: (1) Must be promptly provided to the Administrator; Except, That, where a State organic program exists, all test results and analyses shall be provided to the State organic program's governing State official by the applicable certifying party that requested testing; and

(2) Will be available for public access, unless the testing is part of an ongoing compliance investigation.

(e) If test results indicate a specific agricultural product contains pesticide residues or environmental contaminants that exceed the Food and Drug Administration's or the Environmental Protection Agency's regulatory tolerances, the certifying agent must promptly report such data to the Federal health agency whose regulatory tolerance or action level has been exceeded.

§ 205.671 Exclusion from organic sale.

When residue testing detects prohibited substances at levels that are greater than 5 percent of the Environmental Protection Agency's tolerance for the specific residue detected or unavoidable residual environmental contamination, the agricultural product must not be sold, labeled, or represented as organically produced. The Administrator, the applicable State organic program's governing State official, or the certifying agent may conduct an investigation of the certified operation to determine the cause of the prohibited substance.

§ 205.672 Emergency pest or disease treatment.

When a prohibited substance is applied to a certified operation due to a Federal or State emergency pest or disease treatment program and the certified operation otherwise meets the requirements of this part, the certification status of the operation shall not be affected as a result of the application of the prohibited substance: Provided, That:

(a) Any harvested crop or plant part to be harvested that has contact with a prohibited substance applied as the result of a Federal or State emergency pest or

disease treatment program cannot be sold, labeled, or represented as organically produced; and

(b) Any livestock that are treated with a prohibited substance applied as the result of a Federal or State emergency pest or disease treatment program or product derived from such treated livestock cannot be sold, labeled, or represented as organically produced: Except, That:

(1) Milk or milk products may be sold, labeled, or represented as organically produced beginning 12 months following the last date that the dairy animal was treated with the prohibited substance; and

(2) The offspring of gestating mammalian breeder stock treated with a prohibited substance may be considered organic: Provided, That, the breeder stock was not in the last third of gestation on the date that the breeder stock was treated with the prohibited substance.

§§ 205.673-205.679 [Reserved]

Adverse Action Appeal Process

This portion of subpart G sets forth the procedures for appealing adverse actions under the National Organic Program (NOP). These procedures will be used by: (1) producers and handlers appealing denial of certification and proposed suspension or revocation of certification decisions; and (2) certifying agents appealing denial of accreditation and proposed suspension or revocation of accreditation decisions. The Act and the Administrative Procedure Act (APA) (5 U.S.C. 553-559) provides affected persons with the right to appeal any adverse actions taken against their application for certification or accreditation or their certification or accreditation.

The Administrator will handle certification appeals from operations in States that do not have an approved State organic program (SOP). The Administrator will also handle appeals of accreditation decisions of the NOP Program Manager. The Administrator will issue decisions to sustain or deny appeals. If an appeal is denied, the Administrator will initiate a formal adjudicatory proceeding to deny, suspend, or revoke certification or accreditation. Such proceedings will be conducted pursuant to USDA's Rules of Practice Governing Formal Adjudicatory Proceedings Instituted by the Secretary Under Various Statutes, 7 CFR 1.130 through 1.151. Under these rules of practice, if the Administrative Law Judge denies the appeal, the appellant may appeal the Administrative Law Judge's decision to the Judicial Officer. If the Judicial Officer denies the appeal, the appellant may appeal the Judicial Officer's decision to the United States District Court for the district in which the appellant is located.

In States with approved SOP's, the SOP will oversee certification compliance proceedings and handle appeals from certified operations in the State. An SOP's appeal procedures and rules of procedure must be approved by the Secretary and must be equivalent to those of the NOP and USDA. The final decision on an appeal under the SOP may be appealed by the appellant to United States District Court for the district in which the appellant is located.

Description of Regulations

These appeal procedures provide that: (1) persons, subject to the Act, who believe they are adversely affected by a noncompliance decision of the NOP's Program Manager may appeal such decision to the Administrator; (2) persons, subject to the Act, who believe they are adversely affected by a noncompliance decision of an SOP may appeal such decision to the SOP's governing State official who will initiate handling of the appeal in accordance with the appeal procedures approved by the Secretary; and (3) persons, subject to the Act, who believe they are adversely affected by a noncompliance decision of a certifying agent may appeal such decision to the Administrator unless the person is subject to an approved SOP, in which case the appeal must be made to the SOP.

All written communications between parties involved in appeal proceedings must be sent to the recipient's place of business by a delivery service which provides dated return receipts. All appeals filed under these procedures will be reviewed, heard, and decided by persons not involved with the decision being appealed.

Certification Appeals

Applicants for certification may appeal a certifying agent's notice of denial of certification. Certified operations may appeal a notification of proposed suspension or revocation of their certification issued by their certifying agent. Such appeals will be made to the Administrator unless the person is subject to an approved SOP, in which case the appeal must be made to the SOP.

If the Administrator or SOP sustains an appeal, the applicant or certified operation will be granted certification or continued certification, as applicable to the operation's status. The act of sustaining the appeal will not be considered an adverse action and may not be appealed

by the certifying agent which issued the notice of denial of certification or notification of proposed suspension or revocation of certification.

If the Administrator or SOP denies an appeal, a formal administrative proceeding will be initiated to deny, suspend, or revoke the certification. Such proceeding will be conducted in accordance with USDA's Uniform Rules of Practice or the SOP's rules of procedure.

Accreditation Appeals

Applicants for accreditation may appeal the Program Manager's notification of accreditation denial. Accredited certifying agents may appeal a notification of proposed suspension or revocation of their accreditation issued by the Program Manager. Such appeals will be made to the Administrator. If the Administrator sustains an appeal, the applicant or certifying agent will be granted accreditation or continued accreditation, as applicable to the operation's status. If the Administrator denies an appeal, a formal administrative proceeding will be initiated to deny, suspend, or revoke the accreditation. Such proceeding will be conducted in accordance with USDA's Uniform Rules of Practice.

Filing Period

An appeal of a noncompliance decision must be filed within the time period provided in the letter of notification or within 30 days from the date of receipt of the notification, whichever occurs later. The appeal will be considered "filed" on the date received by the Administrator or, when applicable, the SOP. Unless appealed in a timely manner, a notification to deny, suspend, or revoke a certification or accreditation will become final. The applicant, certified operation, or certifying agent that does not file an appeal in the time period provided waives the right to further appeal of the compliance proceeding.

Where and What to File

Appeals to the Administrator must be filed in writing and sent to: Administrator, USDA-AMS, Room 3071-S, P.O. Box 96456, Washington DC 20090-6456. Appeals to the SOP must be filed in writing to the address and person identified in the letter of notification. All appeals must include a copy of the adverse decision to be reviewed and a statement of the appellant's reasons for believing that the decision was not proper or made in accordance with applicable program regulations, policies, or procedures.

Appeals - Changes Based On Comments

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

(1) To Whom an Appeal Is Made. We have amended section 205.680 to clarify to whom an appeal is made when the noncompliance decision is made by the NOP's Program Manager, an SOP, or a certifying agent. Several commenters requested that we amend section 205.680 to make it consistent with the provision providing that appeals to the Administrator are not allowed in the case of an SOP decision, because such appeals have to be made to the SOP's governing State official.

We agree that section 205.680 did not convey sufficient explanation of to whom an appeal is made. Accordingly, we have amended the language in section 205.680 to clarify through paragraphs (a), (b), and (c) that: (1) persons, subject to the Act, who believe they are adversely affected by a noncompliance decision of the NOP's Program Manager may appeal such decision to the Administrator; (2) persons, subject to the Act, who believe they are adversely affected by a noncompliance decision of an SOP may appeal such decision to the SOP's governing State official who will initiate handling of the appeal pursuant to appeal procedures approved by the Secretary; and (3) persons, subject to the Act, who believe they are adversely affected by a noncompliance decision of a certifying agent may appeal such decision to the Administrator unless the person is subject to an approved SOP, in which case the appeal must be made to the SOP.

(2) Written Communications. We have added a new paragraph (d) to section 205.680, which provides that all written communications between parties involved in appeal proceedings must be sent to the recipient's place of business by a delivery service which provides dated return receipts. We have taken this action to further clarify the appeals process. This addition to section 205.680 implements the same requirements for appeal documents as our addition of new paragraph (d) to section 205.660 stipulates for compliance documents.

(3) Who Shall Handle Appeals. We have added a new paragraph (e) to section 205.680, which provides that all appeals must be reviewed, heard, and decided by persons not involved with the decision being appealed. This provision was added to section 205.680 to allay the fears of commenters that the person making the decision would be the person deciding the appeal. A couple of commenters recommended that an appeal be heard by persons other than those who made the decision being appealed. Specifically, they want the appeal conducted by independent hearing officers who are not responsible for implementation or administration of the NOP. They also want the final decision-making authority in the administrative review process placed in the hands of the Secretary.

Under the NOP, once the compliance procedures are completed at the certifying agent level, the certified operation may appeal the decision of the certifying agent to the Administrator or to the SOP when the certified operation is located within a State with an approved SOP. The Administrator or the SOP will review the case and render an opinion on the appeal. When the appeal is sustained, the certified operation and certifying agent are notified and the case ends. However, if the appeal is denied the certified operation and certifying agent are notified and the certified operation is given an opportunity to appeal the decision of the Administrator or SOP.

Appeals of decisions made by the Administrator will be heard by an Administrative Law Judge. If the Administrative Law Judge rules against the certified operation, the Administrative Law Judge's decision may be appealed by the certified operation to the Judicial Officer. The Judicial Officer is the USDA official delegated authority by the Secretary as the final deciding officer in adjudication proceedings. If the Judicial Officer rules against the certified operation, the Judicial Officer's decision may be appealed by the certified operation to the United States District Court for the district in which the certified operation is located. For additional information see USDA's Uniform Rules of Practice found at 7 CFR Part 1, subpart H.

Appeals of decisions made by an SOP will follow procedures comparable to those just described for an appeal of a decision made by the Administrator. As with a final decision of USDA, a final decision of the State that goes against the certified operation may be appealed to the United States District Court for the district in which the certified operation is located.

(4) Filing Period. We have amended the first sentence of section 205.681(c) by replacing "at least" with "within" and by adding the words, "whichever occurs later," to the end thereof. This amendment has been made to clarify our intent that persons affected by a noncompliance proceeding decision receive not less than 30 days in which to file their appeal of the decision.

(5) Where To File an Appeal. We have amended section 205.681(d) to clarify where appeals are to be filed. First, we have amended what is now paragraph (1) by removing the requirement that the appellant send a copy of the appeal to the certifying agent. This action shifts the responsibility of notifying the certifying agent of the appeal from the appellant to USDA or, when applicable, the SOP. Second, we have added language at paragraph (2) which clarifies that appeals to the SOP must be filed in writing to the address and person identified in the letter of notification. Finally, we have amended what is now paragraph (3) of

section 205.681 by replacing "position" with "reasons for believing" to clarify the intended scope and purpose of the appellant's appeal statement. Clarification of section 205.681(d) was prompted by a commenter who stated that it is discriminatory to require clients of private certifying agents to appeal to USDA in Washington, when State program clients can appeal locally.

There are various levels of appeal within the NOP. Clients of certifying agents (State and private) are provided with an opportunity to rebut the noncompliance findings of the certifying agent. Once the certified operation has exhausted its options at the certifying agent level, the certified operation may appeal the decision of the certifying agent to the Administrator or to the SOP when the certified operation is located within a State with an approved SOP.

The Administrator will review the case and render an opinion on the appeal. This level of appeal will not require the certified operation's representative to travel to the Administrator. An appeal of a decision made by the Administrator will be heard by an Administrative Law Judge as near as possible to the certified operation's representative's place of business or residence. An appeal of a decision made by the Administrative Law Judge will be heard by the Judicial Officer. Again the certified operation's representative will not be required to travel outside of the representative's place of business or residence. If the certified operation appeals the decision of the Judicial Officer, the appeal would be heard by the United States District Court for the district in which the certified operation is located.

Appeals of decisions made by an SOP will follow procedures comparable to those just described for an appeal of a decision made by the Administrator. As with a final decision of USDA, a final decision of the State that goes against the certified operation may be appealed to the United States District Court for the district in which the certified operation is located.

(6) Appeal Reports. We will submit an annual report on appeals to the National Organic Standards Board (NOSB), which will include non-confidential compliance information. A commenter requested that we report quarterly to the NOSB on appeals (number, outcome, kinds, and problems). We agree that it would be appropriate for the NOP to submit an appeals report to the NOSB. We will compile appeal data such as the number, outcome, kinds, and problems encountered. We will maintain this information under the compliance program to be developed within the NOP. We do not believe that it is necessary to put this type of detail or activity into the regulations. Further, we do not believe, at this time, that reporting more frequently than annually will be needed. The NOP, however, will work closely with the NOSB to provide it with the information it may need to recommend program amendments designed to address compliance and appeal issues.

(7) Availability of Appeal Information. We will develop and distribute appeal information. A commenter requested that section 205.680 be amended to require the distribution of an appeal information brochure to any applicant for accreditation or certification. We agree that the development and distribution of such information is a good idea. We do not believe, however, that it is necessary or appropriate to put this type of detail or activity into the regulations. We plan to provide program information, including appeals and related issues, on the NOP website.

Appeals - Changes Requested But Not Made

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

(1) National Appeals Division. Several commenters recommend amending sections 205.680 and 205.681 to provide for appeals to the National Appeals Division under the provisions at 7 CFR Part 11. We disagree with the request that the NOP use the National Appeals Division Rules of Procedure. The Act and its implementing regulations are subject to the

APA for rulemaking and adjudication. The provisions of the APA generally applicable to agency adjudication are not applicable to proceedings under 7 CFR Part 11, National Appeals Division Rules of Procedure. USDA uses 7 CFR Part 1, Rules of Practice Governing Formal Adjudicatory Proceedings Instituted by the Secretary Under Various Statutes, for adjudicatory proceedings involving the denial, suspension, and revocation of certification and accreditation.

Appeals - Clarifications

Clarification is given on the following issues raised by commenters:

(1) Appeals. A commenter stated that appeals of certification decisions should always be taken first to the certifying agent to provide an opportunity to rectify any possible error. Another commenter requested an appeals process that includes private certifying agents.

Section 205.662(a) requires a written notification of noncompliance with opportunity to rebut or correct. When the noncompliance has been resolved due to rebuttal or correction, a written notification of noncompliance resolution is issued in accordance with section 205.662(b). When rebuttal is unsuccessful or correction of the noncompliance is not completed within the prescribed time period, a written notification of proposed suspension or revocation will be issued in accordance with section 205.662(c). This notification will advise the certified operation of its right to request mediation or file an appeal with the Administrator or, when applicable, an SOP. We believe this process of providing a notification of noncompliance with opportunity to rebut or correct, followed by a notification of proposed suspension or revocation, provides ample opportunity for the certified operation to work with its certifying agent to resolve issues of noncompliance.

(2) Timely Notification. A few commenters requested that we amend section 205.680 to include mandatory procedures for timely written notice of an adverse decision, the reasons for the decision, the person's appeal rights, and the procedures for filing an appeal. We recognize that all compliance activities need to be carried out as quickly and expeditiously as possible within the confines of due process. We believe that the commenters' concerns are addressed through various sections of these regulations. Section 205.402(a) requires review of an application upon acceptance of the application. Section 205.405, on denial of certification, requires a notification of noncompliance, followed, as applicable, by a notice of denial of certification.

In accordance with section 205.405(d), the notice of denial of certification will state the reasons for denial and the applicant's right to request mediation or appeal the decision. Section 205.507 on denial of accreditation requires a notification of noncompliance, followed, as applicable, by a denial of accreditation. The notification of accreditation denial will state the reasons for denial and the applicant's right to appeal the decision.

Compliance sections 205.662 for certified operations and 205.665 for certifying agents require a notification of noncompliance with an opportunity to correct or rebut the noncompliance(s). Sections 205.662 and 205.665, when applicable, require the issuance of a notification of proposed suspension or revocation. Such notice must describe the noncompliance and the entity's right to an appeal. Section 205.681 provides the procedures for filing an appeal.

Adverse Action Appeal Process

§ 205.680 General.

(a) Persons subject to the Act who believe they are adversely affected by a noncompliance decision of the National Organic Program's Program Manager may appeal such decision to the Administrator.

(b) Persons subject to the Act who believe that they are adversely affected by a noncompliance decision of a State organic program may appeal such decision to the State organic program's governing State official who will initiate handling of the appeal pursuant to appeal procedures approved by the Secretary.

(c) Persons subject to the Act who believe that they are adversely affected by a noncompliance decision of a certifying agent may appeal such decision to the Administrator, Except, That, when the person is subject to an approved State organic program, the appeal must be made to the State organic program.

(d) All written communications between parties involved in appeal proceedings must be sent to the recipient's place of business by a delivery service which provides dated return receipts.

(e) All appeals shall be reviewed, heard, and decided by persons not involved with the decision being appealed.

§ 205.681 Appeals.

(a) Certification appeals. An applicant for certification may appeal a certifying agent's notice of denial of certification, and a certified operation may appeal a certifying agent's notification of proposed suspension or revocation of certification to the Administrator, Except, That, when the applicant or certified operation is subject to an approved State organic program the appeal must be made to the State organic program which will carry out the appeal pursuant to the State organic program's appeal procedures approved by the Secretary.

(1) If the Administrator or State organic program sustains a certification applicant's or certified operation's appeal of a certifying agent's decision, the applicant will be issued organic certification, or a certified operation will continue its certification, as applicable to the operation. The act of sustaining the appeal shall not be an adverse action subject to appeal by the affected certifying agent.

(2) If the Administrator or State organic program denies an appeal, a formal administrative proceeding will be initiated to deny, suspend, or revoke the certification. Such proceeding shall be conducted pursuant to the U.S. Department of Agriculture's Uniform Rules of Practice or the State organic program's rules of procedure.

(b) Accreditation appeals. An applicant for accreditation and an accredited certifying agent may appeal the Program Manager's denial of accreditation or proposed suspension or revocation of accreditation to the Administrator.

(1) If the Administrator sustains an appeal, an applicant will be issued accreditation, or a certifying agent will continue its accreditation, as applicable to the operation.

(2) If the Administrator denies an appeal, a formal administrative proceeding to deny, suspend, or revoke the accreditation will be initiated. Such proceeding shall be conducted pursuant to the U.S. Department of Agriculture's Uniform Rules of Practice, 7 CFR Part 1, Subpart H.

(c) Filing period. An appeal of a noncompliance decision must be filed within the time period provided in the letter of notification or within 30 days from receipt of the notification,

whichever occurs later. The appeal will be considered "filed" on the date received by the Administrator or by the State organic program. A decision to deny, suspend, or revoke certification or accreditation will become final and non-appealable unless the decision is appealed in a timely manner.

(d) Where and what to file. (1) Appeals to the Administrator must be filed in writing and addressed to Administrator, USDA-AMS, Room 3071-S, P.O. Box 96456, Washington DC 20090-6456.

(2) Appeals to the State organic program must be filed in writing to the address and person identified in the letter of notification.

(3) All appeals must include a copy of the adverse decision and a statement of the appellant's reasons for believing that the decision was not proper or made in accordance with applicable program regulations, policies, or procedures.

§§ 205.682-205.689 [Reserved]

Miscellaneous

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.

Miscellaneous

§ 205.690 OMB control number.

The control number assigned to the information collection requirements in this part by the Office of Management and Budget pursuant to the Paperwork Reduction Act of 1995, 44 U.S.C. Chapter 35, is OMB number 0581-0181.

§§ 205.691-205.699 [Reserved]

PARTS 206-209 [Reserved]

Dated: December 13, 2000

Kathleen A. Merrigan

Administrator

Agricultural Marketing Service

Appendixes to Preamble

Appendix A. -- Regulatory Impact Assessment for Final Rule Implementing the Organic Foods Production Act of 1990

The following regulatory assessment is provided to fulfill the requirements of Executive Order 12866. This assessment consists of a statement of the need for national organic standards, a description of the baseline for the analysis, a summary of the provisions of the final U.S. Department of Agriculture (USDA) rule and the alternative approaches that were examined, and an analysis of the benefits and costs. Much of the analysis is necessarily descriptive of the anticipated effects of the final rule. Because basic market data on the prices and quantities of organic goods and the costs of organic production are limited, it is not possible to provide quantitative estimates of all benefits and costs of the final rule. The cost of fees and recordkeeping in the final USDA rule are quantified, but the anticipated benefits and other costs are not. Consequently, the analysis does not estimate the magnitude or the direction (positive or negative) of net benefits.

Under the final rule, USDA will implement a program of uniform standards of production and certification, as mandated by the Organic Foods Production Act of 1990 (OFPA). The primary benefits from implementation of USDA's National Organic Program (NOP) are standardizing the definitions and the manner in which organic product information is presented to consumers, which may reduce the cost associated with enforcement actions in consumer fraud cases, and improved access to domestic and international markets from harmonizing the various State and private organic standards and elevating reciprocity negotiations to the national level.

The costs of this rule are the direct costs for accreditation and the costs of complying with the specific standards in the proposal, including the reporting and recordkeeping requirements. Certifiers will be charged fees based on the actual costs of the accreditation work done by USDA staff. Smaller certifiers with less complex programs are expected to pay somewhat lower fees. Organic farmers, ranchers, wild-crop harvesters, and handlers will have to pay fees for organic certification from a State or private certifier but will not be charged any additional fees by USDA. The direct accreditation costs to an estimated 59 certifying agents (including all 49 current U.S. certifiers and an estimated 10 foreign agents) during the first 18 months following the final rule are estimated to be approximately \$92,000 to \$124,000 and are being subsidized with appropriated funds derived from the taxpayers. In addition, USDA will use appropriated funds to cover approximately \$270,000-\$448,000 in hourly charges for site evaluation during this period and for other costs associated with starting up the NOP. The magnitude of other compliance costs for adhering to this regulation—including the costs of becoming familiar with and adopting the national standards—have not been measured. For organic farmers who adhere to State regulations or undergo third-party inspection and certification, the compliance cost may not be large. For those who don't, the costs may be more substantial. The impact of this regulation on small certifying agents and other small businesses has also not been measured but may be significant.

To account for significant rule changes from the proposal and to reflect more up-to-date information, we revised some estimates of benefits and costs. We have raised our estimates of current certification fees and USDA accreditation fees. Also, we now project higher USDA accreditation fees after the 18-month implementation period. We revised our estimates of the certification fees charged by a representative set of public and private certifiers in the U.S. based on new data, and our new estimates are about 25 percent higher for small and midsized farmers. Small and midsized farmers are now estimated to pay \$579 and \$1,414 for their first-year certification, respectively. Accreditation costs after the 18-month implementation period are substantially above those estimated in the proposed rule, reflecting a slight increase in the government per diem travel allowance since the proposed

rule was published and a change in the projected number of reviewers needed for site evaluations and renewals after the 18-month implementation period. In the proposed rule, USDA had projected that only one reviewer would be needed for site evaluations and renewals that took place after the 18-month implementation period but has changed that projection to two reviewers based on additional experience with the International Organization for Standardization (ISO Guide 65) program. We estimate that initial accreditation costs after the 18-month implementation period will range from \$6,120 to \$9,700, approximately double our estimate in the March 2000 proposed rule.

Marginal changes have been made in the final rule, in response to comments on the March 2000 proposal, which generally clarify or add flexibility to producer and handler provisions or make them better reflect current industry standards. One key change was to raise the threshold for labeling products as "made with organic ingredients" from 50 percent organic content to 70 percent to be consistent with international industry standards. Although not quantified, we believe that this will increase the cost of the rule. Another key change was to reduce the transition period for a dairy operation to make a whole-herd conversion to organic production in order to make conversion affordable for a wider range of dairy farms, including smaller operations. Although not quantified, we believe that this will decrease the cost of the rule.

The Need for National Standards Over the last several decades, as market demand has grown from a handful of consumers bargaining directly with farmers to millions of consumers acquiring goods from supermarket shelves as well as market stalls, a patchwork of State and private institutions has evolved to set standards and verify label claims. Organically produced food cannot be distinguished visually from conventional food and cannot necessarily be distinguished by taste; therefore, consumers must rely on labels and other advertising tools for product information. Farmers, food handlers, and other businesses that produce and handle organically grown food have a financial incentive to advertise that information because consumers have been willing to pay a price premium for these goods. However, consumers face difficulties in discerning the organic attributes of a product, and many producers and handlers have sought third-party certification of organic claims.

State and private initiatives have resulted in a fairly robust system of standards and certification, and the difficulties in consumer verification have been partially overcome by these initiatives. Private organizations, mostly nonprofits, began developing certification standards in the early 1970's as a way to support organic farming, as well as to strengthen legitimate product claims. The first organization to offer third-party certification, California Certified Organic Farmers, was formed in the early 1970's, and the first State regulations and laws on organic labeling were also passed in the 1970's. Currently, 13 State and 38 private certification programs are operating in the United States, and about half the States currently have some form of regulation. While most States still do not mandate third-party certification and many organic producers still market goods without certification, large food processors, grain traders, and retailers are increasingly requiring certification, and many growers have turned to certification as a marketing tool.

However, even with increasing pressure for growers to use third-party certification services and increasing availability of these services from State and private certifiers, the discrepancies between the certifiers on organic standards and between the States on certification requirements have resulted in several impediments to market development. The patchwork of variable standards has made producer access to organic markets, international and domestic, uneven. The recent emergence of the industry-developed standards may have mitigated some domestic access problems, but two important impediments remain. They are: multi-ingredient certification disputes and barriers to foreign markets.

Difficulty Certifying Multi-ingredient Products

Although the State and private organic standards that have developed over the last several decades have many areas of overlap, particularly for crop production, the differences have caused disagreements among certifying agents over whose standards apply to multi-ingredient organic processed products. These disagreements have created sourcing problems for food. Disagreements about standards also create sourcing problems for handlers of these multi-ingredient products. Certifying agents are able to negotiate and maintain reciprocity agreements at some cost. These reciprocity agreements specify the conditions under which certifying agents recognize each other's standards. Although new organic product offerings have emerged at a fast pace during the 1990's, this pace could eventually slow, assuming that the need for costly reciprocity agreements will continue to persist in the absence of national standards.

Barriers to Foreign Organic Markets

In the absence of a national standard, U.S. producers have taken on costs of private accreditation or shipment-by-shipment certification required to gain access to some foreign markets such as the European Union (EU). However, even with these actions, U.S. organic products may have had some difficulties entering other foreign markets due to high information and search costs on the part of foreign buyers. Some foreign buyers of U.S. organic products may incur costs to determine the compatibility of standards. Such costs may have discouraged purchases of U.S. organic products.

Congress passed the OFPA--Title XXI of the Food, Agriculture, Conservation and Trade Act of 1990, U.S.C. Title 7--largely to address these marketing problems. The OFPA mandates that the Secretary of Agriculture develop a national organic program, and USDA's statutory responsibility is the primary reason why USDA has carried out this rulemaking process. The OFPA requires the Secretary to establish an organic certification program for farmers, wild-crop harvesters, and handlers of agricultural products that have been produced using organic methods as provided for in the OFPA. This legislation requires the Secretary to establish and implement a program to accredit a State program official or any private person who meets the requirements of the Act as a certifying agent to certify that farm, wild-crop harvesting, or handling operations are in compliance with the standards set out in the regulation. As stated by the OFPA in section 6501, the regulations are for the following purposes: (1) to establish national standards governing the marketing of certain agricultural products as organically produced products, (2) to assure consumers that organically produced products meet a consistent standard, and (3) to facilitate interstate commerce in fresh and processed food that is organically produced.

Baseline

After struggling to build market recognition and supply capacity for many decades, the organic farming industry became one of the fastest growing segments of U.S. agriculture during the last decade. Certified organic cropland more than doubled in the United States between 1992 and 1997, and two organic livestock sectors--eggs and dairy--grew even faster (Greene, 2000a). USDA's Economic Research Service estimates that over 1.3 million acres of U.S. farmland were certified in 1997, and more recent data from some of the certifiers indicate that this momentum is continuing (Greene, 2000b). Although national estimates of the amount of uncertified organic acreage are not available, data from California, the largest U.S. producer of organic specialty crops, indicates that most of the State's organic acreage and about half of the growers were certified during the 1997/98 crop year (Klonsky et al., 2000).

Growth in U.S. sales of organic products during the 1990's mirrors the growth in acreage devoted to producing these goods. According to industry data, total organic product sales more than doubled between 1992 and 1996 to \$3.5 billion in sales (table 1). More recent industry data on organic sales through natural product stores, the largest outlet for organic

products, show annual sales growth continuing in the general range of 20-25 percent annually.

The recent growth in organic production and sales has taken place in the absence of national organic standards but with industry expectation that these standards were forthcoming. While the U.S. organic industry is characterized by an array of certification, production, processing, and marketing practices, there are commonalities throughout the industry.

Certification

The number of U.S. certification groups has fluctuated between 40 and 50 during the last decade. Currently, 49 organizations—36 private and 13 State—are advertising that they provide certification services to farmers, handlers (a category that USDA defines to include processors), retailers, or other segments of the food industry. Some certifiers provide services to multiple segments of the food industry. Private certifying agents range from small nonprofit associations that certify only a few growers to large for-profit businesses operating in numerous States and certifying hundreds of producers. Typically, certifying agents review organic production plans, inspect the farm fields and facilities to be certified, periodically reinspect, and may conduct soil tests and tests for residues of prohibited substances. In some cases, certifying agents negotiate reciprocity agreements with other agents.

State laws vary widely on organic certification and registration. Some States, such as California, require only that an organic producer register and make certification voluntary. Other States, including Texas, require certification by the State's own agents, while Minnesota and others accept certification by a private certifying agent. Approximately half of the States have laws that regulate organic production and processing. In many States producers may claim their product is organic but operate without certification or well-defined standards. Many organic producers in States with no State programs voluntarily secure third-party certification to well-defined standards. Certification costs vary with farm size and across certifying agents. Illustrative certification costs are presented in tables 2A and 2B.

Very few certifying agents operate with an external accreditation for the following reasons. There is no law which requires them to be accredited; the price may be unacceptably high in relation to expected benefits; the certifying agent may be unable to find an accrediting party willing to accredit the particular organic program the certifying agent is marketing; and State programs may believe that their status as a government entity obviates the need for external accreditation.

In 1999, USDA began accrediting certifying agents as meeting ISO Guide 65. It is a valuable recognition that the certifying entity satisfies the business capacity standards of ISO Guide 65. EU authorities have accepted verification of certifying agents to ISO Guide 65 as an interim measure to facilitate exports pending the establishment of a national organic program.

Organic Crop and Livestock Production

In 1997, farmers in 49 States used organic production systems and third-party organic certification services on over a million acres of farmland and were raising certified organic livestock production in nearly half the States, according to USDA data (Greene, 2000a). Two-thirds of the farmland was used for growing crops, with Idaho, California, North Dakota, Montana, Minnesota, Wisconsin, Iowa, and Florida as the top producers. Colorado and Alaska had the most organic pasture and rangeland. California overwhelmingly had the most certified organic fruit and vegetable acreage in 1997, but farmers were growing small plots of certified organic vegetables for direct marketing to consumers in over half the States. About 2 percent of the U.S. apple, grape, lettuce, and carrot crops were certified organic in 1997, while only one-tenth of 1 percent of the U.S. corn and soybean crops were grown under

certified organic farming systems. USDA has not estimated the amount of acreage devoted to organic production systems that has not been certified, although data from California suggest that a large number of farmers, mostly those with small operations, produce and market organic goods without third-party certification.

Key production practices followed by certified organic producers include: abstaining from use of certain crop chemicals and animal drugs; ecologically based pest and nutrient management; segregation of organic fields and animals from non-organic fields and animals; following an organic system plan with multiple goals, including sustainability; and recordkeeping to document practices and progress toward the plan's goals. Specific elements of organic production vary, but organic systems generally share a core set of practices. For example, the certification standards of virtually all State and private U.S. certifying agents prohibit the use of synthetic chemical pesticides or animal growth hormones. And most certification standards include a 3-year ban on the use of prohibited substances on cropland before production can be certified as organic.

On the other hand, certification standards for organic livestock production have been more variable for pasture, feed, and other practices. Until 1999, the USDA Food Safety and Inspection Service (FSIS) withheld approval for the use of organic labels on meat and poultry products pending the outcome of this rulemaking. However, the Secretary announced a change in policy in January 1999. Meat and poultry products may be labeled "certified organic by (name of the certifying agent)" if handlers obtain prior label approval from FSIS and the claim meets certain basic criteria. Organic labels have been permitted on eggs and dairy products—which are regulated by the Food and Drug Administration (FDA)—throughout the 1990's, but most certifiers have not yet offered certification services for these products.

We provide a summary of the New Hampshire organic program to highlight the similarities in the core set of practices. It is important to note that this discussion is intended to highlight the conceptual similarities between State and private programs and is not intended to suggest that these programs are identical to each other or to the NOP. Production standards include: a written rotation plan; tillage systems that incorporate organic matter wastes into the topsoil; compliance with limits on the sources of manure and the timing of its application; prohibitions on the use of certain substances (e.g., sewage sludge, synthetic sources of nitrates, synthetic growth regulators, and anhydrous ammonia); a list of accepted and prohibited weed and pest control practices; segregation of organic and non-organic production; recordkeeping regarding fertilization, cropping, and pest management histories; separate sales records for organic and non-organic production; and records of all laboratory analyses. Residue testing may be required if USDA believes that the products or soil used for producing certified products may have become contaminated with prohibited substances. The New Hampshire program requires growers to pay a \$100 annual inspection fee and to provide a written description of their farm operation, including the size of the farm; a field map; a 3-year history of crop production, pest control, and fertilizer use; a crop rotation and a soil management plan; and a description of postharvest storage and handling methods. Applicants for certification must also agree to comply with regulations controlling the use of the New Hampshire certified organic logo.

Organic Food Handling

In addition to growers, who actually produce and harvest products to be marketed as organic, there are handlers who transform and resell the organic products. Not all certifiers have standards for handling organic products. And some certifiers have standards for parts of the food marketing system, such as restaurants, which are not explicitly covered by the OFPA nor encompassed by this final regulation.

Definitions of processing and handling differ across certifying agents and State laws. Some States, such as Washington, distinguish between a processor and a handler, specifying 21 actions which constitute processing and defining a handler as anyone who sells, distributes, or packs organic products. Other States do not distinguish between food processors and handlers. Under the final rule, the term, "handler," includes processors but not final retailers of agricultural products that do not process agricultural products.

Organic Product Marketing

The two largest marketing outlets for organically produced goods are natural foods stores and direct markets—which include farmers markets, roadside stands, and 'community supported agriculture' arrangements—according to industry data. USDA does not have official national level statistics on organic retail sales, but an industry trade publication, the Natural Foods Merchandiser (NFM), reported estimates of total retail sales of organic foods for years 1990-96 and continues to report estimates of natural product stores sales (table 1). The last NFM estimate of total organic sales through all marketing outlets was \$3.5 billion in 1996 (\$3.7 billion in 1999 dollars), less than one percent of total food expenditures by families and individuals that year.

Natural foods stores increased in size and presence in the United States during the 1990's—many are now the size of conventional supermarkets—and about two-thirds of estimated total organic sales during the 1990's were through this outlet (table 1). Natural foods supermarkets, which are similar to conventional in the breadth of supermarket offerings and amount of total sales, accounted for close to 1 percent of total supermarket sales by 1997 (Kaufman 1998). Organic product sales through the natural foods stores outlet, alone, in 1999 were estimated at \$4 billion, and sales through this outlet increased about 20-25 percent annually through the 1990's.

Direct-to-consumer market sales ranged from \$270 to \$390 million during the early 1990's, accounting for between 17 and 22 percent of total organic sales during this period, according to NFM estimates (table 1). Conventional food stores (mass markets) accounted for 6-7 percent of total sales during this period, and export sales accounted for 3-8 percent of the total. A draft report on the U.S. organic export market, partly funded by USDA, indicates that current U.S. export sales are under 5 percent of total organic product sales (Fuchshofen and Fuchshofen 2000).

The United States is both an importer and an exporter of organic foods. The United States does not restrict imports of organic foods. In fact, U.S. Customs accounts do not distinguish between organic and conventional products. The largest markets for organic foods outside the United States are in Europe, Japan, and Canada. There is increasing pressure, particularly in Europe and Japan, for U.S. exports to demonstrate that they meet a national standard rather than a variety of private and State standards. France, for example, has indicated to USDA that it prefers to negotiate with a single national organic program, rather than the dozens of different State and private certifying programs currently operating in the U.S.

The EU is the largest market for organic food outside the United States. The organic food market in the EU was estimated to be worth \$5.2 billion in 1997 (International Trade Centre UNCTAD/WTO 1999). The largest organic retail sales markets in the EU in 1997 were Germany (\$1.8 billion), France (\$720 million), and Italy (\$750 million). Large organic markets outside the EU include Canada and Australia, with approximately \$60 million and \$68 million, respectively, in organic retail sales in 1997 (Lohr 1998). Import share of the organic food market in Europe ranged from 10 percent in France to 70 percent in the United Kingdom, was 80 percent in Canada, and varied from 0 to 13 percent in various Australian States.

Japan is another important market for U.S. organic products. Currently, Japan has voluntary labeling guidelines for 6 categories of nonconventional agricultural products: organic, transitional organic, no pesticide, reduced pesticide, no chemical fertilizer, and reduced chemical fertilizer. Total sales, including foods marketed as "no chemical" and "reduced chemical," are forecast to jump 15 percent in 1999 to almost \$3 billion. Imports of organic agricultural products were valued at \$90 million in 1998. Given Japan's limited agricultural acreage, imports will likely provide an increasingly significant share of Japan's organic food supply (USDA FAS 1999a).

Recently, these markets have adopted or are considering adoption of procedures that may impede the importing of organic food. The EU regulations establishing the basis for equivalency in organic production among EU members and for imports from outside the EU were adopted in 1991 (Council Regulation 2092/91). The EU regulations only allow imports from non-EU countries whose national standards have been recognized as equivalent to the EU standards (Commission Regulation 94/92).

The Ministry of Agriculture, Forestry, and Fisheries (MAFF) in Japan recently announced proposed standards and third-party certification requirements. Under Japan's proposed standards, certifying agents from countries without national organic standards administered by a federal government will face additional financial and administrative costs.

Requirements of the Final Rule

The final rule follows the structure established in the OFPA. By adopting this alternative, the Department is following the legislative direction in the OFPA. All products marketed as organic will have to be produced and handled as provided in the OFPA and these regulations. Compared to current organic practices, the final rule sets a somewhat more stringent system of requirements.

Among many alternatives, two alternatives to the final rule are discussed in this section: continuation of the status quo and use of industry-developed standards. Given the statutory responsibility, USDA is implementing the requirements of the OFPA. However, under the status quo alternative, there would be no national standard or national program of accreditation and certification. No Federal funds would be used, there would be no transfer from Federal taxpayers at large to organic market participants, and there would be no Federal regulatory barriers to entry into organic production and handling. However, growers and handlers would still not have level access, under uniform standards, to the domestic market, and there may be significant enforcement gaps at the State level. International pressure for additional verification would continue to build and would be likely to lead to an increased use of public and private verification and accreditation services, which are provided on a user-fee basis with full cost recovery. Establishing reciprocity between certifying agents in the domestic organic market would continue to be costly and may stifle growth in trade of organic products, although the magnitude of these costs and their effects on growth are unknown. Without further analysis that includes quantification and monetization of benefits and costs, it is not clear whether the net benefits associated with this alternative are greater or less than those associated with the final rule.

Under the other industry-developed standards alternative, USDA could eliminate the costs associated with establishing reciprocity in the domestic market and establish equivalency for access to international markets, but it would be difficult for industry to develop consensus standards. For example, the industry-developed standards recently proposed by the Organic Trade Association were developed with significant industry input but with little public comment. In contrast, several hundred thousand comments have been submitted in the course of the USDA rulemaking process. In addition, the OFPA mandated an advisory role for a 15-member National Organic Standards Board (NOSB), which has wide representation from the organic community and includes members who are farmers, handlers, retailers,

environmentalists, consumers, scientists, and certifiers. The NOSB has assisted in developing the standards promulgated in this final rule and will play an advisory role for the NOP even after the final rule is in place. Without further analysis that includes quantification and monetization of benefits and costs, it is not clear whether the net benefits associated with this alternative are greater or less than those associated with the final rule.

USDA's final rule will be implemented by the NOP staff in the Agricultural Marketing Service (AMS). Major features of the NOP include:

Accreditation and Certification

The rule specifies the accreditation and certification process. Persons providing certification services for organic production and handling must be accredited by USDA through the NOP. Applicants for accreditation must document their abilities to certify according to the national standards and to oversee their client's compliance with the requirements of the OFPA and NOP regulations. Producers and handlers of organic products must be certified by an accredited certifying agent. Producers and handlers are required to document their organic plans and procedures to ensure compliance with the OFPA.

All certifying agents would have to be accredited, and certification by producers and handlers would be mandatory. The exceptions are: (1) growers and handlers with gross organic sales of \$5,000 or less would be exempt from certification, and (2) a handling operation may be exempt or excluded from certification according to provisions described in the rule's subpart B, Applicability.

USDA will charge applicants for accreditation and accreditation renewal (required every 5 years) a \$500 fee at the time of application. USDA will also charge applicants for costs over \$500 for site evaluation of the applicant's business. The applicant would be charged for travel costs, per diem expenses, and any miscellaneous costs incurred with a site evaluation. USDA will also charge accredited certifiers at an hourly rate to review their annual reports.

Producers and handlers will not pay certification fees to USDA. Certification fees will be established by the accredited certifying agents. USDA will not set fees. The rule requires certifying agents to submit a copy of their fee schedules to USDA, post their fees, and provide applicants estimates of the costs for initial certification and for renewal of certification.

Production and Handling

The rule establishes standards for organic production of crops and livestock and handling of organic products. These standards were developed from specific requirements in the OFPA, recommendations from the NOSB, review of existing organic industry practices and standards, public comments received on the 1997 proposal and subsequent issue papers, public meetings, and comments received on the 2000 proposal.

The final rule establishes a number of requirements for producers and handlers of organic food. These requirements will affect farming operations, packaging operations, processing operations and retailers. Some of the major provisions are: (1) land requirements, (2) crop nutrient requirements, (3) crop rotation requirements, (4) pest management requirements, (5) livestock management requirements, (6) processing and handling requirements, and (7) commingling requirements.

National List

The National List lists allowed synthetic substances and prohibited 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 synthetic substances on the National List may be used. The National List also identifies those natural substances that may not be used in organic production, as determined by the Secretary based on the NOSB recommendations.

Testing

When certifying agents have reason to believe organic products contain a prohibited substance, they may conduct residue tests.

Labeling

The rule also states how organic products may be labeled and permitted uses of the USDA organic seal. In addition to the USDA seal and the certifying agent's seal, information on organic food content may be displayed. Small businesses that are certified may use the USDA seal.

Recordkeeping

The rule requires certifying agents, producers, and handlers to keep certain records. Certifying agents are required to file periodic reports with USDA. Producers and handlers are required to notify and submit reports to their certifying agent. While recordkeeping is a standard practice in conventional and organic farming, the final rule adds recordkeeping and reporting requirements that do not exist for growers and handlers operating without certification. Similarly, certifying agents would face additional recordkeeping and reporting requirements, particularly those certifying agents operating without external accreditation. The rule permits certifying agent logos and requires the name of the certifying agent on processed organic foods.

Enforcement

Organic operations that falsely sell or label a product as organic will be subject to civil penalties of up to \$10,000 per violation. The provisions of the final regulation apply to all persons who sell, label, or represent their agricultural product as organic, including operations that aren't certified, and the civil penalties of up to \$10,000 apply to these operations as well. Certifying agents, State organic programs' governing State officials, and USDA will receive complaints alleging violations of the Act or these regulations. In States where there is no State organic program, USDA will investigate allegations of violations of the Act.

Number of Affected Parties and Projections

In assessing the impacts of the rule, we have attempted to determine the number of certifying agents, private and State, that are currently operating and considered the factors likely to affect the number of certifying agents after the rule is implemented. We have attempted to determine the number of currently operating producers and handlers that would be affected. And, we have considered the factors that might affect the number of producers and handlers after the program has been implemented.

For the analysis, USDA assumes the following:

1. Forty-nine domestic certifying agents and ten foreign certifying agents will be affected by the regulation.
2. Approximately 13,650 certified and noncertified organic producers will be affected by the regulation. With the assumed growth rate of 14 percent for certified organic producers and approximately 8 percent for noncertified organic producers, the number of organic producers will grow to 17,150 in 2002.
3. Approximately 1,600 handlers of organic food will be affected by the regulation. This number will grow to 2,250 by 2002.

Certifying Entities

We place the number of certifying agents currently operating at 49, including 13 State programs. The number of certifying agents has remained fairly stable, between 40 and 50, for some years, with entries and exits tending to offset each other. For purposes of estimating the paperwork burden described elsewhere, we assume no growth in the number of domestic certifying agents but project 10 foreign certifying agents will seek and receive USDA accreditation in the first 3 years of the program.

Organic Producers

While some USDA data on the number of certified organic producers in the United States exist, no national data have been collected on the number of producers that produce and market organic goods without third-party certification. Organic farming was not distinguished from conventional agriculture in the last Census of Agriculture in 1997. USDA and Organic Farming Research Foundation (OFRF) data were used in the Regulatory Impact Analysis (RIA) of the March 2000 proposed rule to help estimate the number of certified U.S. growers affected by the regulation. California Department of Food and Agriculture (CDFA) data were used to help estimate the number of uncertified U.S. growers affected by the regulation. All three of these data sources have updated their estimates of the number of certified and uncertified organic producers since the RIA of the proposed rule was published earlier this year. However, the updated numbers do not indicate trends that would fundamentally alter the assumptions used in the RIA of the proposed rule to calculate the number of affected growers, and the estimates made for the March 2000 RIA are retained in this assessment of the final rule.

USDA datum indicates the average annual growth rate in the number of U.S. certified organic growers between 1991 and 1994 was about 14 percent (Dunn 1995b). In April 2000, USDA's Economic Research Service estimated that 5,021 certified organic growers operated 1.347 million acres of U.S. farmland in 1997, indicating that the increase in acreage had outpaced the increase in growers, and showing only an 8 percent annual growth rate in growers between 1994 and 1997 (Greene, 2000b). However, USDA's study indicated that the pace of growth in certified acreage had quickened considerably since 1997, with the amount of certified acreage increasing 38 to 150 percent between 1997 and 1999 by several large certifying organizations across the U.S. And a nonprofit organic research foundation, OFRF, estimates that the number of certified organic producers in the certification organizations that they track—the ones that will release data to them—grew over 20 percent annually between 1997 and 1999, from 4,638 to 6,600 (OFRF 2000). Also, one certifier, Washington State, responded to our request for data on the growth rate, indicating that the number of certified organic producers has increased an average of 17 percent per year between 1994 and 1999 in that State and noting that certification became mandatory by State law in 1993.

In the March 2000 RIA, USDA estimated that the number of certified U.S. organic producers potentially affected by this legislation is approximately 9,350 in 2000 and will be approximately 12,150 in 2002, based on a straight line projection of the 14-percent annual growth rate trend shown by USDA data for 1991-1994. The period, 2000-2002, was chosen for analysis because it encompasses both the period of final rulemaking and the 18-month implementation period. Congress passed the OFPA in 1990, and the 14-percent growth rate in certified growers during the 1991-1994 period reflects their expectation that national organic regulations were forthcoming. Since the recent estimates of industry growth during the 1990's are uneven and the actual growth rate in the number of growers who will become certified after this legislation is implemented is uncertain, the March 2000 estimates are retained in this assessment of the final rule.

The March 2000 RIA also estimated the number of producers who are practicing organic agriculture but who are currently uncertified that would be affected by the rule. In California,

where organic growers are required to register with the State but not to be certified, a large proportion of growers are uncertified. The most recent State data, for the 1997/98 crop year, indicate that 1,526 growers registered as organic, but only 41 percent of them obtained third-party certification (Klonsky et al., 2000). While only a small percentage of growers in the lowest organic sales category (0-\$10,000), where the largest number of growers were clustered, obtained certification, three-quarters or more of the growers earning at least \$50,000 obtained certification, and all of the growers in the highest sales class were certified. USDA did not use the California ratios of certified to uncertified growers in the March 2000 RIA to estimate the number of uncertified growers because the farming structure of California may not be representative of the Nation. For example, California sells at least three times more specialty crops than any other State in the United States—and has an unusual registration program that many growers use instead of certification.

USDA made two assumptions about uncertified production for the March 2000 estimate. The first assumption was that the rate of growth in uncertified production is less than the rate for certified farms because certification has value and organic producers would be expected to take advantage of the marketing advantages of certification. This assumption is consistent with California data that showed an increase in the percent of organic farmers obtaining certification between 1996/97 and 1997/98 in virtually every sales class (Klonsky et al. 2000). Second, the emergence of State certification programs with lower certification fees than private certification entities may have encouraged more organic producers to be certified. Based on these assumptions, USDA assumed that the number of uncertified organic producers is about 4,300 in 2000 and will be about 5,000 in 2002, making the total number of farms potentially affected by the rule about 13,650 in 2000 and 17,150 in 2002.

Organic Handlers

Little information exists on the number of organic product handlers, such as organic soup manufacturers, organic food packaging operations, organic food wholesalers, and feed millers. USDA has estimated that there were 600 entities in this category in 1994 (Dunn 1995b). AMS estimated that the growth rate was 11 percent from 1990 through 1994 (Dunn 1995b). More recent data from CDFA registration records suggest a growth rate of about 28 percent (California Department of Health Services 1999). For projection purposes, we use a growth rate of 20 percent and estimate there are about 1,600 in 2000 and there will be about 2,250 handlers in 2002. Reasons for growth include the general increase in organic production and growth in the market for processed organic foods, including multi-ingredient products. Again, these projections are based on limited data from the early 1990's, and growth may have slowed or increased. These estimates of organic product handlers are slightly higher than the estimates made in the March 2000 RIA because they include about 100 feed millers that were not included in the earlier calculation.

Retail Food Establishments

Retailers of organic food are grocery stores, bakeries and other establishments that process or prepare raw and ready-to-eat food. Most are not currently subject to either voluntary practices or mandatory standards of the organic industry. Although they are excluded from the certification requirements under the final rule, they are subject to other processing, handling, and other production related requirements of the final rule. Some of the grocery stores in the United States, particularly the natural foods stores, sell processed or prepared organic foods and will be affected by these requirements. USDA does not have an estimate of the number of entities affected.

Foreign Entities

In addition to domestic certifying agents, foreign certifying agents may also apply for accreditation under the NOP. At this time, we have no information regarding the number of foreign certifying agents that may seek USDA accreditation. Foreign applicants will face the same base costs for accreditation as domestic applicants but the overall levels of cost are

expected to be higher due to the generally higher costs of foreign travel and per diem expenses for site evaluation and miscellaneous costs such as for translation of documents. For purposes of estimating the paperwork burden described elsewhere, we assume 10 foreign certifying agents will seek and obtain accreditation during the first 3 years of the program.

Benefits of the Final Rule

The benefits of implementing national uniform standards of production and certification include: (1) providing a common set of definitions on organic attributes and standardizing the manner in which the product information is presented, which may reduce the cost associated with enforcement actions in consumer fraud cases; (2) reduced administrative costs; and (3) improved access to organic markets. Not all benefits that may arise from the rule are quantifiable. Where economic data are available, they may relate to costs and are generally not adequate to quantify economic benefits. The regulatory changes in the final rule are not expected to reduce the benefits from those described under the March 2000 proposed rule.

Information

Potential benefits to consumers as a result of the final rule include providing a common set of definitions on organic attributes and standardizing the manner in which the product information is presented. This standardization may reduce the cost associated with enforcement actions in consumer fraud cases.

Organic products cannot be distinguished from conventionally produced products by sight inspection, and consumers rely on verification methods such as certification to ensure that organic claims are true. Self-policing by certifiers of growers and handlers that are certified has been difficult because some certifiers have been under pressure to use weak standards and lax enforcement procedures in order to keep their producer and processor clients from taking their business to other certifiers (Scowcroft 1998).

Anecdotal evidence suggests that consumer fraud involving organic food does occur, and several States successfully pursued civil and criminal prosecution of these cases during the 1990's. The Attorney General of Minnesota successfully prosecuted felony charges in 1987 against the president of Glacial Ridge Foods, a wholesale supplier of beans and grains, for repackaging conventionally produced product and selling approximately \$700,000 worth labeled as certified organic (Mergentime 1997). The San Diego City Attorney's office successfully prosecuted felony charges against Petrou Foods, Inc., an organic oil and vinegar distributor, for misbranding conventional product, based on an investigation by the California Department of Health Services (Scott 1997). Also the California Department of Food and Agriculture conducted spot checks of 51 uncertified organic growers during the mid-1990's, based on complaints, and found 32 violations of California's organic standards (Farmers Market Outlook). However, only about half of the States have any organic legislation, and few of those States have laws with enough teeth to permit prosecution of organic fraud. In States without similar laws, the costs associated with remedies via the tort system may be high. The NOP established in this final rule is expected to fill in important State and regional gaps in enforcement in organic fraud cases.

The USDA organic seal will also provide consumers a quick tool to verify that goods offered for sale as organic are in fact organic.

Reduced Administrative Costs

The rule addresses the problem of existing certifying agents using different standards and not granting reciprocity to other certifying agents. By accrediting certifying agents, the rule establishes the requirements and enforcement mechanisms that would reduce inconsistent certification services and lack of reciprocity between certifying agents. In the current system, the certifying agent of a final product is not required to recognize the certification of an

intermediate product. Both primary farmers and food handlers may face a risk of being unable to sell a certified organic product when more than one certifying agent is involved. By imposing a uniform standard of certification and production, the costs associated with establishing reciprocity between certifying agents will be eliminated, and the market dampening effects that these costs impose will be eliminated. Industry-wide training costs may also decrease. USDA's uniform standards of production and certification should enable organic inspectors to move more easily from one certifying agent to another than under the current system.

Domestic and International Markets

The final rule is expected to improve access to domestic and foreign markets for organically produced goods. The current patchwork of differing State certification requirements and variable State and private standards has given producers and handlers uneven access to the domestic organic market and to the price premiums associated with this market. Livestock producers, in particular, may have limited their organic production because they lacked access to a State or private organic livestock certification program or were uncertain about the standards that would be implemented under the NOP.

The final rule could also improve access to EU and other foreign markets for U.S. organic products. For example, the EU may determine that the NOP is acceptable vis-a-vis EU regulation 2092/91. Article 11 of EU Reg. 2092/91 establishes the conditions under which organic products may be imported from third countries and addresses the framework for equivalency. The NOP is a national program that should be acceptable to the EU and other governments. Foreign acceptance of the U.S. national standard would reduce costs of negotiating and documenting shipment by shipment. Reducing these transaction costs may reduce entry costs for U.S. producers to foreign organic markets. These benefits would not accrue until after negotiations for an equivalency agreement have been held and completed successfully, which could be a lengthy process.

An estimated 5 percent of total U.S. sales are from exports. Currently, despite restricted access to the European market, the United States is the most important non-EU supplier of organic products to EU countries (Foreign Agriculture Service (FAS), 1995). Import authorizations have been granted for a number of raw and processed commodities, including sunflowers, buckwheat, beans, sugar, and apples. Demand is strong throughout the European market, and the organic market share was 1-2 percent of total food sales in 1997 (Collins 1999). Medium-term growth rate forecasts range from 5-10 percent for Germany to 30-40 percent for Denmark, and is 20-30 percent in most of the EU countries, according to the International Trade Centre UNCTAD/WTO. However, most analysts are basing their projected future growth rates on straight-line extrapolations of current sales and growth rates without understanding the underlying market mechanisms and price elasticities (Lohr 1998).

Costs of the Final Rule

The costs of the regulation are the direct costs of complying with the specific standards. It is important to note that while some costs associated with accreditation and certification are quantified, costs stemming from other provisions of the final regulations are not. In addition, this is a short-run analysis. The analysis examines the costs that may be incurred through 2002. It is not possible at this time to conduct a longer run analysis because we do not know enough about the fundamental supply and demand relationships to make economically sound long-run projections.

Accreditation Costs

USDA has identified 36 private certifying agents and 13 State programs providing certification in the United States. These 49 entities are considered likely applicants during the first 18 months during which USDA will not charge application fees or hourly fees for accreditation. An unknown number of new entrants to the certifying business may also apply.

However, over the last 10 years, the number of certifying agents does not appear to have grown significantly, with the net effect of entries and exits maintaining a population of certifying agents at about 40-50.

The final rule allows USDA to collect fees from certifying agents for USDA accreditation. The first proposal would have permitted USDA to collect fees from producers and handlers as well, but USDA decided that it would be administratively simpler to collect fees only from certifiers and would enable State programs that want to keep client costs low to be able to do so.

Applicants for accreditation will be required to submit a nonrefundable fee of \$500 at the time of application, which will be applied to the applicant's fees for service account. This means that the \$500 fee paid at the time of application is credited against any subsequent costs of accreditation arising from the initial review and the site evaluation. The \$500 fee is the direct cost to applicants who are denied accreditation based on the initial review of the information submitted with their application. Charges for the site evaluation visit will cover travel costs from the duty station of USDA employees, per diem expenses for USDA employees performing the site evaluation, an hourly charge (per each employee) for services during normal working hours (higher hourly rates will be charged for overtime and for work on holidays), and other costs associated with providing service to the applicant or certifying agent.

At present, the base per diem for places in the United States is \$85 (\$55 for lodging and \$30 for meals and incidental expenses). Per diem rates are higher than \$85 in most large cities and urbanized places, but over half of the current U.S. certifiers are located in places that have an \$85 per diem rate, and that is the rate used to calculate average certifier expenses in table 3. A review of domestic travel by USDA staff during fiscal year 1999 indicates transportation costs ranging from \$500 to \$600 per person. Miscellaneous costs are estimated to add another \$50 to each site visit.

The hourly rate that USDA anticipates charging for accreditation is the rate that USDA currently charges for services under the Quality Systems Certification Program (QSCP). Our preliminary estimate that this rate will be no more than \$95 per hour is presented to give the public some indication of the rate that will be charged following the 18-month transition period. QSCP is an audit-based program administered by AMS, which provides meat producers, handlers (packers and processors), and other businesses in the livestock and meat trade with the opportunity to have special processes or documented quality management systems verified. The procedures for accreditation evaluation are similar to those used to certify other types of product or system certification programs under QSCP.

Accreditation will include verification of adherence to ISO Guide 65 and the regulations. Although much of the site evaluation for accreditation will involve comparisons against ISO Guide 65, additional hours will be required because USDA will be evaluating additional aspects of the applicant's operation to determine if the applicant is qualified to perform as an accredited agent for the NOP. Based on experience with the QSCP and more limited experience performing audits verifying that certifying agents meet ISO Guide 65, we project that a site evaluation visit for small applicants with a simple business structure will require 3 days of review, and for those large applicants with more complex business structure will require 5 days of review.

USDA will use two reviewers for each site evaluation visit during the 18-month implementation period, as well as for new applicants after that period. One reviewer will come from the QSCP audit staff and will be familiar with the ISO Guide 65 verification; the other reviewer will come from the NOP staff and will be familiar with requirements of the organic program. The two will conduct the site evaluation jointly. Two reviewers will also be needed for the site evaluation visits for the accreditation renewals, which will take place

every 5 years. In the proposed rule, USDA had projected that only one reviewer would be needed for site evaluations and renewals that took place after the 18-month implementation period but has changed that projection based on additional experience with the ISO Guide 65 program.

During the 18-month implementation period, applicants will be charged for travel and per diem costs for two persons and for miscellaneous expenses but will not be charged application fees or hourly fees. The estimated expenditures for these initial accreditations is \$1,560-\$2,100, with \$510-\$850 for per diem expenses, \$1,000-\$1,200 for travel expenses, and \$50 for miscellaneous expenses (table 3). The cost of initial site evaluation visits will vary with the cost of travel from the USDA reviewer's duty station to the applicant's place of business. In general, more distant and remote locations will involve higher travel costs.

USDA estimates the costs of a site evaluation visit after the transition period may average \$6,120-\$9,700, depending on the characteristics of the applicant, including \$4,500-\$7,600 for the hourly site evaluation charges that are not billed to the certifier during the first 18 months (table 3). USDA has received appropriated funds to pay for the hourly site evaluation charges only during the first 18 months of the program.

Currently, few private certifying agents are operating with third-party accreditation. Fetter (1999) reports that in a sample of 18 certification programs, four programs were accredited, and one had accreditation pending. All of these were large, private certifying agents. Those certifying agents currently accredited by third parties will likely pay less for USDA accreditation. In its first proposal, USDA stated at FR 62:65860, "We are aware that certifiers currently may pay in excess of \$15,000 for accreditation by a private organization." Commenters thought this figure was too high. One commenter, which operates the International Federation of Organic Agriculture Movements (IFOAM) Accreditation Programme under license to IFOAM, stated, "It is possible that the largest programme operating a chapter system with activities in many countries (which is included in their IFOAM evaluation) paid this amount in their first year. On the other hand the average cost to a medium sized certifier works out at around \$3000 to \$4000 per year." Another commenter stated, "At the present time IFOAM accreditation costs less than \$10,000/year for the largest certifier and \$3-5,000 for smaller certifiers."

The 18-month NOP implementation period affects the distribution of program costs between the organic industry and the taxpayer. Some of the costs of accreditation would be absorbed by the NOP operation budget appropriated by Congress. In effect, the taxpayers are subsidizing the organic industry. Without this subsidy, the total cost of accreditation would approach \$1 million.

The direct accreditation costs to an estimated 59 certifying agents (including all 49 current U.S. certifiers and an estimated 10 foreign certifiers) during the first 18 months following the final rule, are approximately \$92,000 to \$124,000. This figure is derived from the per-firm costs in table 3. In addition, USDA will use appropriated funds to cover approximately \$270,000-\$448,000 in hourly charges for site evaluation. USDA will also use appropriated funds to cover the costs of producing and publishing an accreditation handbook in several languages, translating USDA reports to foreign clients, and developing and funding a peer review panel to evaluate NOP's adherence to its accreditation procedures. And if more than the estimated 59 certifiers apply for accreditation during the first 18 months of the program, USDA will use appropriated funds to cover additional hourly charges for site evaluation.

Private certifying agents and State programs that do not mirror the regulation may incur additional costs to change their programs to adopt the national standards. The discussion on the effect of the regulation on existing State programs is in "State Program Costs." The cost associated with changing existing private certifying programs is not quantified.

Also, certifying agents who have been operating without third party accreditation will face new costs. For certifying agents who currently obtain third-party accreditation, the direct costs of USDA accreditation, which are only incurred every 5 years, may be lower on an annual basis compared to the direct costs for third-party certification of \$3,000-\$5,000 per year indicated by the commenters. The direct costs for certifying agents obtaining accreditation during the first 18 months, when USDA will not impose an application fee or hourly charges, will be limited to travel, per diem, and miscellaneous expenses.

A national accreditation program may shrink the market for a third-party accreditation. Certifying agents will have little incentive to maintain or seek a second accreditation by a private organization unless that accreditation sufficiently enhances the market value of the certifying agent's services. Thus, the market will determine whether other accrediting entities continue to have a U.S. market for their services.

Training programs are currently offered by the Independent Organic Inspectors Association (IOIA), an organization of approximately 165 organic certification inspectors, and by some of the larger certifying agents (IOIA). Costs to existing certifying agents to provide additional training to other staff are difficult to measure in the absence of information on current staff skill levels or the existence of formal training other than inspector training. Some agencies rely on volunteer staff who may have had no formal training, but the extent of this practice is unknown. AMS intends to offer assistance to certifying agents, producers, and handlers by providing accreditation training for certification agents and other printed material that would enable participants to better understand the regulations. In addition, AMS intends to continue open and frequent communication with certifying agents and inspectors to provide as much information as possible to aid them in fulfilling the requirements of the regulations.

The OFPA requires that private certifying agents furnish reasonable security for the purpose of protecting the rights of participants in the organic certification program. It is expected that there will be costs to certifying agents from these requirements.

Implementation of the final rule will also impose a less tangible cost on some certifiers. Some private certifiers have advertised their program and logo as representing higher standards than other programs. The brand value associated with the logos of these certifiers will be lost when uniform standards are implemented as part of the national program. However, certifiers will still be able to distinguish themselves to clients based on the quality of their services and other characteristics.

A key change was made in the final rule, based on comments to the March 2000 proposal, to make the standard used by certifiers to determine maximum allowable pesticide residues (the level above which a product could not be called organic) consistent with the current industry standard and with NOSB recommendations. In the final rule, the standard will be set at 5 percent of the pesticide residue tolerances calculated by the Environmental Protection Agency (EPA). This change could conceptually reduce costs, but the magnitude of this reduction is uncertain.

Certification Costs

Under the final rule, USDA will not impose any direct fees on producers and handlers. Certifying agents will establish a fee schedule for their certification services that will be filed with the Secretary. Certifying agents will provide all persons inquiring about the application process with a copy of their fees. The certifying agent will provide each applicant with an estimate of the total cost of certification and an estimate of the annual costs of updating the certification. Under the proposed rule, certifiers could charge a maximum of \$250 at the time of application, but under the final rule, certifiers are not limited in the amount of certification fees that they may charge at the time of application.

Some States charge minimal fees for certification by subsidizing operating costs from general revenues. The majority of certifying agents structure their fee schedules on a sliding scale based on a measure of size, usually represented by the client's gross sales of organic products but sometimes based on the acres operated (Fetter 1999 and Graf and Lohr 1999). Some certifying agents charge an hourly rate for inspection and audit services.

Graf and Lohr have applied fee schedules provided by ten certifying agents to four hypothetical farms, small, medium, large, and a super farm. Tables 2A and 2B summarize the fees that Graf and Lohr found by applying schedules of each certifying agent to hypothetical farms. Total first-year costs and subsequent-year (renewal) costs for certification are shown. The average cost for each size class should be interpreted with care because it is not weighted by the number of clients certified. In their study, the Texas Department of Agriculture program is the low-cost certifying agent for all-size operations. The high-cost certifying agent differs across farm sizes. None of these certification programs mentions costs for residue testing, which the NOP will require in the form of preharvest testing when there is reason to believe that agricultural products have come into contact with prohibited substances. Preharvest testing is expected to be infrequent. Some certifying agents currently require soil nutrient testing and water quality testing. The estimated total initial costs for a producer or handler to become certified are presented in table 3.

We have not extended the average costs reported in Tables 2A and 2B to aggregate certification costs for all organic farms because the number of organic farms is not known with precision, nor is their geographic location, and there are no data to distribute the population of organic farms across size classes. The data from California suggest that a large number of small farmers produce and market organic goods without third-party certification, but those data may not be representative of the national trend. Although many of the smallest farms would qualify for the small farm exemption from certification, if consumers accept the labeling practices required by this final rule, small farmers may obtain certification to stay in the organic market, which may involve some cost.

In response to comments, the March 2000 proposal was changed to provide that if a conflict of interest is identified within 12 months of certification, the certifying agent must reconsider the application and may reinspect the operation if necessary. Additionally, if a conflict of interest is identified, the certifying agent must refer the operation to a different accredited certifying agent. These provisions would likely increase costs to certifiers; however, the magnitude of this increase is unknown.

Production and Handling Costs

Producers and handlers currently active in the organic industry may bear costs under the national standards. We believe that while most provisions of the program mirror current industry practices, there are some differences. In addition to the cost associated with becoming familiar with the national program, any adjustments stemming from these differences will result in costs. These costs were qualitatively discussed in the March 2000 RIA for major provisions of the rule and are described below. The March 2000 proposal adhered closely to recommendations from the NOSB and largely reflected current industry standards. Marginal changes have been made in the final rule in response to comments on the March 2000 proposal. These changes have been made in concert with NOSB recommendations and, in general, have been made to clarify or add flexibility to producer and handler provisions or to make them better reflect current industry standards.

Producers

Producers of organic food will face numerous provisions that will regulate their production methods. As indicated in the Baseline section, many of the requirements are currently followed by certified organic farmers. Farming operations that are not certified but are

registered with a State government, such as California, receive copies of the State laws to which they must comply. The costs associated with adjusting to provisions in the final rule may be minimal for certified and State-registered growers but may be more substantial for noncertified organic producers that do not follow a specific set of guidelines or regulations. Some organic producers are neither certified nor registered and, therefore, may not practice the requirements in the final rule. Major provisions of the final rule—the withdrawal period required for land to be free of prohibited substances, National List, animal drug use, and residue tests—are discussed to illustrate costs; other provisions may also impose additional costs.

A 3-year withdrawal period, during which prohibited materials cannot be applied to a field to be certified as organic, is currently required by most private and State organic standards, and the final rule also specifies a 3-year period. The effect of this provision on the currently certified organic farming operations may be minimal, but the effect on farming operations that are neither certified nor registered may be significant. Farming operations that have completed a 3-year withdrawal period will not be affected by this requirement. To stay in the organic industry, those who have not completed the 3-year period must comply with this requirement. They may incur the cost of organic production for a significant length of time, yet not be allowed to sell their products as organic. Hence, some small organic operations may exit the industry.

The impact of the National List, which lists allowed synthetic substances and prohibited non-synthetic substances that may or may not be used in organic production and handling operations, will be determined by how the national standards differ from current certification standards and from actual practice. Lists of approved synthetic materials, including soil amendments and pesticides, vary from one certification program to another, but a detailed analysis of specific differences in the various existing materials lists shows them to be overlapping in most cases with each other and with the National List. The degree of overlap should mitigate the costs for certified operations, but farming operations, particularly those that aren't certified, may need to make some adjustments to comply with the list. These adjustments will impose costs on these operations. The magnitude of the costs resulting from these adjustments is not quantified.

Where livestock standards have been adopted by existing State programs and by private certifying agents, most prohibit the use of animal drugs except for the treatment of a specific disease condition, and use of animal drugs is generally prohibited within 90 days prior to the sale of milk or eggs as organic. Some State and private certifiers allow the use of animal drugs in animals for slaughter under certain conditions, while others prohibit the use of animal drugs. The standards in the final rule would prohibit the sale as organic of edible products derived from an animal treated with antibiotics or other unapproved substances. The standards may not differ from existing State or private standards in prohibiting the use of drugs on healthy animals. However, the effect of this provision may differ among certified and registered organic farms. The effect on the certified farming operations is unknown. We assume that this provision may have costs, but the magnitude of these costs is not quantified.

Additional costs may be imposed by several further changes to the March 2000 proposal. These changes involve the use of treated lumber, confinement requirements, and the commercial availability of ingredients in products labeled "organic."

The replacement of lumber treated with prohibited substances that comes into contact with soil, crops, or livestock under organic management with treated lumber is now specifically prohibited in organic systems. Since the use of lumber treated with prohibited substances for the purpose of preventing degradation is not a common practice in livestock production, this prohibition is not expected to increase producer costs substantially. The exact magnitude of

any increase is uncertain and mainly dependent upon the number of producers seeking organic certification that currently use treated lumber in their operations and are planning to replace that lumber.

The confinement provisions in the March 2000 proposal have been slightly modified. Access to the outdoors is now an explicitly required element for all organically raised livestock. We expect this change to have a minor impact on overall producer costs, since we assume most producers raising organic livestock already provide access to the outdoors. Additionally, the term, "pasture," has been defined to emphasize that livestock producers must manage their land to provide nutritional benefit to grazing animals while maintaining or improving soil, water, and vegetative resources of the operation. To the extent producers desiring to raise organic livestock do not currently manage pasture in this manner, we expect livestock production costs to increase.

The organic plan now requires using organically produced minor agricultural ingredients unless not commercially available. This applies to the previously allowed 5-percent non-organic agricultural and other ingredients in products labeled "organic." Handlers of organically produced minor ingredients, especially herbs and spices, are likely to benefit from this market incentive, while producers of non-organic minor ingredients will likely be adversely affected. Producers will also realize a burden associated with providing the documentation of commercial availability for ingredients in the 5-percent component. Since the criteria to determine commercial availability will be developed after additional comments and information are considered, the magnitude of the cost and benefit implications from this standard are currently unquantifiable but will likely be largely dependent upon the stringency of the developed criteria.

Producers will also have administrative costs for reporting and recordkeeping, although producers who currently are active in the organic industry already perform most of these administrative functions, and additional costs to them would depend upon the extent to which their current practices are different from the requirements of the final rule. The annual reporting and recordkeeping burden on producers is estimated at 24 hours for certified producers and 1 hour of recordkeeping for small producers who choose to operate as exempt entities and is valued at \$23 per hour.

Other provisions of the final rule, such as those on residue testing, livestock housing and feed, and health care practices, may vary enough from those followed by some growers that they may impose costs due to the variability in current housing, feed, and health care practices, but lacking information, we have not quantified these costs.

There were also several key changes made in the final rule, based on comments to the March 2000 proposal, that will add flexibility to producer standards. A specific type of production facility was required for composting manure in the proposal, and this provision has been modified to ensure that manure is adequately composted while allowing variation in the type of facility that is used. Also, the transition period of a dairy operation to make a whole-herd conversion to organic production has been reduced in order to make conversion affordable for a wider range of dairy farms, including smaller operations. Finally, the requirement that slaughter stock sold, labeled, or represented as organic be under continuous organic management from birth was changed to require continuous organic management from the last third of gestation. This change is also expected to provide possible cost savings and added flexibility for producers.

Handlers

Handlers of organic food are defined and regulated differently across different certifying agents and States. Due to this variability, handlers may incur some cost associated with complying with the requirements of the regulation. Several key changes were made in the

final rule, based on comments to the March 2000 proposal, to make handler standards more consistent with current industry standards. The proposal prohibited the addition of sulfites to wine as required by OFPA. The statute has been changed since March, and the final rule will permit added sulfites in wine labeled "made with organic grapes," consistent with industry standards and NOSB recommendations.

Also, the March proposal required products labeled "made with organic ingredients" to have ingredients that were at least 50 percent organic, and this threshold has been raised to 70 percent in the final rule. Some certifiers set their thresholds at 50 percent, others at 70 percent, while others restrict labeling to individual ingredients only. The international industry standard outside the United States is set at 70 percent. The threshold is set at 70 percent in the final rule in response to comments received on the proposal and to be consistent with international standards, which will help ease export of U.S. organic product into those markets. Alternatively, to the extent handlers do not currently meet the 70-percent threshold to label products "made with organic ingredients," handlers may incur additional costs to reach the threshold or exit the industry. The magnitude of those effects is unknown.

In addition to the labeling requirement, a handler's current use of non-synthetic and synthetic substances may change in response to the final rule. The March 2000 proposal provided for the use of any prohibited substance to prevent or control pests. This provision has been changed to first limit the use of non-synthetic and synthetic substances to substances which are on the National List before allowing the use of any synthetic substance. To the extent to which handlers are now required to consider substances on the National List before using a prohibited substance and these substances on the National List are priced differently from the substance otherwise used, handlers may incur a change in production costs. This requirement may increase costs on handlers, but the magnitude of this increase is unknown. In addition, the commercial availability requirement in the final rule, described in the producer costs section, may also create a burden on handlers to consistently apply the standard. To the extent to which sourcing organically produced ingredients in excess of 95 percent of the finished product is more expensive than sourcing non-organically produced ingredients, handlers seeking the "organic" label for their products will incur additional costs. As previously described, the magnitude of the cost implications from this standard is currently unquantifiable but will likely be largely dependent upon the stringency of the standard that is developed.

Handlers will also have administrative costs for reporting and recordkeeping, although handlers who currently are active in the organic industry already perform most of these administrative functions, and additional costs to them would depend upon the extent to which their current practices are different from the requirements of the final rule. The annual reporting and recordkeeping burden on handlers is estimated at 63 hours for certified handlers and 1 hour of recordkeeping for small handlers who choose to operate as exempt entities and is valued at \$23 per hour.

Retail Food Establishments

Most retailers are not currently subject to either voluntary practices or mandatory standards of the organic industry. Retailers that have organic processing operations, such as organic food delis and bakeries, are not required to be certified in the final rule. However, retailers will be subject to requirements such as prevention of contamination of organic products with prohibited substances, and commingling organic with non-organic products. Obtaining certification and complying with these provisions will incur some cost.

Labeling Costs

Certified handlers will have to comply with requirements regarding the approved use of labels. In addition, any producers, handlers, and retailers who are not currently certified but who package organic products are also subject to the labeling requirements. The estimated

annual cost for handlers to determine the composition of 20 products to be reported on labels is \$1,647,000. This figure is based on an average of 1 hour per product per handler and an hourly cost of \$27. Similarly, certified handlers will have to design their labels to comply with the regulation. This is expected to take 1 hour per label at \$27 per hour for a compliance cost of \$1,647,000. Total label costs for handlers are \$3.3 million. Any changes to existing labels and new labels that need to conform to the regulation will incur a cost. The costs associated with these activities are not quantified. Hence, the lower bound on the labeling cost is approximately \$4 million.

State Program Costs

The national program may impose additional costs on States by requiring changes in their existing programs. The rule encompasses most of the principles of existing State programs. However, there are also departures.

Where State standards are below Federal standards or where elements of the Federal standards are missing from a State program, these States would be required to make changes in their programs that they might otherwise not make. Where State programs have standards in addition to the Federal standards and they are not approved by the Secretary, States also would be required to make changes in their programs. States without organic standards or whose current standards either would conform to those of the national program or would be approved by the Secretary would not incur additional costs resulting from required changes. Currently, USDA cannot predict which States may be required to adjust their existing programs.

States that conduct certification activities will be charged for accreditation, something none of them pay for now. The cost associated with this provision is discussed in the Accreditation section.

Enforcement costs

Enforcement costs will fall upon USDA's NOP, States operating State organic programs, and on State and private certifying agents. Certifying agents will review clients' operations and will notify clients of deficiencies. Certifying agents can initiate suspension or revocation of certification. Certifying agents will be aware of these overhead costs, and we assume that they will establish fee schedules that will cover these costs. Actual costs to certifying agents for enforcement activities will depend on the number of clients, how well informed clients are of their obligations, and client conduct. State certifying agents will face the same obligations and types of costs as private certifying agents.

In States operating State organic programs (SOP), State enforcement costs are costs associated with ensuring that certified operations fulfill their obligations. These States will bear the costs of investigating complaints, monitoring use of the State organic seal and organic labeling, and taking corrective action when needed. These States will bear costs related to reviewing an applicant's or certified operation's appeal and for administrative proceedings. Many of these activities are already a routine part of the certification program in States that have programs, and USDA will fill in gaps in enforcement in States that choose not to have programs.

USDA's enforcement costs are costs associated with ensuring that certifying agents fulfill their obligations. In States without an organic program, USDA will bear the costs of investigating complaints, monitoring use of the USDA organic seal and organic labeling, and taking corrective action when needed. USDA will bear costs related to reviewing an applicant's or certified or accredited operation's appeal and for administrative proceedings. USDA expects to effectively carry out its enforcement responsibilities using funds that are already allocated for operating the NOP. To the extent to which we did not estimate the likely noncompliance rate, the cost associated with enforcement remains unknown.

Reporting and Recordkeeping Costs

The Paperwork Reduction Act of 1995 requires an estimate of the annual reporting and recordkeeping burden of the NOP. The estimated annual reporting and recordkeeping burden reported is approximately \$13 million. This figure should be understood within the context of the requirements of the Paperwork Reduction Act. The Paperwork Reduction Act requires the estimation of the amount of time necessary for participants to comply with the regulation in addition to the burden they currently have. Information gathered by AMS in auditing activities in conjunction with ISO Guide 65 verifications leads us to believe that the paperwork burden on current certifying agents and certified operators will be 10 to 15 percent greater than their current business practices as a result of this final rule.

Certifying Agents. The regulation will impose administrative costs on certifying agents for reporting and recordkeeping. The actual amount of the additional administrative costs that would be imposed by the rule is expected to be different for those entities that would begin their activities only after the national program is implemented. Certifying agents that currently are active in the organic industry already perform most of these administrative functions; therefore, the additional costs to them would depend upon the extent to which their current practices are different from the requirements of the regulation. An estimate of the cost of compliance is the annual reporting and recordkeeping burden documented in the Paperwork Reduction Act of 1995 analysis. Table 4 shows the estimated annual costs for certifying agents. Certifying agencies each have an estimated burden of 1,068 hours valued at roughly \$27,729.

The following list describes several of the most significant administrative requirements or optional submissions and the probable resources required for compliance. Details on the reporting and recordkeeping burdens estimated for each item are in the paperwork analysis.

1. A list of farmers, wild-crop harvesters, and handlers currently certified. This information can be compiled from existing records. After implementation, certifying agents will be required to submit on a quarterly basis a list of operations certified during that quarter.
2. A copy of procedures used for certification decisions, complying with recordkeeping requirements, maintaining confidentiality of client's business-related information, preventing conflicts of interest, sampling and residue testing, training and supervising personnel, and public disclosure of prescribed information concerning operations they have certified and laboratory analyses. These policies may have to be created or modified to conform to the regulation.
3. Documentation on the qualifications of all personnel used in the certification operation, annual performance appraisals for each inspector and personnel involved in the certification, and an annual internal program evaluation. Existing certifying agents may already perform these operations. New certifying agents will have to establish procedures to achieve these things.
4. Documentation on the financial capacity and compliance with other administrative requirements (e.g., fee structure, reasonable security to protect the rights of the certifying agent's clients as provided in the NOP, and business relationships showing absence of conflicts of interest). Some of this information can be compiled from existing records, e.g., fee schedules, and some may be generated from other sources.
5. Copies must be submitted to USDA of all notices that are issued on certification denial, noncompliance, and suspension or revocation of certification. This requirement will be fulfilled simultaneously with sending notices to applicants or clients.

6. An annual report to the Administrator including an update of previously submitted business information, information supporting any requested changes in the areas of accreditation, and steps taken to respond to previously identified concerns of the Administrator regarding the certifying agent's suitability for continued accreditation. The annual report requirement will draw on records created in the normal course of business.

7. Retention of records created by the certifying agent regarding applicants and certified operations for not less than 10 years, retention of records obtained from applicants and certified operations for not less than 5 years, and retention of other records created or received for USDA accreditation for not less than 5 years. This activity requires records, database management capabilities, and resources (storage space, file cabinets, electronic storage, etc.). In an informal inquiry, AMS found that most existing certifying agents currently retain records for at least 10 years and use both electronic and paper storage. We believe that this requirement will not pose an additional burden on existing certifying agents.

8. Public access to certification records, such as a list of certified farmers and handlers, their dates of certification, products produced, and the results of pesticide residue tests. This requirement will have minimal impact given the requirements for retaining records.

9. Providing program information to certification applicants. To comply with this requirement, certifying agents may need to modify existing standards and practices. The criteria for qualified personnel in the rule may likely result in an increase in labor costs for some existing certifying agents and, initially, an increase in training costs. The amount of additional costs to these certifying agents would depend on the level of expertise among current certification agency staff, the extent to which certifying agents currently rely on volunteers, and the current costs of training certification staff.

Producers and Handlers. The regulation will impose administrative costs on producers and handlers for reporting and recordkeeping. The actual amount of the additional administrative costs that would be imposed by the final rule is expected to be different for those entities that would begin their activities only after the national program is implemented. Producers and handlers who currently are active in the organic industry already perform most of these administrative functions; therefore, the additional costs to them would depend upon the extent to which their current practices are different from the requirements of the final regulation. An estimate of the cost of compliance is the annual reporting and recordkeeping burden documented in the Paperwork Reduction Act of 1995 analysis.

The following list describes several administrative requirements or optional submissions and the probable resources required for compliance.

1. Establish, implement, and update annually an organic production or handling plan. Organic plans are a standard feature in the organic industry and are required by certifying agents. Thus, producers and handlers who are already involved in organics can rely on their current plan with revisions as needed to meet elements of the national program which are new to them or differ from their current practice. Although producers and handlers are generally aware of the goals of organic plans, current practice may fall short of the rigor that will be required by the national program. New producers and handlers will have higher costs because they will have to prepare a plan from scratch.

2. Maintain records pertaining to their organic operation for at least 5 years and allow authorized representatives of the Secretary, the applicable State organic program's governing State official, and the certifying agent access to records. Existing organic producers and handlers maintain records. New producers and handlers will have to develop records systems. Access is expected to be infrequent, will require little time of the certified entity, and will not require buildings or equipment other than what is required for storing records.

3. Notify the certifying agent as required (e.g., when drift of a prohibited substance may have occurred) and complete a statement of compliance with the provisions of the NOP. Notifications are expected to be infrequent.

The total reporting burden includes creation and submission of documents. It covers the greatest amount of reporting burden that might occur for any single creation or submission of a document during any one of the first 3 years following program implementation; i.e., 2000, 2001, and 2002. The total estimated reporting burden reflects the average burden for each reporting activity that might occur in 1 year of this 3-year period.

The total recordkeeping burden is the amount of time needed to store and maintain records. For the purpose of measuring the recordkeeping burden, the year 2002 is used as the reporting year for which the largest number of records might be stored and maintained.

The annual reporting and recordkeeping burden on producers, handlers, and certifying agents is summarized in table 4. The annual burden on certified producers is estimated at 24 hours and \$552. Certified handlers have an estimated burden of 63 hours valued at \$1,449. The burden on small producers and handlers who choose to operate as exempt entities is minimal, 1 hour of recordkeeping valued at \$23. If this cost is applied to the total estimated number of affected producers, the reporting and recordkeeping cost would be \$5,260,100 in 2000 and \$6,835,554 in 2002. By applying this cost figure to the estimated total number of affected handlers, the reporting and recordkeeping cost would be \$2,143,002 in 2000 and \$3,013,552 in 2002.

Barriers to Entry - Importers of Organic Products

Currently, there are no Federal restrictions on importing organic products to the United States in addition to those regulations applying to conventional products. If the imposition of the NOP decreases the importation of organic food into the United States, then this regulatory action may result in some cost.

Small Business Ramifications

USDA's final rule has an 18-month period during which applicants for accreditation would not be billed for hourly services. The rationale for this transition period is to reduce the costs to certifying agents and, thus, increase the prospect that certifying agents, producers, and handlers will be able to afford to participate in the national program. The choice of 18 months is intended to provide sufficient time for parties desiring accreditation to submit their application and prepare for a site evaluation.

USDA will operate the program partially with appropriated funds, in effect sharing the cost of the program between taxpayers and the organic industry, to respond to public concerns regarding the effects of the regulation on small businesses. Thousands of comments were received opposing the first proposal's fee provisions with most focusing on the substantial impact on small certifying agents.

Congress has expressed public policy concern with the impacts of regulations on small entities generally and with the impacts on the NOP regulations on small entities particularly. The Small Business Regulatory Enforcement Fairness Act of 1996 and the Regulatory Flexibility Act express Congressional concern regarding regulatory burden on small businesses. The Report from the Committee on Appropriations regarding the Agriculture, Rural Development, Food and Drug Administration, and Related Agencies Appropriations Bill, 2000, includes the following language (U.S. Senate 1999):

"The Committee continues to recognize the importance of organic markets for small farmers and fishermen. The Committee expects the Secretary to construct a national organic program that takes into consideration the needs of small farmers and fishermen.

Furthermore, the Committee expects that of the funding available for the National Organic Program, necessary funds should be used to offset the initial costs of accreditation services, a subsidy necessary due to the lack of expertise in the Department of Agriculture in the areas of organic accreditation and insufficient data on the industry."

Certifying agents applying for accreditation during the first 18 months following the final regulation will face lower direct costs than subsequent applicants. The cost for later applicants for accreditation will be higher because they will have to pay a \$500 application fee and hourly charges for completing their site evaluation. The requirement for accreditation was established in the OFPA in 1990 and the accreditation program was part of the 1997 proposal. Because in this final rule, USDA is using appropriated funds to cover some of the costs of initial accreditation during the first 18 months of the program, certifying agents may set lower fees initially benefiting the producers and handlers who are certified during this period.

It is important to note that many small organic operations may not be certified currently. In California, for example, many small farms are registered but not certified. Even if certifying agents pass on the cost savings of the 18-month period provision to applicants for certification, the cost of certification may be higher than the cost of registration. Hence, becoming a certified operation for small organic producers and handlers may be more costly than the current practices.

The costs imposed on small operations may be mitigated by a \$5000 certification exemption to aid the smallest organic operations. However, these operations are still subject to other requirements of the regulation. To the extent that these requirements differ from their current practices, complying with the national standards may be costly for exempt operations. In addition, the certification exemption allowed under the regulation includes limits on what an exempt operation may do. Without the certification, small organic operations may not display the USDA seal and may not use a certifying agent's seal. If the consumers of organic food view the seals as important information tools on organic food; that is, if consumers of organic products insist on only certified organic products, the inability of small operations to display these seals may prevent them from realizing the price premiums associated with certified organic products.

Industry Composition

The imposition of the national standards may change the composition of the organic industry. Even with the small business exemptions, some small organic operations may choose to exit the industry, and small organic operations may also be discouraged from entering the industry, resulting in a higher concentration of larger firms. On the other hand, it may be easier for small operations to comply with certain NOP standards, such as the livestock standards that prohibit confinement production systems and require 100 percent organic feed. And State and Federal certification and conservation cost-share programs and other government programs may help lower the impact on small producers.

References

- Byng, John. 1994. UK and European Community (EC) Legislation. In Handbook of Organic Food Processing and Production. Simon Wright (ed.). pp. 17-30. Glasgow: Blackie Academic and Professional.
- California Department of Health Services (DHS). 1999. Report on the Registration of California Organic Processed Food Firms. Sacramento: State of California. September 1999. Figures obtained via personal communication with DHS.
- California Department of Health Services. 1995. Report on the Registration of California Organic Processed Food Firms. Sacramento: State of California.
- Collins, Shane. 1999. "Rosy future forecast for Europe's organic market," Eurofruit Magazine, September.
- Dunn, Julie Anton. 1995a. Organic Food and Fiber: An Analysis of 1994 Certified Production in the United States. U.S. Department of Agriculture, Agricultural Marketing Service.
- Dunn, Julie Anton. 1995b. "Organic Foods Find Opportunity in Natural Foods Industry," Food Review, Vol. 18, Issue 3, Sep.-Dec.
- Dunn, Julie Anton. 1997. AgriSystems International Reports Certified Organic production in the United States: Half a Decade of Growth. AgriSystems International: Wind Gap, PA.
- Emerich, Monica. 1996. Industry Growth: 22.6%. Natural Foods Merchandiser (June): 1-39.
- Farmers Market Outlook. 1996. "Waiting for Organic Inspections," September-October issue.
- Farmers Market Outlook. Various issues. www.seasonalchef.com/orgnews1.htm.
- Fetter, Robert T. 1999. Economic Impacts of Alternative Scenarios of Organic Products Regulation. Senior Honors Thesis. University of Massachusetts, Amherst, MA.
- Fuchshofen, Winfried and Silke Fuchshofen. 2000. "Export Study for U.S. Organic Products into Asia and Europe," Draft Report, Organic Insights, Inc.
- Graf, Anita and Luanne Lohr. 1999. "Analysis of certification program costs," Working Paper, Fund for Rural America project, Market Development for Organic Agriculture Products, Grant No. 97-36200-5.
- Greene, Catherine. 2000a. "U.S. Organic Farming," USDA, Economic Research Service Issues Center, www.ers.usda.gov.
- Greene, Catherine. 2000b. "U.S. Organic Agriculture Gaining Ground," Economic Research Service, U.S. Department of Agriculture, Agricultural Outlook, AGO-270, April.
- Hammitt, James K. 1990. Risk Perceptions and Food Choice: An Exploratory Analysis of Organic - Versus Conventional-Produce Buyers. Risk Analysis, Vol.10, No. 3: 367-374.
- Hammitt, James K. 1993. Consumer Willingness to Pay to Avoid Pesticide Residues. Statistica Sinica, 3.
- Independent Organic Inspectors Association. 1996. IOIA 1996 Membership Directory. Winona, MN.
- International Trade Centre UNCTAD/WTO. 1999. Organic Food and beverages: World Supply and Major European Markets. Geneva: ITC, xiv, 271 p.

- Jolly, Desmond A., Howard G. Schutz, Katherine V. Diaz-Knauf, and Jagjeet Johal. 1989. Organic Foods: Consumer Attitudes and Use. *Food Technology* (November): 60-66.
- Jolly, Desmond A. 1991. Differences Between Buyers and Nonbuyers of Organic Produce and Willingness to Pay Organic Price Premiums. *Journal of Agribusiness* (Spring): 97-111.
- Kaufman, Phil. 1998. "Natural Foods Supermarkets Gaining in Popularity," Economic Research Service, U.S. Department of Agriculture, *FoodReview*, Volume 21, Issue 3, September-December.
- Klonsky, Karen and Laura Tourte. 1995. Statistical Review of California's Organic Agriculture, 1992-93. Report prepared for the California Department of Food and Agriculture Organic Program. Cooperative Extension, Department of Agricultural Economics, University of California, Davis.
- Klonsky, Karen and Laura Tourte. 1998a. 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.
- Klonsky, Karen and Laura Tourte. 1998b. Organic Agricultural Production in the United States: Debates and Directions. *Amer. J. Agr. Econ.* Vol. 80, No. 5: 1119-1124.
- Klonsky, Karen, Laura Tourte, Robin Kozloff, and Benjamin Shouse. 2000. Statistical Review of California Organic Agriculture, 1995-98, forthcoming.
- Lohr, Luanne. 1998. Implications of Organic Certification for Market Structure and Trade. *Amer. J. Agr. Econ.* Vol. 80, No. 5: 1125-1129.
- Mergentime, Ken. 1997. "Organic Fraud Case Deepens; Possible Link Causes OCIA Turmoil," *the Natural Foods Merchandiser*, March.
- Mergentime, Ken and Monica Emerich. 1995. Organic Sales Jump Over \$2 Billion Mark in 1994. *Natural Foods Merchandiser* (June): 74-76.
- Mergentime, Ken and Monica Emerich. 1996. Widening Market Carries Organic Sales to \$2.8 Billion in 1995. *Natural Foods Merchandiser* (June): 36-38.
- Misra, Sukant, Chung L. Huang, and Stephen L. Ott. 1991. *Georgia Consumers' Preference for Organically Grown Fresh Produce*. *Journal of Agribusiness* (Fall): 53-65.
- National Commission on Small Farms. 1998, A Time to Act: A Report of the USDA National Commission on Small Farms, Miscellaneous Publication 1545, January.
- Natural Foods Merchandiser. 1995. Organic Update: Reciprocity Controversies Intensify, Exacerbating Certifier/Manufacturer Tensions. April.
- Organic Farming Research Foundation. 1999. Final Results of the Third Biennial National Organic Farmers' Survey. E. Walz, Program Coordinator. Santa Cruz, CA.
- Organic Farming Research Foundation. 2000. "Organic Certifiers Directory," on-line publication, www.ofrf.org.

Park, Timothy A. and Luanne Lohr. 1996. *Supply and Demand Factors for Organic Produce*. American Journal of Agricultural Economics, Vol.78 (August): 647-655.

Scott, Mary. 1997. "Olive Oil Company Accused of Fraud," *Natural Foods Merchandiser*, December.

Scott, Mary. 1997. "OFMA Activists Urge States to Enact Organic Laws," *Natural Foods Merchandiser*, May.

Scowcroft, Bob. 1998. "Organic Standards and Enforcement: The Public's Right to Know," *Organic Farming Research Foundation, Information Bulletin Newsletter, Number 5, Summer Issue*.

Thompson, Gary D. 1998. *Consumer Demand for Organic Foods: What We Know and What We Need to Know*. Amer. J. Agr. Econ. Vol. 80, No. 5: 1113-1118.

Underhill, S. E. and E. E. Figueroa. 1993. *Consumer Preferences for Non-Conventionally Grown Produce*. Paper presented at the Valuing Food Safety and Nutrition Conference, organized by the NE-165 Regional Research Project. Alexandria, VA, June 2-4.

USDA Foreign Agricultural Service. 1995. *Agricultural Situation: Agricultural Highlights, Winter 1995*. Report from Austria. Code 24, Sequence No. 007.

USDA Foreign Agricultural Service. 1995. *Agricultural Situation: Organic Food*. Report from Germany. Code 24, Sequence No. 011.

USDA Foreign Agricultural Service. 1996. *Agricultural Situation: Organic Food Market Potential and Regulations*. Report from France. Code 24, Sequence No. 002.

USDA Foreign Agricultural Service. 1999a. *Report on organic agriculture in Japan*. Attache report JA91234. October 5.

USDA Foreign Agricultural Service. 1999b. *Report on organic agriculture in France*. Attache report FR9070. October 18.

U.S. Senate. 1999. Report 106-80. *Agriculture, Rural Development, Food and Drug Administration, and Related Agencies Appropriation Bill 2000*. Committee on Appropriations. Page 56.

Weaver, Robert D., David J. Evans, and A. E. Luloff. 1992. *Pesticide Use in Tomato Production: Consumer Concerns and Willingness-to-Pay*. *Agribusiness*, Vol.8 No.2: 131-142. Table 1.

TABLE 3 -- U.S. ORGANIC PRODUCT SALES, 1990-99 (\$ billions)

Year	Export	Direct	Export/Direct Subtotal	Mass Market	Natural Foods Stores	Natural Foods Stores (1999 \$)	Total Sales	Total Sales (1999 \$)
1990	--	--	--	--	--	--	1	1.27
1991	0.04	0.27	0.31	0.09	0.85	1.04	1.25	1.53
1992	0.07	0.32	0.39	0.12	1.03	1.22	1.54	1.83
1993	0.11	0.36	0.47	0.14	1.29	1.49	1.90	2.19
1994	0.20	0.39	0.60	0.17	1.54	1.73	2.31	2.60
1995	1/	1/	0.71	0.21	1.87	2.04	2.79	3.05
1996	--	--	1/	1/	1/	1/	3.5	3.72
1997	--	--	--	--	2/	--	--	--
1998	--	--	--	--	3.28	3.35	--	--
1999	--	--	--	--	4.00	4.00	--	--

Source: Natural Foods Merchandiser, New Hope Communications. -- = Not reported.

1/ New Hope Communications reported a combined estimate for export and direct sales in 1995 and reported a different set of subcategories in 1996 and has reported only on sales in natural foods stores since 1996.

2/ New Hope Communications did not estimate natural product store sales in 1997, but the Hartman Group estimated these sales at \$4.9 billion.

**TABLE 4 -- FIRST-YEAR CERTIFICATION COSTS, FROM GRAF AND LOHR ANALYSIS
(dollars)**

Certifying agent	Small farm	Medium farm	Large farm	Super farm
CCOF	850	1,750	4,850	51,250
FVO	698	1,737	5,214	51,550
FOG	810	1,860	4,860	51,210
NOFA-VT	335	535	585	585
NC/SCS	700	900	1,000	2,000
OGBA	1,290	3,300	12,300	33,296
OTCO-In	608	1,603	2,517	150,300
OTCO-Out	768	1,698	2,852	12,052
OCIA-WI	315	1,590	6,090	75,090
OCIA-VA	258	320	495	1,745
TDA	90	155	200	575
WSDA	480	1,555	3,040	12,480
Average cost	579	1,414	3,623	33,276

Notes:

- CCOF--California Certified Organic Farmers
- FVO--Farm Verified Organic
- FOG--Florida Certified Organic Growers & Consumers
- NOFA-VT--Northeast Organic Farming Association - Vermont
- NC/SCS--NutriClean/Scientific Certification Systems
- OBBA--Organic Growers and Buyers Association
- OTCO-In--Oregon Tilth Certified Organic, inside Oregon
- OTCO-Out--Oregon Tilth Certified Organic, outside Oregon
- OCIA-WI--Organic Crop Improvement Association, Wisconsin chapter
- OCIA-VA--Organic Crop Improvement Association, Virginia chapter
- TDA--Texas Department of Agriculture
- WSDA--Washington State Department of Agriculture
- Small farm--25 acres with annual sales of \$30,000.
- Medium farm--150 acres with annual sales of \$200,000.
- Large farm--500 acres with annual sales of \$800,000.
- Super farm--3,000 acres with annual sales of \$10,000,000.

TABLE 5 – SUBSEQUENT-YEAR CERTIFICATION COSTS, FROM GRAF AND LOHR ANALYSIS (dollars)

Certifying agent	Small farm	Medium farm	Large farm	Super farm
CCOF	425	1,300	4,350	50,550
FVO	510	1,499	4,851	51,187
FOG	325	845	2,525	25,525
NOFA-VT	300	500	550	550
OTCO-In	454	1,811	2,362	11,363
OTCO-Out	424	1,353	2,207	11,208
OCIA-WI	290	1,585	6,065	75,065
OCIA-VA	233	295	470	1,720
TDA	90	155	200	515
WSDA	330	1,375	2,800	12,000
NC/SCS	700	900	1,000	2,000
Average cost	371	1,036	2,489	21,971

Notes:

- CCOF--California Certified Organic Farmers
- FVO--Farm Verified Organic
- FOG--Florida Certified Organic Growers & Consumers
- NOFA-VT--Northeast Organic Farming Association - Vermont
- NC/SCS--NutriClean/Scientific Certification Systems
- OBBA--Organic Growers and Buyers Association
- OTCO-In--Oregon Tilth Certified Organic, inside Oregon
- OTCO-Out--Oregon Tilth Certified Organic, outside Oregon
- OCIA-WI--Organic Crop Improvement Association, Wisconsin chapter
- OCIA-VA--Organic Crop Improvement Association, Virginia chapter
- TDA--Texas Department of Agriculture
- WSDA--Washington State Department of Agriculture
- Small farm--25 acres with annual sales of \$30,000.
- Medium farm--150 acres with annual sales of \$200,000.
- Large farm--500 acres with annual sales of \$800,000.
- Super farm--3,000 acres with annual sales of \$10,000,000.

TABLE 6 – COSTS OF ACCREDITATION AND CERTIFICATION
Estimated costs to certifying agents during first 18 months

<u>Application fee</u> ¹	<u>\$0</u>
Site evaluation costs (two person team)	
Per diem (3 to 5 days at \$85/day)	\$510 to \$850
Travel (domestic)	\$1,000 to \$1,200
Hourly charges (not billed during the first 18 months)	\$0
<u>Miscellaneous charges (copying, phone, and similar costs)</u>	<u>\$50</u>
Total	\$1,560 to \$2,100

Estimated costs to certifying agents for initial accreditation after first 18 months

Site evaluation costs (two person team)	\$510 to \$850
Per diem (3 to 5 days)	\$1,000 to \$1,200
Travel (domestic)	\$4,560 to \$7,600
Hourly charges (24 to 40 hours at \$95/hour)	\$50
<u>Miscellaneous charges (copying, phone, and similar costs)</u>	<u>\$50</u>
Total	\$6,120 to \$9,700

Annual review fees for certifying agents (2 to 8 hours at \$95/hour)² \$190 to \$760

Estimated costs to producers for certification³

Certification fee (renewals) \$730

Estimated costs to handlers for certification⁴

Certification fee (initial certification) \$2,337
Certification fee (renewals) \$1,065

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, 8 hours to certify; (3) large farm (commercial farm): 500 acres, \$800,000 annual sales, 8 hours to certify; and (4) super farm: 3,000 acres, \$10,000,000 annual sales, 16 hours to certify. Our estimated certification fees only include those charged for small and medium farms because most organic producers fall into these categories as defined by Graf and Lohr. In the 1997 OFRF survey, 90 percent of respondents had gross organic farming income of less than \$250,000, with 82 percent less than \$100,000.

The average current certification cost for most organic producers is about \$1,025 for the first year of certification (\$579 for small and \$1,414 for medium farms) and about \$705 for subsequent years (\$371 for small and \$1,036 for medium farms). Approximately \$25 is added to cover the costs associated with the National Organic Program for an estimated first-year certification fee of \$1,000 and subsequent-year certification fee of \$730 for producers. Larger producers could expect higher fees.

⁴ Because Graf and Lohr do not estimate certification fees for handlers, we estimate these fees by applying a ratio of handler-to-producer certification fees from the regulatory impact assessment from 1997. The ratio is 2:28 and results in estimated fees of \$2,337 and \$2,665, respectively.

TABLE 7 – ESTIMATED ANNUAL REPORTING AND RECORDKEEPING BURDEN

Type of respondent	Annual hours per respondent	Hourly rate	Annual cost
Certified producer	24	\$23	\$552
Certified handler	63	\$23	\$1,449
Exempt producers and handlers	1	\$23	\$23
Certifying agency	1,068	\$27	\$27,729

Note: Estimates derived from Paperwork Reduction Act of 1995 analysis.

Appendix B.—Unfunded Mandates Reform Act

This rule has been reviewed under the Unfunded Mandates Reform Act (P.L. 104-4). The Act requires that agencies prepare a qualitative and quantitative assessment of the anticipated costs and benefits before issuing any rule that may result in annual expenditures by State, local, and tribal governments, in the aggregate, or by the private sector of \$100 million (adjusted annually for inflation) in any 1 year. According to the Act, the term, "Federal mandate," means any provision in legislation, statute, or regulation that would impose an enforceable duty upon State, local, or tribal governments or the private sector, except a duty arising from participation in a voluntary Federal program.

The National Organic Foods Production Act (OFPA) of 1990 mandates that the Secretary develop a national organic program to accredit eligible governing State officials or private persons as certifying agents who would certify producers or handlers of agricultural products that have been produced using organic methods as provided for in the OFPA. The OFPA also permits a governing State official to voluntarily establish a State organic program (SOP) if the program is approved by the Secretary and meets the requirements of the OFPA. The OFPA does not require that States establish their own SOP's or that State, local, or tribal governments or the private sector become accredited; therefore, the OFPA is not subject to the Unfunded Mandates Reform Act because it is a voluntary program.

Although the U.S. Department of Agriculture has determined that this rule is not subject to the Unfunded Mandates Reform Act, USDA has sought to consider the rule's impact on various entities. USDA prepared a Regulatory Impact Assessment (RIA) that is discussed in the section entitled "Executive Order 12866" (also attached as an appendix to this regulation). The RIA consists of a statement of the need for the action, an examination of alternative approaches, and an analysis of the benefits and costs. Much of the analysis is necessarily descriptive of the anticipated impacts of the rule. Because basic market data on the prices and quantities of organic goods and services and the costs of organic production are limited, it is not possible to provide quantitative estimates of all benefits and costs of the rule. The cost of fees and recordkeeping required by USDA are quantified, but the anticipated benefits are not. Consequently, the analysis does not contain an estimate of net benefits.

The analysis employed in reaching a determination that this rule is the least costly and least burdensome to the regulated parties is discussed in the sections entitled "The Regulatory Flexibility Act and the Effects on Small Businesses" and "Paperwork Reduction Act of 1995." The rule has been designed to be as consistent as possible with existing industry practices, while satisfying the specific requirements of the OFPA.

We have had numerous occasions during which to communicate with various entities during the development of the rule; States, for example. Currently, there are 32 States with some standards governing the production or handling of organic food and 13 States with organic certifying programs. Representatives of State governments have participated in public meetings with the National Organic Standards Board, while the NOP staff has made presentations, received comments, and consulted with States and local and regional organic conferences, workshops, and trade shows. States have been actively involved in training sessions for organic inspectors; public hearings concerning standards for livestock products during 1994; a national Organic Certifiers meeting on July 21, 1995; a USDA-hosted meeting on February 26, 1996; a State certifiers meeting in February 1999; and an International Organization for Standardization (ISO) 65 assessment training session for certifiers in April-May 1999. More detail about contact with States regarding this rule is in the Federalism section. It is unknown at this time how many States, if any, might voluntarily establish their own SOP's pursuant to the OFPA and the regulations.

Appendix C -- Final Regulatory Flexibility Analysis

The Regulatory Flexibility Act (5 U.S.C. 601 et seq.) requires agencies to consider the economic impact of each rule on small entities and evaluate alternatives that would accomplish the objectives of the rule without unduly burdening small entities or erecting barriers that would restrict their ability to compete in the market. The purpose is to fit regulatory actions to the scale of businesses subject to the action.

1. Need for and objectives of the National Organic Rule

Currently, organic certification is voluntary and self-imposed. Members of organic industries across the United States have experienced numerous problems marketing their organically produced and handled agricultural products. Inconsistent and conflicting organic production standards may have been an obstacle to the effective marketing of organic products. There are currently 36 private and 13 State organic certification agencies (certifying agents) in the United States, each with its own standards and identifying marks.

Some existing private certifying agents are concerned that States might impose registration or licensing fees which would limit or prevent private certification activities in those States. Labeling problems have confronted manufacturers of 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.

In 1990, Congress enacted the Organic Foods Production Act of 1990, as amended (7 U.S.C. 6501 et seq.) (OFPA). The OFPA requires all agricultural products labeled as "organically produced" to originate from farms or handling operations certified by a State or private agency that has been accredited by USDA.

The purposes of the OFPA, set forth in section 2102 (7 U.S.C. 6501), are to: (1) establish national standards governing the marketing of certain agricultural products as organically produced products; (2) assure consumers that organically produced products meet a consistent standard; and (3) facilitate commerce in fresh and processed food that is organically produced. The National Organic Program (NOP) is the result of the OFPA. Recently, the Organic Trade Association published *American Organic Standards, Guidelines for the Organic Industry* (AOS). However, not all participants in the organic industry elected to participate in developing the AOS. Many certifying agents preferred to wait for implementation of the national standards, and some certifying agents disagree with portions of the AOS. For these reasons, USDA will implement a regulation for the NOP. .

2. Summary of the significant issues raised by public comments in response to the Initial Regulatory Flexibility Analysis (IRFA), a summary of agency assessment of such issues, and a statement of any changes made in the final rule as a result of such comments.

Although we received many individual comments in reference to the proposed rule's IRFA, they were, for the most part, variations of several form letters. Most of the concern on the

part of commenters regarded the fees that small certifying agents would be subject to under the rule.

Comments Accepted:

(1) We received numerous comments to the effect that the fees, recordkeeping, and paperwork requirements for producer and handler certification must be kept as low as possible while still offering a quality certification program. We believe that we have made every effort in this rule to minimize the cost and paperwork burden to certifiers and certified operations as much as possible. We have permitted certifiers and certified operations to develop their own recordkeeping and reporting systems-so long as they conform to the needs of the program. For the most part, the paperwork and recordkeeping requirements for certified operations conform to the requirements that they presently face under existing certification programs. In order to minimize the cost to the industry of transitioning to a system where certifying agents are accredited (assuming that there will be a learning curve as agents familiarize themselves with the requirements of accreditation), we have waived the per-hour cost that USDA will charge to conduct an accreditation review for the first 18 months of the program.

(2) In the proposed rule, we requested comment on the benefits of an exemption for small certifiers similar to that for small producers. We received comments in opposition to such an exemption because commenters wanted to maintain documented verification of standards that is afforded by certification and accreditation. They felt that exemptions weakened the organic system in its ability to assure consumers of products that meet a consistent standard. We concurred with this comment and have not developed an exemption for certifiers in the final rule.

Comments Rejected:

(3) We received comments suggesting that, in order to lower the direct cost of accreditation to smaller certifier applicants, we should eliminate on-site visits during accreditation or extend the time beyond the initial on-site visit for a subsequent visit. Although eliminating the on-site visits would certainly lower the applicant's costs, we have not made the change to reduce or eliminate on-site visits. We did not see how USDA could make an informed decision about whether or not to continue to accredit a certifying agent without complete access to the relevant records documenting the agent's business practices. This can only be efficiently done through a site visit.

(4) We received numerous comments that the fees proposed by USDA will result in certification fees that are excessive for small farming operations. The commenters suggested that USDA impose fees on a sliding scale based on a farmer's income so as not to drive these farmers out of business and deprive consumers of the benefits of these operations. We received a similar comment to the Fees section of the proposed rule, and our response is the same. Although one of our top priorities is assisting the small farmer, AMS is primarily a user-fee-based Federal agency. We are aware that our accreditation fees will figure into the fees that certifiers charge their clients. However, the fee we will charge to accredit an applicant is based not on earning profits, but on recovery of costs. In addition, our waiver of the hourly service charges for accreditation during the first 18 months of the program should help to keep the cost of accreditation to certifying agents down. We believe the requirements that fees charged by a certifying agent must be reasonable and that certifiers must file a fee schedule for approval by the Administrator will help to keep costs under control. Since certifiers are required to provide their approved fee schedules to applicants for certification, the applicants will be able to base their selection of certifying agent on price if the applicants so choose. In addition, nothing in the regulations precludes certifying agents from pricing their services on a sliding scale

so long as their fees are consistent and nondiscriminatory and are approved during the accreditation process.

(5) Other commenters were concerned that in the rule USDA neglects to establish "reasonable fees" annually for farm/site/wild crop production and handling operation certification. Commenters did not believe that a valid Regulatory Flexibility Act analysis could be made without the annual farm and handling operation fee projection. We have not established guidelines for what constitutes a "reasonable fee" in the final rule. Accredited certifying agents will be required to submit a proposed fee schedule as a part of their application. At that time, we will work with applicants for accreditation to ensure that their fees are appropriate. In addition, certifying agents will be required to send a copy of their fee schedule to anyone who requests one. This will allow operations that wish to be certified to shop around and will provide a disincentive for accredited agents to price themselves out of the market.

3. Description of and an estimate of the number of small entities to which the rule will apply. Small business size standards, Standard Industrial Code (SIC) (13 CFR part 121), are developed by an interagency group, published by the Office of Management and Budget, and used by the Small Business Administration (SBA) to identify small businesses. These standards represent the number of employees or annual receipts constituting the largest size that a for-profit enterprise (together with its affiliates) may be and remain eligible as a small business for various SBA and other Federal Government programs.

There are three categories of operations that contain small business entities that would be affected by this rule: certifying agents, organic producers, and/or organic handlers. The term, "certifying agent," means the chief executive officer of a State or, in the case of a State that provides for the statewide election of an official to be responsible solely for the administration of the agricultural operations of a State, such official and any person (including private entities) who is accredited by the Secretary as a certifying agent for the purpose of certifying a farm or handling operation as a certified organic farm or handling operation.

According to the most complete data available to USDA's Agricultural Marketing Service (AMS), there are 49 certifying agents (36 private and 13 State) in the United States. More than half of the private and State certifying agents certify both producers and handlers, while the others certify only producers. Over three-fourths of private and State certifying agents each certify fewer than 150 producers and 20 handlers. The number of certifying agents has remained fairly stable, between 40 and 50, for some years, with entries and exits tending to offset each other. The NOP staff anticipates that, in addition to the 49 domestic certifying agents, 10 foreign certifying agents may seek accreditation during the initial phase of the program.

Small businesses in the agricultural services sector, such as certifying agents, include firms with average annual revenues of less than \$5 million (SIC Division A Major Group 7). Based on SBA's small business size standards for the agricultural services sector, it is not likely that many, if any, of the 49 domestic certifying agents have annual revenue greater than \$5 million. All private, nonprofit certifying agents would be considered small by SBA's standards. Based on anecdotal information, only a few private, for-profit, certifying agents might be categorized as large businesses. In addition, the 13 State certifying agents, although not exceeding the revenue threshold, would not be considered to be small entities under the Act as only government jurisdictions with populations under 50,000 are considered to be small entities under section 601(5). Therefore, at least 30 certifying agents would qualify as a small business.

The term, "producer," means a person who engages in the business of growing or producing food or feed. It is more difficult to establish the number of organic producers. Organic farming was not distinguished from conventional agriculture in the 1997 Census of Agriculture. There are sources which give insight into the number of producers. The Organic Farming Research Foundation (OFRF), a California-based nonprofit organization, has conducted three nationwide surveys of certified organic producers from lists provided by cooperating certifying agents. The most recent survey applies to the 1997 production year (1). OFRF sent its 1997 survey to 4,638 names and received 1,192 responses. Because OFRF did not obtain lists from all certifying organizations or their chapters (55 out of a total of 64 identified entities provided lists), its list count is likely an understatement of the number of certified organic producers. Note that the estimated number of organic producers includes only certified organic farms. Comments filed in response to the first proposal and studies indicate that the total number of organic farms is higher.

Dunn has estimated the number of certified organic producers in the United States (2, 3) Dunn's 1995 work, a USDA study, estimated the number of certified producers at 4,060 in 1994; this estimate was used in the first proposal. Dunn's 1997 work reported 4,060 certified organic farms in 1994 and 4,856 in 1995.

Data collected by AMS indicate that the number of organic farmers increased about 12 percent per year during the period 1990 to 1994. OFRF survey efforts indicate that growth has continued, although it is not clear whether the growth rate has changed. Similarly, growth in retail sales, the addition of meat and poultry to organic production, and the possibility of increased exports suggest that the number of operations has continued to increase. Lacking an alternative estimate of the growth rate for the number of certified organic producers, we use the average growth rate of about 14 percent from Dunn's 1997 study. The true rate of growth could be higher or lower. Applying the 14-percent growth rate to Dunn's estimate of certified producers in 1995 gives an estimate of 8,200 organic producers for 1999.

An adjustment is needed to account for the number of producers who are practicing organic agriculture but who are not certified and who would be affected by this regulation. We assume that the number of organic but not certified producers in 1999 is about 4,000. This assumption is based on very limited information about the number of registered but not certified organic producers in California in 1995. Thus, the total number of certified organic producers used in assessing the impact of the rule is 12,176.

Producers with crop production (SIC Division A Major Group 1) and annual average revenues under \$500,000 are small businesses. Producers with livestock or animal specialties are also considered small if annual average revenues are under \$500,000 (SIC Division A Major Group 2), with the exception of custom beef cattle feedlots and chicken eggs, which are considered small if annual average revenues are under \$1,500,000.

Based on SBA's small business size standards for producers, it is likely that almost all organic producers would be considered small. The OFRF survey asked for the producer's total gross organic farming income during 1997. Only 35 (less than 3 percent) of the survey respondents reported gross income greater than \$500,000, the SBA's cutoff between small and large businesses. Over 70 percent reported gross income of less than \$50,000. The OFRF survey does caution readers about potential survey "errors." It is particularly important to emphasize potential "non-response error"; that is, it is unknown if those who responded to the survey accurately represent the entire population of certified organic growers. Also, some producers combine organic and conventional production on the same operation, some with total sales that may exceed \$500,000. However, it is likely that a majority of organic producers would be considered small. We have estimated that there would be 12,176

producers certified in the first year and of those 97 percent, or 11,811, based on OFRF's survey results, would qualify as a small business.

The term, "handler," means any person engaged in the business of handling agricultural products, excluding final retailers of agricultural products that do not process agricultural products. Little information exists on the numbers of handlers and processors. USDA has estimated that there were 600 entities in this category in 1994. In California, there were 208 registered organic processed food firms in 1995 and 376 in 1999, a growth rate of 20 percent (4). We assume that this growth rate is applicable to the U.S. and project 2,077 certified handlers in 2001. This figure includes 100 livestock feed handlers who would become certified organic. Again, the rate of growth could be higher or lower.

In handling operations, a small business has fewer than 500 employees (SIC Division D Major Group 20). It is also likely that the vast majority of handlers would be considered small, based on SBA's small business size standards for handlers. Based on informal conversations with organic certifying agents, currently, about 25 (about 2 percent) of the estimated 1,250 organic handlers in 1999 had more than 500 employees. This includes firms that handle or process both organic and conventional foods. We have estimated that 2,077 handlers would be certified organic in the first year. Based on this information, 98 percent or 2,035 would qualify as a small business.

4. An estimate of the projected reporting, recordkeeping, and other compliance requirements of the rule, including an estimate of the classes of small entities which will be subject to the requirement and the type of professional skills necessary for preparation of the report or record.

The reporting, recordkeeping, and compliance requirements of the rule will directly affect three sectors of the organic industry that contain small business entities: accredited certifying agents, organic producers, and organic handlers. We have examined the requirements of the rule as it pertains to each of these entities, however several requirements to complete this Regulatory Flexibility Analysis (RFA) overlap with the Regulatory Impact Assessment (RIA) and the Paperwork Reduction Act (PRA) section. In order to avoid duplication, we combine some analyses as allowed in section 605(b) of the Act. This RFA provides information specific to small entities, while the RIA or PRA should be referred to for more detail. For example, the RFA requires an analysis of the rule's costs to small entities. The RIA provides an analysis of the benefits and costs of this regulation. This RFA uses the RIA information to estimate the impact on small entities. Likewise, the RFA requires a description of the projected reporting, recordkeeping, and other compliance requirements of the final rule. The PRA section estimates the reporting and recordkeeping (information collection) requirements that would be required by this rule from individuals, businesses, other private institutions, and State and local governments. The burden of these requirements is measured in terms of the amount of time required of program participants and its cost. This RFA uses the PRA information to estimate the burden on small entities.

Certifying Agents

We have identified 36 private certifying agents and 13 State programs providing certification. These 49 domestic entities are considered likely applicants during the first 12 months, as are an estimated 10 foreign certifying agents. An unknown number of new entrants to the certifying business may also apply. However, over the last 10 years, the number of certifying agents does not appear to have grown significantly, with the net effect of entries and exits maintaining a population of U.S.-based certifying agents at about 40 to 50. Of the 49 domestic certifying agents, based on information discussed previously, we estimate that 30 of the 36 private certifying agents are small businesses.

The recordkeeping and paperwork requirements are outlined in the Paperwork Reduction Act section. The requirements for small and large certifying agents are identical. The

recordkeeping and paperwork requirements for accreditation will be a new burden to most agents as the majority of them have not been accredited in the past. However, the actual amount of the additional administrative costs that would be imposed by the final rule is expected to be different for those entities that would begin their activities only after the national program is implemented. Certifying agents that currently are active in the organic industry already perform most of these required administrative functions; therefore, the additional costs to them would depend upon the extent to which their current practices are different from the requirements of the final regulation. Because the rule does not require any particular system or technology, it does not discriminate against small businesses. The ability of an agent to carry out the paperwork and record keeping sections of the rule will be more dependent on the administrative skill and capacity of their particular organization than their size. We did not receive significant comments about the paperwork requirements of the proposed rule that would indicate that they will be onerous for small certifying agents.

Certifying agents will be the front line in monitoring and ensuring that certified operations stay in compliance with the Act and the regulations. However, most of the compliance requirements, with the exception of some reporting requirements, are consistent with what certifiers are currently expected to do. Like the paperwork and reporting requirements, the additional costs to an agent will depend on how different their current practices are from the final regulation.

The final, and probably most significant, area in which certifying agents are affected by the rule is in the fees that they must pay for accreditation. Certifying agents will be assessed for the actual time and travel expenses necessary for the NOP to perform accreditation services, including initial accreditations, 5-year renewals of accreditation, review of annual reports, and changes to accreditation. Although the fees have not been set yet, we are using as a starting point the hourly fees that are charged for the voluntary, fee-for-service program provided by AMS to certification bodies requesting conformity assessment to the ISO Guide 65, "General Requirements for Bodies Operating Product Certification Systems." We expect that at the time the NOP's final rule is implemented, the fees will be approximately \$95 per hour with higher overtime and holiday rates. Certifying agents will also be charged for travel, per diem, and other related costs associated with accreditation. To ease the financial burden of accreditation during the 18 month transition period after the NOP has been implemented, USDA will not impose hourly charges on certifying agents. The direct costs for certifying agents to obtain accreditation will be limited to per diem and transportation costs to the site evaluation. Review of the certifying agent's annual report is anticipated to range from 2 to 8 hours at the ISO Guide 65 hourly rate. Also, if certifying agents wish to become accredited in additional areas for which they were not accredited previously, a site evaluation (with associated fees) will be necessary. Detail about the expected costs of accreditation can be found in the RIA.

Several factors will influence the amount of time needed to complete an accreditation audit. An operation in which documents are well organized and that has few nonconformities within the quality system will require less time for an audit than an organization in which documents are scattered and there are many nonconformities (7). Similarly, in a 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 non-organic ingredients, and establish that foreign-produced ingredients originate from approved entities. Finally, the complexity of the agricultural practices certified could influence the amount of time necessary to complete an accreditation audit. An agency whose certification covers only producers who grow and harvest one crop per field per year, such as wheat or sugar beets, could quickly be audited. An agency whose producers grow several different crops per field per year or an agency that certifies producers of crops and livestock as well as handlers would require a greater amount of time.

All of these factors will affect both small and large certifying agents. A small certifying agent could be assumed to have a less complex organization or have fewer clients, and, thus, potentially less time would be necessary for review. However, other factors, such as the degree of paperwork organization or the complexity of the agricultural practices certified, may influence the time needed for review for any size of business.

Currently, relatively few certifying agents have third-party accreditation because accreditation of certifying agents is voluntary. Fetter reports that in a sample of 18 certification programs, selected to include six large, private programs, six smaller private programs, and six State programs, four programs were accredited and one had accreditation pending (8). All of these were large private certifying agents. Three of the certifying agents identified by Fetter as accredited requested ISO Guide 65 assessments by USDA and have been approved for selling organic products into the international market. Those certifying agents currently accredited by third parties will likely pay less for USDA accreditation because their documents are organized and they have fewer nonconformities.

It is expected that all certifying agents will set their fee schedule to recover costs for their certification services, including the costs of accreditation. The larger the number of clients per certifying agent, the more fixed costs can be spread out. It is possible, however, that small certifying agents could be significantly affected by this final rule and may not be able to continue in business from a financial standpoint.

Costs to Producers and Handlers

The OFPA established a small farmer exemption from certification and submission of organic plans for small producers with a maximum of \$5,000 in gross sales of organic products. For purposes of the exemption, the OFPA defines a "small farmer" as those who sell no more than \$5,000 annually in value of agricultural products. In this rule, we have clarified that the exemption applies to producers and handlers who sell no more than \$5,000 annually in value of organic products (9). In addition, handling operations are exempt if they: are a retail food establishment that handles organically produced agricultural products but does not process them; handles agricultural products that contain less than 70 percent organic ingredients by weight of finished product; or does not use the word, "organic," on any package panel other than the information panel if the agricultural product contains at least 70 percent organic ingredients by weight of finished product.

A handling operation or specific portion of a handling operation is excluded from certification if it handles packaged certified organic products that were enclosed in their packages or containers prior to being acquired and remain in the same package and are not otherwise

processed by the handler, or it is a retail food establishment that processes or prepares on its own premises raw and ready-to-eat food from certified organic products.

According to the OFRF survey, 27 percent of currently certified farms that responded to the survey would fall under the producer exemption. This percentage does not take into account those organic farms that are not currently certified by a private or State certifying agent. A study of California organic farms found that, of all organic farms (10) in 1994-95, about 66 percent have revenues less than \$10,000 (11). If California is representative and the distribution within the sub-\$10,000 category is uniform, then a third of the farms would be classified as small for purposes of the statutory exemption with annual sales less than \$5,000. Based on the California study and the OFRF survey results, we estimate that between 25 and 33 percent of organic producers are small and would qualify for exemption from the certification requirements.

We have estimated that there are 4,801 small organic producers and 173 handlers that will be exempt from certification (this figure does not include excluded operations). These operations would be required to comply with the production and handling standards and labeling requirements set forth under the NOP. They do not have to meet the paperwork requirements of certification and they must only keep records that document compliance with the law for 3 years (rather than 5 for certified operations). We anticipate that this exemption will be used primarily by small market gardeners and hobbyists who grow and process produce and other agricultural products for sale at farmers markets and roadside stands to consumers within their communities.

Exempt producers will be allowed to market their products as organically produced without being certified by a certifying agent. Products marketed by exempt producers cannot be represented as certified organic or display the USDA organic seal. Products produced or handled on an exempt operation may be identified as organic ingredients in a multi-ingredient product produced by the exempt operation, but they may not be identified as organic in a product processed by others. These limitations may discourage some small producers from seeking exemption, who instead may choose to become certified. In this case, the costs of certification would apply. The value associated with having organic certification may outweigh the costs of certification.

As with accredited certifying agents, the regulation will impose administrative costs on certified producers and handlers for reporting, recordkeeping, residue testing, and other compliance requirements. The actual amount of the additional administrative costs that would be imposed by the final rule is expected to be different for those entities that become certified only after the national program is implemented. Producers and handlers who currently are active in the organic industry already perform most of these administrative functions; therefore, the additional costs to them would depend upon the extent to which their current practices differ from the requirements of the final regulation. Projected reporting, recordkeeping, and other compliance requirements of certifying agents are discussed in greater detail in the PRA and the RIA. The only distinction made in the final rule between large and small entities for reporting, recordkeeping, and compliance is for operators who produce less than \$5000 per year in organic products as stated above.

As with the certifying agents, most of the concern this rule generated for small certified operations revolves around fees. Under this rule, USDA will not impose any direct fees on producers and handlers. Certifying agents will establish a fee schedule for their certification services that will be filed with the Secretary and posted in a place accessible to the public. Certifying agents will provide all persons inquiring about the application process with a copy of their fees. The certifying agent may only charge those fees that it has filed with the Secretary. Furthermore, the certifying agent will provide each applicant with an estimate of the total cost of certification and an estimate of the annual costs of updating the certification.

Currently, supply and demand for certification services determine the fees charged in most areas. Some States charge minimal fees for certification and instead subsidize operating costs from general revenues. According to separate studies by Fetter, and Graf and Lohr, the majority of certifying agents structure their fee schedules on a sliding scale based on a measure of size, usually represented by the client's gross sales of organic products but sometimes based on the acres operated. Some certifying agents charge an hourly rate for inspection and audit services.

Graf and Lohr's study indicates that even small farms require significant time for the certification process, and this time does not increase proportionately as farm size increases. None of the existing certification programs mention costs for residue testing, which the NOP will require in the form of preharvest testing when there is reason to believe that agricultural products have come into contact with prohibited substances. Preharvest testing is expected to be infrequent. Certifiers will recover the costs of preharvest testing through explicit charges to the producer whose crop is tested or through a generally higher fee structure that spreads the expected costs of tests over all clients.

This rule imposes no requirements that would cause certifying agents that are presently using a sliding-scale type fee schedule to abandon their current fee system. Certifying agents could recover their net additional costs by increasing their flat-fee component, their incremental charges, or both. Because accreditations are renewed only every 5 years, certifying agents will have 5 years to recover their net new costs. Certifying agents who become accredited during the first year of the program would have fewer direct costs to recover because they will not be charged the application fee and hourly charges for accreditation services.

Those currently receiving voluntary certification will likely see a modest increase as the certifying agent passes on its cost incurred under the NOP. Those not currently receiving certification and producing over \$5,000 annually in organic products will be required to become certified, and they will incur the actual costs of certification.

Some States, such as Texas and Washington, charge producers and handlers nominal fees for certification, and it is possible that more States might provide certification services as the NOP is implemented. Other States, such as Minnesota, have cost-share programs to help offset costs for organic producers.

Conclusion

This rule will primarily affect small businesses. We have, therefore, attempted to make the paperwork, recordkeeping, and compliance provisions as flexible as possible without sacrificing the integrity of the program. We are not requiring specific technologies or practices and with the 18-month phase-in of the program we are attempting to give both certifying agents and certified operators an opportunity to adapt their current practices to conform with the rule. Because we have attempted to make the rule conform with existing industry standards, including ISO guide 65 for certification and ISO guide 61 for accreditation, the changes for most organizations and operations should be relatively straightforward.

The fees required for accreditation will be the most significant change faced by most operations-and this was apparent in the comments received. While we understand the concerns of the affected organizations, in order to administer an accreditation program, it is necessary that we recover our costs. We are hoping that the elimination of the hourly charges in the first round of accreditation will help to alleviate some of this burden.

1. Organic Farming Research Foundation. 1999. *Final Results of the Third Biennial National Organic Farmers' Survey*. Santa Cruz, CA.
2. Dunn, Julie Anton. 1995. *Organic Food and Fiber: An Analysis of 1994 Certified Production in the United States*. U.S. Department of Agriculture, Agricultural Marketing Service.
3. Dunn, Julie Anton. 1997. *AgriSystems International Reports Certified Organic Production in the United States: Half a Decade of Growth*. AgriSystems International: Wind Gap, PA.
4. California Department of Health Services (DHS). 1995. *Report on the Registration of California Organic Processed Food Firms*. Sacramento: State of California. September 1999 figures obtained via personal communication with California DHS.
5. Graf, Anita and Luanne Lohr. 1999. *Analysis of certification program costs*. Working Paper, Fund for Rural America project, Market Development for Organic Agriculture Products, Grant No. 97-36200-5.
6. During the first 18 months, site evaluation for initial accreditation will be conducted jointly by two reviewers. Two reviewers offers: (1) anticipated faster 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 NOP staff and would be familiar with the requirements of the program; and (3) consistency with the organic industry's desire to have reviewers from both areas of expertise during ISO Guide 65 assessments. AMS would consider sending one reviewer, rather than two, for the site evaluation of small certification agents if an individual possessing both reviewing skill and knowledge of the NOP is available. We anticipate only one reviewer would be required after the 18-month transition period.
7. Adequate advance notice will be given to certifying agents to allow them the opportunity to organize their records prior to the audit and minimize the costs of accreditation.
8. Fetter, Robert T. 1999. *Economic Impacts of Alternative Scenarios of Organic Products Regulation*. Senior Honors Thesis. University of Massachusetts, Amherst, MA.
9. We asked for comments on the first proposal as to whether the current statutory limitation of \$5,000 for exemption from certification should be raised to \$10,000 or to another amount and why such an increased monetary limitation for exemption from certification would be appropriate. Few commenters offered recommendations as to a maximum sales volume to exempt producers. Amounts ranged from \$2,000 to \$50,000, with a few suggesting \$10,000 and \$20,000 exemptions. These proposed exemption levels and justifications in comments received are not sufficiently consistent enough for us to recommend changing the statute requirement of the \$5,000 maximum sales volume exemption.
10. California State law requires organic farmers to register with the State. Certification is voluntary at the current time.
11. Klonsky, Karen, and Laura Tourte. 1998. *Statistical Review of California's Organic Agriculture, 1992-95*. Report prepared for the California Department of Food and Agriculture Organic Program. Cooperative Extension, Department of Agricultural Economics, University of California, Davis.

Appendix D -- Executive Order 12988, Civil Justice Reform

Executive Order 12988, Civil Justice Reform, instructs each executive agency to adhere to certain requirements in the development of new and revised regulations in order to avoid unduly burdening the court system. The revised proposal was reviewed under this Executive Order. No comments were received on that review, and no additional related information has been obtained since then. This rule is not intended to have retroactive effect.

States and local jurisdictions are preempted under section 2115 of the Organic Foods Production Act (OFPA) (7 U.S.C. 6514) from creating programs of accreditation for private persons or State officials who want to become certifying agents of organic farms or handling operations. A governing State official would have to apply to USDA to be accredited as a certifying agent, as described in section 2115(b) of the OFPA (7 U.S.C. 6514(b)). States also are preempted under sections 2104 through 2108 of the OFPA (7 U.S.C. 6503 through 6507) from creating certification programs to certify organic farms or handling operations unless the State programs have been submitted to, and approved by, the Secretary as meeting the requirements of the OFPA.

Pursuant to section 2108(b)(2) of the OFPA (7 U.S.C. 6507(b)(2)), a State organic certification program may contain additional requirements for the production and handling of organically produced agricultural products that are produced in the State and for the certification of organic farm and handling operations located within the State under certain circumstances. Such additional requirements must: (a) further the purposes of the OFPA, (b) not be inconsistent with the OFPA, (c) not be discriminatory toward agricultural commodities organically produced in other States, and (d) not be effective until approved by the Secretary.

Pursuant to section 2120(f) of the OFPA (7 U.S.C. 6519(f)), this regulation would not alter the authority of the Secretary under the Federal Meat Inspection Act (21 U.S.C. 601 et seq.), the Poultry Products Inspections Act (21 U.S.C. 451 et seq.), or the Egg Products Inspection Act (21 U.S.C. 1031 et seq.), concerning meat, poultry, and egg products, nor any of the authorities of the Secretary of Health and Human Services under the Federal Food, Drug and Cosmetic Act (21 U.S.C. 301 et seq.), nor the authority of the Administrator of the Environmental Protection Agency (EPA) under the Federal Insecticide, Fungicide and Rodenticide Act (7 U.S.C. 136 et seq.).

Section 2121 of the OFPA (7 U.S.C. 6520) provides for the Secretary to establish an expedited administrative appeals procedure under which persons may appeal an action of the Secretary, the applicable governing State official, or a certifying agent under this title that adversely affects such person or is inconsistent with the organic certification program established under this title. The Act also provides that the U.S. District Court for the district in which a person is located has jurisdiction to review the Secretary's decision.

Appendix E – Executive Order 13132, Federalism

This final rule has been reviewed under Executive Order 13132, Federalism. This Order requires that regulations that have federalism implications provide a federalism impact statement that: (1) demonstrates the Agency consulted with the State and local officials before developing the final rule, (2) summarizes State concerns, (3) provides the Agency's position supporting the need for the regulation, and (4) describes how the concerns of State officials have been met. The Order indicates that, where National standards are required by Federal statutes, Agencies shall consult with appropriate State and local officials in developing those standards.

The Organic Foods Production Act (OFPA) of 1990 (7 U.S.C. 6501 *et seq.*) establishes national standards regarding the marketing of agricultural products as organically produced, assures consumers that organically produced products meet a consistent standard, and facilitates interstate commerce in fresh and processed food that is organically produced. There has been a great deal of support for this law and these regulations from the organic community.

OFPA and these regulations do preempt State statutes and regulations related to organic agriculture. OFPA establishes national standards regarding the marketing of agricultural products as organically produced, assures consumers that organically produced products meet a consistent standard, and facilitates interstate commerce in fresh and processed food that is organically produced. Currently, 32 States have organic statutes on their books and have implemented them to various degrees. However, the Act contemplates a significant role for the States and, in fact, envisions a partnership between the States and the Federal Government in meeting the requirements of the Statute. The Act allows the States to determine the degree to which they are involved in the organic program. States may choose to: (1) carry out the requirements of the Act by establishing a State organic program (SOP) and becoming accredited to certify operations, (2) establish an SOP but utilize private accredited certifying agents, (3) become accredited to certify and operate under the National Organic Program (NOP) as implemented by the Secretary, or (4) not play an active role in the NOP. 7 U.S.C. 6507 provides that States may establish an SOP consistent with the national program. SOP's may contain more restrictive requirements than the NOP established by the Secretary of Agriculture. To be more restrictive, SOP's must: further the purposes of the Act, be consistent with the Act, not discriminate against organic products of another State, and be approved by the Secretary.

Because implementation of OFPA will have a significant effect on many States' existing State statutes and programs, the U.S. Department of Agriculture (USDA) has reached out to States and actively sought their input throughout the entire process of developing the organic rule. On publication of the first proposal on December 16, 1997, an announcement and information packet summarizing the proposal was sent to more than 1,000 interested parties, including State governors and State department of agriculture secretaries, commissioners, or directors. Over a period of 6 years, numerous meetings were held to provide States an opportunity to provide information and feedback to the rule. In 1994, States were invited to participate in four public hearings held in Washington, DC; Rosemont, IL; Denver, CO; and Sacramento, CA, to gather information to guide development of standards for livestock products. States were also provided the opportunity to comment specifically on State issues at a National Organic Certifiers meeting held on July 21, 1995. They were invited to discuss accreditation issues at a meeting held on February 26, 1996. Following the publication of the first proposal, State and local jurisdictions had the opportunity to provide input at four listening sessions held in February and March 1998 in Austin, TX; Ames, IA; Seattle, WA; and New Brunswick, NJ. A meeting to discuss the role of States in the NOP was held in February 1999. A State organic certifiers meeting to discuss State issues was held at a March 2000 meeting with the National Association of State Organic Programs.

USDA also drew extensively on the expertise of States and the organic industry by working closely with the National Organic Standards Board. The Board met 12 times before publication of the proposed rule on December 16, 1997, and met five times during 1998 and 1999 and two times in 2000. States were invited to attend each of these meetings, and official State certifier representatives participated in Board deliberations in meetings held in July 1998, July 1999, and March 2000.

Public input sessions were held at each meeting to gather information from all interested persons, including State and local jurisdictions. NOP staff also received comments and consulted with States at public events. They made presentations, received comments, and consulted with States at local and regional organic conferences and workshops and at national and international organic and natural food shows. States were consulted in training sessions held for organic inspectors, as well as numerous question and answer sessions at speaking engagements of the Agricultural Marketing Service (AMS) Administrator, the NOP Program Manager, and NOP staff.

In addition, during August and September 2000, the Administrator and NOP staff engaged in extensive efforts to discuss the proposed rule. While many organizations declined opportunities for these briefings, AMS staff did meet with the National Conference of State Legislatures (NCSL) and, at their request, in lieu of a meeting, provided information to the National Governor's Association (NGA). NGA and NCSL representatives stated they were aware of the development of the final rule but offered no comments during these consultations beyond those submitted by the individual States during the proposed rule's comment period. In addition, between August and October 2000, NOP staff had telephone or e-mail contact with the State organic program directors or other State department of agriculture representatives in 25 States to determine the scope and status of each State's organic program in the context of the issuance of the final rule. These State representatives stated that they were eagerly awaiting the publication of the final rule and had already begun adjusting their programs to conform to the March 2000 proposed rule in anticipation of the publication of the final rule. Finally, States have had the opportunity to comment on two proposed rules. More than 275,000 comments were received on the first proposal, and 40,000 on the second proposed rule-including extensive comments from twelve State departments of agriculture, one State legislator, two members of Congress, and the National Association of State Organic Programs.

Through this outreach and consultation process, States have both provided general feedback to the rule and expressed several specific concerns about how this rule will affect State programs. Overwhelmingly, States were extremely supportive of the March 2000 proposed rule. With a few exceptions, most notably who should bear the cost of enforcement of an SOP, States are supportive of the Federal legislation. We did not receive a single comment from a State that indicated that there should not be a national organic program. The most prevalent issues they raised regarding the March 2000 proposed rule as to how this rule will affect organic programs in their States, along with USDA's response, are described below. We received no direct comments from States on the Federalism section in the proposed rule. Many of these concerns and others are addressed in more detail in the relevant sections of the rule.

Applicability

Regarding section 205.100(b), five States currently offer a "transition to organic" label for producers who are in the process of becoming certified. Many of these States would like to continue to offer this label. However, OFPA does not authorize a "transition to organic" label. Although the States (or private certifiers) are free to come up with a different label for these farmers, they cannot utilize the term, "organic," in any seal or labeling associated with the conversion period. There is no change in this provision from the proposed rule.

Accreditation

Regarding section 205.501(a), many States wanted the NOP to add an additional subsection to the Accreditation section requiring certifiers to prove that they can carry out a State's more restrictive standards in order to be accredited to certify in that State. AMS concurs with this suggestion and has added a new paragraph 205.502(a)(20) requiring the certifying agent to demonstrate its ability to comply with a State's additional requirements.

Regarding section 205.501(b), there was strong support by all of the States for the provision that States with SOP's are able to have higher standards than the NOP for operations within their State. However, there was not consensus among the States on the prohibition on private certifiers requiring more stringent standards.

Although most supported the prohibition on private certifiers imposing additional requirements as a condition of certification because they perceived that it lowered barriers to farmers and processors in their States, three States were strongly opposed to this provision. Because having a consistent national standard is one of the primary purposes of the legislation, there is no change in this provision from the proposed rule.

State Programs

There was general confusion about what is the difference between a State organic certification program and an SOP. In addition, some States wanted the scope of the NOP's oversight for State organic activities to be limited to certification. A State organic certification program is equivalent to a private or foreign certification program. States wishing to certify operations in their State must apply to the NOP for accreditation.

An SOP, on the other hand, requires the State to submit a plan to the NOP for approval to, in effect, administer the NOP within their State. Included in this is the opportunity to include requirements that differ from the NOP. In creating an SOP, a State is also agreeing to take on enforcement activities that would otherwise be the responsibility of the NOP. One exception to a State's enforcement authority is that States with SOP's do not have jurisdiction over the accreditation of certifying agents and cannot revoke accreditation. They can investigate and report accreditation violations to the NOP. States with only an accredited certification program are only responsible for the level of enforcement that all accredited certifying agents, State, private, or foreign, are required to take on.

Regarding section 205.620(c), several States want broader language than "unique environmental conditions" to be the basis for a State to have the right to establish more restrictive requirements under an SOP. AMS does not concur. There is no change to this language in the final rule. It is the opinion of AMS that the current language is broad enough to cover the scope of more restrictive requirements as authorized by OFPA.

Regarding section 205.620(d), many States want it to be optional for States with SOP's to take on enforcement obligations; several want funding from USDA for enforcement activities. AMS does not concur with this change. AMS does not envision that participation under the NOP will impose additional fiscal costs on States with existing organic programs, other than the costs of accreditation.

Regarding section 205.621(b), several States commented that States with SOP's should not be required to publish proposed changes to their programs in the Federal Register for public comment. AMS concurs with this comment. This language was an oversight from the first proposed rule.

Fees

A few States commented that the proposed fees for accreditation could cost more than some States could afford to pay. They made some suggestions for reducing accreditation fees,

ranging from no fees (a completely federally funded program) to charging reduced rates for travel or eliminating hourly charges. AMS has no plans to change the fee structure. As in the proposed rule, hourly charges for accreditation will be waived for all applicants in the first 18 months of the program to facilitate the conversion to a national accreditation system.

Compliance

Regarding section 205.665, several States wanted to know what their authority was to revoke the accreditation of private certifiers in their State who do not meet additional State standards under an SOP. An SOP's governing State official is authorized to review and investigate complaints of noncompliance with the Act or regulations concerning accreditation of certifying agents operating in their State. If they discover a noncompliance, they shall send a written report to the NOP program manager. Because accreditation is a Federal license, States do not have the authority to revoke a certifying agent's accreditation. There is no change in this section from the proposed rule

Appeals

Regarding section 205.668(b), several State commenters want appeals from SOP's to go to State district court rather than Federal district court. AMS disagrees. The Act provides that a final decision of the Secretary may be appealed to the U.S. District Court for the district in which the person is located. AMS considers an approved SOP to be the NOP for that State. As such, AMS considers the governing State official of such State program to be the equivalent of a representative of the Secretary for the purpose of the appeals procedures under the NOP. Because the final decision of the governing State official is considered the final decision of the Secretary, under the Act it is then appealable to the U.S. District Court, not the State district court.

Regarding section 205.680, State commenters want a process by which people who feel they were adversely affected by the organic program in a State with an SOP may appeal to the SOP's governing State official, rather than the Administrator. AMS has amended the language in section 205.680 to clarify to whom an appeal is made under various situations. If persons believe that they were adversely affected by a decision made by the NOP Program Manager, they appeal to the Administrator. If they were adversely affected by a decision made by a certifying agent (State, private, or foreign), they appeal to the Administrator unless they are in a State with an SOP, in which case, they appeal to the SOP's governing State official. If persons believe that they were adversely affected by a decision made by a representative of an SOP, they appeal such decision to the SOP's governing State official or such official's designee.

Appendix 10

Application for Accreditation to USDA's National Organic Program

FORM APPROVED - OMB NO. 0581-0191

U.S. DEPARTMENT OF AGRICULTURE AGRICULTURAL MARKETING SERVICE APPLICATION FOR ACCREDITATION	Please fax to (202) 205-7808 - mail original to: Program Manager, National Organic Program, USDA/AMS/TM/NOP Room 2945-So., Ag Stop 0288, P.O. Box 98456 Washington, DC 20090-6456
--	--

According to the Paperwork Reduction Act of 1995, an agency may not conduct or sponsor, and a person is not required to respond to a collection of information unless it displays a valid OMB control number. The valid OMB control number for this information collection is 0581-0191. The time required to complete this information collection is estimated to average 93 hours per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. The U.S. Department of Agriculture (USDA) prohibits discrimination in all its programs and activities on the basis of race, color, national origin, sex, religion, age, disability, political beliefs, sexual orientation, or marital or family status. (Not all prohibited bases apply to all programs.) Persons with disabilities who require alternative means for communication of program information (Braille, large print, audiotape, etc.) should contact USDA's TARGET Center at 202-720-2600 (voice and TDD). To file a complaint of discrimination, write USDA, Director, Office of Civil Rights, Room 328-W, Whitten Building, 14th and Independence Avenue, SW, Washington, DC 20250-8410 or call 202-720-5964 (voice and TDD). USDA is an equal opportunity provider and employer.

The undersigned hereby applies for accreditation to the National Organic Program, U.S. Department of Agriculture.

Business Name, Mailing Address, and Primary Office Location (<i>if different</i>)	Name of person responsible for day-to-day operations: Title of person responsible for day-to-day operations: Tax ID#
Telephone Number: Fax Number:	Internet address:

PLEASE ESTIMATE THE ANNUAL ANTICIPATED NUMBER OF CERTIFICATIONS FOR EACH TYPE OF ACCREDITATION

CROPS	LIVESTOCK	WILD CROP	HANDLING
-------	-----------	-----------	----------

LEGAL STATUS (Check one)

GOVERNMENT	FOR-PROFIT BUSINESS	NOT FOR PROFIT BUSINESS	OTHER (SPECIFY)
------------	---------------------	-------------------------	-----------------

I, (We), affirm that, if granted accreditation, I (we) will carry out the provisions of 7 CFR Part 205 including:

1. Accepting the certification decisions made by another certifying agent accredited or accepted by USDA;
2. Refraining from making false or misleading claims about my (our) accreditation status, the USDA accreditation program for certifying agents, or the nature or qualities of products labeled as organically produced;
3. Conducting an annual performance evaluation of all persons who review applications for certification, perform on-site inspections, review certification documents, evaluate qualifications for certification, make recommendations concerning certification, or make certification decisions and implement measures to correct any deficiencies in certification services;
4. Having an annual internal program review conducted of my (our) certification activities by myself, my (our) staff, an outside auditor, or a consultant who has the expertise to conduct such reviews and implement measures to correct any noncompliance's with the Organic Foods Production Act of 1990 (Act) and the provisions of 7 CFR Part 205;
5. Paying and submitting fees to AMS;
6. Complying with, implementing, and carrying out any other terms and conditions determined by the Administrator to be necessary;
7. (Items 7, 8, and 9 apply only to private entities)
Holding the Secretary harmless for any failure on my (our) part to carry out the provisions of the Act and 7 CFR Part 205;
8. Furnishing 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 that I (we) certify under the Act and 7 CFR Part 205;
9. Transferring to USDA and making available to the applicable State organic program's governing State official all records or copies of records concerning my (our) certification activities in the event that I (we) dissolve or lose my (our) accreditation.
Such transfer does not apply to a merger, sale, or other transfer of ownership of a certifying agent.

SIGNATURE OF APPLICANT OR REPRESENTATIVE	PRINT OR TYPE NAME OF SIGNEE
TITLE OF APPLICANT OR REPRESENTATIVE	DATE

PLEASE ATTACH:

1) A list of each organizational unit, such as chapters or a subsidiary office including the name, office location, mailing address, and contact numbers (telephone, facsimile, and internet address), and the name of a contact person for each unit; 2) A copy of the fee schedule for all services to be provided under these regulations by the applicant; 3) For a government entity, a copy of the official's authority to conduct certification services under 7 CFR Part 205; 4) For 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 it's date of establishment; 5) 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 and handling operations; 6) The requirements of 7 CFR Part 205, § 205.504, Evidence of expertise and ability.

DATE OF RECEIPT	NAME OF RECIPIENT	SIGNATURE OF RECIPIENT