DEPARTMENT OF AGRICULTURE

Agricultural Marketing Service

7 CFR Part 205

[Docket Number: TMD–94–00–2]

RIN: 0581–AA40

National Organic Program

AGENCY: Agricultural Marketing Service, USDA.

ACTION: Proposed rule.

SUMMARY: The Agricultural Marketing Service (AMS) is seeking comments on a proposal to establish a National Organic Program (NOP or program). The program is proposed under the Organic Foods Production Act of 1990 (OFPA or Act), as amended, which requires the establishment of national standards governing the marketing of certain agricultural products as organically produced to facilitate commerce in fresh and processed food that is organically produced and to assure consumers that such products meet consistent standards. This program would establish national standards for the organic production and handling of agricultural products, which would include a National List of synthetic substances approved for use in the production and handling of organically produced products. It also would establish an accreditation program for State officials and private persons who want to be accredited to certify farm, wild crop harvesting, and handling operations that comply with the program's requirements, and a certification program for farm, wild crop harvesting, and handling operations that want to be certified as meeting the program's requirements. The program additionally would include labeling requirements for organic products and products containing organic ingredients, and enforcement provisions. Further, the proposed rule provides for the approval of State organic programs and the importation into the United States of organic agricultural products from foreign programs determined to have equivalent requirements.

DATES: Comments must be submitted on or before March 16, 1998.

ADDRESSES: Interested persons are invited to submit written comments on this proposal to: Eileen S. Stommes, Deputy Administrator, USDA–AMS–TM–NOP, Room 4007–So., Ag Stop 0275, P.O. Box 96456, Washington, DC 20090–6456. Comments also may be sent by fax to (202) 690–4632. Additionally, comments may be sent via the Internet through the National Organic Program's homepage at: http://www.ams.usda.gov/nop. See the **SUPPLEMENTARY INFORMATION** section for further details on submitting comments.

FOR FURTHER INFORMATION CONTACT: Michael I. Hankin, Senior Agricultural Marketing Specialist, USDA–AMS–TM–NOP, Room 2510-So., P.O. Box 96456, Washington, DC 20090–6456; Telephone: (202) 720–3252; Fax: (202) 690–3924.

SUPPLEMENTARY INFORMATION:

Submission of Comments

Written comments submitted by regular mail and faxed comments should be identified with the docket number found in brackets in the heading of this document. Multiple page comments submitted by regular mail should not be stapled or clipped to facilitate the timely scanning and posting of these comments to the NOP homepage. Persons submitting written or faxed comments are requested to identify the topic and section number, if applicable, to which the comment refers: for example, for a comment regarding feed for organic livestock, reference Livestock and section 205.13. Topics should be selected from the following list: General, Proposed Effective Date, Regulatory Impact Assessment, Regulatory Flexibility Analysis, Paperwork Reduction Act, Definitions, Applicability (section 205.3), Crops, Livestock, Handling, National List, Labeling, Certification, Accreditation, State Programs, Fees, Compliance, Appeals, and Equivalency.

It is our intention to have all comments, whether mailed, faxed, or submitted via the Internet, available for viewing on the NOP homepage at http://www.ams.usda.gov/nop in a timely manner. Comments submitted in response to this proposal will be available for viewing at the USDA–AMS, Transportation and Marketing, Room 2945-South Building, 14th and Independence Ave., S.W., Washington, D.C., from 9:00 a.m. to 1:00 p.m., and from 2:00 p.m. to 4:30 p.m., Monday through Friday (except official Federal holidays). Persons wanting to visit the USDA South Building to view comments received in response to this proposal are requested to make an appointment in advance by calling Martha Bearer at (202) 720–8037.

Purpose and Background of the National Organic Program

Members of organic industries across the U.S. have experienced numerous problems marketing their organically produced and handled agricultural products. Inconsistent and conflicting organic production standards may have been an obstacle to the effective marketing of organic products. There are currently 33 private and 11 State organic certification agencies (certifiers), each with their own standards and identifying marks. Some existing private certifying agencies are concerned that States might impose registration or licensing fees which would limit or prevent the private certifiers from conducting certification activities in those States. Labeling problems have confronted manufacturers of multi-ingredient organic food products containing ingredients certified by different certifiers because reciprocity agreements have to be negotiated between certifiers. Consumer confusion may exist because of the variety of seals, labels, and logos used by certifiers and State programs. Also, there is no industry wide agreement on an accepted list of substances that should be permitted or prohibited for use in organic production and handling. Finally, a lack of national organic standards may inhibit organic farmers and handlers from taking full advantage of international organic markets and may reduce consumer choices in the variety of organic products available in the marketplace.

To address these problems, the organic industry trade association attempted to establish a national voluntary organic certification program. However, the industry could not develop a consensus on the standards that should be adopted. Thereafter, Congress was petitioned by the organic industry trade association to establish a mandatory national organic program. Congress, in 1990, enacted the Organic Foods Production Act of 1990, as amended (7 U.S.C. 6501 *et seq.*). The purposes of the OFPA, set forth in section 2102 (7 U.S.C. 6501) are to: (1) establish national standards governing the marketing of certain agricultural products as organically produced products; (2) assure consumers that organically produced products meet a consistent standard; and (3) facilitate commerce in fresh and processed food that is organically produced.

The National Organic Standards Board

Pursuant to section 2119 of the OFPA (7 U.S.C. 6518), the Secretary of Agriculture, hereafter referred to as the Secretary, established a National Organic Standards Board (NOSB or Board). The NOSB has assisted the Secretary in developing a National List of substances to be used in organic production and handling and has advised the Secretary on other aspects

of implementing the National Organic Program.

The Act establishes what the composition of the Board should be. In accordance with the Act, the Secretary appointed 14 members in January 1992 that included 4 organic farmers, 2 organic handlers, 1 owner or operator of a retail establishment with significant trade in organic products, 3 experts in environmental protection and resource conservation, 3 representatives of public interest or consumer interest groups, and 1 expert in the field of either toxicology, ecology, or biochemistry. The 15th member, an accredited certifier, would be appointed after certifying agents are accredited by the Secretary. The Act also provides that members of the NOSB be appointed for 5 year terms and that the original members be appointed to staggered terms of 3, 4 and 5 years to provide continuity of membership on the Board.

The NOSB has held 12 full Board meetings and 5 joint committee meetings since the appointment of its members in 1992. To make recommendations regarding specific issues, the Board formed 6 working committees: Crops Standards; Livestock (and Livestock products) Standards; Processing, Packaging and Labeling Standards; Materials; Accreditation; and International Committees. Each committee reviewed the provisions of the OFPA and standards previously established by other organic organizations to determine for which subject areas position papers would be developed. Based on the position papers developed, public input given by persons at NOSB meetings, and an extensive review and comment process used to develop draft recommendations, the Board provided recommendations to the Secretary about various matters. The recommendations included ones regarding production and handling standards, labeling, accreditation, product residue testing, and emergency spray programs.

The Board has provided recommendations regarding which synthetic substances should be permitted to be used in organic production and handling and which non-synthetic substances should be prohibited for use, in order to recommend to the Secretary whether they should be placed on the National List as synthetic substances approved for use or non-synthetic substances not approved for use. The Board has reviewed approximately 170 substances, including botanical pesticides as required in section 2119(k)(4) of the OFPA (7 U.S.C. 6518(k)(4)), for possible placement on the National List, and the Board used technical advisory panels to provide scientific evaluation of the materials considered in its review of the substances.

The NOSB's initial recommendations were presented to the Secretary on August 1, 1994. The NOSB has continued to make recommendations and has submitted 30 addenda to its initial recommendations. A copy of the NOSB recommendations may be viewed on the NOP home page at: http://www.ams.usda.gov/nop, or obtained by writing to: Maria Strother, Agricultural Marketing Specialist, USDA–AMS–TM–NOP, Room 2510-So., P.O. Box 96456, Washington, DC 20090–6456.

All of the NOSB recommendations were considered by AMS in developing the proposed regulation for the National Organic Program. The discussions and public input involved in generating the recommendations have been invaluable in assisting AMS to become aware of the complexity of various issues and to arrive at solutions that represent the interests of farmers, handlers and consumers. We have written a proposed regulation that incorporates to the greatest extent possible the organic principles and specifics contained in the NOSB recommendations. Many of the recommendations were restructured, reordered, or combined to be compatible with the format of the proposed rule. In the few instances where a section of our proposed rule does not reflect the NOSB recommendation, we explain the variation in the preamble for the specific section.

The NOSB recommendations and discussions on the following topics were especially helpful to AMS in developing the proposed rule: accreditation; labeling; importation; organic farm and handling plans; split operations; planting stock policies; emergency pest or disease treatments; livestock feed and health care; commercial availability; drift of synthetic substances; small farmer exemption; phase-in of NOP implementation; fiber processing; and the National List substance review process.

Public Input

In addition to the NOSB recommendations, AMS has received considerable input from interested persons regarding establishment of the National Organic Program and this proposed rule.

Section 2110(g) of the OFPA (7 U.S.C. 6509(g)) requires the Secretary to hold public hearings to obtain information to guide the implementation of standards for livestock products. Four such hearings were held during 1994: January 27–28 in Washington, DC; February 10 in Rosemont, Illinois; February 24 in Denver, Colorado; and March 22 in Sacramento, California. Oral and written testimony was received from more than 70 persons, including livestock producers, veterinarians, certifying agents, processors and members of the NOSB. Comments covered livestock production and product marketing, antibiotic use, livestock living conditions, feed availability, provisions for conversion to organic production, and label requirements. These comments have been beneficial in developing this proposed rule.

Prior to publication of this proposed rule, public comment also was received at public events attended by NOP staff members. Public comment was received at the 12 full Board and 5 joint committee meetings. NOP staff made presentations and received comments at local and regional organic conferences and workshops and at national and international organic and natural food shows. Comments also were received at: a national organic certifiers meeting held on July 21, 1995, to discuss accreditation issues; a meeting of State officials held on February 26, 1996, to discuss the role of States in the NOP; training sessions for organic inspectors; and numerous speaking engagements of the AMS Administrator, the NOP program manager, and the NOP staff where the public had an opportunity to participate in question and answer sessions.

Proposed Effective Date of the Regulation

We have received inquiries about when the various provisions of a final rule will be effective.

The final rule would establish a procedure and a time frame for designating private persons and State officials as accredited certifying agents under the program. One option would be to require organizations desiring to be included on the initial list of certifying agents accredited under the National Organic Program to submit their applications within approximately two months after publication of the final regulation. Applications submitted later than two months after publication of the final rule would not be considered for inclusion on the initial list of certifying agents, but would be reviewed as soon as possible after publication of the initial list of accredited certifying agents. Subsequent lists of accredited certifying agents would be published as they are developed.

If we adopted this option, we would publish an initial list of accredited certifiers in the **Federal Register** after

reviewing the applications received during the first two months after publication of the final regulation. We will publish subsequent lists of accredited certifying agents as new applicants become accredited. We would expect publication of the initial list to occur within six months after publication of the final rule. Only after publication of that list would the provisions of the regulation applicable to certification become effective. Thus, the provisions in the proposal that address the application process for, and decisions to be made about, the certification of farms, wild crop harvesting operations, and handling operations, would become effective only after certifiers have become accredited. Certifiers would begin certifying individual operations under the NOP six months after publication of the final rule.

In order for accredited certifying agents to begin certifying operations under the NOP six months after publication of the final rule, we believe we would need, as we previously indicated, to have accreditation applications submitted within two months after publication of the final regulation. We believe that the initiation of certification activities by accredited certifying agents six months after publication of the final rule would permit the implementation of the national standards for organic products within a reasonable time frame after publication of the final rule.

We request comments from all interested parties, particularly small businesses that want to obtain accreditation as certifying agents, as to whether a two month time frame after publication of the final rule for submission of applications for accreditation is a sufficient time period, or whether an extended time period, such as three or four months after publication of the final rule, should be permitted for those who want to be listed on the initial list of accredited certifiers. Any such extension, of course, would lengthen the implementation schedule.

In this implementation option, we would expect to allow a 12-month period of time after publication of the initial list of certifying agents for operations to become certified under the relevant provision of the final regulation. Thus, all provisions of the NOP would be implemented 18 months after publication of the final rule. On that date, which will be stated in the final rule, all organic operations required to be certified will have to be certified in order to sell or label their products as organic. Operations that are certified prior to 18 months after publication of the final regulation would be permitted to use the USDA organic seal upon certification by a USDA accredited certification organization.

We would like comments, particularly from small farm or handling operations, as to whether the 12-month period of time we anticipate allowing for farm, wild crop harvesting, and handling operations to become certified is a reasonable period of time for such operations to become certified. We are particularly interested in learning whether there are any economic or other factors that would create difficulties in obtaining certification within the 12-month time period we expect to provide for obtaining certification.

Several people have raised questions about what the impact of the rule would be when it is effective. Some farmers whose operations are currently certified as organic under private or State standards have asked what the status of their certified farming operations would be if a substance allowed for use under their current private or State certification is not on the National List, and, therefore, not allowed under the National Organic Program.

The OFPA requires that a product sold or labeled as an organically produced agricultural product must, except as otherwise provided in the Act and excluding livestock, be produced on land to which no prohibited substances, including synthetic chemicals, have been applied during the three years immediately preceding harvest of the agricultural product. We have incorporated this prohibition in our proposal. Thus, a farm would not be able to become certified under the National Organic Program until three years after the time any prohibited substance was last applied. Therefore, at the time the final rule becomes effective, such farming operations previously certified under private or State programs would not be able to sell or represent their products as organically produced if they could not satisfy the three year period established for nonuse of a prohibited substance.

Petitions, however, to amend the National List may be submitted immediately after publication of the final rule by using the petition process proposed in section 205.28 of subpart B. It may be possible, therefore, for a person who submits a petition immediately after publication of the final rule to the NOSB for review of a new synthetic substance to be included on the National List, to have this substance approved for use by the Secretary prior to the effective date of the program. If this were to occur, then prior use of the substance would not prevent the products from being sold or represented as organically produced.

Processors also have asked what impact the program's requirements would have on their existing product and label inventories. With regard to existing product and label inventories, we believe that our intended 18-month delayed effective date for the complete rule would provide ample time for handlers to use up existing product and label inventories required under their existing organic certification program before the rule becomes effective.

States also have asked what effect the rule would have on their current organic regulations. With regard to current State organic regulations, we also believe that the anticipated 18-month delayed effective date should provide State officials with ample time to make the necessary changes to their State regulations and submit their State proposed organic program to the Secretary for approval.

Because it is the intent of AMS to provide a final rule which facilitates trade and which is the least disruptive as possible for the production, handling and marketing of organic products, we request comment on our intended schedule of effective dates for the provisions of the rule. We also request comments on any problems that organic farmers and handlers, States, and others may encounter when adjusting their operations to meet the requirements of the National Organic Program, including the OFPA requirement of a 3-year period prior to the harvest of organic products from land to which a prohibited substance is applied. A time-table for implementation of the program would be published in the final rule.

Prior Documents in This Proceeding

The following notices related to the National Organic Standards Board and the development of this proposed regulation have been published in the **Federal Register**. Four notices of nominations for membership on the National Organic Standards Board were published between April 1991 and July 1996 (56 FR 15323, 59 FR 43807, 60 FR 40153, 61 FR 33897). Two notices of extension of time for submitting nominations were published on September 22, 1995, and September 23, 1996 (60 FR 49246, 61 FR 49725). Twelve notices of meetings of the National Organic Standard Board were published between March 1992 and August 1996 (57 FR 7094, 57 FR 27017, 57 FR 36974, 58 FR 85, 58 FR 105, 58 FR 171, 59 FR 58, 59 FR 26186, 59 FR 49385, 60 FR 51980, 60 FR 15532, 61 FR

43520). One notice of public hearings on organic livestock and livestock products was published on December 30, 1993 (58 FR 69315). One notice specifying a procedure to submit names of substances for inclusion on the National List was published on March 27, 1995 (60 FR 15744).

Executive Order 12988

This proposal has been reviewed under Executive Order 12988, Civil Justice Reform. This rule is not intended to have retroactive effect.

States and local jurisdictions are preempted under section 2115 of the OFPA (7 U.S.C. 6514) from creating programs of accreditation for private persons or State officials who want to become certifying agents of organic farms or handling operations. A governing State official would have to apply to the USDA to be accredited as a certifying agent, as described in section 2115(b) of the OFPA (7 U.S.C. 6514(b)). States also are preempted under sections 2104 through 2108 of the OFPA (7 U.S.C. 6503 through 6507) from creating certification programs to certify organic farms or handling operations unless the State programs have been submitted to, and approved by, the Secretary as meeting the requirements of the OFPA.

Pursuant to section 2108(b)(2) of the OFPA (7 U.S.C. 6507(b)(2)), a State organic certification program may contain additional requirements for the production and handling of organically produced agricultural products that are produced in the State, and for the certification of organic farm and handling operations located within the State, under certain circumstances. Such additional requirements must: (a) further the purposes of the OFPA; (b) not be inconsistent with the OFPA; (c) not be discriminatory towards agricultural commodities organically produced in other States; and (d) not be effective until approved by the Secretary.

Pursuant to section 2120(f) of the OFPA (7 U.S.C. 6519(f)), this proposal would not alter the authority of the Secretary under the Federal Meat Inspection Act (21 U.S.C. 601 *et seq.*), the Poultry Products Inspections Act (21 U.S.C. 451 *et seq.*) or the Egg Products Inspection Act (21 U.S.C. 1031 *et seq.*), concerning meat, poultry, and egg products, nor any of the authorities of the Secretary of Health and Human Services under the Federal Food, Drug and Cosmetic Act (21 U.S.C. 301 *et seq.*), nor the authority of the Administrator of the Environmental Protection Agency (EPA) under the Federal Insecticide, Fungicide and Rodenticide Act (7 U.S.C. 136 *et seq.*).

Section 2121 of the OFPA (7 U.S.C. 6520) provides for the Secretary to establish an expedited administrative appeals procedure under which persons may appeal an action of the Secretary, the applicable governing State official, or a certifying agent under this title that adversely affects such person or is inconsistent with the organic certification program established under this title. The Act also provides that the U.S. District Court for the district in which a person is located has jurisdiction to review the Secretary's decision.

Executive Order 12866

This proposed rule has been determined to be economically significant for the purposes of Executive Order 12866 and, therefore, has been reviewed by the Office of Management and Budget (OMB). When proposing a regulation which has been determined to be economically significant, agencies are required to: assess the costs and benefits of available regulatory alternatives; base regulatory decisions on the best reasonably obtainable technical, economic, and other information; avoid duplicative regulations; and tailor regulations to impose the least burden on society consistent with obtaining regulatory objectives. Therefore, to assist in fulfilling the objectives of Executive Order 12866, and the Unfunded Mandates Reform Act of 1995, the USDA has prepared a Regulatory Impact Assessment (RIA) which is attached as an appendix to this proposed rule and from which the following summaries of the costs and benefits of the proposed National Organic Program have been taken.

Ideally, the net benefits of the proposed rule would be estimated by employing a quantitative analysis using information about the cost structure of the industry, the demand for organic food, and projected shifts in supply and demand resulting from the various factors discussed in the assessment. However, although researchers have conducted numerous small-scale studies to determine consumer willingness to pay for organic products and to identify reasons why conventional food buyers do not choose organic food products, the available data are insufficient to support a quantitative assessment of this type. At this time, USDA invites public input to provide additional data that may aid in the development of a quantitative assessment. This data should be submitted in response to the questions included in the Conclusion section of the RIA. These questions are intended to solicit information needed to develop baseline data about the potential program participants, the costs of organic production, revenues from organic sales, and the impact of the program on market growth.

Summary of the Costs of the Proposed Rule

The proposed rule would impose direct costs in the form of fees charged to certifiers for USDA accreditation and to farmers, wild crop harvesters and handlers for support of the National Organic Program. The proposed rule also would impose administrative costs, such as submission of information, recordkeeping, and access to records that may constitute an additional burden. The actual amount of the additional administrative costs that would be imposed by the final rule is expected to be different for those entities who currently are active in the organic industry, as compared to those new entities who would begin their activities only after the national program is implemented. Certifiers, farmers, wild crop harvesters and handlers who currently are active in the organic industry already perform most of these administrative functions; therefore, the additional costs to them would depend upon the extent to which their current practices are different from the requirements of the final regulation.

Farmers, wild crop harvesters and handlers would be required to produce and handle products in accordance with the standards set forth in the rule and provide certifiers with the required information necessary to verify certification requirements. Farmers, wild crop harvesters, and handlers would be charged a fee by the certifying agent for these certification services. We were not able to estimate the exact cost of certification fees that would be charged by certifying agents after implementation of the national program because these fees currently vary widely among existing certifiers: some existing private certifying agents are non-profit; some States who currently conduct certification activities subsidize these activities from other revenue sources; some existing certifying agents include the cost of inspection and, in some cases, laboratory testing, in their certification fee; and some existing larger certifying agents may charge lower fees because they are able to spread their fixed costs over a larger number of clients.

Farmers, wild crop harvesters, and handlers may experience certain costs to comply with the final regulations. For example, there may be costs associated

with the proposed requirement that organic products not come in contact with prohibited substances, or with the proposed requirement that pest control substances be used only if pest prevention measures are ineffective. However, since the proposed rule is a synthesis of existing State and private organic certification programs and the NOSB recommendations, we believe that farmers, wild crop harvesters and handlers who currently participate in existing State or private organic certification programs would experience little or no increased compliance costs as a result of implementation of the National Organic Program. Additionally, farmers and handlers who would be exempted or excluded under the rule, but who choose to become certified in order to receive the benefits of certification, would be subject to the additional cost of certification and recordkeeping. USDA requests data on the costs of organic production and the revenues from organic farming, and on a comparison of these costs and revenues to conventional systems.

The following are the upper-bound estimates of the cost of initial certification under the National Organic Program:

Estimated Cost to Farmers and Wild Crop Harvesters for Initial Certification

Certification fee *	$413	
USDA fee	50	
Total fees	463	
Paperwork reporting burden	[1] 381	
Paperwork recordkeeping burden	34	
Total reporting and recordkeeping	415	
ESTIMATED COST TO FARMERS AND WILD CROP HARVESTERS FOR INITIAL CERTIFICATION		$878

Estimated Cost to Handlers for Initial Certification

Certification fee *	$943	
USDA fee	500	
Total fees	1,443	
Paperwork reporting burden	[2] 433	
Paperwork recordkeeping burden	34	
Total reporting and recordkeeping	467	
ESTIMATED TOTAL COST TO HANDLERS FOR INITIAL CERTIFICATION		$1,910

* The estimated certification fee is based on the average of fees charged by a representative group of certifying agents: private non-profit, private for-profit and a State agency. Most certifying agents in our representative group include the cost of inspection and, if applicable, required laboratory testing in the certification fee.

[1] For new organic producers.

[2] For new organic handlers.

USDA requests data on certification fees currently paid by existing organic farmers, wild crop harvesters, and handlers in order to better assess the impact of the proposed program.

After implementation, all organic certification agencies, whether private or State, would be accredited by USDA and would pay fees for the following services provided by USDA: application review, annual report review, site evaluation visits, and administrative duties. A certifier who currently is accredited by a private accreditation organization might pay USDA lower site evaluation visit fees than a certifier who is not currently accredited, because of measures that are implemented by the certifier to receive its private accreditation. Additionally, as required by the OFPA, a private certifying agent would have to furnish reasonable security for the purpose of protecting the rights of farms and handling operations certified by the agent. The amount and type of security would be established through future rulemaking.

States that currently perform organic certification activities under their own regulations, or that have laws pertaining to the certification of organically produced and handled products, or that plan to have an organic program in the future, may incur some additional costs. For example, States with existing organic programs or regulations may be required to supplement or revise them in order to meet the criteria of the OFPA, including the provisions set forth in section 2107 of the OFPA (7 U.S.C. 6506). A State without an existing organic program that initiates a new State organic program would be expected to incur greater costs to establish its program.

The following are the upper-bound estimates for the cost of initial accreditation under the National Organic Program:

Estimated Cost to Certifying Agents for Initial Accreditation

Accreditation application fee	$640	
Site evaluation fee *	3,500	
USDA Administrative fee	2,000	
Total fees	6,140	
Paperwork reporting burden	[1] 23,931	
Paperwork recordkeeping burden	60	
Total reporting and recordkeeping	23,991	
ESTIMATED TOTAL COST FOR INITIAL ACCREDITATION		$30,131

*Each certifying agent would have a site-evaluation to confirm accreditation, and thereafter a subsequent renewal evaluation at least every 5 years following confirmation of accreditation. In some cases, a pre-confirmation site visit may be necessary. We anticipate that the frequency of site evaluations would be based on the performance of the certifying agent and would be higher during the initial years of the program.

[1] For new organic certifiers.

The USDA requests data on the fees currently paid by existing organic certifying agents for accreditation in order to better assess the impact of the proposed program.

The requirement in the proposed rule for qualified certification personnel to be used to evaluate certification applications and contribute to certification decisions may result in an increase in labor and training costs for some existing certifiers. The amount of additional costs to these certifiers would depend on the level of expertise among current certification personnel, the extent to which certifiers currently rely on volunteers, and the costs of training these persons. Our proposed inspector training requirements conform to current established practice in the industry and are not expected to impose an additional burden on existing certifiers who utilize inspectors.

We also have identified non-quantifiable costs that may result. Some certifiers consider the loss of independence in setting certification standards under a national program as imposing a cost. Other certifiers consider the establishment of uniform national standards and an accreditation program as a benefit in that the risk of potentially costly disputes over acceptance of other certifier's standards (reciprocity) is eliminated. We anticipate that the net impact would be positive because the reciprocity dispute problems would be eliminated.

Another non-quantifiable cost could result from the proposed requirements that certifiers provide access to all their records to the Secretary and the applicable governing State official, and provide access to laboratory analyses and certification documents, other than

confidential business information, to the general public. Although not quantifiable, these requirements may represent a change in the way some existing certifiers currently maintain these records.

Summary of Benefits of the Proposed Rule

In the absence of a nationally recognized definition of organic, consumers may be mislead by labels on products claiming to be organic, or claiming to contain organic ingredients, when in fact some of the products or ingredients may not have been organically produced. Because many consumers are willing to pay price premiums for organic food, producers have an economic incentive to label their products organic. But consumers generally are unable to distinguish organic products from conventionally produced products by sight inspection; hence, consumers rely on verification methods such as certification by private entities or verification by retailers. The USDA requests data to determine the extent to which mislabeling of non-organically produced products as organic occurs and the market impacts of mislabeling in terms of quantities of organic goods sold and the prices for organic goods.

Individual ingredients in multi-ingredient processed products may be certified under different standards of organic production, thus making it difficult for a consumer to determine the production standards under which each of the ingredients was produced. The proposed standards for organic production, enforced through accreditation of certifiers, would assure consumers that the organic ingredients were produced under one national standard. Furthermore, USDA regulation of labeling claims for organic food would allow the USDA and other federal agencies whose jurisdiction includes ensuring the veracity of labeling claims to prosecute those who mislabel products sold as organic.

Establishing a national definition for organic would be expected to increase the supply and variety of organic products, especially meat and poultry, available to consumers. The Food and Drug Administration (FDA) and the Bureau of Alcohol, Tobacco and Firearms (ATF) currently allow use of the word organic on most food and alcohol labels, but USDA has withheld approval for the use of organic labels on meat and poultry pending the outcome of this rule making. Without the regulation, however, FDA may decide to disallow use of the term organic on labels and USDA may continue their current restrictions on the use of organic on meat and poultry labels. The increased variety of organic products, especially meat and poultry, that might be marketed after implementation of the final rule may increase the variety of available organic products so as to parallel the variety of non-organic products. The USDA requests data and analyses which would support projections of the demand for organic meat and poultry.

By providing for the accreditation of certifiers, the proposed rule would establish the requirements and enforcement mechanism to protect producers and handlers from inconsistent certification services, lack of reciprocity between certifiers, and competition from fraudulent products, which can increase costs or reduce revenue for organic farmers and handlers. In the absence of the National Organic Program, the certifier of a final product may not be required to recognize the certification of an intermediate organic product used in the final product. Thus, both farmers and primary food processors face a risk of being unable to sell an organic product identified as certified when more than one certifier is involved. Monitoring by USDA of certification inspections and certifier personnel training and qualifications would help to ensure the quality of the certification, the use of consistent criteria for certification, and the use of certification personnel who are knowledgeable and free from conflicts of interest.

National organic standards and the assurance provided by the USDA accreditation of certifiers would benefit farmers and handlers by opening access to international markets. The trade restrictions that currently exist would be resolved if foreign countries who import organic products recognize the National Organic Program as equivalent. Farmers and handlers in the United States may expect larger growth in exports of organic products to follow implementation of the final rule.

The contributions of national organic standards to increased domestic demand and to expanded international markets for organic products may provide opportunities for current organic producers to expand the scale of their operations. Increased organic production also may provide incentives for input industries to develop new technologies which could lower producers' costs of organic production. Input costs also may decline as a result of economies of scale being achieved in input industries producing for the organic market. Expanded markets could encourage additional farmers and handlers to enter the marketplace, resulting in a potential decline of certifiers' average costs of operation as fixed costs are spread over a growing number of clients. The USDA requests information to determine whether the organic industry and consumers of organic goods have benefitted from industry growth resulting in economies of scale and production and marketing efficiencies, and whether industry participants anticipate such benefits from this rule.

There are three ways in which certifiers' administrative costs could be reduced as a result of the regulation. First, certifiers' costs of maintaining access to organic markets for their clients should be reduced because costs associated with determining equivalency between certifiers would be reduced or eliminated. Accreditation and uniform national standards would alleviate the need to negotiate individual reciprocity agreements with other certifiers. Furthermore, USDA oversight of certifiers would simplify the process of certifying multiple ingredient products, thus reducing certification costs. The responsibility for meeting production and certification requirements of each ingredient would rest with the certified producers and accredited certifying agents of the individual ingredients. National standards also would eliminate costly equivalency disputes between States which may affect interstate commerce.

Second, certifiers would no longer have to pay private organizations for the accreditation required to gain access to some international markets. This would be of particular benefit to the smaller certifiers who may have been unable to enter these markets because of the high cost of international accreditation. A portion of the administrative fees paid by each certifying agent would support USDA activities to negotiate equivalency of organic standards in world markets so that producer clients of all USDA accredited certifiers could have access to these markets.

Third, in the long run, uniform standards of production, certification and accreditation should reduce the cost of training certification staff. Industry-wide training costs may increase initially, but should decline as the pool of trained certifiers and certification personnel increases and the corresponding cost of training new certification personnel decreases, especially in those instances where personnel transfer from one certifier to another. Standardized materials, such as compliance guides and training manuals, also should contribute to a reduction in the cost of training

certification staff. In addition, USDA accreditation of certifiers would present opportunities for sharing information about standards, practices and the general requirements of the program through the National Organic Program staff.

Unfunded Mandates Reform Act

The Unfunded Mandates Reform Act (Pub. L. 104–4) requires (in Section 202) that agencies prepare a qualitative and quantitative assessment of the anticipated costs and benefits before proposing any rule that may result in annual expenditures by State, local, and tribal governments, in the aggregate, or by the private sector, of $100,000,000 (adjusted annually for inflation) in any one year. As discussed in the preceding section entitled ''Executive Order 12866'', USDA has prepared a Regulatory Impact Assessment (RIA) to assess the costs and benefits of this proposed rule. As explained in the RIA, which is attached as an appendix to this proposed rule, USDA was unable to provide a quantitative assessment of the costs and benefits of the proposed rule, except for the cost of fees and recordkeeping that would result from the proposed rule, because of insufficient data available to support a quantitative assessment. The cost of fees resulting from this proposed rule is estimated to be $1,000,000 during the first year of program implementation, and the cost of recordkeeping is estimated not to exceed $4,700,000 during any one of the first three years of program implementation. The RIA does, however, provide a qualitative assessment of the proposed rule's costs and benefits.

The USDA has posed a list of questions in the RIA to assist in the development of a quantitative assessment for the final RIA that will be published as part of the final rule for the National Organic Program. We will utilize public input received in response to these questions and to other provisions of this proposed rule, as well as other resources available to USDA before publication of the final rule, to develop a quantitative assessment of the costs and benefits of the final rule.

Although USDA has not determined whether this proposed rule would result in annual expenditures by State, local, and tribal governments, in the aggregate, or by the private sector, of $100,000,000, USDA has sought to meet the objectives of the Unfunded Mandates Reform Act. In addition to its qualitative cost/benefit assessment, USDA has identified in the RIA three regulatory alternatives to the proposed rule. We also discuss in the preamble sections entitled ''Paperwork Reduction Act of 1995'' and ''The Regulatory Flexibility Act and the Effects on Small Businesses'', the analysis we have employed in reaching a determination that this proposed rule is the least costly and least burdensome to the regulated parties, in that we have designed the proposed rule to be as consistent as possible with existing industry practices, while satisfying the specific requirements of the OFPA.

Additionally, we have had numerous occasions to communicate with State governments during the development of the proposed rule. Representatives of various State governments participated in several public meetings of the NOSB and they have provided valuable input to the NOSB for its recommendations on standards and the National List. USDA also hosted a meeting on February 26, 1996, to discuss with many State officials the status of the proposed rule and to listen to concerns about such topics as fees, enforcement, certifier logo use, and the range of additional requirements that States may include in their State programs. On numerous other occasions, AMS staff has had discussions with a wide array of State officials on subjects related to this proposed rule or the establishment of, or amendment to, State organic certification programs. USDA will continue to provide effective opportunities for the broadest possible input by States and all interested parties throughout the rulemaking process.

The Regulatory Flexibility Act and the Effects on Small Businesses

Pursuant to the requirements set forth in the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*), the Agricultural Marketing Service (AMS) has considered the economic impact of the proposed rule on small entities. The AMS' analysis, as required by the RFA, considers the impact of this proposed regulation on small entities and evaluates alternatives that would accomplish the objectives of the rule without unduly burdening small entities or erecting barriers that would restrict their ability to compete in the organic market. The following Initial Regulatory Flexibility Analysis was written with guidance from the Small Business Administration (SBA).

The size of the organic industry has risen dramatically in recent years from a low of $78 million in 1980, to $1 billion in 1990, to a total retail sales level of $3.5 billion in 1996. Certified organic cropland production has expanded from 473,000 acres to 667,000 acres in the period 1992 to 1994, and is expected to reach 2 million acres by the year 2000. Despite this rapid growth, it should be noted that the organic industry represents a very small percentage of total agricultural production and sales, and that organic certifiers, farmers and handlers tend to own smaller operations rather than larger ones.

Currently, organic certification is voluntary and self-imposed. According to the most complete data available to the AMS, there are 33 private and 11 State certifying agencies certifying approximately 4,000 farmers and 600 handlers in the United States. Over half of the private and State agencies certify both farm and handling operations, while the others certify only farms. Over three-fourths of State and private agencies each certify fewer than 150 farms and 20 handlers. Based on a review conducted by AMS of 16 certifiers, who provided information on the organic sales of products produced on certified farms, most of the farms certified have less than $25,000 in gross sales.

A national organic program would benefit farmers by opening access to international markets. U.S. exports of organic products totaled $203 million in 1994 or about 9 percent of the organic output. Export markets may become more substantial and offer price premiums for organic products with increased world-wide consumption of organically produced food. For example, the organic market share in the European Union (EU) has been projected to reach 2.5 percent of total food consumption expenditures by 1998. Austria expects its organic market share to equal one third of all food sales by the year 2000. In 1994, France and Germany combined had total retail sales of organic foods equal to that of the United States in the same year (approximately $2 billion). Japan's retail sales for that year were estimated to be $688 million. Other EU countries report growth rates equal to or greater than the current growth rate in the United States of about 20 percent per year.

The reason for regulatory action is fully explained in the Regulatory Impact Assessment which is attached as an appendix to this proposed regulation. In short, the organic market may be precluded from reaching its full potential until there is a definition of the term organic, which would be achieved by implementation of this proposed regulation that provides regulations for production, handling, labeling, certification and accreditation of U.S. certifiers. Domestic and international trade in organic products may also be hampered by the need to negotiate reciprocity agreements because of the differing standards of

production and handling that currently exist; meat and poultry, including processed products containing meat and poultry as ingredients, cannot be labeled organic; and few enforcement mechanisms exist to protect consumers against fraudulent organic labeling.

The statutory authority for this proposed rule is the OFPA, which in section 2104(a) (7 U.S.C. 6503(a)) requires the Secretary of Agriculture to develop a national organic program. In general, the Secretary must establish an organic certification program for farmers and handlers of agricultural products that have been produced using organic methods as provided for in the OFPA. In addition, section 2115 of the OFPA (7 U.S.C. 6514) requires the Secretary to establish and implement a program to accredit a governing State official and any private person who meets the requirements of the OFPA and the regulations in part 205 as a certifying agent for the purpose of certifying a farm or handling operation as being in compliance with the standards set forth in this proposed regulation.

The purpose of the RFA is to fit regulatory actions to the scale of business subject to the actions in order that small businesses would not be unduly or disproportionately burdened. To accomplish this purpose, it first is necessary to define a small business. According to the Standard Industrial Codes (SIC) (13 CFR Part 121) which are developed by an inter-agency group, published by the Office and Management and Budget (OMB), and used by the SBA to identify small businesses, nearly all of the entities affected by this proposed regulation would be considered small businesses. According to the SIC, a small business in the agricultural services sector, such as certifiers, includes firms with revenues of less than $3.5 million (SIC Division A Major Group 07). In crop production, the SIC definition of a small business includes all farms with annual gross sales under $500,000 (SIC 0111–0191). (Most of the farms currently certified have less than $25,000 in gross sales of organic production. However, many farms combine organic and conventional production on the same operation, some with total sales that may exceed $500,000). In handling operations, according to the SIC, a small business is defined as having fewer than 500 employees (SIC Division D Major Group 20). (The workforce data needed to determine whether any organic handling operations exceed 500 employees is not available, but anecdotal information leads us to believe that no organic handling operations employ more than 499 persons).

We consulted with the SBA Office of Advocacy regarding the use of size standards different from those in 13 CFR 121. For the purpose of identifying those entities who would be most affected by this proposed regulation, alternative definitions were established for the purpose of this analysis. The alternative definition of a small certifier which we established for this analysis is one with total revenue from certification of less than $25,000. The alternative definition of a small farm which we established is one with a maximum of $5,000 in gross sales of agricultural products, as is set forth in section 2106(d) of the OFPA (7 U.S.C. 6505(d)). Additionally, for this analysis, we established the alternative definition of a small handling operations to be one whose sales are $50,000 or less.

Development of regulations for the National Organic Program began with the premise that the industry should be burdened as little as possible by the OFPA regulation. To accomplish the goal of regulation with minimal burden, we initially determined that most of the information needed for organic farmers and handlers to become certified, and for certifiers to become accredited, already exists for those entities currently operating. The challenge was to create a regulation which complied with the OFPA mandates and which embodied the customary and usual business practices already being carried out by the industry. No new forms have been proposed and few additional documents would be required in this proposed regulation. Certifiers may need to create some of the documents proposed for the application process; farmers may have to keep records for longer periods of time; and handlers may need to refine recordkeeping to ensure a clear audit trail. However, they would be allowed the flexibility to use the easiest and least expensive means available to provide information, as long as the required information is adequate to ensure compliance with the regulations.

Small and large farmers, handlers, and certifiers would be affected by additional fees resulting from implementation of the National Organic Program. Certifiers may be burdened with the accreditation requirements for business related activities, such as the requirement for a financial audit. However, because no particular form is required, current business records may be sufficient to provide the necessary information. The requirements to keep personnel records, explain administrative procedures, and evaluate personnel may be burdensome to small certification businesses. Yet, we have received the comment from at least one small business that requirements such as these can increase efficiency and make a small business more cost effective.

Section 2112(d) of the OFPA (7 U.S.C. 6511(d)) requires farmers and handlers to maintain records for five years, and section 2116 (c)(1) of the OFPA (7 U.S.C. 6515(c)(1)) requires certifiers to maintain records for ten years. Our research of the industry indicates that farmers and handlers already maintain records for five years and certifiers do not discard historical documents. This regulation, therefore, should not significantly increase the record retention burden beyond current industry practice. However, under the requirements of the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3506 and 3507), a burden is created when a law or regulation requires the storage of information. The burden to the industry is calculated on the time required to file a document. Under the PRA we are required to estimate and account for this burden.

No other burdens are expected to fall upon the organic industry as a result of overlapping Federal rules. This proposed regulation would not duplicate, overlap or conflict with any existing Federal rules. In preparing this proposed regulation, AMS consulted other Federal agencies such as the FDA, EPA, ATF, and the USDA's Food Safety and Inspection Service (FSIS) to ensure that this proposed regulation would complement existing regulations.

Whether using the SIC definitions for small businesses or the alternative definitions created for this analysis, our proposed regulation would have a significant impact on a substantial number of small businesses. However, we have considered several options with the intention of mitigating negative economic impacts. The following options were considered by AMS prior to and during the development of the proposed regulation.

Regulatory Options

Option 1: The Organic Market in the Absence of Regulation

We have explored the alternative of no government regulation of the organic industry. However, current problems in the organic industry would continue to affect small entities as well as large ones. In fact, it is likely that the effect of no regulation would negatively impact small businesses to a greater degree than larger ones. For example, without regulation, smaller certifiers

entering the industry with growth expectations based on implementation of the OFPA through Federal regulation would be negatively affected to a greater degree than larger certifiers who can spread fixed costs over a larger number of clients. Larger businesses do not depend as heavily on industry growth to maintain their business operations.

Organic farmers who have integrated livestock into their agricultural operation are negatively impacted in two ways without regulation of the organic industry. First, they do not receive the price premium for organic meat and poultry because at the present time FSIS does not allow for the use of the term organic on meat and poultry labels. This would impact small farmers to a greater extent because they have fewer animals from which to profit from a price premium. Second, to feed their livestock, farmers either must pay a higher price for organically produced livestock feed or raise the feed on their own land which otherwise could be used to produce organic cash crops. Smaller farmers are disproportionately impacted because the ratio of the number of livestock per acre of land is limited by the number of acres they must use for organic crop production in order to be a profitable business. Larger farmers face the same decision of whether to purchase organic feed or raise their own, but they have more acres over which to spread the cost of either choice.

Without Federal regulation, small certifiers and farmers wishing to export agricultural products are negatively impacted to a greater degree than larger organizations by a lack of resources and influence over foreign market systems. Also, completing the paperwork required for exporting products is disproportionately costly to small entities because of their limited resources. The burden of completing this paperwork can be eased if the certifier has attained private, third-party accreditation. We are aware that certifiers currently may pay in excess of $15,000 for accreditation by a private organization. Smaller certifiers cannot afford these fees, and therefore, potential clients wishing to export organic products choose to be certified by the larger, privately-accredited organizations.

Finally, we are required by the OFPA to regulate the industry through the National Organic Program. In fact, we have received requests from many small businesses, certifiers, farmers, and handlers, to move forward with implementation of a national program as quickly as possible. Therefore, we believe that regulating the organic industry would be the most appropriate action to help small businesses.

Option 2: Exemption of Small Certifiers From Accreditation

We considered the option to exempt small certifiers from accreditation requirements, just as small farmers and handlers are exempt from certification. However, the OFPA does not provide for such an exemption and this, therefore, would require a legislative amendment. Additionally, we do not believe that exempting small certifiers would be in the best interest of the industry or the small certifiers.

The exemption of small farmers carries with it limitations which may discourage some small farmers from claiming exemption, preferring instead to become certified. In this proposed regulation, small farmers who are not certified and who use the term organic to identify their products must comply with the USDA standards, yet they may not display the USDA seal or a certifying agent's logo on the labels or the labeling of their products. Furthermore, organic agricultural products produced on small farms that claim exemption from certification requirements cannot be labeled as organic ingredients in products processed by a certified operation. As a result, consumers and processors may not wish to pay a price premium for organic products from a non-certified operation.

The exemption of small certifiers from accreditation would carry with it limitations resulting from the absence of Federal oversight. Interstate and international trade would be hampered because it would likely be limited to products certified by accredited certifiers. Distinguishing exempt certifiers from accredited ones might require that product labels of accredited certifiers' clients include the USDA logo and lead to consumer confusion over labels in the marketplace.

Protecting consumers from fraudulent certification claims on labels would be difficult at the Federal level since AMS and other enforcement agencies, such as the FDA, ATF, and FSIS, would have to distinguish accredited certifiers from those who are exempt. Costly spot checks or site visits would be required by AMS to verify that products sold or labeled as organic are produced under systems that are consistent with the national program. To accomplish this, a mechanism would have to be established to charge exempt certifiers for spot checks or site visits and these charges might be more costly than becoming accredited.

One of the purposes of the OFPA is to assure consumers that organically produced products meet a consistent standard. Without the assurance provided by Federal oversight of certifiers through USDA accreditation, there is no way to ensure that one national standard of production and handling for organic agricultural products would be employed. The result could be the continuation of costly reciprocity agreements among small, exempt certifiers and large, USDA accredited certifiers. This could prove to be more costly to small entities than accreditation. For all of these reasons, we have determined that option 2 is not a viable alternative.

Option 3: The Proposed Regulation

The regulation we propose is a synthesis of existing organic standards and certification programs. We have done extensive outreach which is explained in the **SUPPLEMENTARY INFORMATION** section entitled ''Public Input''. After gathering the necessary information, we developed this proposed regulation to ensure industry integrity and help the organic industry grow. In this section, we will discuss how this proposed Federal regulation of the organic industry would: eliminate costly administrative tasks now necessary under current industry practice and thus mitigate the financial burden of USDA accreditation; level the playing field, enabling small entities to better compete in the industry; and benefit all farmers and handlers through industry growth. Finally, this proposed regulation includes three factors that would decrease its overall burden by providing flexibility in compliance and fees.

Certification organizations currently develop and interpret their own standards of production and handling. The consensus of our outreach to the industry is that one national standard with interpretation, decision making, and enforcement authority at the Federal level would eliminate the need for certifiers to develop and amend standards. Federal regulation also would provide a consistent process for certifying operations that produce and handle products bearing an organic label. Smaller certifiers would benefit to a greater degree than larger certifiers because the resources saved from creating and interpreting their own standards could be directed toward improving their business operations and offsetting any additional burden imposed by accreditation.

One national standard would eliminate the need to negotiate costly reciprocity agreements and thus save

certifiers' resources used to negotiate the agreements, while also expanding markets for organic farmers and handlers certified by smaller organizations which currently do not have, or have a limited number of, such agreements. Eliminating the need for accreditation by private organizations prior to export would relieve certifiers of current financial and paperwork burdens while leveling the playing field for large and small organic entities wishing to export organic agricultural products.

An expanded market caused by the introduction of organic meat and poultry, added consumer confidence backed by consistent standards of production and handling, and additional export volumes of organic agricultural products would benefit all of the organic industry.

Another benefit of this proposed regulation to smaller certifiers would be an extended network of information exchange. Presently, information dissemination occurs on a one-to-one basis and through participation in industry groups, meetings, workshops and international trade fairs. Participation in these activities, which often are dominated by issues of the larger certifiers, is costly and frequently prohibitive to smaller entities. This proposed regulation would facilitate providing certifiers with information about the program, including standards, practices and general requirements. Small certifiers would have access to the same information at the same time as large certifiers, which could be passed on to their clients, typically small farmers and handlers.

In our previously discussed implementation option, we consider allowing a 6-month period of time after publication of the final rule for certifying agents to gain initial accreditation, followed by a 12-month period of time for farm, wild crop harvesting, and handling operations to become certified under the relevant provision of the final regulation. Thus, we intend that the provisions of the NOP would be implemented approximately 18 months after publication of the final rule. On that date, which will be stated in the final rule, all organic operations required to be certified in order to sell or label their products as organic would have to be certified. Operations that are certified prior to 18-months after publication of the final regulation would be permitted to use the USDA organic seal upon certification by a USDA accredited certification organization.

We would like comments, particularly from small farm or handling operations, as to whether the 12-month period of time we anticipate allowing for farm and handling operations to become certified is a reasonable period of time for such operations to become certified. We are particularly interested in learning whether there are any economic or other factors that would create difficulties in obtaining certification within the 12-month time period we expect to provide for obtaining certification.

Small certifiers have expressed concern that they may not have the expertise necessary to become accredited by USDA or to carry out the responsibilities associated with accreditation. However, we believe that this proposed regulation is consistent with, and builds upon, current industry practice. It was designed to allow existing certifiers, farmers and handlers to continue to operate within the organic industry.

In developing our proposal, we considered requiring that accreditation be renewed annually by large certifiers and bi-annually by small certifiers. However, annual or bi-annual preparation of accreditation application materials and the review of applications would be burdensome to accredited certifiers and the NOP staff, respectively. Therefore, in this regulation we have proposed that rather than extending the length of accreditation for small certifiers, we would require that all certifiers submit annually only information about their operation that had changed from the previous year. This requirement would eliminate the burden of certifiers annually refiling all of the information submitted in the initial accreditation. Renewal of accreditation would occur every fifth year.

Finally, this proposed regulation has three elements of flexibility that are advantageous to small entities: performance based production and handling standards and certifier requirements; production and handling standards that contain a range of allowable practices; and certifier site-evaluation fees that would reflect actual costs incurred in connection with the site-evaluation.

The standards in this proposed regulation are performance standards based on the results of a management system, rather than prescriptive or design standards that prescribe specific technology or a precise procedure for compliance. Performance standards allow for flexibility in compliance, which is especially important to organic farmers, handlers and certifiers with limited resources. Performance standards promote innovation and the development of new technologies which would help the industry as a whole be more efficient. Finally, they provide a less costly means of compliance than design standards. Small entities, in particular, benefit because compliance with performance standards allows for the adaptation of existing systems without costly capital investment.

The proposed rule allows for flexibility by providing a range of farming and handling practices that can be used when necessary to maintain the organic integrity of the operation. The use of a practice or substance that is allowable only when necessary must be described in the organic plan, as set forth in section 205.205 of subpart D of this proposed regulation, as a record for consideration by the certifier during a certification review. The benefit in providing a range of practices is that a farmer or handler would not lose their investment in an organic operation because of certain conditions, such as adverse weather or commercial unavailability. This is especially important to small farmers and handlers who depend on the organic price premium to a greater extent than larger firms.

Section 2107(a)(10) of the OFPA (7 U.S.C. 6506(a)(10)) authorizes the collection of reasonable fees from farmers, handlers, and certifying agents who participate in the national organic program. When developing this proposed rule, two alternative fee models were considered. The fee for direct services model proposed in sections 205.421 through 205.424 of this proposed regulation combines a fixed fee for all farmers, handlers and certifiers with a variable fee for certain direct services provided by AMS in the accreditation of certifiers. The second model considered, but not used in this proposal, was the fee per certification model which would have based accreditation fees on the numbers of farmers and handlers certified.

The fee for direct services model proposes to distribute program costs for services to certified farmers and handlers through fixed fees of $50 and $500, respectively. The difference between farmer and handler fees is designed to account for the greater overhead and staff time devoted to handler and processed product issues as compared to farmer and raw product issues. A more extensive explanation of farmer and handler fees is provided in the **SUPPLEMENTARY INFORMATION** section entitled ''Fees''. Additionally in this model, certifiers would be required to pay a fee of $640 when applying for accreditation and submitting annual reports to cover staff time needed to

process the application or review the report, and an annual administrative fee of $2,000 for program costs that cannot be allocated to a specific certifier. The balance of accreditation costs would be billed to certifiers on a time rate for direct services. A certifier would have to collect sufficient funds from the farmers and handlers it certifies to cover these program fees. Due to the fixed components of the fees in this model, large farmers and handlers, as well as large certifiers, would have the ability to spread their costs over a larger base and, consequently, lower their fixed costs per unit.

Under the fee for direct services model, labor hours, travel, and per diem costs for the site inspections required for accreditation would be included in the variable fee for direct services. AMS estimates the average cost to conduct an accreditation site visit to be $3,500 per visit. The travel cost component of this figure would vary based on the certifier's distance from Washington, D.C., because site visits would be conducted by the National Organic Program staff working away from program headquarters. An alternative method of distributing travel costs would be to estimate an average annual cost per trip, given the expected number of trips and the geographic distribution of certifiers, and charge that amount for all site visits regardless of location.

The advantage of the fee for direct services model is that it incorporates a measure of size in the fee structure, i.e., the time spent on each accreditation by National Organic Program staff. The variable portion of the fee would distribute program costs among certifiers according to the resources actually consumed in providing the accreditation service. The disadvantage of this model is that it introduces a source of variation in fees for which the derivation is not wholly transparent or predictable. With several National Organic Program staff conducting accreditation evaluations, a complaint about the efficiency of an individual accreditation would be difficult to resolve on the basis of objective measures.

Under the fee per certification model that we did not use in this proposal, in which certifiers would pay a fee to the USDA for each certification performed, the smallest one half of certifiers, who certify about 10 percent of organic operations, would pay about 10 percent of the estimated costs associated with accreditation. The largest 10 percent of certifiers, who certify about 45 percent of organic operations, would pay about 45 percent of accreditation costs. The remaining 40 percent of certifiers in the middle would pay 45 percent of the costs. The fee per certification would be fixed, regardless of the size of the operation being certified. This feature has the potential to create a barrier to market access for the smaller operations. Certifiers who charge farmers and handlers for certification based on size and scope of the operation would maximize their profits by certifying only the larger farmers and handlers from whom they would realize a higher return. If certifiers were to discriminate in this manner in favor of larger operations, smaller farmers and handlers would find the certification services available to them to be relatively limited and possibly more expensive than under the fee for direct services model that includes a variable fee for site visits. A fixed fee per certification also would not take into account, in the distribution of costs, the large difference in size between processors and primary producers. Processors are generally much larger than primary producers in terms of both total output and total revenue.

Even with the flexibility proposed in the regulation and the expanded market opportunities brought about by implementation of the National Organic Program, some small organic certifiers, farmers and handlers may choose not to continue because of the proposed fees. We invite comments concerning the expected benefits and costs to small entities as presented in this analysis.

Paperwork Reduction Act of 1995

This proposed rule contains recordkeeping and submission requirements that are subject to public comment and to review by the Office of Management and Budget under the Paperwork Reduction Act of 1995 (44 U.S.C. 3506 and 3507). Therefore, in accordance with 5 CFR Part 1320, we are providing a description of the reporting and recordkeeping requirements and an estimate of the annual burden on the organic industry. The proposed requirements would not become effective prior to OMB approval.

Title: National Organic Program.

OMB Number: New collection.

Expiration Date of Approval: Three years from date of approval.

Type of Request: New.

Abstract: The information collection requirements in this proposed regulation are essential to carry out the mandate of the Organic Foods Production Act of 1990 (OFPA or Act). The OFPA requires the Secretary of Agriculture to establish and implement a program to accredit a governing State official, or any private person, who meets the requirements of the Act and the proposed regulations, as a certifying agent for the purpose of certifying a farm, wild crop harvesting, or handling operation as being in compliance with the standards set forth in the Act and this proposed regulation. After implementation of the National Organic Program, any agricultural product labeled as organic or made with certain organic ingredients would have to originate from an operation that is certified by an accredited USDA certifier.

The OFPA requires certified farms, wild crop harvesting operations and handling operations to maintain records for 5 years and certifying agents to maintain records for 10 years. The OFPA exempts from certification farm operations with gross agricultural sales of less than $5,000, and the proposed regulation also exempts handling operations with gross agricultural sales of less than $5,000. We propose that each exempt operation would be required to maintain records for one year that verify that such sales are less than $5,000. We also propose that operations that handle only multi-ingredient agricultural products that only represent the organic nature of ingredients in the ingredients statement would not have to be certified. These operations would be required to maintain records for one year that verify the source of organic products received and the operations to whom final organic products are sold. The OFPA also exempts from certification any retail operation, or portion of a retail operation, that only handles organically produced agricultural products, but does not process them. The exemptions and exclusions from certification requirements proposed in this regulation are discussed in the supplementary information provided for section 205.202 of subpart D.

Other information collection requirements proposed in this regulation include: petitioning the NOSB to review a substance for inclusion on the National List; developing labels; preparing inspector and peer review panel reports; documenting methods to prevent commingling of organic with non-organic products; notifying the proper authority in the case of non-compliance with the regulations or the possible violation of food safety laws; and submitting State organic certification programs to the Secretary for approval.

The USDA conducted extensive research while developing this proposed regulation so as to minimize disruption to the customary and usual business practices of certifiers, farms, wild crop harvesting operations and handling

operations. The research included consultation with administrators of existing certification agencies; a review of certifiers' publications, recordkeeping forms, and business characteristics; discussions at meetings with State and private certifiers about their concerns regarding accreditation; communications with the organic industry trade association; and a review of the National Organic Standards Board recommendations that were presented to the Secretary after extensive public input. This research helped us determine that certifiers conduct their certification of farms, wild crop harvesting operations and handling operations in a similar manner and have similar recordkeeping systems and business operating practices. We also determined that most of the information we would require to conduct accreditation could be collected from certifiers' existing materials without creating new forms, and that the information currently used by certifiers to certify farmers, wild crop harvesters and handlers could be adapted to comply with this proposed regulation.

We are required under the PRA to report the amount of time necessary for participants to comply with the proposed regulation as if there were no previously existing documents. The PRA requires that our total reporting (creation and submission of documents) burden cover the greatest amount of reporting burden that might occur for any single creation or submission of a document during any one of the first three years following program implementation, i.e: 1999, 2000, and 2001. Therefore, our total estimated reporting burden reflects the greatest possible burden for each reporting activity that might occur during this three year period. We also are required by the PRA to measure the recordkeeping burden. The recordkeeping burden is the amount of time needed to store and maintain records. For the purpose of measuring the recordkeeping burden for our proposed rule, we use the burden for the year 2001, the reporting year for which we estimated that the largest number of records might be stored and maintained.

The USDA estimated the number of program participants who would be required to either create, submit, or store documents as a result of the proposed rule. To determine the number of organic farmers and handlers, we conducted an analysis of existing certified organic farmers and handlers in the United States for 1994, (Dunn, Julie Anton. 1995. ''Organic Food and Fiber: An Analysis of 1994 Certified Production in the United States.'' U.S. Department of Agriculture, Agriculture) and examined an analysis of data collected for the California Department of Food and Agriculture Organic Program concerning registered organic farms and handling operations in that state (Klonsky, Karen, and Laura Tourte. September 1995. ''Statistical Review of California's Organic Agriculture, 1992–93''. Cooperative Extension, Department of Agricultural Economics, University of California, Davis). Our analysis indicated that an estimated 4,000 farms and 600 handling operations were certified by 33 private and 11 State certifiers. The data collected in the USDA analysis indicated that the number of certified organic farmers increased at an average rate of 12 percent in the period from 1991 to 1994, and the number of certified organic handlers increased at an average rate of 11 percent over the same 3 years. Based on this rate of growth, we estimate that 7,049 farmers and 1,011 handlers will seek certification in the year 1999 and that these numbers would increase to 8,843 farmers and 1,245 handlers in the year 2001. We also estimate, based on our inquiries to existing certifiers, that in the year 1999: 50 percent of certified organic farms will include livestock, 25 percent of certified organic farms and 75 percent of certified organic handling operations will be split operations, and 150 wild crop harvesting operations will seek certification.

Data from the California Department of Food and Agriculture study indicated that 50 percent of registered organic farmers in California had incomes below $10,000 in 1994. For the purposes of this burden analysis, we estimated for the year 2001 that 25 percent of all organic farmers and handlers would have an income of less than $5,000 from the sale of agricultural products and, therefore, would be exempt from certification. Based on our estimated rate of growth for organic farmers and handlers, we anticipate that there would be a total of 11,788 non-certified and certified organic farms and a total of 1,660 non-certified and certified organic handling operations in the year 2001. Of these farms and handling operations, we estimated that 25 percent (2,947 farms and 415 handling operations) could be exempt from certification. As proposed in this regulation, each exempt operation would be required to maintain records to verify that its gross sales of agricultural products is below $5,000. We request data and public input that would assist us to better determine the percentage of certified organic farms with livestock and the percentage of certified operations that may be split operations, the percentage of organic farms and handling operations that may be exempt from certification because they have sales less than $5,000, and the number of wild crop harvesters.

Our inquires to several existing certifiers indicated that of the total number of operations seeking certification, approximately 5 percent of farms and handling operations are denied certification; most of the farms and handling operations denied certification received certification after they reapply. Additionally, approximately 25 percent of certified operations were identified by certifiers during an annual review as having some deficiency; most of these operations retained their certification status.

Other than farmers and handlers, we have made burden estimates for other entities who will create, submit or maintain records as a result of the proposed National Organic Program. For instance, we expect to receive 5 petitions annually for substances to be reviewed by the NOSB for inclusion on the National List. We estimated a low number of petitions because prior to proposing the National List the NOSB researched and determined which substances are currently in use in the organic industry, and because the NOSB itself will be identifying new substances for inclusion on the National List.

We also estimated the time spent to develop product labels for products sold, labeled, or represented as organic or made with certain organic ingredients, or which use the term organic to modify an ingredient in the ingredients statement. The time spent deciding about use of the USDA seal, a State emblem, or the seal of a private certifier also is included in this burden. Our research indicated that operations using product labels containing the term organic handle an average of 19.5 product labels. Additional research indicated that there are currently about 16,000 products with the term organic used on the product label and that the number has been increasing by 250 products annually, based on marketing data from 1994, 1995 and 1996. We estimate, therefore, that by the year 2001, 17,000 products will be marketed with the label term organic.

Regarding operations that handle products that only represent the organic nature of ingredients in an ingredients statement, or that handle prepackaged organic products and do not remove them from the packaging (such as a warehouse or terminal market), the proposed rule contains certain recordkeeping requirements in addition to the requirement to document the procedures to prevent the commingling

of organic with non-organic products and the exposure of organic products to prohibited substances. These recordkeeping requirements are that documentation is to be maintained for 1 year to verify the source and quantity of organic products received and to verify the destination and quantity of products shipped from the operation. At this time, we do not have information as to the number of such operations, nor can we identify a means of collecting this information. We request public input to assist us in determining the number of such operations.

We estimated that the number of certifying agents would remain constant during the years 1999, 2000, and 2001 because our research indicates that the total number has remained unchanged since 1994. Although we predicted in the Regulatory Flexibility Analysis that some of the smallest entities may cease operation as a result of the NOP, we know of new certifying agents that have begun certifying operations, and others who intend to begin so after implementation of the NOP. We also know of existing certifiers who have ceased their operations. We further estimated that the number of organic inspectors would increase by the year 2001. We based this estimate on information obtained from a private organic inspector organization which indicated that each inspector performed approximately 35 inspections in 1996. Using this average of 35 inspections per inspector, we estimate that 293 inspectors would be required in the year 2001 to inspect the estimated 10,238 operations to be certified.

The proposed regulation has certain requirements for laboratory testing of products that are produced on certified organic farms or wild crop harvesting operations and handled through certified handling operations. These tests would be required to be conducted of certified operations not less frequently than every five years; therefore, approximately 20 percent of the total number of certified operations would have products tested each year. Based on our estimate that 10,238 operations would be certified in the year 2001, we estimate that 2,048 operations would have products tested in that year. Other residue testing may be conducted randomly of products at any point of production or distribution. Pre-harvest tissue testing is proposed to be conducted of crops grown on soil suspected of harboring a contaminant. We estimate that certifiers would be required to collect a combined total of 32 samples as part of this random and pre-harvest testing, and would report violations of food safety laws to the appropriate health agencies in 10 instances. We also propose that producers, handlers, and wild crop harvesters report to their certifier any instance of an application of a prohibited substance. We estimate that 25 such instances would be reported to a certifier.

We estimate that approximately 30 foreign programs would submit their programs to USDA in the year 1999 for review in order to seek equivalency with the NOP. These programs are important to handlers of multi-ingredient organic products, especially for the spices and flavoring agents that cannot be produced in the U.S. We also estimate that 15 approved foreign programs would be reviewed again by the Secretary for continued equivalency in the year 2001 and that 5 approved programs would submit substantive program amendments to the Secretary also in the year 2001.

ESTIMATED ANNUAL REPORTING BURDEN

Burden element	Respondents	Number of responses	Average hours per response	Total hours	Total cost
Monitor for measurable degradation of soil and water.	Farmers/handlers, harvesters.	2,560	4.00	10,238.00	$102,380
Petition to add to the National List	Interested parties	5	10.00	50.00	500
Development of a label	Farmers/handlers, harvesters.	17,056	2.00	34,113.00	682,260
Application for certification	Farmers/handlers, harvesters.	8,210	1.00	8,210.00	82,100
Farm organic plan (crops) [1]	Farmers	7,049	14.75	103,972.75	1,039,730
Farms with livestock [2]	Farmers	3,525	3.00	10,575.00	105,750
Split farms [2]	Farmers	1,762	2.50	4,405.00	44,050
Wild crop organic plan	Harvesters	150	9.50	1,425.00	14,250
Handler organic plan	Handlers	1,011	13.00	13,143.00	131,430
Handler split operation [2]	Handlers	759	5.00	3,795.00	37,950
Statement of compliance to USDA regulations	Farmers/handlers, harvesters.	8,210	0.50	4,105.00	41,050
Inspector report	Inspectors	10,240	4.00	40,960.00	409,640
Determination of certification status [3]	Certifying agents, farmers/handlers, harvesters.	8,254	1.24	10,209.10	102,090
Annual continuation of certification	Farmers/handlers, harvesters.	10,238	3.78	38,648.70	386,490
Notification to certified operation of non-compliance	Certifying agents	2,561	2.23	5,711.44	114,220
Certifying agent notification of Administrator [4]	Certifying agents	12,769	0.85	10,848.20	216,960
Accreditation requirements (other than record-keeping) [5].	Certifying agents	8,272	03.06	25,344.00	506,880
Accreditation application	Certifying agents	44	1.67	73.50	1,480
Evidence of ability to certify	Certifying agents	44	23.28	1,024.50	20,500
Statements of agreement	Certifying agents	44	0.69	30.25	600
Peer review panel [6]	Panel members, certifying agents.	72	11.00	792.00	15,840
Annual continuation of accreditation	Certifying agents	44	10.36	456.00	9,120
Transfer of records to Secretary	Certifying agents	2	40.00	80.00	1,600
Suspended certifying agent submits new application	Certifying agents	1	16.00	16.00	320
State program application	State officials	11	42.73	470.00	9,400
Periodic sampling for compliance	Certifying agents	2,048	3.00	6,144.00	122,880

ESTIMATED ANNUAL REPORTING BURDEN—Continued

Burden element	Respondents	Number of responses	Average hours per response	Total hours	Total cost
Additional sampling and residue testing	Certifying agents	22	3.00	66.00	1,320
Report residue and pre-harvest test results	Certifying agents	20	0.50	10.00	200
Report application of prohibited substances	Certifying agents, farmers/handlers, harvesters.	25	0.15	3.75	80
Equivalency of foreign programs	Foreign program officials	30	128.33	3,850.00	77,000
Total				338,771.00	4,278,034

[1] We do not have information to estimate the number of livestock operations that do not produce crops; therefore, it is not possible to estimate the burden hours for such an operation.

[2] Estimated hours for farms with livestock and split operations are in addition to the hours needed to complete a farm plan for crops or a handler plan.

[3] Respondents in the determination of certification status include 44 certifying agents who determine to grant or deny certification to 8,210 applicants. The time elements include the exchange of information necessary for a certifying agent to decide whether to grant or deny certification, issuance of a certificate, and notification of the Administrator when certification is denied and when applicants do not reapply.

[4] Notification of certification status includes notification of the Administrator by the certifier of both the operations that have been certified and those operations not in compliance. We estimate that about 25 percent of all operations will not be in compliance, and would be granted a continuation of certification with restrictions.

[5] The burden elements accounted for in this entry are not mentioned in other sections of the proposed rule. These include the time necessary to provide information to persons seeking certification and to establish a State or certifying agent logo, seal or identification.

[6] We estimate that 72 persons (50 peer review pool members and 22 certifying agents) would participate in the peer review panel process.

ESTIMATED ANNUAL REPORTING BURDEN

Burden element	Respondents	Number of responses	Average hours per response	Total hours	Total cost
Exempt and excluded operations	Farmers/handlers, harvesters.	3,362	1.00	3,362.0	$33,620
Production records	Farmers/handlers, harvesters.	10,238	3.41	34,905.5	349,055
Certification records	Certifying agent	44	3.00	132.0	2,640
Total				38,399.5	385,315

Annual Reporting and Recordkeeping Burden:

Estimated number of respondents: 13,967.

Total annual hours: 377,171.

Total Cost: $ 4,663,349.

It is important to note that the burden being reported is an estimate of the amount of time that would be required of program participants. It is not a measurement of the burden that would be required of existing certifying agents and currently certified farmers, harvesters and handlers in addition to the reporting and recordkeeping activities that they currently perform. In writing the proposed regulation, we carefully reviewed existing industry practice and made every effort to incorporate the documents and practices currently being used within the industry as a means of minimizing reporting and recordkeeping costs when the program begins full operation.

The USDA encourages farmers, handlers and certifiers to use any electronic means available to them to create, submit and store records, including: keeping data base records of crops or livestock produced on operations that are certified; lists of farm and handling operations and their location; creating certification or training documents; maintaining business accounting records; and sending documents by fax or over the Internet. Research of the industry indicates that most certifiers use electronic data creation and storage, fax machines, and the Internet. Some farm and handling operations use computers and word processors for their recordkeeping. Based on this information, we estimated that 25 percent of the collection of information would be performed by automated, electronic, mechanical, or other technological means. We request comments to help assess the number of organizations using computers, word processors, and other electronic equipment to create and store documents, as well as the extent to which the Internet is used to exchange information.

Additionally, comments are invited on: (1) whether the proposed collection of information is necessary for the proper performance of the functions of the USDA, including whether the information would have practical utility; (2) the accuracy of the USDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on those who are to respond, including the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology. Comments should be sent to: Office of Management and Budget, New Executive Office Building, 725 17th Street, N.W., Room 725, Washington, DC 20503, Attention: Lisa Grove, Desk Officer. Comments also should be sent to: Don Hulcher, Clearance Officer, USDA–OICO, Room 404W, Jamie Whitten Building, Ag Stop 7602, P.O. Box 96456, Washington, DC 20090–6456. Additionally, comments may be sent by fax to (202) 690–4632 or submitted via the Internet through the National Organic Program's homepage at: http://www.ams.usda.gov/nop.

Comments are best assured of having full effect if they are received within 30 days after publication of the proposed rule in the **Federal Register**.

National Organic Program Overview

Pursuant to the OFPA, this rule proposes regulations for the production, handling and marketing of organically produced agricultural products and for the management of the National Organic Program. The major components of the national organic program are summarized below. A reference to the placement of the regulatory text of the summarized topic is entered at the end of each program component's summary.

Definitions: Various terms used in the proposal are defined to ensure that regulatory requirements that must be met are clear. Subpart A.

Production and handling requirements: The OFPA requires that national standards be established for the organic production and handling of agricultural products. Agricultural products are any agricultural commodity, whether raw or processed, including any commodity or product derived from livestock that is marketed in the United States for human or livestock consumption. To establish consistent national standards for organic production and handling of agricultural products, this proposed rule provides for the implementation of a system of organic farming and handling that is consistent with the provisions of the OFPA. The standards proposed would apply to the production of crops and livestock and the harvesting of wild crops, and to fresh or processed agricultural products that are, or that are intended to be, sold, labeled, or represented as organically produced or as containing organic ingredients.

The proposed regulation provides for flexibility in the application of the proposed national organic standards and takes into account specific conditions that may occur at different production and handling sites. Under the proposal, each organic farmer and handler would be required to develop an organic plan for their operations. The plan would be evaluated and approved by an accredited certifying agent if it were determined to meet the requirements of the OFPA and the regulations promulgated under the OFPA. The performance of each farmer and handler in meeting the approved practices in their organic plans would be monitored by their certifiers. Subpart B.

National List: This proposal includes a National List of allowed synthetic substances that can be used, and provides for the development of a list of non-synthetic substances that cannot be used, in the production and handling of organically produced agricultural products. The NOSB provided recommendations to the Secretary with regard to synthetic substances it believed should be permitted to be used and the non-synthetic substances it believed should be prohibited for use. The Act establishes the criteria that must be considered before a synthetic substance can be placed on the National List of substances approved for use, and criteria that must be considered before a non-synthetic substance can be placed on the National List of substances prohibited for use. A procedure for petitioning the Secretary and the NOSB to have changes made to the National List of substances approved or prohibited for use is incorporated in the proposed regulations. Subpart B.

Labeling: This rule proposes regulations for the label, labeling, and market information for organically produced agricultural products. The proposal applies to agricultural products that contain various percentages of organic ingredients. The proposal also provides for the use of the USDA organic seal, States' organic seals, and a certifying agent's name, seal or logo, under certain conditions. Subpart C.

Certification: The proposed rule provides the requirements and procedures for farms, wild crop harvesting operations, and handling operations applying for organic certification under the NOP. The proposed rule would permit Indian tribes that as an entity operate a farm, a wild crop harvesting operation, and/or a handling operation, as well as individual tribal members who carry out such operations, to apply for organic certification for these operations. The application process for certification and the requirements that must be met to obtain certification, including the submission of an organic plan, are in the proposed regulations. The proposed regulations provide, in accordance with the Act, that the determination of whether a farm, wild crop harvesting, or handling operation should be certified as an organic farm, wild crop harvesting, or handling operation, would be made by certifying agents accredited by the Secretary. If a certifying agent initially determines that certification should not be granted, the proposed rule allows the applicant for certification to reapply under certain conditions. Additionally, the proposed rule provides for the denial of an application for certification and the termination of certification. It also provides for notice of these actions to the applicant or certified operation and an opportunity for the applicant or certified operation to respond to the notice prior to the denial or termination action. Subpart D.

Accreditation: This proposed rule establishes an accreditation program for persons who want to be accredited as a certifying agent. Persons who could become accredited if they meet the OFPA's requirements for accreditation would include Indian tribes or individual tribal members. Accredited certifying agents would be authorized to certify operations that meet the requirements of the OFPA and the regulations in part 205 as certified farms, certified wild crop harvesting operations, and certified handling operations. State governing officials and private persons may apply for and be accredited by the Secretary as certifying agents. Qualifications needed to obtain and to maintain accreditation are specified in the proposed rule. Procedures for denying, terminating, and suspending accreditation also are proposed. Subpart E.

State organic programs: This proposal permits States to establish or continue to operate their own organic programs, provided that the program reflects the requirements of the OFPA and its implementing regulations, and is approved by the Secretary.

In order for a State program to be approved as meeting the general requirements set forth in section 2107 of the OFPA (7 U.S.C. 6506), the program must have regulatory provisions that meet the following requirements: (1) provide that an agricultural product to be sold or labeled as organically produced must be produced only on certified organic farms and handled only through certified organic handling operations in accordance with the OFPA's requirements and be produced and handled in accordance with such program; (2) require that producers and handlers desiring to participate under such program establish an organic plan as provided for in section 2114 of the OFPA (7 U.S.C. 6513); (3) provide for procedures that allow producers and handlers to appeal an adverse administrative determination under this Act; (4) require each certified organic farm, certified organic wild crop operation, and each certified organic handling operation to certify to the governing State official, on an annual basis, that such farmer or handler has not produced or handled any agricultural product sold or labeled as organically produced except in accordance with this title; (5) provide for annual on-site inspection by the certifying agent of each farm, wild crop

harvesting, and handling operation that has been certified under the OFPA requirements; (6) require periodic residue testing by certifying agents of agricultural products that have been produced on certified organic farms and handled through certified organic handling operations to determine whether such products contain any pesticide or other nonorganic residue or natural toxicants and to require certifying agents, to the extent that such agents are aware of a violation of applicable laws relating to food safety, to report such violation to the appropriate health agencies; (7) provide for appropriate and adequate enforcement procedures; (8) protect against conflicts-of-interest; (9) provide for public access to certification documents and laboratory analyses that pertain to certification; (10) provide for the collection of reasonable fees from producers, certifying agents and handlers who participate in the program; and (11) require such other terms and conditions as may be determined by the Secretary to be necessary.

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

In order to be certified under the State program, an operation would have to meet the State certification requirements. These certification requirements, as discussed previously, must reflect the requirements in the National Organic Program. Thus, certified operations in States that have their own program would be producing products that are represented as organically produced in accordance with the requirements of the National Organic Program that have been included in the State program, in accordance with section 2107 or the OFPA (7 U.S.C. 6506). Therefore, the provisions set forth in our proposal in part 205 would be applicable to operations that are located in States that have their own programs since these provisions would be included in programs that are approved by the Secretary.

States, however, could have requirements that are in addition to those of the NOP if they are approved by the Secretary and meet the statutory criteria for approval. This means that if a State has applied for, and received, approval from the Secretary for requirements in its program that are in addition to those in the NOP, farm, wild crop harvesting, and handling operations that operate in that State would have to comply with these additional requirements that have been approved. However, a State would not be allowed to require farm, wild crop harvesting, and handling operations in other States to comply with any additional requirements that the Secretary has approved for use by that State.

Fees: The proposed rule establishes a system of fees to be paid by farmers, wild crop harvesters, handlers, and certifying agents based on the services provided to them by the USDA. The fees collected from applicants for accreditation and from accredited certifying agents would be for reviewing applications and annual reports, performing administrative services for the benefit of all accredited certifying agents, and for conducting site evaluations to evaluate the certifying agent's performance. The fees collected from farmers, wild crop harvesters, and handlers would be assessed as a fixed fee for each category. Farmers, wild crop harvesters, and handlers operating under a State organic program would pay fees directly to USDA. Subpart F.

Compliance review and other testing: This proposal establishes a system for sampling and testing organically produced and handled products. It provides for pre-harvest tissue testing and residue testing to aid in enforcement of the regulations. Subpart F.

Appeals: The OFPA provides for the Secretary to establish an expedited administrative appeals procedure under which persons may appeal an action of the Secretary or a certifying agent under this title that adversely affects such person or is inconsistent with the organic certification program established under this title. This proposal provides a procedure for the appeal of these actions. Subpart F.

Equivalency of imported organic products: This proposal, in accordance with the OFPA, permits organic products produced and handled in foreign countries to be imported into the United States, and represented as organically produced, under certain conditions. These products would have to be produced and handled under an organic certification program that provide safeguards and guidelines that are at least equivalent to the requirements of the OFPA and the National Organic Program. Under this proposal, the Secretary would review and approve, if equivalent, the foreign organic programs. Subpart F.

Subpart A—Definitions

A number of the definitions provided in this proposed rule are terms defined in the Act, and for these definitions we have used the language provided in the Act. Some definitions are discussed in other parts of the supplementary information and other definitions provided are self-explanatory. However, for certain definitions, we have discussed below our reasons for establishing these definitions to help ensure that appropriate and consistent procedures are followed in complying with other requirements proposed here.

Active ingredient is a term found in section 2118(c)(1)(B)(i) of the OFPA (7 U.S.C. 6517(c)(1)(B)(i)). This section describes categories of substances that may include active synthetic ingredients that may be considered to be included on the National List. Although the Act does not specifically define the term active ingredient, EPA does define this term in section 2(a) of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) (7 U.S.C. 136(a)), as amended. The EPA defines the term active ingredient to be pesticides, herbicides, and other substances covered by the FIFRA. We have included the EPA definition of active ingredient as one of our definitions for this term, i.e., the definition that covers active ingredients in pesticide formulations.

The EPA definition, however, does not cover the full scope of all active synthetic substances that the Act would authorize for inclusion on the National List. Therefore, our other proposed definition for active ingredients, ''active ingredients in any input other than pesticide formulations'', covers these other substances. One type of substance that is included in this definition of active ingredient is a substance used in any aspect of organic production or handling that becomes chemically functional within an agroecosystem. A chemically functional substance is one that would be absorbed by plants or that would affect soil chemistry when used as permitted under this proposal, such as a micronutrient or a cation balancing agent. Substances or materials that do not fit this description, such as plastic mulches, sticky barriers or row covers, thereby would not be considered as

active ingredients under this definition. Our proposed definition also covers substances required to be listed as ingredients or additives on food labels, but it does not include incidental additives and processing aids that are not required to be listed on food labels.

The *agroecosystem* is a term that encompasses all the elements of a system of organic farming and handling, and as such is the primary focus of the proposed organic crop and livestock production standards. Section 2119(m)(5) of the OFPA (7 U.S.C. 6518(m)(5)) specifically indicates that the effects of a substance on the agroecosystem is a criterion that must be evaluated before a synthetic substance can be included on the National List of substances allowed for use.

Biodegradable refers to a specific quality of a material or substance that is used on or applied to the soil that makes the material or substance susceptible to biological decomposition. Most biodegradable materials are organic matter obtained from plant or animal sources. A material such as plastic that is not biodegradable will resist decomposition and persist in the soil, and may enter into unknown chemical interactions with soil and water. While chemical degradation of non-biodegradable materials into simpler compounds eventually occurs, this process happens very slowly compared to biological decomposition. The use of non-biodegradable materials as production inputs is considered to be incompatible with a system of organic farming or handling because they may leave residues of synthetic substances in the soil.

Chapter is defined here with reference to our proposal for the accreditation of certifying agents in subpart E. We are aware of two existing certifying agents that each operate as a single certification body through a system of chapters. We believe that this is an acceptable practice. Such chapters would, however, be expected to comply with the Act and the regulations in this part.

Commercially available is a term that was the subject of extensive deliberation by the NOSB, and our proposed definition reflects their recommendation. We believe that this definition is essential in order for producers and handlers to make appropriate decisions about whether it is necessary to use certain materials, such as the use of non-organically produced planting stock or livestock feed. It also is necessary to help certifying agents evaluate whether the use of such materials is justified or should be discontinued.

Contaminant is a term used in section 2112(b) of the OFPA (7 U.S.C. 6511(b)) with reference to substances that persist in the environment, that may be suspected to be present in soil, and which may necessitate a preharvest tissue test of crops grown on that soil to determine the level of the contaminant in an organically produced crop.

Cytotoxic mode of action is used in sections 205.9(f) and 205.21(a) of subpart B to describe the activity of a type of synthetic substance that is prohibited for use in organic production. Substances of this type chemically interact with plant and animal cells and interfere with normal cell functions. Our definition describes synthetic substances that are cytotoxic and that, therefore, would be prohibited for use.

Degradation is defined to allow organic producers, handlers and certifying agents to accurately identify when the use of a practice or substance that is otherwise permitted under this proposal should be ended or modified. This would occur when it results in measurable degradation of soil or water quality. For example, if nitrate levels in an adjacent well are found to increase over two or more crop years following application of a highly soluble mined source of nitrogen to soil, as set forth in proposed section 205.7 (c)(2) of subpart B, then the practice would have to be terminated or modified to prevent further adverse effects on water nitrate levels.

Detectable residue level (DRL) is proposed for the purposes of this part as being a residue of a pesticide or other prohibited substance that is five percent or greater than the established EPA tolerance level for the product that was tested, provided that if there is no tolerance level established but an action level has been established, the DRL will be the action level established by the FDA for the product tested. EPA tolerance levels, expressed in terms of parts of a pesticide residue per million parts of the food (ppm), refer to the amount of a pesticide residue that may be present in or on a raw agricultural commodity, processed food or processed feed. These tolerance levels are listed in 40 CFR Part 180 (raw agricultural commodities), Part 185 (processed foods) and Part 186 (processed feed). The FDA action levels are used to regulate the occurrence of very low levels of pesticide residues that result from the persistence of a pesticide in the environment and for which there is no tolerance level established by EPA. The action levels for certain pesticides found as residues in agricultural commodities, processed foods or processed feeds are listed in the FDA publication entitled ''Action Levels for Poisonous or Deleterious Substances in Human Food and Animal Feed.'' Certain pesticide residues may not be detectable by available residue testing techniques at a level as low as five percent of the EPA tolerance level; in these cases, we would consider the detectable residue level to be the lowest level measurable by available techniques.

The purpose of defining the DRL at the proposed levels is to establish a practical level for determining when to conduct an investigation, as required in section 2112(c)(2)(B) of the OFPA (7 U.S.C. 6511(c)(2)(B)), to determine when a residue is the result of an intentional application or when it is justified by site-specific unavoidable residual environment contamination due to the persistence of the detected substance. The proposed DRL should help eliminate unnecessary investigations and test procedures and is within the range of tolerance levels developed by existing State and private organic programs. As discussed with reference to unavoidable residual environmental contamination, the Secretary would establish on a case by case basis the residue levels which would indicate that a prohibited substance had been intentionally applied.

Fertilizers are addressed in section 2109(b)(1) of the OFPA (7 U.S.C. 6508(b)(1)), which prohibits the use in organic production of fertilizers that contain synthetic ingredients or any commercially blended fertilizers that contain prohibited substances under the Act or a State program. Although the Act does not define the term fertilizers, we have proposed a definition in order to clarify the kinds of synthetic soil amendment substances that may be considered for inclusion on the National List. Our proposed definition of fertilizers is consistent with those used by various State agencies that regulate the labeling of fertilizers, and refers to materials that supply the major plant nutrients nitrogen, phosphorus and potassium. Synthetic mineral substances, such as micronutrients and cation balancing agents, which do not supply quantities of the three major plant nutrients, would not be considered fertilizers under this definition and could, therefore, be considered for inclusion on the National List because they are not prohibited under section 2109(b)(1) of the OFPA (7 U.S.C. 6508(b)(1)).

Incidental additive is defined so that handlers clearly know that the substances included in this category may be used in handling organic

products, even though the incidental additive itself may not be included on the National List.

Inert ingredient refers to any substance or group of structurally similar substances if designated by the EPA, other than an active ingredient that is intentionally included in a pesticide or formulated product. Inert ingredients used in pesticides are specifically regulated by EPA and have been classified by EPA with respect to their relative toxicity. This EPA classification of inert ingredients is referred to in Section 2118(c)(1)(B)(ii) of the OFPA (7 U.S.C. 6517(c)(1)(B)(ii)) and has been used in this proposal to indicate the types of inert ingredients that may be used in any pesticide product allowed for use on a certified farm or handling operation.

However, the EPA definition does not cover the full scope of inert ingredients that may be used in formulated products allowed for use in organic farming. Our proposed definition of this term also includes inert ingredients intentionally included in any product used in organic crop production, such as fertilizers or foliar sprays.

Non-agricultural ingredient is a term we use in various sections of this proposal to delineate the type and category of substances allowed for use as ingredients in or on organically produced agricultural products if the substance is included on the National List in section 205.26 of subpart B. As discussed in the supplementary information section in reference to the National List, we have used this term in order to accurately describe those substances that would satisfy the provisions of section 2118(c)(1) of the OFPA (7 U.S.C. 6517(c)(1)) related to handling.

Non-synthetic is a term used throughout our proposal to describe those substances that are not synthetic. As discussed in the supplementary information for the National List, we determined that this term is more appropriate than the word natural, which is not defined in the Act and which has other regulatory and marketing meanings.

Packaging is defined here as any material used to wrap, cover, or contain an agricultural product, and also includes wax applied directly to an edible surface of an agricultural product. This definition is proposed in response to the public input that expressed concerns that waxes that contain synthetic fungicides or preservatives may be used on organic products, such as fresh produce or cheese. We believe that this definition is needed to implement the prohibition against the use of packaging materials containing such prohibited substances, as set forth in section 2111(a)(5) of the OFPA (7 U.S.C. 6510(a)(5)), to any material that contacts an edible surface of an organic product.

Production aid is any substance, material, device or structure, but not an organism, that is used to produce an agricultural product. A production aid may or may not be synthetic, and may or may not function as an active ingredient. Examples of production aids are provided in section 2118(c)(1)(B)(i) of the OFPA (7 U.S.C. 6517(c)(1)(B)(i)) and include netting, tree wraps and seals, insect traps, sticky barriers, row covers, and equipment cleansers. Any production aid that is determined to be active and synthetic must appear on the National List in either sections 205.22 or 205.24 of subpart B before it may be used in organic farming.

Putrefaction is defined in order to clarify the reasons why plant and animal materials that are prone to putrefaction are less preferable for use in proper manuring practice than those materials that are not prone to putrefaction, as proposed in section 205.7 of subpart B.

Soil quality is a term that serves as a central performance standard for the use of any method or substance in an organic farming system, in that such use may not result in measurable degradation of soil or water quality, as proposed in section 205.3(b)(1). In order to determine whether a given operation is in compliance with the regulations, farmers and certifiers must have a clear understanding of what soil quality is and how it may be measured. Our proposed definition of this term encompasses physical, chemical and biological soil quality indicators that could readily be measured or observed at a given location. Examples of soil quality indicators commonly measured in organic farming systems include erosion, aggregation, compaction, drainage, organic content, nutrient content, pH, cation balances, presence of contaminants, leaf tissue analysis, presence of indicator weed species, presence of pathogens, earthworm populations, and legume nodulation.

Subtherapeutic is a term used in section 2110(d)(1)(A) of the OFPA (7 U.S.C. 6509(d)(1)(A)) to refer to a dosage level of antibiotics that is prohibited for administration to organically managed livestock. Our proposed definition of this term indicates one of the circumstances in which use of an antibiotic is prohibited.

System of organic farming and handling is a term used throughout our proposal to refer to the general set of principles and objectives of the Act. This term also serves as the foundation of the organic production and handling provisions proposed here, and is discussed more fully in the supplementary information that introduces Subpart B.

Unavoidable residual environmental contamination (UREC) is a term used in section 2112(c)(2)(B) of the OFPA (7 U.S.C. 6511(c)(2)(B)) which we define as the residue level of a prohibited substance that could be expected to exist in the soil at, or in a product originating from, a specific production site to which the prohibited substance had not been applied for a minimum of three years. If a residue test of an organically produced product originating from a specific certified site reveals a detectable residue level of a prohibited substance, then the UREC level for the specific certified site would be determined by the Secretary in consultation with the applicable governing State official, and the appropriate environmental regulatory agency. A product found to contain a detectable residue level exceeding the UREC level for the specific site may not be sold or labeled as organic.

Subpart B—Organic Crop and Livestock Production and Handling Requirements

Introduction

USDA's proposed requirements for organic farming and handling, encompassed in subpart B, sections 205.3, 205.5 through 205.9, and 205.11 through 205.28, set forth the requirements for organic crop production, wild crop harvesting, organic livestock production, organic handling, and for products and substances allowed and prohibited in organic farming and handling. These requirements are proposed to implement the purposes of the Act as set forth in section 2102 of the OFPA (7 U.S.C. 6501) to establish national standards governing the marketing of organically produced agricultural products; to assure consumers that organically produced products meet a consistent standard; and to facilitate interstate commerce in fresh and processed food that is organically produced. Section 2106 of the OFPA (7 U.S.C. 6505) requires that any agricultural product that is sold or labeled as organically produced be produced and handled in accordance with the standards established under the Act. Section 2118 of the OFPA (7 U.S.C. 6517) requires that a National List of substances approved and prohibited for use in organic farming

and handling established by the Secretary be included in the standards. Active synthetic substances must appear on the National List as approved substances in order to be used in organic production, and a non-synthetic (natural) substance may not be used if it appears on the National List of substances prohibited for use.

We would like to point out that the word substance is used in a variety of ways in this docket. When the word substance refers to a material that meets the OFPA's definition of a synthetic substance, it is described as a ''synthetic substance''. When the word substance refers to a non-synthetic material (i.e., natural material), which is one that does not come within the OFPA's definition of a synthetic substance, it is described as a ''non-synthetic substance.'' When the word substance refers to a material prohibited for use in the organic program, whether it be synthetic or non-synthetic (i.e., natural), it is described as a ''prohibited substance.'' An example of such a prohibited material is a synthetic substance that does not appear on the National List of synthetic substances permitted for use in organic farming and handling. When the word substance is used without any modifiers, it is used to describe all materials (substances), regardless of whether such substances are synthetic or non-synthetic, or prohibited or allowed for use in organic farming and handling.

We have crafted this subpart to be consistent with the requirements of the Act, including its principles for organic farming and handling systems. Although the Act does not specifically define what a system of organic farming and handling is, it does refer in sections 2103(4) and (5) of the OFPA (7 U.S.C. 6502(4) and (5)) to a system of organic farming and a system of organic handling, respectively, as described in the Act. In order to establish consistent national standards for organic production and handling, we have determined that it is necessary to define what a system of organic farming and handling is, and to describe those practices that are consistent with such a system. Another purpose of this definition will be to provide an explicit point of reference for the organic industry to make determinations as to whether various practices and substances are consistent with organic farming and handling. We further expect the proposed definition of a system of organic farming and handling to serve as a reference point for program matters it is determined need further development.

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

Our proposed definition has been derived from the underlying premises of what constitutes organic farming and handling systems, as reflected in various provisions of the Act. This definition also is consistent with the definitions and principles established by the existing public and private organic programs that we have reviewed and the definitions and principles of organic agriculture and production systems adopted by the National Organic Standards Board. The principles reflected in our definition of a system of organic farming and handling are incorporated in the regulations we are proposing.

The concept of maintaining the integrity of organic agricultural products is established by one of the purposes of the Act, stated in section 2102(2) of the OFPA (7 U.S.C. 6501(2)), to assure consumers that organically produced products meet a consistent standard. The Act generally delineates methods and substances that may or may not be used in organic farming and handling in furtherance of this purpose. Additionally, in section 2104 of the OFPA (7 U.S.C. 6503) it specifically provides for an organic certification program for producers and handlers of organic agricultural products. Such a program helps to ensure the integrity of organic products.

There is a preference for the use of cultural, biological and mechanical methods wherever possible, as opposed to using substances, in organic farming and handling. Examples of methods that do not involve the use of any substances are the planting of green manure crops instead of applying fertilizer substances, and the use of crop rotations and disease resistant plant varieties instead of applying disease-suppressing substances. Section 2105(1) of the OFPA (7 U.S.C. 6504(1)) provides that an organically produced agricultural product must be produced and handled without the use of synthetic chemicals, except as otherwise provided for in the Act. Further, the Act provides in section 2118 (7 U.S.C. 6517) a detailed scheme and criteria for determining whether a particular active synthetic substance may be exempted from the general prohibition on the use of synthetic chemicals, and further provides in that section for the prohibition of the use of certain substances that are not synthetic. Also, the Act specifically directs in section 2119(m)(6) of the OFPA (7 U.S.C. 6518(m)(6)) that the NOSB consider the use of practices or other available materials as alternatives to a synthetic substance being included on the National List. Furthermore, the use of certain substances in organic crop and livestock production and organic handling is specifically prohibited in several provisions of the Act, such as portions of sections 2109, 2110, and 2111 of the OFPA (7 U.S.C. 6508, 6509 and 6510). Therefore, we are proposing in our definition of a system of organic farming and handling that, where possible, cultural, biological and mechanical methods, as opposed to using substances, are preferred. These provisions support the concept that both non-synthetic substances and methods that do not involve the use of any substances, such as cultural, biological, and mechanical methods, are preferred alternatives to the use of synthetic chemicals.

The tenets of maintaining long-term soil fertility and increasing soil biological activity are established in section 2114(b)(1) of the OFPA (7 U.S.C. 6513(b)(1)), which requires that an organic plan contain provisions designed to foster soil fertility, primarily through the management of the organic content of the soil. The Act further addresses soil biological activity in section 2119(m)(5) of the OFPA (7 U.S.C. 6518(m)(5)) when it requires that the physiological effects of a synthetic substance on soil organisms be taken into consideration before the substance is allowed for use in organic production.

The need for effective pest management methods in an organic farming system is established in section 2109(c) of the OFPA (7 U.S.C. 6508(c)) which prohibits the use of certain substances and materials for the control of pests, weeds, and diseases. This section, considered together with the Act's prohibition of the use of most synthetic chemicals in organic production systems, necessitates that crop pest management methods be implemented that avoid the need to use

synthetic substances and materials. In addition, the inclusion of crop rotation practices in an organic plan, as set forth in section 2114(b)(1) of the OFPA (7 U.S.C. 6513(b)(1)), is critical to implementing effective pest management strategies and soil fertility management in an organic farming system.

Recycling wastes to return nutrients to the land is a principle expressed in the language of section 2114(b)(1) of the OFPA (7 U.S.C. 6513(b)(1)) which requires the fostering of soil fertility and which provides for proper manuring to be used to manage soil organic content, and in section 2114(b)(2) of the OFPA (7 U.S.C. 6513(b)(2)) which delineates more specific requirements for the application of manure to crops. Although the use of livestock manure is one means of complying with this requirement, our proposed definition of proper manuring also includes the use of other plant or animal wastes to improve soil organic content and provide crop nutrients.

Attentive care for farm animals is implicit in the provisions of sections 2110(c) and (d) of the OFPA (7 U.S.C. 6509(c) and (d)), which specify what may or may not be fed to organically managed livestock, prohibit certain health care practices, and require the NOSB to recommend additional standards for the care of organic livestock. The alternative to using the methods and practices prohibited under this section of the Act is expressed by the concept of attentive care which is essential when relying on management methods, rather than substances such as medications, to maintain livestock health.

This proposed rule also incorporates the principle that organic agricultural products are to be handled without the use of extraneous synthetic additives and processing. Examples of extraneous additives are synthetic preservatives, coloring agents and flavors. These are not allowed because the Act, in section 6510(a)(1), prohibits the addition of any synthetic ingredient during the processing or postharvest handling of an agricultural product. Extraneous processing generally involves the use of additional substances during and after the processing. Extraneous processing would entail, for example, unnecessarily subjecting a product to temperatures that degrade its inherent antioxidant content, thereby requiring supplementation with an antioxidant to maintain the product's stability.

Our proposed program encompasses all agricultural products, as defined in section 2103 of the OFPA (7 U.S.C. 6502), and all aspects of their production and handling, ranging from soil fertility management to the packaging and labeling of the final product. Our requirements address the systems used to produce an agricultural product rather than the physical qualities of the product itself. No distinctions should be made between organically and non-organically produced products in terms of quality, appearance, or safety.

We believe that an effective regulatory scheme, which has to be applicable to diverse types of operations and geographic regions must be as flexible as possible and take into account site-specific conditions. We accordingly have developed this proposal to provide, within the parameters of the Act, provisions that take into account site specific conditions without impairing the organic integrity of the product produced. In creating this proposal, we examined various examples of, and ideas for, such provisions, including standards developed by existing organic programs, guidelines of international organic interest groups and standards setting organizations, recommendations of the NOSB, and suggestions provided in public input received in the course of NOSB meetings and as response to NOSB draft documents.

Existing organic certification programs, both State and private, have grappled with the need to provide flexibility in their allowed standards and procedures. One method that existing organic programs have used is to distinguish in their standards between practices that they consider to be acceptable for use without restrictions, those that they consider to be acceptable for use only in certain conditions (i.e., restricted practices), and those that they do not consider to be acceptable for use under any circumstance. An example of restricted use is illustrated by the case of botanical pesticides, which most organic practitioners consider to be a last resort for pest control, and which are considered acceptable for use only under certain circumstances. Many existing organic certification programs have thus included such substances within the area of restricted practices that must be closely evaluated and justified by site-specific needs.

We have approached this need for flexibility by incorporating two types of regulatory provisions into our proposed standards. The first type of regulatory provision establishes, where appropriate, an order of preference for selecting practices or materials. For example, we propose in section 205.7(b) of subpart B an order of preferred selection of five types of materials that would be acceptable for use in proper manuring. We also propose in section 205.9 of subpart B an order of preferred selection for the use of practices and substances to prevent and control crop pests, weeds, and diseases. We would like to solicit public comment as to whether or not the establishment of orders of preference would impose an unnecessary burden on organic producers.

The second type of regulatory provision we propose would permit the use of certain practices or substances only if necessary. The producer or handler would base their determination of the need to use a particular method or substance on site specific circumstances. The basis for a producer or handler determining that a certain practice or substance is necessary would be described in the organic plan, or update to the organic plan, and would be reviewed and evaluated by the certifying agent. An example of a practice that we are proposing be used only if necessary is the use of non-organically produced feedstuffs as a portion of an animal's feed ration, as proposed in section 205.13(a) of subpart B.

A number of the regulations are written as performance standards. Performance standards are generally written in terms of the results expected, rather than the specific actions that must be taken to achieve the desired result. An example of a performance standard is the requirement proposed in section 205.3(b) of subpart B that the use or application of any practice or substance must not result in measurable degradation of soil or water quality. This proposed provision requires that practices used in an organic operation be implemented in a manner that maintains soil and water quality, but does not specify the practices that have to be used.

Subpart B—Regulatory Overview

Subpart B of part 205 consists of USDA's proposed organic production and handling requirements, and a proposed list of (1) synthetic substances allowed and non-synthetic (natural) substances prohibited for use in organic crop and livestock production and (2) non-agricultural substances and non-organically produced agricultural products allowed in or on processed organic products. The proposed requirements for organic production and handling, and the provisions for the proposed National List and use of substances, have been integrated as a unified whole consistent with our

proposed definition of a system of organic farming and handling.

Section 205.3 (applicability) of subpart B delineates proposed general requirements and conditions for organic production and handling. Section 205.3 of subpart B includes the general requirement that the use of any method or substance not result in measurable degradation of soil or water quality. This section is followed by the sections that set forth the requirements for organic crop production (sections 205.5 through 205.9), wild crop harvesting (section 205.11), organic livestock management (sections 205.12 through 205.15), and organic handling (sections 205.16 through 205.19). Following the sections on production and handling, sections 205.20 through 205.28 contain the proposed National List. The proposed National List regulations consist of sections that describe the active synthetic substances that are allowed for use in organic crop and livestock production, the non-synthetic (natural) substances that are prohibited for use in organic crop or livestock production, and the non-agricultural and non-organically produced ingredients allowed in or on processed organic products. (The OFPA does not require non-synthetic (natural) substances allowed for use in organic crop and livestock production, or non-organically produced products prohibited for use in or on processed organic products, to be included in the National List). Sections 205.20 and 205.21 summarize all of the categories and types of substances allowed and prohibited for use in organic farming and handling, as provided under the Act and the proposed regulations in Subpart B.

Applicability—Section 205.3

In paragraph (a) of this section, we propose to establish the requirement that any agricultural product that is sold, labeled or represented as organic be produced in compliance with the relevant proposed crop, wild crop, livestock and handling requirements, including those of the National List. Crops and livestock would have to be produced or harvested on a certified organic farming operation and handled by a certified organic handling operation under a system of organic farming and handling.

We propose in paragraph (b) of this section that any use or application of a method or substance under these proposed requirements must be used in accordance with all applicable requirements of part 205 and must not result in measurable degradation of soil or water quality. This provision is proposed to clarify that all methods and substances used in a certified operation shall be consistent with a system of organic farming and handling, the purposes of the Act, and any other requirements in the regulations in part 205. This provision also is consistent with the recognition in the Act of the relation between organic practices and soil and water quality.

In most instances we are not proposing to require that any specific indicators of soil or water quality be monitored for compliance with this provision. Rather, we expect that appropriate and reliable indicators of soil or water quality would be chosen according to site-specific considerations, such as the nature of the crops or livestock being produced, the location and scale of the operation, and the kinds of practices being used. By not requiring monitoring of specific indicators, except in certain cases, we thus intend to leave the decision as to whether to monitor the effects of a method or substance, as well as the choice of indicators to be monitored, to the producer or handler in consultation with the certifying agent. We would expect any such monitoring activities to be described in the applicable organic plan, and therefore subject to approval by the certifying agent, who might require changes.

For example, if a certifying agent had some concerns about the impact on soil quality of any practice, such as the planting of a sloping field prone to erosion with corn or sorghum, the certifying agent might require the producer to monitor erosion in that field to ensure that soil quality was not being degraded. This could occur following a review of an organic plan or any required annual inspection of a certified operation. This provision also would address the requirement set forth in section 2114(b)(1) of the OFPA (7 U.S.C. 6513(b)(1)) that soil fertility be addressed in an organic farm plan for crop production. Additionally, a certifier who was concerned about the compliance of a cattle feeding operation with the manure management requirements proposed in section 205.15(c) might require that the producer monitor nitrate levels in a nearby well to show that cattle holding areas were not discharging manure-laden runoff into groundwater. A wild crop harvester similarly might be required by a certifier to estimate the population of the harvested plant species that remain in a given area after each harvest, to ensure that the harvesting was being done in compliance with section 2114(f) of the OFPA (7 U.S.C. 6513(f)), which requires that harvesting does not deplete the plant species being harvested (as proposed in section 205.11(b)).

Other indicators of soil or water quality that might be appropriate to monitor, depending on the situation, would include: residues in soil or water of substances prohibited for use in organic farming; soil biological activity as indicated by earthworm populations; soil organic matter and nutrient content; or soil compaction. It should be noted that much of this monitoring activity is widely practiced in the course of managing a farm or handling operation, and in many cases would coincide with measurements, assessments or observations already being undertaken routinely by a producer.

Although not required by statute, the NOSB recommended that irrigation and water management be addressed within an organic farm plan. At this time, however, we are not proposing regulations specifically for the quality of irrigation water.

Section 205.3(b)(2) further would require that, if the same function within an organic farming or handling operation may be fulfilled by either a commercially available non-synthetic substance or an allowed synthetic substance equally suitable for the intended use, then the producer or handler must choose the non-synthetic substance in preference to the synthetic substance if there is no discernable difference between the two in terms of impacts on soil or water quality. We recognize that such choices may seldom have to be made in any operation. However, we are proposing this provision to further reinforce the preference for the use of non-synthetic substances, as opposed to synthetic substances, that is implicit in the Act, as previously discussed. Any allowed synthetic substance will have been evaluated by the NOSB according to section 2119(m)(6) of the OFPA (7 U.S.C. 6518(m)(6)), regarding alternative practices and available materials, and our proposed requirement makes clear the choice producers and handlers must make in a situation where an equally suitable non-synthetic alternative is available.

Organic Crop Production Requirements

Land Requirements—Section 205.5

This proposed section addresses overall land management practices that we have determined are needed to ensure that the area on which organic crops are produced meets the requirements of the Act and the proposed regulations in subpart B. We have proposed in paragraph (a) of this

section, in accordance with section 2105 of the OFPA (7 U.S.C. 6504), that land not have had any prohibited substances applied to it for at least three years prior to harvest of an organically produced crop.

We are proposing further that any land on which organic crops are produced have clearly defined and identifiable boundaries, as provided under section 2107(b)(1)(A) of the OFPA (7 U.S.C. 6506(b)(1)(A)). We believe that this requirement should apply to all land on which crops are grown under organic management for two reasons. First, organically managed fields must be clearly identifiable so that an inspector may verify that the observed conditions on a farm operation are consistent with the information provided by the producer in the application for certification. Secondly, organically managed fields need to be clearly identifiable to anyone who may be using prohibited substances on adjoining lands in order to help prevent unintentional application of prohibited substances to organically managed areas.

Paragraph (b) of this section would apply to any organically managed land area that adjoins land that is not organically managed, and would require that a producer implement, or propose a plan to implement, some means to prevent the possibility of unintended application of prohibited substances to land and contact of a prohibited substance with the land from which organically produced crops are to be harvested. This could be done through establishment of physical barriers, diversion of runoff, buffer zones, or other means, in accordance with section 2107(b)(1)(A) of the OFPA (7 U.S.C. 6506(b)(1)(A)). Existing State and private organic standards have customarily required producers to establish and maintain adequate buffer zones between adjoining organic and non-organic field units and usually specify the minimum size of a buffer area. The information we have reviewed indicates that such specific minimum size requirements should not be included in our proposal because they would not be applicable to every situation and could impose unnecessary burdens on some organic producers.

Crop Rotation—Section 205.6

Crop rotations, or other means of ensuring soil fertility and effective pest management, are the cornerstone of successful organic crop production. They are essential considerations in establishing and maintaining an organic farm system because they help to prevent pest, weed and disease problems; disrupt crop pest, weed, and disease cycles; provide habitat for beneficial organisms; stimulate positive biological and chemical interactions in the agroecosystem; and maintain soil and water quality in a manner that diminishes the need for the use of synthetic substances.

Section 2114(b)(1) of the OFPA (7 U.S.C. 6513 (b)(1)) requires a crop production farm (organic) plan to foster soil fertility through practices that include crop rotation. Although the Act includes a provision for crop rotations as a means of improving soil fertility, crop rotations also serve additional critical functions in an organic farming system. Primary among these functions are: the prevention of weed, pest and disease problems by the planting of species that do not support the pest organisms or that provide food or habitat for beneficial insects; the stimulation of populations of beneficial soil organisms, such as mycorrhizal fungi and predacious nematodes; and the occurrence of alellopathic effects that suppress weed growth.

Such functions similarly may be accomplished by techniques other than crop rotation. Additionally, crop rotation practiced in the production of annual crops, such as corn or soybeans, may not be feasible in the production of perennial crops, such as tree fruits or hay. Therefore, we are providing for alternative practices to crop rotations that also serve the purposes of ensuring soil fertility and effective pest management.

Examples of alternative practices which a producer might use include the following: one method would be to establish or preserve non-agricultural areas such as hedgerows, wetlands, native prairies and woodland, adjacent to or adjoining a farm or field, to serve, for example, as habitat for beneficial organisms. A second related method would be to plant species that serve this same function adjacent to or between rows of crops. A third related method would be the use on pasture areas of rotational or intensive grazing methods in which animals are moved frequently to fresh pasture in order to optimize nutritional content of the forage and extend the pasture season. Other methods commonly used in managing perennial plantings, which cannot be rotated from field to field, include interplanting, alley cropping, strip cropping and introduction of livestock into perennial systems.

As proposed in section 205.2, a crop rotation is defined as the practice of alternating the annual crops grown on a specific field in a planned pattern or sequence in successive crop years, so that crops of the same species or family are not grown repeatedly without interruption on the same field during two or more crop years. This rotation might include the use of sod, legumes or other nitrogen-fixing plants, or green manures in alternation with cultivated crops. These crops are universally recognized in the applicable literature as highly desirable methods of improving soil organic matter content and long-term fertility, as well as conferring other benefits associated with crop rotation.

However, a producer could repeatedly plant the same species or family in a given field over more than two crop years, provided that practices which ensure soil fertility and effective pest management, and which do not result in measurable degradation of soil or water quality, as proposed in section 205.3(b)(1), are used. For example, use of living mulches, such as clover interplanted between rows of carrots, could accomplish the same result as a more frequent rotation of carrots with other crops. Other examples of practices that might be used in place of the rotation of annual crops are the application of large amounts of leaf mulch or compost to beds in which the same crop family is grown several seasons in succession by a small-scale vegetable producer, and a grain operation in which early annual weeds may serve as a green manure crop that replenishes soil fertility and provides the other beneficial effects of crop rotations despite the continual commercial production of a single species in a field.

Soil Fertility and Crop Nutrient Management—Section 205.7

Section 2114(b) of the OFPA (7 U.S.C. 6513(b)) requires that an organic plan provide for the management of soil organic content through proper tillage, crop rotation and manuring, thereby acknowledging the importance of soil fertility for organic crop production. A fundamental tenet of organic management systems is that the primary objective of soil management is to nourish soil organisms which will in turn ensure soil fertility and properly balanced crop nutrition. We have incorporated this concept in drafting this proposal.

We consider the term proper manuring as used in section 2114(b) of the OFPA (7 U.S.C. 6513(b)) to mean any use or application of plant or animal materials, including green manure crops, to improve soil fertility, especially its organic content. The use of compost and other recycled organic wastes, whether or not they contain

livestock manure, are therefore considered to be part of proper manuring. Any practice, however, that could contribute significantly to water contamination by nitrates and bacteria, including human pathogens, or otherwise result in measurable degradation of soil or water quality, would accordingly not be considered proper manuring.

Section 2109(b) of the OFPA (7 U.S.C. 6508(b)) specifically addresses prohibitions on the use of certain materials as fertilizers and soil amendments; these provisions also are addressed in this section of the proposal. The practices we propose for fertility and nutrient management are also relevant to and essential for the prevention of pest, weed and disease problems that might otherwise have to be controlled through the use of synthetic substances.

Section 205.7(a) would require that any tillage or cultivation implements and practices be selected and used by an organic producer in a manner that does not result in measurable degradation of soil quality. Soil physical qualities include soil structure, aggregation, aeration, drainage and erodibility, all of which are indicators of soil fertility. While we have not proposed to prohibit any specific tillage or cultivation implement or practice, our proposal would require producers to select tools and practices that do not harm soil quality. For example, excessive use of rototillers has been shown to damage soil structure and lead to accelerated loss of organic content, while improper moldboard plowing may induce soil compaction. We would expect an organic producer to manage such tools or practices so that no measurable degradation of soil quality resulted.

Proper Manuring—Section 205.7(b)

In section 205.7(b) we propose the types of plant and animal wastes that may be used in an organic system. These materials would represent the methods, in conjunction with crop rotations and green manure crops, that can be used to build soil organic matter and provide essential crop nutrients in accordance with section 2114(b) of the OFPA (7 U.S.C. 6513(b)). The practices proposed are stated in an order of preference for choosing among available alternatives because we believe that these preferences most accurately reflect the concept of proper manuring. As proposed here, the preferred choices in this order of preference are for the practices that are least likely to result in measurable degradation of soil or water quality. For example, the application of compost, as provided in paragraph (b)(1) of this section, is least likely to contribute to contamination of water by nitrates and bacteria, including human pathogens, whereas uncomposted materials having a high soluble nutrient content, as provided in paragraph (b)(3) of this section, are more likely to adversely affect water quality. Because section 2114(b)(2)(C) of the OFPA (7 U.S.C. 6513(b)(2)(C)) requires manuring practices to not significantly contribute to water contamination by nitrates or bacteria, this section also would require that any application of plant or animal waste materials does not do so.

The first choice of materials, as stated in paragraph (b)(1) of this section, would be certain composted materials; these include materials such as livestock manure, food processing wastes, crop residues, spoiled hay and similar materials. The use of composted plant and animal matter recycles nutrients and builds soil organic content with minimal concern for measurable degradation of soil or water quality, and is fully compatible with our proposed definition of a system of organic farming and handling. This practice does not include composts made with certain materials that may pose greater concerns for soil or water quality, which are addressed in paragraphs (b)(4) and (b)(5) of this section.

Paragraph (b)(2) of this section includes plant or animal materials that are neither susceptible to anaerobic decomposition (which presents potential odor and pathogen problems) nor high in soluble nutrients (that may pollute water) and which therefore are suitable for application to soil without first being composted. These materials are the second best choice because applying them directly to soil permits them to decompose and contribute to soil organic content and fertility, thereby functioning in a manner similar to composted materials. This choice also is consistent with the proposed definition of a system of organic farming and handling because it furthers the use of methods in preference to substances. Paragraph (b)(2) of this section would cover materials such as seaweed, sawdust, peat, earthworm castings, leaves, rice hulls and similar dry, stable substances. Well-aged and fully decomposed animal manure that has not been subjected to a composting process might also be used under proposed paragraph (b)(2) of this section.

We propose in section 205.7(b)(3) to allow the use of agricultural waste materials that are known to be susceptible to anaerobic decomposition or that are high in soluble nutrients. These materials are the third choice because they require care in use and application in order to avoid causing measurable degradation of soil or water quality. However, we believe that their use should still be permitted because they are a potentially valuable source of soil organic content and crop nutrients. Examples of such materials include food processing wastes, such as fruit peelings or culls, slaughterhouse by-products, fish wastes, whey, and highly nitrogenous plant concentrates like alfalfa or soybean meal. This category also would include the use of raw animal manure.

Section 2114(b) of the OFPA (7 U.S.C. 6513(b)) permits the application of raw manure to any green manure crop, any perennial crop, and any crop not for human consumption. This section of the OFPA also restricts the use of raw manure, in that raw manure may only be applied to a crop intended for human consumption if the crop is harvested after a reasonable period of time determined by the certifying agent to ensure the safety of the crop, but in no event may the period be less than 60 days after the application of raw manure. Furthermore, section 2114 (b)(2)(C) of the OFPA (7 U.S.C. 6513 (b)(2)(C)) prohibits raw manure from being applied to any crop in a way that significantly contributes to water contamination by nitrates or bacteria.

Over recent months and years, there has been an increase in the incidence of food borne illness caused by certain human pathogens found in animal manure. In consideration of this increased incidence of illness, this proposed regulation does not address in detail the use of raw animal manure in crops intended for human consumption because of the need to develop more and better scientific data regarding the safety of the crop after application of raw manure. Although we acknowledge that the use of animal manure, whether applied directly to the field or composted, is common in organic agriculture, there is inadequate data to make the determinations necessary regarding the safety of the crop after application of raw manure. Similarly, data are needed to make the determinations necessary to ensure that livestock exposure to pathogens does not occur in cases where raw manure is used.

We are soliciting public comment and scientific and technical data in regard to the minimum time which must pass before a crop raised for human consumption on land to which raw manure has been applied may be harvested. Such technical information might include differentiating the type of crops to which differently treated manure can be applied with safety and,

in addition, suitable time and temperature standards for composting animal manures. The Act specifies that when raw manure has been applied to land used to raise a crop intended for human consumption, at least 60 days must pass between application and harvesting to ensure the safety of the crop. If and when regulations regarding the safety of any food grown on land to which raw manure has been applied are promulgated by FDA, EPA and/or USDA, these regulations would be applicable to the use of raw manure in organic agriculture.

We also would like to obtain public comment and scientific and technical data as to whether there are any situations where composted manure would have essentially the same characteristics as raw manure, thus necessitating special measures to ensure the safety of the food. We would like to receive data as to whether under any circumstances, and if so which circumstances, the application of composted material to crops, or the method of preparation of composted material which is intended to be applied to crops, would create any human health or food safety concerns.

On October 2, 1997, President Clinton announced a plan to further ensure the safety of the nation's food supply. The plan, entitled ''Initiative to Ensure the Safety of Imported and Domestic Fruits and Vegetables,'' is geared towards increasing assurances that fruits and vegetables, whether produced domestically or imported, are safe. As part of this initiative, the President directed the Secretary of Health and Human Services, in partnership with the Secretary of Agriculture, and in close cooperation with the agricultural community, to issue guidance on good agricultural practices (GAP's) and good manufacturing practices (GMP's) for fruits and vegetables.

In response to this directive, FDA and USDA are developing guidance to minimize microbial food safety hazards for fresh fruits and vegetables. The guidance is intended to assist growers and handlers in continuing to improve the safety of domestic and imported produce. The agencies have identified several potential vehicles or mechanisms for pathogenic contamination of fruits and vegetables, including but not limited to: (1) Water; (2) the application of manure and municipal wastewater; (3) worker and field sanitation and hygiene; and (4) transportation and handling. The agencies will be publishing draft general guidance for public comment shortly.

Proposed paragraph (b)(4) of this section addresses the use of plant and animal waste materials containing a non-active residue of a substance. We define a non-active residue in section 205.2 as: any synthetic substance that does not appear on the National List of synthetic substances allowed for use, any non-synthetic substance that does appear on the National List of non-synthetic substances prohibited for use, or any non-synthetic (natural) poison (such as arsenic or lead salts) that has long-term effects and persists in the environment, and which occurs in a very small quantity as a non-active substance in a production input or water. This provision would apply to plant or animal waste materials resulting from industrial food or fiber processing, municipal solid waste streams, and similar sources in which the materials have been treated or mixed with other substances. These kinds of materials include non-organically produced cotton gin trash, cocoa hulls, and confinement livestock manure from animals that are known to have been treated with synthetic substances. Municipal yard wastes, including leaves, grass trimmings and prunings, also might fall into this category.

As discussed in the supplementary information to the National List, plant or animal materials that only have been treated or mixed with synthetic substances, but not chemically altered by such treatment, are not considered synthetic under the definition provided by section 2103(21) of the OFPA (7 U.S.C. 6502(21)), and are therefore not prohibited under the Act. Additionally, any non-active residues of substances found on such materials would have minimal or no impact on the organic agroecosystem and therefore the residues are not consistent with the definition of an active substance or ingredient when found in a compost feedstock. Furthermore, the residues themselves are not used to produce an organic crop since they occur as unintended additives that are not intentionally applied and do not perform nor interfere with any function in the agroecosystem.

Such materials would therefore be permitted for use as compost feedstock in organic crop production, but we are proposing that their use be restricted by the requirements that they be composted prior to application to soil, and that levels of any non-active residues detected in the raw plant or animal waste materials not increase in soil. Although certain synthetic substances resist decomposition or may persist if composting is incomplete, most residues present in these materials will decompose sufficiently when subjected to proper composting processes so as to be of negligible concern. A producer using these composted waste materials would be expected to use them in such a way that any persistent residues did not increase in the soil or accumulate to a level that caused measurable degradation to soil or water quality.

In paragraph (b)(5) of this section, we propose to permit the use of plant and animal waste materials that have been chemically altered (by the industrial process), and which are therefore considered active synthetic substances under section 2103(21) of the OFPA (7 U.S.C. 6502(21)), and can only be used if they appear on the National List of active synthetic substances allowed for use in organic farming. Unlike non-synthetic materials that may contain synthetic substances as non-active residues as permitted under paragraph (b)(4) of this section, this provision refers to materials derived from a process that chemically changes the material. Such materials might include leather meal, newspaper and kiln dust. Although this type of material would not have to be composted prior to application, a farmer using such substances in a system of organic farming would be expected to use them in such a way so that measurable degradation of soil or water quality did not occur.

Providing Mineral Nutrients—Section 205.7(c)

In section 205.7(c), we propose that certain mineral substances could be used as a means of fostering soil fertility by providing major nutrients or micronutrients. While use of proper rotations and recycled plant and animal wastes can often provide all the mineral nutrients required by crops, supplemental sources of these nutrients sometimes are needed. We have divided paragraph (c) into two subsections, which represent two broad types of mineral substances that may be used. The first two types consist of non-synthetic substances of low solubility and salinity, including mined substances such as lime, greensand and rock phosphate, and substances extracted from a plant or animal substance, such as liquid seaweed extracts, or from a mined mineral. Such substances historically have been accepted in organic production, and because they are not synthetic chemicals their use is consistent with the Act and with a system of organic farming and handling. It should be noted that, as we discuss in the supplemental information to the National List, we do not consider the extraction method to be consequential

when used to obtain substances from non-synthetic sources that are used in crop production. The extraction method alone would not cause the substance to be considered synthetic nor would we expect the resultant substances to have detrimental effects on biological and chemical interactions in the agroecosystem or cause any measurable degradation of soil or water quality. Fish emulsion products which contain synthetic stabilizers also would not be considered to be synthetic under this proposal because the stabilizers are not active synthetic ingredients, as discussed in the supplementary information to the National List.

The use of ash derived from the burning of a plant or animal material, such as wood or sunflower hulls, is also included in this category of non-synthetic mineral nutrient sources, except for certain instances. The use of ash would be prohibited if the ash is obtained from a practice prohibited under paragraphs (d)(2) or (3) of this section or if the ash appears on the National List of prohibited non-synthetic substances or if the material burned to create the ash had been treated or combined with a prohibited substance. It should be noted that a product of the combustion of an inorganic or mineral substance, such as sulfur or calcium carbonate, would be considered a synthetic substance under this proposal.

The second category of substances that could be used as sources of crop nutrients comprises any highly soluble or synthetic substance, which we propose may be added to soil to correct a known nutrient deficiency provided that its use does not result in measurable degradation of soil or water quality. These substances have historically been permitted by most organic certification programs we have reviewed, but with restrictions placed on their use. We would like to receive comment as to whether or not further restrictions on the use of any of these substances would be appropriate. Such restrictions might, for example, include designating this type of substance as representing a lower order of preference than substances included in paragraph (c)(1) of this section, or might include permitting their use only if necessary.

The three types of substances that would be covered by this second category include synthetic micronutrient substances, non-synthetic minerals that are highly soluble and have a high salt index, and cation balancing agents. Synthetic micronutrient minerals, such as soluble boron and chelated trace minerals (e.g. zinc, manganese, iron, and copper), may often be the most effective and practical choice for correcting soil deficiencies of these essential nutrients, and when properly used can be considered a beneficial practice in an organic soil management system. Their proposed use is restricted because, in addition to being synthetic substances, misuse or overuse of these substances can cause measurable degradation of soil or water quality. Synthetic micronutrients, which are minerals that we propose to consider as active ingredients in an organic system, are proposed in section 205.22(f) for inclusion on the National List as allowed synthetic crop production substances. However, the NOSB has recommended, and we agree, that it is not acceptable to use any of these substances in a way that takes advantage of their herbicidal nature which could result in measurable degradation of soil quality.

Other substances in this category include highly soluble and saline non-synthetic mined minerals, such as sodium (Chilean) nitrate or potassium nitrate (niter), which may be applied as a source of nitrogen, as well as potassium chloride (muriate of potash), langbeinite (sulfate of potash magnesia), and potassium sulfate, which are sometimes used to balance the soil cation nutrient content. Such substances are usually available as non-synthetic mined minerals, but are proposed to be restricted to cases of known nutrient deficiency because of their potential to degrade soil quality by contributing to soil salinization when excessively applied. While the Act makes no mention of these specific materials, section 2109(b)(2) of the OFPA (7 U.S.C. 6508(b)(2)) indicates that certain mineral nutrients and nitrogen should not be permitted if they are inconsistent with the applicable organic certification program. Soil amendment substances, such as langbeinite and potassium sulfate, used to balance cation nutrients are more widely considered to be acceptable adjuncts to an organic fertility management system, but are included in this category due to their high solubility and salinity, which could cause measurable degradation of soil quality if overused. As previously stated, a producer could use these substances only to correct a known nutrient deficiency.

As proposed and discussed in section 205.22(c) for allowed synthetic crop substances, certain cation balancing agents, such as potassium sulfate, may be available on the market either as non-synthetic mined minerals or as synthetic by-products of an industrial process. In cases where the origin of such a substance cannot be determined from readily available information, such as a label or labeling accompanying the product, the mineral is presumed to be synthetic and must appear on the National List as an allowed synthetic crop production substance before it may be used. This presumption would prevent the inadvertent application of a prohibited substance when the producer cannot readily determine the origin of a cation balancing agent.

Finally, we propose in paragraph (d) of this section to prohibit: the use of any fertilizers or commercially blended fertilizers that contain an active synthetic ingredient not allowed for use in crop production as provided for in section 205.22, or that contains an active prohibited substance; the use of ash obtained from the disposal of manure by burning; and burning as a means of disposal of manure or of crop residues produced on the farm. The first prohibition is proposed in accordance with section 2109(b)(1) of the OFPA (7 U.S.C. 6508(b)(1)) which requires that such a prohibition be established. The second and third prohibitions are proposed in agreement with the recommendations received from the NOSB. Burning these materials is not an appropriate method to use to recycle organic wastes and would not be considered as a proper method in a manuring program because burning removes the carbon from these wastes and thereby destroys the value of the materials for restoring soil organic content. Burning as a disposal method of these materials would therefore not be consistent with section 2114(b)(1) of the OFPA (7 U.S.C. 6513(b)(1)).

Selection and Use of Seeds, Seedlings and Planting Stock—Section 205.8

Section 2109(a) of the OFPA (7 U.S.C. 6508(a)) prohibits an organic producer from applying materials to or engaging in practices on seeds or seedlings that are inconsistent with the program established under the Act. Therefore, we are proposing that all seeds and planting stock, including annual seedlings and transplants, be organically produced. However, we recognize that at the present time this is impractical for many farms because organically produced seeds and planting stock are not widely commercially available; thus, we are proposing to permit exceptions to this requirement. It is our expectation that our requiring organic producers to use organic seed and planting stock except in limited circumstances will stimulate increased organic production of these essential farm inputs.

This proposal would permit the use of non-organically produced seeds and planting stock in producing an organic

crop only when an equivalent organically produced variety is not commercially available. Planting stock includes, as we define it, any plant material used for plant reproduction, except seeds, and includes such materials as seedlings, cuttings, tubers, roots, slips, rhizomes, crowns, and plantlets derived through tissue culture techniques. Our proposal also would require that untreated planting stock be selected in preference to treated planting stock whenever there is a choice. With the exception of annual seedlings, most organic farm operations are not equipped to produce planting stock on the farm. In addition, certain planting stock, such as berry plants and tubers, are required by some State regulations to be treated with pesticides to prevent the introduction of plant diseases and other pests.

Although we have received some input in favor of prohibiting all uses of non-organically produced annual seedlings, we believe that the inclusion of such annual seedlings under this proposed rule is justified. The flexibility of allowing the use of non-organically produced annual seedlings would permit a farmer who lost a crop due to unanticipated or emergency circumstances shortly after transplanting to replant with a similar non-organically produced variety that was either treated or untreated. It should be noted that any annual seedlings that are produced and replanted on the same certified organic farm are considered transplants and could not be treated with prohibited substances, as proposed in section 205.8(c).

We are proposing that treated seeds could only be used if untreated seeds of the same variety are commercially unavailable or it is infeasible to obtain untreated seeds due to unanticipated or emergency circumstances. As discussed in the supplementary information for the National List, we are not proposing any seed treatment substance to be included on the National List because we are not proposing to allow a producer to use any seed treatment on a certified organic farm. Treated seeds under our proposal are not an active synthetic ingredient in the organic farming system and therefore are not required to appear on the National List. A producer could not use the treated seed in order to take advantage of the functional application of the seed treatment (this would be using the seed treatment as an active ingredient) or to use up treated seed remaining from the previous year if the appropriate untreated seed had since become available.

Because a full range of untreated non-organically produced crop seeds is widely available, the circumstances under which this exception would be justified are limited. These circumstances might include situations in which untreated seeds are not obtainable due, for example, to the fact that untreated seeds must sometimes be ordered well in advance of expected delivery or the fact that it may not be possible to order very small amounts of untreated seed of a new seed variety that a producer wishes to use on a trial basis. Emergency or unanticipated circumstances would include loss of a crop to flood or frost and untreated seeds were no longer available for replanting.

In section 205.8(b) we propose the requirements for how non-organically produced planting stock used as planting stock to produce a perennial crop could be sold, labeled or represented as organic. We propose this provision, as authorized by section 2107(a)(11) of the OFPA (7 U.S.C. 6506(a)(11)), in order to provide the means by which a nursery operation that operates in accordance with the Act and our proposed regulations in part 205 could purchase planting stock from a non-organic operation and later resell this stock as organically produced. This proposal would permit perennial planting stock to be represented as organic after it had been maintained under organic management on a certified organic farm for a period of at least one crop year. For example, a certified organic nursery operation could purchase non-organic dwarf apple rootstock and graft it with locally adapted varieties, then sell the resultant planting stock as organically produced after raising it organically for at least one year. We have proposed the one year period because we do not consider nursery stock that is held on a certified operation for less than a year before it is resold to have been organically produced. This provision is intended to stimulate a wider availability of key organic production inputs and thus make the ability to comply with the requirement that organic sources of planting stock be used, as set forth in proposed section 205.8(a), more feasible for organic producers.

In section 205.8(c), we propose to prohibit the use of transplants treated with a prohibited substance, as provided for in section 2109(c)(3) of the OFPA (7 U.S.C. 6508(c)(3)). It should be noted that we have defined a transplant as an annual seedling produced on an organic farm and transplanted to a field on the same farm operation to raise an organically produced crop. This definition also is consistent with section 2109(a) of the OFPA (7 U.S.C. 6508(a)) which prohibits farm producers from applying substances to seeds or seedlings that are contrary to or inconsistent with the proposed program. We do not propose to prohibit the use of seedlings or other planting stock that may have been treated with synthetic substances before reaching the organic farm since the treatment itself is not applied on, or intended to be used on, the organic farm.

While the OFPA mandates that the Secretary develop organic standards, it is silent on the issue of genetically engineered organisms (GEOs) and their products. However, the accompanying Senate report language states that ''* * * as time goes on, various scientific breakthroughs, including biotechnology techniques, will require scrutiny for their application to organic production. The committee is concerned that production materials keep pace with our evolving knowledge of production systems.''

In the time since the OFPA was passed, GEOs and their products have assumed a more significant role in agricultural production. The policy of the United States Government is that GEOs and their products should be regulated based on risk, not on how they are produced. The NOSB has recommended to the Secretary as a policy matter that GEOs should not be allowed in organic farming and handling.

Public comment is invited with respect to the use of GEOs or their products in a system of organic farming and handling. The USDA specifically invites comments on whether the use of GEOs or their products in organic farming and handling should be permitted, prohibited, or allowed on a case-by-case basis. Comments should detail the basis for the commenter's recommendations, including the agricultural, technical, or scientific factors involved. Comments should also identify the criteria that should be applied to case-by-case determinations.

Prevention and Control of Crop Pests, Weeds, and Diseases—Section 205.9

Section 2109(c) of the OFPA (7 U.S.C. 6508(c)) sets forth practices, such as the use of natural poisons that persist in the environment, or plastic mulches, that are prohibited or restricted in the control of pests, weeds and diseases in organic crops. Section 2118(c)(1)(B)(i) of the OFPA (7 U.S.C. 6517(c)(1)(B)(i)) lists the following categories of active synthetic substances (used for pest, weed, and disease control) that may be considered for exemption if they are

included on the National List: copper and sulfur compounds; toxins derived from bacteria; pheromones, soaps, horticultural oils, vitamins and minerals, and production aids including netting, tree wraps and seals, insect traps, and sticky barriers.

This section is designed to implement these two provisions of the Act and is consistent with the NOSB recommendations and public comments received by the NOSB, as well as being consistent with the proposed definition of a system of organic farming and handling. The structure of this section reflects an order of preference, in which the first choice is the use of management methods to prevent the occurrence of weeds, pests, and diseases, and the second choice is the use of methods and certain substances to control occurrences that may develop. This section is consistent with the definition of a system of organic farming and handling and with the NOSB recommendations because it requires that methods be chosen in preference to substances and that toxic substances, whether allowed synthetic substances or non-synthetic substances, be permitted only as a last resort.

In section 205.9(a), we propose to require that preventive measures be used by an organic producer for the prevention of pest, weed and disease problems in crops, including, but not limited to: crop rotations or other practices provided for by section 205.6; replenishment and maintenance of soil fertility, as proposed in section 205.7; appropriate sanitation measures, such as composting plant debris to remove disease vectors, weed seeds and pest habitat; cultural practices such as irrigation or timing of plantings to enhance crop health and avoid peak pest hatchings; and selection of species and varieties for traits such as disease resistance and suitability to local climate conditions.

When prevention is inadequate, sections 205.9(b) through (d) of our proposal would provide for a range of practices that could be used to control pest, weed, and disease problems. These methods are consistent with the section 2105(1) of the OFPA (7 U.S.C. 6504(1)) requirement that organic production not include the use of synthetic chemicals unless otherwise provided for in the Act. Although a preventive management approach, as exemplified in proposed section 205.9(a), would be preferable, we recognize that once pests or weeds are present they must be controlled in order to avoid economic or otherwise significant damage to crops. Pest control practices, as proposed in section 205.9(b), are: augmentation or introduction of predators or parasites, such as trichogramma wasps and ladybugs; mechanical or physical controls, such as pest barriers or traps; and use of non-synthetic and non-toxic controls, such as repellants or lures. All of these methods are fully consistent with a system of organic farming, as defined in section 205.2, and do not entail the use of any active synthetic substance.

Practices proposed in section 205.9(c) that could be used for weed control when preventive measures are not effective are: mulching with fully biodegradable materials, which include plant-derived matter such as straw, bark, leaves and paper, but do not include plastics that disintegrate but do not biodegrade; livestock grazing to reduce weed competition; any mechanical or physical controls, such as weeding and cultivation techniques; and, in accordance with section 2109(c)(2) of the OFPA (7 U.S.C. 6508(c)(2)), plastic or other synthetic mulches provided that they are removed from the field at the end of the growing or harvest season. It should be noted that the use of cultivation to control weeds under this proposal also would have to be consistent with the provisions proposed in section 205.7(a) for protecting soil quality.

In paragraph (d) of this section, we propose that practices that are intended to prevent the spread of diseases, such as steam sterilization to eliminate disease organisms from greenhouse growing media, could be used if disease preventive measures are not effective. Plant diseases, once they occur, are difficult to control with existing organic technologies, although some success has been demonstrated with the use of compost preparations that actively suppress plant pathogens, a practice that would be included in this provision.

In paragraph (e) of this section, we are proposing to permit the use of certain methods and substances to control pests, weeds, and diseases in an organic farming system if the practices proposed in paragraphs (a) through (d) are not effective, provided that their use does not result in measurable degradation of soil or water quality. Although the use of the proposed substances is often necessary, the use of these substances may pose concerns for soil or water quality when overused. Therefore, a producer who used any substance proposed for use in paragraph (e) of this section would have to describe in the organic plan how use of the substance was not resulting in measurable degradation of soil or water quality.

Botanical pesticides are specifically addressed in section 2119(k)(4) of the OFPA (7 U.S.C. 6518(k)(4)) as requiring a special review to determine whether any of them should be placed on the National List of prohibited natural substances. This review was undertaken by the NOSB at its meeting in Rohnert Park, California, in October, 1994. Considerable public input also has been received concerning the use of botanical pesticides in organic production. Some public input expressed concern as to whether organic farmers should be permitted to use any pesticide sprays, even if they are non-synthetic. Many organic practitioners who acknowledged the need to use botanical pesticides stated that they used them only after more ecologically compatible alternatives proved to be unsuccessful. Our review of existing organic programs and public input also indicated that non-synthetic substances used as biological controls may pose concerns for soil and water quality if used indiscriminately. Concerns also have been expressed that the use of these substances may impact biological and chemical interactions in the agroecosystem, including the possibility of inducing accelerated resistance in pest populations.

While many producers may not need to use botanical pesticides, prohibiting these materials entirely would severely restrict the availability of a wide range of organically produced crops. After concluding its technical review process, the NOSB recommended that neem, pyrethrums, rotenone, ryania, and sabadilla be allowed for use in organic agriculture. We agree with the NOSB recommendations on the basis of the aforementioned public input, and therefore provide in section 205.9(e) for the use of botanical pesticides under certain circumstances, provided that the botanical substance is not included as a prohibited non-synthetic (natural) substance on the National List.

Our proposal also would allow the use of any synthetic weed, pest, or disease control substance that is included on the National List as a crop production substance, such as dormant oils, vitamin-D based rodenticides, pheromones, and copper or sulfur fungicides. In addition, non-synthetic, biologically based materials, such as bacterial toxins, that are used to kill pests, weeds or plant diseases also would be included under this paragraph of our proposal.

This paragraph of section 205.9 also would permit the use of allowed synthetic substances for the purpose of cotton defoliation. We have determined that this provision should be proposed

after reviewing testimony from organic cotton producers and scientific evidence that the substances in question, which are mineral compounds having a high salt index and solubility (and usually synthetically derived) are ordinarily not used in amounts that could cause concern for adverse impacts on soil fertility.

Prohibited Pest, Weed and Disease Control Practices—Section 205.9(f)

In section 205.9(f), we propose to prohibit the use of a synthetic carbon-based compound that kills insects, weeds, diseases or other pests through a cytotoxic mode of action. We have defined the phrase cytotoxic mode of action to mean having a toxic effect by means of interference with normal cell functions. We believe this proposal is appropriate because section 2118 (c)(1)(B)(i) of the OFPA (7 U.S.C. 6517(c)(1)(B)(i)) does not delineate this category of substances as a category of active synthetic substances that could be considered for inclusion on the National List of permitted synthetic substances. In addition, these substances are prohibited under all existing State, private and international organic programs that we reviewed, and public input received from organic producers and other members of the public has raised frequent concerns that such substances potentially might be allowed for use in organic production. We therefore have determined that the use of any substance in this category would be inconsistent with a system of organic farming, as defined under proposed section 205.2, and with the organic certification program established under the Act.

Wild Crop Harvesting—Section 205.11

Wild crops are generally not produced and managed on a farming operation, but rather are harvested from public or private lands; therefore, most of the farming and management practices and materials described in this proposal, such as soil management practices or weed, pest and disease control, would not be applicable. However, because wild crops are addressed in section 2114(f) of the OFPA (7 U.S.C. 6513(f)) and because they are used extensively as ingredients in many organic products, we are proposing in this section provisions for the harvesting of organic wild crops. We note here that if management practices such as cultivation or fertilization are undertaken prior to the harvest of a wild crop, the wild crop would be considered as a managed agricultural product and would be subject instead to the relevant requirements proposed for organic crop production. This idea is reflected in our proposed definition of a wild crop as being harvested from an area of land that is not maintained under cultivation or other agricultural management. It should be noted that this section would apply only to crops harvested from the wild, and that game animals harvested from the wild are not addressed in this proposal.

As required under section 2105(2) of the OFPA (7 U.S.C. 6504(2)) and section 2114(f)(2) of the OFPA (7 U.S.C. 6513(f)(2)), we propose in section 205.11(a) that the land from which wild crops are harvested for sale as organic must have had no prohibited substances applied to it for the three years immediately preceding the harvest of the wild crop and any time thereafter. Our proposal requires that wild crop harvesting be done in a manner that would not be destructive to the environment and which would sustain the growth and production of the wild crop, as required under section 2114(f)(3) of the OFPA (7 U.S.C. 6513(f)(3)).

Organic Livestock Production Requirements

Section 2110 of the OFPA (7 U.S.C. 6509) sets forth certain requirements and prohibitions for organic animal production. It requires the Secretary to hold public hearings to guide the implementation of standards for livestock products. It also states that the NOSB shall recommend additional standards for livestock health care to ensure that such livestock is organically produced. Accordingly, the Secretary held public hearings in Washington, DC, on January 27–28, 1994; Rosemont, IL, on February 10, 1994; Denver, CO, on February 24, 1994; and Sacramento, CA, on March 22, 1994 on this matter. Additionally, the NOSB provided recommendations to the Secretary on August 1, 1994 and subsequently, as required in the Act. We have developed the provisions proposed in sections 205.12 through 205.15 in accordance with section 2110 of the OFPA (7 U.S.C. 6509), the input received at the public hearings, and the NOSB recommendations.

Origin of Livestock—Section 205.12

Livestock as defined in section 2103(11) of the OFPA (7 U.S.C. 6502(11)) are cattle, sheep, goats, swine, poultry, equine animals used for food or in the production of food, fish used for food, wild or domesticated game, or other nonplant life. Organically raised livestock should be the offspring of organically raised parents and live under organic management beginning with their first day of life. We propose in paragraph (a) of this section that livestock raised on a certified organic farm for the production of meat, milk, eggs, or other products to be sold, labeled, or represented as organically produced be under organic management from birth or hatching, or be the offspring of parents that have been under organic management, except in certain cases. These exceptions are based on the provisions of section 2110 of the OFPA (7 U.S.C. 6509) that provides that breeder stock, poultry from which meat or eggs are derived, and dairy animals from which milk and milk products are derived, can be purchased from non-organic sources and subsequently raised as organic livestock.

Paragraphs (a)(1) through (3) of this section are proposed in accordance with section 2110 of the OFPA (7 U.S.C. 6509). Paragraph (a)(1) of this section would permit the purchase of livestock from any source for use as breeder stock of organic livestock, except that a gestating mammal would have to be brought onto a certified facility prior to the last third of pregnancy. Paragraph (a)(2) of this section would permit dairy animals from which milk or milk products will be sold, represented, or labeled as organically produced to be brought onto a certified facility beginning no later than 12-months prior to the production of milk or milk products that are to be sold, represented, or labeled as organic. Paragraph (a)(3) of this section would permit the purchase of poultry from any source for use as organic slaughter stock (meat) or for organic egg production provided that the poultry are brought onto a certified facility no later than the second day of life.

We have proposed other provisions that cover what the practices are for bringing other types of livestock, such as bees, fish, and mammalian livestock designated as organic slaughter stock, into an organic operation to produce such products as fiber, honey, meat and caviar. These provisions are based on public input received at the USDA livestock hearings, NOSB meetings and public response to NOSB draft recommendations.

In section 205.12(a)(4) we propose that livestock may be designated for the production of non-edible organic products, such as hides, feathers, fur and fiber, if the animal is raised in compliance with one of the other provisions proposed in paragraph (a) of this section, as appropriate to the species. Additionally, we propose that livestock not raised under organic management from birth or hatching,

such as male breeder stock purchased from non-organic sources and subsequently raised as organic livestock for the production of certain non-edible products, shall have been maintained under organic management no less than 90 days prior to harvest of the organic product. For example, wool from a buck sheep designated as organic breeder stock in accordance with paragraph (a)(1) of this section could be sold or represented as organically produced only after the buck had been maintained under organic management for at least 90 days prior to the time of shearing. This time period is proposed in order to ensure that non-edible products, such as wool or hides, from breeder animals brought under organic management could not be represented as organically produced until the producer had included the livestock in the overall farm management system.

In section 205.12(a)(5) we are proposing how livestock types such as fish, crustaceans, mammalian livestock designated as organic slaughter stock, and other species not addressed in the previous four provisions, could be introduced onto an organic operation for the production of edible organic products.

We specifically propose in paragraph (a)(5)(i) that bees may be brought onto a certified facility at any stage of life. We propose this because we determined that the production of honey depends on the nature of the forage available to the bees at the time of honey flow. Additionally, because of the ephemeral life cycle of individual bees, previous locations of the hive would be inconsequential to the honey harvested at the certified organic facility.

We propose in paragraph (a)(5)(ii) of this section that, if necessary, mammalian livestock from any source could be used as organic slaughter stock for the production of meat if it is brought onto a certified facility no later than the 15th day of life. This proposed provision would allow producers a reasonable length of time to integrate animals from non-organic sources into their organic operation, while still ensuring that the animal is brought onto the certified facility early enough in life to develop primarily and substantially under organic care. Allowing a mammal up to 15 days to be introduced onto the certified facility would provide adequate time for the young stock to receive its mother's first milk, gain strength and be transported over any distance to the organic farm.

As noted, a producer could use non-organic sources of mammalian livestock to be designated as organic slaughter stock only if the use of non-organic livestock is necessary. The determination of necessity would be based on site-specific conditions that would be described by a producer in an organic plan, or updates to an organic plan, and reviewed by the certifying agent. Examples of site specific conditions that may serve as a basis for supporting the determination to purchase livestock from non-organic sources are: commercial unavailability of livestock from organic sources, and unanticipated or emergency circumstances that prevent the purchase of commercially available organic livestock.

We are requesting public comment as to the conditions under which non-organic mammalian livestock may be used as organic slaughter stock. For example, we would like public comment as to whether specific conditions, such as commercial unavailability of organic livestock or an emergency situation, should be a prerequisite for allowing mammalian livestock of non-organic origin to be designated as organic slaughter stock and, if so, what these conditions should be. We also request comment as to whether we should provide for the use of mammalian livestock of non-organic origin in the production of organic meat.

We propose in paragraph (a)(5)(iii) that all livestock types other than those described in paragraphs (a)(1) through (5)(ii) may be brought onto a certified facility no later than the earliest commercially available stage of life. Other livestock types represent a wide range of life spans and levels of commercial availability, and there is no basis for proposing specific time limits for their introduction into an organic facility. Sufficient time is required to raise the young of any such species from its earliest commercially available stage to reach marketable size; this time period will ensure that the stock is raised primarily under organic management.

Prohibited Practices for Origin of Livestock—Section 205.12(b)

In section 205.12(b)(1), we propose that producers be prohibited from moving animals in and out of organic care for the purpose of circumventing the proposed requirements. This provision addresses our concerns that the leeway provided by proposed paragraph (a)(1) of this section for the purchase of non-organic breeder stock might be misused by a producer who might, for example, repeatedly bring a pregnant mammal onto a certified farm just prior to the last third of pregnancy, remove the mammal from organic care after the offspring is born, and then reintroduce her to organic management again just before the last third of the next pregnancy. Paragraph (b)(2) of this section is consistent with section 2110(c)(3) of the OFPA (7 U.S.C. 6509 (c)(3)), which prohibits the use of hormones to stimulate the growth or production of organically produced livestock. In paragraph (b)(2) of this section we propose that the use of hormones for any breeding purposes be prohibited.

Livestock Feed—Section 205.13

Organically produced feed is one of the foundations of organic livestock management. Section 2110(c)(1) of the OFPA (7 U.S.C. 6509(c)(1)) requires producers of organic livestock to provide organically produced feed that meets the requirements of the Act to their livestock. Therefore, we propose in paragraph (a) of this section that the total feed ration for organically raised livestock be organically produced. This requirement would include all pasture or rangeland on which the livestock are grazed. Forage from rangeland would be considered a wild crop and, thus, would be considered to be organically produced if it complied with the proposed wild crop harvesting requirements proposed in section 205.11. Purchased feed supplements, such as soybean protein concentrates, would have to be produced in compliance with the Act and the regulations in subpart B to be considered organically produced.

During the livestock hearings conducted by USDA, producers expressed concerns that unless an allowance was provided for non-organic animal feed, the organic status of livestock could be jeopardized by unavoidable circumstances that would cause or prevent livestock from consuming non-organic feed. Some of the circumstances cited by the producers were poor growing conditions, severe weather, commercial unavailability and fence jumping. We believe that these concerns are valid and, therefore, propose in paragraph (a)(1)(i) through (iv) of this section to permit, if necessary, that livestock under organic management be allowed to receive other than a total feed ration that is organically produced. We believe that our additional proposed provisions are consistent with a system of organic farming and handling and that they will not result in a compromise of the integrity of organic products.

We propose in paragraph (a)(1)(i) of this section that an animal be allowed to receive up to twenty percent non-organic feed as part of its total feed ration in a given year. Paragraph

(a)(1)(ii) of this section proposes that in emergency situations which affect the commercial availability of organic feed, such as weather related disasters, the Administrator could authorize the use of non-organic feed greater than the twenty percent non-organic feed allowed in paragraph (a)(1)(i) of this section.

As noted, a producer could use non-organic sources of feed if the use of non-organic feed is necessary. As previously described in regard to the use of non-organic sources of mammalian livestock to be designated as organic slaughter stock, determination of necessity would be based on site-specific conditions that would be described by a producer in an organic plan, or updates to an organic plan, and reviewed by the certifying agent.

We are requesting public comment as to conditions under which non-organic feed may be used. For example, we would like public comment as to whether specific conditions, such as commercial unavailability of organic feed, regional environmental factors, or an unanticipated situation, should be a prerequisite for allowing non-organic feed and, if so, what these conditions should be. We also request comment as to whether we should provide for the use of feed of non-organic origin in the production of organic livestock on certified organic farms.

In paragraph (a)(1)(iii) of this section, we propose an exemption that would allow an entire, distinct dairy herd, that is converted to organic management for the first time, to be fed non-organic feed up to 90 days prior to the production of milk or milk products labeled, sold, or represented as organic. In testimony received at the USDA public hearings, milk producers expressed concern that purchasing organic feed for twelve months prior to selling the milk as organic could hinder or prevent a producer from deciding to make the transition from non-organic to organic production. They further explained that the twelve-month period for feeding organic feed grown on the farm could not be initiated until after the farm was certified as organic, which might be three years after the producer first decided to make the transition to organic production so as to comply with section 2105(2) of the OFPA (7 U.S.C. 6504(2)) regarding prohibited substances applied to the land.

Our proposal would permit use of this exception only one time for any given discrete dairy herd. This exception applies only to feed; producers still would have to comply with all other organic livestock management requirements for the 12-month period prior to selling the milk or milk products from these animals as organic, as required in section 2110(e)(2) of the OFPA (7 U.S.C. 6509(e)(2)).

We propose in section 205.13(a)(1)(iv) that bees from which organic honey and other products are harvested be provided with access to enough organically managed forage to provide them with a predominant portion of their needs. The NOSB received many comments about organic honey production and considered several suggestions without making a recommendation to the Secretary. One suggestion considered by the NOSB was that the producers monitor their honey bees to ensure that only organic forage was accessed by the bees; honey producers maintain that it is infeasible to monitor and control all bee forage areas. Another suggestion considered was to require the hive to be surrounded by organic forage areas for the total radius of the distance for which bees are known to fly. However, this radius may vary and is impractical in most regions because the estimated two mile radius that bees are known to cover would entail more than 12.5 square miles of continuous organic forage area surrounding each hive.

In creating the proposed provision for bee forage areas, we considered the applicability of the proposed provision in paragraph (a)(1)(i) of this section for twenty percent non-organic feed. However, we decided that it would not be possible for a producer or certifier to ascertain the exact forage percentages for bees. We expect that producers of organic honey would meet our proposed requirement that bee forage areas be predominantly organic by actively managing on-farm plantings, including crops, buffer zones, biological islands, roadsides or other available areas during honey flows. A producer also could satisfy this provision by moving hives to other organically managed areas to take advantage of organic off-farm acreage.

The NOSB received public comments regarding the addition of vitamin and mineral supplements to an organic feed ration to prevent deficiency diseases. In their deliberations, the NOSB recognized that producers cannot easily determine whether an animal's nutritional requirements are being satisfied solely by the organically grown feed provided to them, especially in the case of grazing animals.

The NOSB subsequently recommended that organic feed be allowed to be supplemented with vitamins and minerals, as needed, to ensure an animal's health. Deficiency diseases, such as milk fever, may not be recognized until an animal becomes debilitated; moreover, allowing any animal to become weakened because of vitamin and mineral deficiencies may lead to more serious health problems. Accordingly, we propose in paragraph (a)(2) of this section that the use of non-agricultural products as vitamin and mineral supplements to satisfy the health requirements of livestock be permitted, provided that any synthetic supplement used in organic livestock production is included as an allowed synthetic on the National list in section 205.24. In accordance with section 2118(c)(1) of the OFPA (7 U.S.C. 6517(c)(1)), trace minerals and dietary supplements are included in proposed section 205.24 as synthetic substances permitted for use in organic livestock production.

We propose in section 205.13(a)(3) that producers be allowed to use synthetic amino acid additives as necessary for the purpose of fulfilling the nutritional requirements of the livestock, if the synthetic amino acid used is included as an allowed synthetic on the National list in section 205.24. During the USDA public hearings and NOSB meetings, organic livestock producers stated that it is sometimes necessary to add amino acid (protein) additives to feed rations to ensure optimal health and growth. They explained that producers cannot control, even by diversifying the feed ration, the quantity and type of protein available in organic feedstuffs. For example, the lysine content of many feedstuffs is known to be inadequate.

Tests to analyze the essential amino acid content in feed are inexpensive, and the National Research Council's Committee on Animal Nutrition publishes nutrient requirements for domestic animals, including requirements for essential amino acids, where applicable. These levels could be used as guidelines for producers and certifying agents to ensure that the amino acids were not used at levels high enough to artificially stimulate growth or production in the animal, which is proposed to be prohibited under section 205.13(b)(2). An analysis of feed showing that it required use of amino acid supplementation would constitute a site-specific condition that could be used to demonstrate that its use was necessary to fulfill the nutritional requirement of the livestock.

Prohibited Livestock Feeding Practices—Section 205.13(b)

Sections 2110(c)(2) and (3) of the OFPA (7 U.S.C. 6509(c)(2) and (3)) prohibit the use of plastic pellets for roughage; manure refeeding; feed formulas containing urea; and the use of

growth promoters and hormones, including antibiotics and synthetic trace elements to stimulate growth or production. We therefore propose in paragraphs (b)(1) through (3) of this section that these materials and practices be prohibited. It should be noted that this proposal differs from the language given in the Act for the purpose of clarifying the intent of this prohibition. This clarification is necessary because synthetic trace elements and other feed supplements, which are stated in the Act as prohibited when used to stimulate livestock growth or production, are proposed to be permitted, as allowed by the Act, in section 205.13(a) when used only to provide essential nutritional elements to supplement livestock feed. In accordance with section 2118(c)(1) of the OFPA (7 U.S.C. 6517(c)(1)), trace minerals and nutritional supplements are proposed to be included as synthetic substances permitted for use in organic livestock production in section 205.24 of the proposed National List.

Livestock Health Care—Section 205.14

In developing our proposed organic livestock health care requirements, we considered information from a number of sources. This research was necessary because the Act does not provide affirmative requirements for the health care of livestock in an organic operation. The primary sources of information we used were the NOSB recommendations, provided in accordance with section 2110(d)(2) of the OFPA (7 U.S.C. 6509(d)(2)), and public input received during the USDA organic livestock hearings held in accordance with section 2110(g) of the OFPA (7 U.S.C. 6509(g)). We also reviewed comments from the public provided during input sessions at NOSB meetings and in response to NOSB draft recommendations. And, finally, we reviewed the livestock production standards of the existing State and private certification organizations in an effort to learn as much as possible about the practices currently being used.

As a result of the research we did, we determined that health care in organic livestock production should be based on the prevention of diseases and should include the provisions of adequate feed, living conditions and attentive care so as to ensure a healthful living environment and prevent the occurrence of disease and injury.

We propose in paragraph (a) that the practice for maintaining livestock health would be a preventive management system. Preventive management includes providing diverse feedstuffs while minimizing conditions favorable to disease, illness, injury and parasites. Techniques such as providing isolation facilities for sick animals, rotating pastures, and introducing species that disrupt parasite reproduction would be appropriate for a certified operation. Sanitation practices, such as the use of antiseptics to cleanse wounds, and the removal of manure, spilled fodder, and soiled bedding material, would be suitable practices to prevent the occurrence and spread of infectious organisms.

We further propose to permit the use of veterinary biologics, such as vaccines and inoculants, as well as vitamins and minerals, to effectively prevent disease or injury. In fact, Federal and State regulations may require the use of vaccines and inoculants, and organic livestock producers would be expected to comply with any applicable regulations regarding mandatory vaccinations. Additionally, the practice of breeding animals for adaptability to site-specific conditions, including resistance to local diseases and parasites, also would play an important role in a system of organic farming.

The OFPA does not contain affirmative requirements for administering animal drugs in the event of illness or injury; section 2110(d)(1) of the OFPA (7 U.S.C. 6509(d)(1)) prohibits administering medications, other than vaccinations, in the absences of illness. This suggests that the use of medications in organic livestock production may be permitted. In determining the appropriate use of medications in organic livestock production, we reviewed the NOSB recommendations, public input received at NOSB meetings, livestock hearings testimony, and existing State and private standards. The result of this research indicated that there is little agreement about the kinds of medications that are appropriate in organic livestock production and how they should be used. There was agreement, however, that even with the best preventive management, animals sometimes become ill, injured or infested with parasites and that producers should be provided with a means of administering medications to sick or injured animals. We have used the term *animal drug* to include three of the terms used in the Act: ''medication, antibiotic and parasiticide'', since animal drug is the term commonly used by the Center for Veterinary Medicine of the FDA in referring to these substances.

In section 205.14(b) we propose that, in a situation where the preventive measures provided for in paragraph (a) were not effective in maintaining livestock health, animal drugs, except as prohibited in paragraph (d) of this section, may be administered to organic livestock and that they may be used at any life stage; restrictions are provided only for mammals and other stock intended for slaughter stock.

Our research indicated that it is appropriate in organic livestock health care to administer parasiticides either internally or externally to any animal at any life-stage, provided that the producer complies with the prohibition against routine use of a synthetic internal parasiticide, set forth in section 2110(d)(1)(B) of the OFPA (7 U.S.C. 6509(d)(1)(B)). Routine use is defined in section 205.2 as administering a parasiticide to an animal without cause. While some public comment favored prohibiting the use of internal parasiticides and the NOSB recommended a restricted use of parasiticides, many producers stated that parasites can threaten animal health at any life-stage and that the use of parasiticides is essential in certain regions of the country. Even under highly controlled situations, some parasites endemic to certain regions can be carried by wild birds, water, or feed. Concerns for the overall health of an animal would indicate that parasiticides be used as soon as possible after determining the presence of parasites at a level that would affect the health of the infected livestock.

Our review of information concerning organic livestock health care revealed a good deal of difference in the use of antibiotics. We found that most of the concern about this drug use in animals was with the subtherapeutic use of antibiotics, which is prohibited by the Act. The NOSB recommended prohibiting the use of antibiotics in the production of organic slaughter stock and restricting the use of antibiotics for other livestock. Public comment suggested that the health of organic livestock might benefit from receiving antibiotics. We would like to solicit public comment on the use of animal drugs in the production of organic livestock, including organic slaughter stock.

Based on the above reasons and after careful consideration of the information available, we propose to restrict the use of animal drugs in animals intended as organic slaughter stock. We propose in sections 205.14(b)(1) and (2) that animal drugs, other than those administered topically and parasiticides, could be administered to mammals intended as slaughter stock only during the first 21 days of life, and to all other slaughter stock only during the first 7 days after arrival at the certified facility. Animal drugs administered topically and

parasiticides could be administered at any time of life.

We propose to permit this limited allowance for the use of animal drugs in slaughter stock due to the concerns about the vulnerability of newly born or hatched livestock brought onto a certified operation from a non-organic source. Newborn animals are particularly vulnerable to diseases, such as diarrhea and pneumonia, during the time immediately following transport, as a result of the stress of adapting to a new environment. Allowing the use of animal drugs would be an appropriate safety net for young organic livestock during their first week of organic management. Since mammals may be as old as 15 days of age when brought onto an organic operation, as proposed in section 205.12(a)(5)(ii) dealing with the sourcing of animals, mammals could receive animal drugs up to the 21st day of life, or 7 days after the last possible date after arrival at the certified facility. This is consistent with the 7-day time period in which animal drugs may be administered to non-mammals after their arrivals onto an organic facility. We believe that restricting the use of animal drugs in organic slaughter stock production is consistent with a system of organic farming and handling which uses prevention methods, rather than substances, to optimize health.

Proposed section 205.14(c) restricts the sale of products from organic livestock to which an animal drug has been administered. We propose in this paragraph that the products from treated livestock could be obtained and thereafter sold, labeled, or represented as organic only after the producer has determined that the animal had fully recovered from the conditions being treated, but in no case sooner than the applicable withdrawal period stated on the label or labeling of the animal drug or as required by the veterinarian. This proposal was developed after a lengthy and extensive review of significant amounts of public input. Also, the NOSB submitted to the Secretary a subsequent addenda to their recommendations on the use of antibiotics and parasiticides in livestock used to produce milk and eggs, which stated:

> Just as soil health must be restored after the use of restricted materials, animals whose health has been threatened by illness or infection must be allowed adequate time to recuperate after administration of an antibiotic or parasiticide. The restoration of health is effected through adequate recovery management. Products from both restored soil and restored animals may then be labeled as organically produced.

In determining when animal health has been restored, a producer might observe the somatic cell counts in milk, the resumption of normal weight gain in a young animal, or an increase of egg production in a laying flock. Under this proposal, an organic producer might reasonably decide to withhold a product from the organic market beyond the withdrawal period specified on the label based on observations of the animal's health.

Some of the input received by the NOSB and the USDA requested extending FDA withdrawal period after internally administering animal drugs, particularly antibiotics or parasiticides, to organic livestock. The extended withdrawal periods suggested by the public input ranged from twice the FDA withdrawal time to a minimum of 90 days. However, our proposal does not make such a requirement because an extended withholding time does not further the goals of a system of organic farming and handling. We wish to point out that under our proposal, animals used for breeding or as a source of other products could later be sold as organic slaughter stock only if the animal complied with all of the other requirements for organic slaughter stock.

Prohibited Livestock Health Care Practices—Section 205.14(d)

Section 2110(d) of the OFPA (7 U.S.C. 6509(d)) prohibits producers from using subtherapeutic doses of antibiotics, synthetic internal parasiticides on a routine basis, or medications, other than vaccinations, in the absence of illness. Accordingly, we propose in paragraph (d) of this section to prohibit administering any medication, other than vaccinations, in the absence of illness; the routine use of synthetic internal parasiticides; and the subtherapeutic use of antibiotics.

Livestock Living Conditions and Manure Management—Section 205.15

Living conditions play a significant role in livestock health and production. At the USDA hearings and NOSB meetings, extensive testimony was received addressing the issue of livestock living conditions. As provided for under section 2110(d)(2) of the OFPA (7 U.S.C. 6509(d)(2)), the NOSB developed specific recommendations for additional standards for livestock living conditions, including manure management. This proposal is consistent with the NOSB recommendations.

In section 205.15(a), we propose to require that the following living conditions be provided, as appropriate to the species, to promote livestock health: protection from the elements; space for movement; clean and dry living conditions; and appropriate access to the outdoors, food and clean water. These conditions would provide a healthful environment to raise organically produced livestock and reduce or eliminate the need to administer animal drugs.

We propose in section 205.15(b) that, if necessary, animals could be maintained under conditions that restrict the available space for movement or access to outdoors, provided that other living conditions are adequate to maintain the animals' health without the use of animal drugs, except as provided in 205.14(b). In developing this proposal, we considered public input regarding the effects of climate, geographical location and physical surroundings on the ability of animals to have access to the outdoors. The premise that organic management is soil based and that animals should be allowed, as appropriate, access to the soil was considered in balance with animal health issues, such as prevention of exposure to harmful organisms carried by wild animals and the need to keep animals indoors during extended periods of inclement weather. The flexibility provided by the provisions of 205.15(b) would allow operations without facilities for outdoor access to be certified for organic livestock production and also would permit animals to be confined during critical periods such as farrowing.

As noted, the producer could maintain animals under conditions that restrict the available space for movement or access to outside only if the practice is appropriate and necessary. As previously discussed in regards to the use of non-organic sources of livestock feed and mammalian livestock designated as organic slaughter stock, the determination of necessity would be based on site-specific conditions that would be described by the producer in an organic plan, or updates to an organic plan, and reviewed and evaluated by the certifying agent.

We are requesting public comment as to the conditions under which animals may be maintained so as to restrict the available space for movement or access to outdoors. Examples of site-specific conditions which might serve as a basis for maintaining animals under conditions that restrict the available space for movement or access to outdoors are: emergency or unanticipated circumstances and site-specific soil, climate, animal health, or other environmental factors. We also

request comment as to whether we should allow practices that restrict the available space for movement or access to outdoors.

Manure Management—Section 205.15(c)

In section 205.15(c), we propose that in any area where livestock are housed, pastured or penned, manure would have to be managed in a way that does not cause measurable degradation of soil quality; does not significantly contribute to contamination of water by nitrates and bacteria, including human pathogens; optimizes nutrient recycling; and does not include burning or any practice inconsistent with section 205.14(a) of this subpart which addresses prevention of livestock health problems. These provisions are consistent with sections 2114(b)(1) and (2) of the OFPA (7 U.S.C. 6513(b)(1) and (2)) that address proper manuring and methods for applying livestock manure to soil. The proper management of manure requires that it be used in a way that optimizes nutrient recycling to be consistent with a system of organic farming. As discussed in the supplementary information for proposed section 205.7(d)(3), the disposal of manure by burning cannot be considered proper manuring.

Organic Handling Requirements

Product Composition—Section 205.16

This section of our proposal addresses the requirements and prohibitions for ingredients used in products that would be permitted to use the word organic in some manner on a label or labeling of an agricultural product. These provisions are in accordance with: section 2106(a)(1)(A) of the OFPA (7 U.S.C. 6505(a)(1)(A)) which requires that any product that is sold, labeled, or represented as organic must be produced and handled in accordance with the Act; section 2111(a)(4) of the OFPA (7 U.S.C. 6510(a)(4)) which provides for an organic product to contain up to 5 percent by total weight of the finished product, exclusive of water and salt, of non-organically produced ingredients that are on the National List; and sections 2106(c)(1) and (2) of the OFPA (7 U.S.C. 6505(c)(1) and (2)) which permit certain exemptions for agricultural products that contain more than 5 percent non-organically produced ingredients.

In paragraph (a)(1) of this section, we propose that an agricultural product, including a raw agricultural product, sold, labeled, or represented as organic, contain only organically produced agricultural ingredients, exclusive of water or salt, except in one circumstance. This exception is based on section 2111(a)(4) of the OFPA (7 U.S.C. 6510(a)(4)) which allows an organically produced agricultural product to contain up to 5 percent non-organically produced ingredients that are on the National List. Accordingly, we propose in paragraphs (a)(1)(i) and (ii) of this section that a product sold, labeled, or represented as organic could contain non-organically produced agricultural products and non-agricultural ingredients that are included on the National List, up to 5 percent of the total weight of the finished product, exclusive of water or salt. As proposed and discussed in the supplementary information to the National List section 205.27 for non-organic agricultural products, all non-organically produced agricultural products are proposed to be included on the National List, and therefore would be permitted for use in an organic product in accordance with section 2111(a)(4) of the OFPA (7 U.S.C. 6510(a)(4)).

We propose in paragraph (a)(2) of this section the order of preference by which all ingredients used in an organic product would have to be selected. We have determined that the provisions of paragraph (a)(2) of this section are needed to ensure the integrity of products sold, labeled, or represented as organic and to ensure that organic products are handled in accordance with a system of organic farming and handling, as defined in proposed section 205.2 of subpart A. Accordingly, we propose in paragraph (a)(2)(i) that a handler would have to select commercially available organically produced agricultural products as ingredients in preference to non-organic agricultural products and non-agricultural ingredients. For example, in a bread that contains 97 percent organically produced flour and also sesame seeds, a handler would have to use organically produced sesame seeds whenever they were commercially available.

We propose in paragraph (a)(2)(ii) that a handler would have to choose a commercially available non-organically produced agricultural product as an ingredient in preference to a non-agricultural ingredient. For example, a thickener such as corn starch or arrowroot, if commercially available, would need to be selected as an ingredient in a salad dressing in preference to a non-agricultural ingredient, such as disodium phosphate. Paragraphs (i) and (ii) of this section together would direct a handler toward the use of an organically produced agricultural product whenever possible for a given function in the product. The provisions of these two paragraphs are consistent with the NOSB recommendation that organic ingredients be used in a multi-ingredient product to the extent possible.

We propose in paragraph (a)(2)(iii) of this section that a non-organically produced agricultural product or non-agricultural ingredient that is extracted without the use of a synthetic volatile solvent, or which does not contain propylene glycol as a carrier, if commercially available, must be used as an ingredient in preference to a non-organically produced agricultural product or non-agricultural ingredient that is extracted with a synthetic volatile solvent or which contains propylene glycol as a carrier.

Although the NOSB recommended that substances extracted with a synthetic volatile solvent (such as hexane) or that contain propylene glycol as a carrier be prohibited for use in organic products, we believe our proposal to allow their use only when alternative substances or products are not commercially available does not affect the integrity of organically produced products.

Section 2106(c)(1) of the OFPA (7 U.S.C. 6505(c)(1)) authorizes products that contain at least 50 percent (but less than 95 percent) organically produced ingredients to use the word organic on the principal display panel of the product to describe those ingredients that are organically produced. Accordingly, the Secretary, in consultation with the NOSB and the Secretary of Health and Human Services, is proposing in subpart C of this part to allow the statement made with certain organic ingredients to appear on the principal display panel of this type of product.

We propose in paragraph (b) the composition requirements for a product labeled as made with certain organic ingredients. These proposed requirements are that the total weight of the finished product that is not comprised of organic agricultural products, excluding water and salt, shall consist of some combination of non-organically produced agricultural products and non-agricultural ingredients included on the National List. This is consistent with the proposed composition requirement for non-organic ingredients in products labeled as organic and is consistent with the composition requirements of section 2111(a)(4) of the OFPA (7 U.S.C. 6510(a)(4)).

Proposed paragraph (b)(3) of this section would require that products sold, labeled, or represented as made with certain organic ingredients have been produced in compliance with sections 205.16 through 205.19 of this proposal, with the exception of sections 205.16 (a) and (c) of this subpart. Section 205.16(a) applies to agricultural products, including raw agricultural products, that are labeled as organic. Section 205.16(c) applies to multi-ingredient agricultural products that only represent the organic nature of such ingredients in the ingredients statement and which themselves are not sold, labeled or represented as organic or made with certain organic ingredients. The provisions of proposed paragraph (b)(3) are necessary to assure consumers that products in which the predominant portion of ingredients are represented as organically produced have been produced and handled in accordance with a consistent standard, as provided under section 2102(2) of the OFPA (7 U.S.C. 6501(2)).

We note that processed agricultural products sold, labeled, or represented as made with certain organic ingredients are exempted by section 2106(c)(1) of the OFPA (7 U.S.C. 6505(c)(1)) from complying with the provisions of the Act, except as required by the Secretary in consultation with the NOSB and the Secretary of HHS. Therefore, handlers of this type of product can be exempted from complying with certain provisions of this proposal, provided that the exemptions do not affect the integrity of the organic ingredients in the product. Accordingly, as proposed and discussed in the supplementary information for section 205.201(b) of subpart D regarding an exemption for handlers of this type of product from the requirement set forth in section 205.3(b)(2) of subpart B that a commercially available non-synthetic substance be selected in preference to an allowed synthetic substance, we note that a handling operation that produces products sold, labeled, or represented as made with certain organic ingredients also would not be subject to the provisions in section 205.16(a) and (c) with respect to the handling of this type of product. For example, a manufacturer of a product sold, labeled, or represented as made with certain organic ingredients could use a non-organic agricultural ingredient instead of a commercially available organic agricultural ingredient, as is required in proposed section 205.16(a)(2) for the manufacturer of a product to be sold, labeled or represented as organic. However, the handling operation would be required to be certified and to demonstrate in the organic plan compliance with the applicable handling requirements in subpart B. We believe that these provisions will help assure the integrity of the organic ingredients in this type of product without imposing undue requirements on the handlers who produce them.

Paragraph (c) of this section is proposed in accordance with section 2106(c)(2) of the OFPA (7 U.S.C. 6505(c)(2)) and would exempt a multi-ingredient product that only represents the organic nature of such ingredients in the ingredients statement, and which itself is not sold, labeled or represented as organic or made with certain organic ingredients, from complying with the requirements proposed in this subpart. It is not critical for either the purposes of the Act or the integrity of the organic ingredients if a finished product that cannot be sold, labeled, or represented as organic or as made with certain organic ingredients on its principal display panel is not subject to the provisions of this subpart. We note, however, that although a finished product that contains less than 50 percent organically produced ingredients, or any other multi-ingredient product that represents the organic nature of ingredients in the ingredients statement and which is not labeled as organic or made with certain organic ingredients, need not be handled by a certified organic handling operation, the ingredients represented as organic in such a product must have been produced and handled in accordance with all the applicable provisions of the Act and the regulations of this part. In addition, while handling operations which handle only this type of product would not be required to become certified under the provisions proposed in section 205.202 of subpart D, this proposal would still require such operations to maintain records to show that any organic ingredients listed on product labels were obtained from operations that were certified in compliance with the Act and the regulations of this part.

Paragraph (d) of this section would prohibit the use of organic and non-organic forms of the same agricultural ingredient if the ingredient is listed as organic in the ingredients statement. We believe that such a provision is needed in order to avoid any possibility of confusion concerning the source and percentage of the organic ingredients in the product.

Paragraph (e) of this section would prohibit, in accordance with sections 2111(a)(3) and (7) of the OFPA (7 U.S.C. 6510(a)(3) and (7)), the addition of sulfites, nitrates, or nitrites to an organic food product, or the addition to the food of water that does not meet the Safe Drinking Water Act requirements (42 U.S.C. 300f *et seq.*).

Processing Practices—Section 205.17

In paragraph (a) of this section we propose that biological methods, such as fermentation, or mechanical methods, such as grinding, pressing, heating or drying, be used to process an agricultural product intended to be sold, labeled, or represented as organic or made with certain organic ingredients for the purpose of retarding spoilage or otherwise preparing an agricultural product for market. However, an incidental additive, except for the prohibition on the use of volatile synthetic solvents proposed in section 205.17(b)(3), may be used, if necessary, to process an agricultural product intended to be sold, labeled, or represented as organic or made with certain organic ingredients. An incidental additive used in the processing of agricultural products is defined in proposed section 205.2 as an additive present in an agricultural product at an insignificant level and that does not have any technical or functional effect in the product, and is therefore not considered an active ingredient. As discussed in the supplementary information for section 205.26 of subpart B, incidental additives may be used in organic handling without inclusion on the National List. Section 205.17(a) is consistent with the principles stated in our proposed definition of a system of organic farming and handling (section 205.2) and as further discussed in the introduction to the supplementary information for subpart B.

The NOSB recommended that handlers document that a food could not be processed without the use of a synthetic incidental additive and that the handler demonstrate progress to replace the synthetic incidental additive over time. The NOSB language is consistent with our proposal to permit the use of such substances only if necessary. By including several synthetic incidental additives in its National List recommendations, the NOSB also recognized that a wide range of currently available organic products could not be manufactured feasibly without the use of incidental additives, such as defoaming agents, adjuvants, clarifiers, filtering agents and equipment cleansers.

As noted, a producer could use an incidental additive if the use of the additive is necessary. As previously

described in the supplementary information for sections 205.12, 205.13, and 205.15 of subpart B regarding livestock production, determination of necessity would be based on site-specific conditions that would be described by a producer in an organic plan, or updates to an organic plan, and reviewed by the certifying agent.

We are requesting public comment as to the conditions under which incidental additives may be used. For example, we would like public comment as to whether specific conditions, such as the inefficacy or unavailability of mechanical or biological methods, should be a prerequisite for using an incidental additive and, if so, what these conditions should be. We also request comment as to whether handlers who handle only products sold, labeled, or represented as made with certain organic ingredients should be exempted from the restriction of using incidental additives only if necessary.

Paragraph (b) of this section proposes several practices that would be prohibited for the processing and preparation of any raw agricultural product, and on a finished agricultural product, sold, labeled, or represented as organic or as made with certain organic ingredients.

Paragraphs (b)(1) and (b)(2) of this section are proposed in accordance with sections 2111(a)(5) and (6) of the OFPA (7 U.S.C. 6510(a)(5) and (6)) and would prohibit the use of storage containers or bins, including packages and packaging materials that contain synthetic fungicides, preservatives or fumigants, and also would prohibit the use or reuse of any bag or container that previously had been in contact with any substance that could compromise the organic integrity of its contents. Our proposed definition of packaging set forth in section 205.2 encompasses waxes used in contact with an edible surface of an agricultural product.

Proposed paragraph (b)(3) of this section would prohibit the use of a volatile synthetic solvent. Volatile synthetic solvents, such as hexane or isopropyl alcohol, are used in processing and extraction. This proposed prohibition is made under the authority of section 2107(a)(11) of the OFPA (7 U.S.C. 6506(a)(11)) which authorizes this program to require such terms and conditions as are determined necessary. The prohibition of the use of a volatile synthetic solvent is in agreement with the NOSB recommendation that the use of a volatile synthetic solvent is not essential, and therefore should not be permitted in the handling of an organically produced product or a product sold, labeled, or represented as organic or made with certain organic ingredients.

As previously discussed in regard to the use of raw manure in organic crop production (section 205.7 of subpart B), there has been an increase in the incidence of food borne illness caused by certain pathogens. The application of ionizing radiation as a sanitation or preservation treatment currently is permitted by FDA for a wide range of agricultural products. Additionally, a request to permit the use of ionizing radiation on red meat products was recently approved by FDA. The NOSB has recommended to the Secretary that the practice of ionizing radiation should not be allowed in organic handling, and its use is prohibited by most existing organic certification programs which we have reviewed.

Public comment is invited with respect to the compatibility of the use of ionizing radiation with a system of organic farming and handling. The USDA also invites comments on whether there are effective alternatives to ionizing radiation, such as sanitary practices, heat pasteurization and incidental additives, that are compatible with a system of organic farming and handling, and, if so, how they are compatible. Additionally, we are soliciting comment as to whether the use of ionizing radiation is considered an essential standard industry practice, or good manufacturing practice, in the processing of any agricultural product: for example, in the sanitary handling of herbs and spices.

Prevention and Control of Facility Pests—Section 205.18

We are proposing provisions to safeguard the integrity of organic products that are handled in facilities in which pest control substances may be used. The NOSB recommendations and our review of most existing organic programs indicate that this area needs to be addressed. We have accordingly determined, as authorized by section 2107(a)(11) of the OFPA (7 U.S.C. 6506(a)(11)), which authorizes this program to require such terms and conditions as are determined necessary, that the proposed requirements for facility pest management in an organic handling operation are necessary and appropriate for an organic certification program.

As is true with crop production and livestock health care, prevention of pest occurrences should be the first strategy used by an organic handler. This is also consistent with the goal of maintaining the integrity of organic products by avoiding the need to use pest control substances in handling facilities, as reflected in our definition of a system of organic farming and handling. We propose in paragraph (a) of this section that the best practice for control and prevention of facility pests would be a preventive management system. This system would include measures to remove pest habitat and to prevent pests from gaining entrance to the handling facility, as well as managing environmental factors inside the facility such as temperature, light, air circulation and humidity to discourage proliferation of pest populations.

If prevention measures are not effective and pests do appear in organic handling facilities, we propose in paragraph (b) of this section for facility pest control to permit the use of pest control techniques, which include: mechanical controls such as traps or barriers; augmentation and introduction of predators and parasites for the pest species; and non-toxic, non-synthetic substances such as lures and repellants. Pest prevention and control is further discussed in the supplementary information provided in section 205.9 for crop pests, weeds and diseases.

However, if pest prevention or control measures provided in paragraph (a) and (b) of this section are not effective, we propose in paragraph (c) of this section to permit the use of any substance to control pests, provided the substance is approved for its intended use by the appropriate regulatory authority and the substance is applied in a manner that prevents such substance from contacting any ingredient or finished product intended to be sold, labeled, or represented as organic or made with certain organic ingredients. We have proposed paragraph (c) in recognition of the fact that handling facilities are subject to federal, state, and local regulations concerning food safety. The use of the practices in paragraph (c) of this section would entail maintaining adequate safeguards to protect organic products and ingredients from being contacted by any pest control substance.

As noted, proposed paragraph (c) would allow the use of any substance to control pests, provided such substances were used only when methods to prevent or control pests were not effective. Additionally, any substance used must be applied in a manner that prevents such substance from contacting any ingredient or finished product intended to be sold, labeled, or represented as organic or made with certain organic ingredients. Because eradication of a pest infestation may necessitate the use of substances, we are proposing to allow the use of any

substance approved for use by the appropriate Federal, State or local regulatory agency to assure that organic handling operations have sufficient practices available to deal effectively with severe pest infestations. Structural pest control is unique in that substances used for this purpose are not considered to be used in the production and handling of organic crops, and are not applied to land used in the production of organic crops.

Many existing certification programs restrict synthetic substances used to control pests in certified handling facilities to substances reviewed and allowed for use by the certification agency. We request comment as to whether only those substances included on the National List of active synthetic substances allowed for use in organic crop production, as set forth in section 205.22, should be permitted to be used to control pests in certified handling facilities. Additionally, if the use of synthetic substances in structural pest control should not be restricted solely to those synthetic substances included on the National List of active synthetic substances, we request comment as to whether handlers should be required to use synthetic substances included on the National List of active synthetic substances (or a non-synthetic biological or botanical substance) before the use of synthetic substances not included on the National List.

Prevention of Commingling and Contact With Prohibited Substances—Section 205.19

There are two primary threats to organic integrity: the possibility of commingling organic products with similar products that were not organically produced, and the possibility of the organic product coming into contact with a prohibited substance. Since there is no apparent physical difference between an organically produced product and a non-organic product, commingling is a serious concern and an organic handling operation must make every effort to provide adequate measures to ensure that commingling does not occur, in addition to adopting measures to protect organic products from contacting prohibited substances.

Sections 2107(b)(1)(C) and 2111(b) of the OFPA (7 U.S.C. 6506(b)(1)(C) and 6510(b)) specifically provide for the prevention of commingling of organic and non-organic products, especially meat, in any operation that handles both types of products, and the implementation of practices that protect organic products from contact with prohibited substances. Therefore, we propose in this section that a certified handling operation, and a handling operation that is exempt or excluded from certification in accordance with section 205.202(a)(3) or section 205.202(b) of subpart D, shall be required to establish appropriate safeguards during handling, storage and transportation to both prevent the commingling of organic and non-organic products and to assure that organic products are protected from contact with prohibited substances.

These safeguards could take many forms depending on the nature of the products and the certified handling operation, and should encompass each step of the manufacturing or handling process, including storage and transportation. A certified handling operation that receives certification under our proposal might consist of disparate locations and facilities, including some that handle both non-organic and organic products. The public input we have received indicates that many certified handling operations use subcontractors to perform certain processing functions, such as dehydrating or freezing, rather than performing the function within the facilities maintained by the certified operation. Our primary concern in these instances is that adequate safeguards are maintained by the certified operation and the subcontractor to ensure that commingling and contact of organic products with prohibited substances did not occur. A certified handling operation that subcontracted with different facilities for cold storage, for example, would have to make sure that its products were clearly segregated from non-organic products and that an inspector examined all such subcontracted facilities as a part of the site visit to the certified operation. A certified handling operation also would have to take appropriate measures to ensure that organic products or ingredients were transported under conditions that protected their integrity. We note that the best method to prevent commingling or contact with prohibited substances would be to eliminate the possibility of such occurrences, such as when a certified operation handles only organic products and uses no prohibited pest control substances.

Subpart B—National List

Purpose and Basis of the Proposed National List

The National standards for organic production, provided for in section 2105 of the OFPA (7 U.S.C. 6504), include the requirement that an organically produced agricultural product shall have been produced without the use of synthetic chemicals, except as otherwise provided for in the Act. The exemptions to which section 2105 refers are specifically delineated in section 2118 of the OFPA (7 U.S.C. 6517), which provides for the establishment of a National List of substances that may be allowed for use in an organic farming or handling operation that are otherwise prohibited for use under the Act. This section also provides for the establishment of a National List of non-synthetic substances, that are otherwise allowed under the Act, that may not be used in organic farming or handling.

Section 2118(a) of the OFPA (7 U.S.C. 6517(a)) provides that the Secretary shall establish the National List of approved and prohibited substances, and section 2118(d)(1) of the OFPA (7 U.S.C. 6517(d)(1)) provides that the National List shall be based upon a proposed national list developed by the NOSB. In accordance with section 2119 of the OFPA (7 U.S.C. 6518), the NOSB conducted the prescribed review process, and solicited public comment at meetings, before recommending an initial proposed national list to the Secretary. The NOSB recommendations were based on at least one technical advisory panel review of each substance in question, as required in section 2119(k)(3) of the OFPA (7 U.S.C. 6518(k)(3)). The NOSB also reviewed available information from the Environmental Protection Agency, the National Institute of Environmental Health Studies, and other appropriate sources, as required in section 2119(l)(1) of the OFPA (7 U.S.C. 6518(l)(1)), to assist it in evaluating each substance under consideration in accordance with the criteria delineated in section 2119(m) of the OFPA (7 U.S.C. 6518(m)). The criteria that were considered for each substance are: the potential of the substance for detrimental chemical interactions with other materials used in organic farming systems; the toxicity and mode of action of the substance and of its breakdown products or any contaminants, and their persistence in the environment; the probability of environmental contamination during manufacture, use, misuse or disposal of the substance; its effects on human health; the effects of the substance on biological and chemical interactions in the agroecosystem; the alternatives to using the substance; and the compatibility of the substance with a system of sustainable agriculture. The NOSB recommendations, along with the results of the required evaluation and technical advisory panel review for each

substance, were considered by the Secretary in accordance with the requirements of section 2118(d) of the OFPA (7 U.S.C. 6517(d)).

Basis for Inclusion of Substances and Ingredients on the National List

Basis for Inclusion of Specific Synthetic Substances on the National List of Synthetic Substances Allowed for Use in Organic Farming and Handling

Section 2118(c)(1) of the OFPA (7 U.S.C. 6517(c)(1)) provides three sets of criteria upon which determinations to allow the use of substances that are otherwise prohibited by the Act must be based. The first set of criteria, in section 2118(c)(1)(A) of the OFPA (7 U.S.C. 6517(c)(1)(A)), requires that the Secretary, in consultation with the Secretary of the Department of Health and Human Services and the Administrator of EPA, determine that: use of the substance would not be harmful to human health or the environment; the substance is necessary to the production or handling of an agricultural product because of the unavailability of wholly natural substitute products; and the use of the substance is consistent with organic farming and handling.

The second set of criteria in section 2118(c)(1)(B) of the OFPA (7 U.S.C. 6517(c)(1)(B)) describes the types of substances that may be considered for use if they are included on the National List. The first type of substance is one that is used in production and contains an active synthetic ingredient that falls into one of the following categories: copper and sulfur compounds; toxins derived from bacteria; pheromones; soaps; horticultural oils; fish emulsions; treated seed; vitamins and minerals; livestock parasiticides and medicines; and production aids, including netting, tree wraps and seals, insect traps, sticky barriers, row covers, and equipment cleansers. The Secretary has accordingly reviewed each substance proposed in sections 205.22 and 205.24 for inclusion on the National List to determine that it is an active synthetic ingredient or includes an active synthetic ingredient. The second type is a substance that is used (in a formulation) in production and (the formulation) contains synthetic inert ingredients that the Administrator of the EPA has not classified as inerts of toxicological concern; and the third type of substance is one that is used in handling and is non-synthetic but is not organically produced.

The third criterion in section 2118(c)(1)(C) of the OFPA (7 U.S.C. 6517(c)(1)(C)) is that each specific exemption be developed according to the procedure described in section 2118(d) of the OFPA (7 U.S.C. 6517(d)) for establishing and amending the National List. This procedure includes basing the proposed National List on the recommendations received from the NOSB, and publishing such proposed National List in the **Federal Register** for public comment before establishing the National List. The same procedure must be used in developing any amendments to the National List.

After receiving the NOSB's recommendations, the Secretary determined, in consultation with the Secretary of HHS and the Administrator of the EPA that the use of each substance or ingredient being considered for inclusion on the proposed National List of synthetic substances allowed for use in organic farming would meet the first set of criteria. We then examined the second set of criteria to make determinations concerning substances being considered for inclusion on the National List of allowed synthetic substances. For each substance considered, it was first necessary to determine whether the substance is synthetic according to the definition provided by the Act. The Act defines a synthetic substance to be ''a substance that is formulated or manufactured by a chemical process or by a process that chemically changes a substance extracted from naturally occurring plant, animal, or mineral sources, except that such term shall not apply to substances created by naturally occurring biological processes.''

The language in section 2118(c)(1)(B)(i) of the OFPA (7 U.S.C. 6517)(c)(1)(B)(i)), which provides one set of criteria for placing a substance on the National List, makes it clear that only synthetic substances that contain active ingredients need to be on the National List in order to be permitted for use in organic production. This provision only encompasses active synthetic ingredients that are used in production and that come within certain categories. We have accordingly proposed a definition of an active ingredient or substance (in any input other than pesticide formulations) to include any substance that, when used in a system of organic farming or handling, becomes a chemically functional part of that system, or is otherwise of significant consequence to the production, handling and integrity of an organically produced product. This definition excludes substances that are present in insignificant amounts in the agroecosystem, such as equipment cleansers; do not chemically interact with the system, such as plastic mulches or row covers; or are otherwise inconsequential to the performance of any function within the system.

It should be noted that a formulated product that contains a substance that is an active synthetic ingredient and which also contains a synthetic inert ingredient may only be used if the active synthetic ingredient is included in one of the proposed allowed synthetic categories. Section 2118(c)(1)(B)(ii) of the OFPA (7 U.S.C. 6517(c)(1)(B)(ii)) does not require that inert ingredients be included as a separate category of the National List in order to be permitted for use in organic production. Rather, the Act requires only that the inert ingredients not be classified by the Administrator of the EPA as inerts of toxicological concern in order for the substance to be permitted for use. Our proposal for evaluating formulations that contain synthetic inert ingredients is included and discussed in proposed sections 205.20 through 205.21 and the corresponding supplementary information.

The discussions held by the NOSB as they evaluated substances under consideration, and their recommendations for their proposed National List, served as the primary basis for our determinations as to whether or not a particular substance is active and synthetic, and if so, whether to include it as an allowed synthetic substance on the proposed National List. A discussion of those substances that we have determined to be synthetic, but not active, and which therefore are not required to be included on the National List in order to be used in organic farming and handling, is included in the supplementary information to section 205.20 of this proposal, which sets forth all the categories of substances and ingredients that can be used in organic production and handling.

Basis for Including Specific Natural (Non-synthetic) Substances on the National List of Non-synthetic Substances Prohibited for Use in Organic Farming and Handling

In this proposal the word non-synthetic is used to address substances that are described in the Act as either natural or non-synthetic. No definition is provided in the OFPA for the word natural. There is also a great deal of ambiguity currently surrounding the use and meaning of the term in regard to production inputs, nutritional supplements, cosmetics and other products. The use of the term non-synthetic in section 2118 of the OFPA (7 U.S.C. 6517) provides us with the basis for using this term in our proposed rule to describe substances that are not

synthetic. By using this one term to describe substances that are not determined to be synthetic, we hope to avoid the uncertainty that surrounds the current use of the term natural in the marketplace. Therefore, in agreement with the recommendations provided by the NOSB, we will use the word non-synthetic in this and all other provisions of this proposal to address substances that are described in the Act either as natural or non-synthetic substances.

Natural (non-synthetic) substances are generally allowed under the Act for use in organic farming and handling and thus do not have to be included on the National List in order to be used. However, the Act does provide for specific natural (non-synthetic) substances to be prohibited for use in organic farming and handling if certain criteria are met. The Act also provides that the specified natural (non-synthetic) substances which are prohibited for use in organic farming and handling are to be put on the National List of prohibited substances.

Section 2118(c)(2) of the OFPA (7 U.S.C. 6517(c)(2)) delineates the criteria upon which the decision to prohibit the use of a specific natural substance is to be based. These criteria require that the Secretary determine, in consultation with the Secretary of HHS and the Administrator of the EPA, that the use of the substance would be harmful to human health or the environment, and that its use would be inconsistent with organic farming or handling and the purposes of the Act.

Basis for Inclusion of Non-agricultural Substances and Non-organically Produced Agricultural Products on the National List as Substances Permitted for Use as Ingredients In or On Processed Organic Products.

One criterion provided by section 2118(c)(1)(A)(ii) of the OFPA (7 U.S.C. 6517(c)(1)(A)(ii)) for inclusion of a substance on the National List of synthetic substances permitted to be used is that it must be necessary to the production or handling of the agricultural product because of the unavailability of wholly natural substitute products. Thus, synthetic substances used in handling an organic product may be considered for inclusion on the National List of substances permitted to be used. Such substances, however, must be evaluated according to the same criteria as synthetic substances permitted to be used in crop or livestock production, in accordance with section 2118(c)(1)(A) of the OFPA (7 U.S.C. 6517(c)(1)(A)). Section 2118(c)(1)(B)(iii) of the OFPA (7 U.S.C. 6517(c)(1)(B)(iii)) permits the consideration of the inclusion of non-synthetic non-organically produced substances on the National List for use in handling organic processed products if they meet the same criteria set forth for synthetic substances in section 2118(c)(1)(A) of the OFPA (7 U.S.C. 6517(c)(1)(A)). Because a substance that is not an agricultural product is considered to be non-organically produced, this OFPA provision requires that the NOSB and the Secretary evaluate non-synthetic non-agricultural substances according to the same criteria and procedure as an active synthetic substance used in crop or livestock production or handling. For these reasons, we are proposing in section 205.26 a National List category of non-agricultural substances allowed as ingredients in or on organic processed products, that consists of both synthetic and non-synthetic substances. A separate category of non-organically produced agricultural products allowed as ingredients in organic processed products is proposed in section 205.27, also in accordance with section 2118(c)(1)(B)(iii) of the OFPA (7 U.S.C. 6517(c)(1)(B)(iii)).

Summary of the National List and Petition Process for Adding New Substances

Sections 205.20 and 205.21 of subpart B provide a summary of all the categories of substances, ingredients and formulated products that are either allowed or prohibited for use in organic farming and handling. These sections are proposed in order to make clear the status of any substance that may be considered for use in a certified operation. The following are the categories of substances that we propose comprise the National List: active synthetic substances allowed for use in organic crop production (section 205.22); non-synthetic substances prohibited for use in organic crop production (section 205.23); active synthetic substances allowed for use in organic livestock production (section 205.24); non-synthetic substances prohibited for use in organic livestock production (section 205.25); non-agricultural substances allowed as ingredients in or on processed products labeled as organic or as made with certain organic ingredients (section 205.26); and non-organically produced agricultural products allowed as ingredients in or on processed products labeled as organic or as made with certain organic ingredients (section 205.27).

The six categories of substances we propose for the National List delineate the substances that can and cannot be used in organic crop production, in organic livestock production, and in processed products labeled as organic or made with certain organic ingredients. Accordingly, only a substance that appears in more than one category, such as synthetic mineral nutrients that are proposed for use in both crop production and as livestock feed supplements, may be used for more than one purpose.

Proposed section 205.28 delineates the process by which a person may petition the NOSB to add new substances to the National List in any of the six aforementioned categories, which entails the submission of specified information to USDA.

Relationship of the National List to the Organic Production and Handling Requirements

Section 2118(a) of the OFPA (7 U.S.C. 6517(a)) requires the Secretary to establish a National List to be included in the standards for organic production and handling established under the Act. We have accordingly developed the proposed production and handling requirements (sections 205.3 through 205.19) and the National List (sections 205.22 through 205.28) as a unified whole. The practices delineated within the proposed requirements for organic production and handling include appropriate restrictions and conditions on the use of substances, while the National List delineates what substances may or may not be used. These standards also are intended to be consistent with our proposed definition of a system of organic farming and handling, which, as discussed previously, was created in order to provide a concise summary of the underlying principles implicit in the Act. Under this proposal, any substance that is permitted to be used in organic farming or handling must be used in compliance with the regulations delineated in sections 205.5 through 205.19 of subpart B and must also meet the requirements proposed in section 205.3(b)(1) that its use not result in any measurable degradation of soil or water quality. We believe that the provisions proposed here for the appropriate use and application of substances is consistent with the provisions of the Act that address the National List and with the definition of a system of organic farming and handling.

General Rules for Categories of Substances and Ingredients Permitted for Use in Organic Farming and Handling—Section 205.20

Section 205.20 has been proposed to make it clear that a substance or

ingredient on the National List of substances permitted to be used in organic farming and handling may have its use restricted under other proposed regulatory provisions.

In section 205.20(a) we propose that all active synthetic substances or non-organically produced ingredients that are included on the National List in sections 205.22, 205.24, 205.26, or 205.27, and therefore permitted to be used in organic farming and handling, would have to be used in compliance with the Act and all the regulations we are proposing. In paragraph (b) of this section we propose that any other substance that may be used in a system of organic farming and handling also would have to be used in compliance with the Act and the regulations. Thus, any substance or ingredient that is permitted for use only could be used if its use complied with any applicable restrictions on its use that are provided for in other sections of the proposed regulations. For example, section 205.7(c)(2)(i) permits the use of synthetic micronutrients to produce organic crops provided that the micronutrients are not applied in a manner intended to be herbicidal, and section 205.16(a) permits the use of non-organically produced ingredients in a product labeled as organic provided that the ingredients comprise less than 5 percent of the total weight of the product, excluding water and salt. Of course, all substances used in organic farming or handling also must be used in accordance with any other applicable Federal, State, or local regulations.

In section 205.20(b) we propose three categories of substances that are not required to be included on the National List in order to be permitted for use in the production or handling of organic products. A substance that does not appear on the National List would have to be included in one of these categories in order to be used in organic farming or handling, as applicable.

The first category of substances permitted for use in organic farming or handling, as proposed in paragraph (b) of this section, comprises non-synthetic substances that are not included on the National List in section 205.23 or section 205.25 as a non-synthetic substance prohibited for use. Section 2118(c)(2) of the OFPA (7 U.S.C. 6517(c)(2)) provides for a non-synthetic substance to be prohibited in organic farming and handling only when it is included as a prohibited substance on the National List. Also, section 2113 of the OFPA (7 U.S.C. 6512) states that a production or handling practice is permitted under the Act unless it is prohibited or otherwise restricted, or is determined to be inconsistent with the certification program established under the Act.

The following list contains various substances that we have reviewed in consultation with the NOSB and determined to be both non-synthetic and as not meeting the Act's criteria that would prohibit their use. Therefore, these substances are permitted for use in organic crop production. This list is not intended to be inclusive of all non-synthetic substances allowed for use. It is, however, based on lists of substances historically permitted for use in organic production by existing certification programs and is included here as a reference guide.

A List of Natural (Non-Synthetic) Substances Reviewed for Use in Organic Crop Production (Non-Inclusive, for Reference Only)

Animal substances or byproducts:
- Blood meal
- Bone meal and bones
- Feather meal
- Fish emulsions
- Fish hydrolysate
- Fish products (fish meal, fish bones, and fish powder)
- Fish solubles
- Guano, bat or bird
- Hoof and horn meal
- Insect extracts
- Manures, animal
- Manure tea
- Oyster shells and other sea shells
- Oyster shell lime
- Sea animal wastes
- Tankage
- Whey, dairy
- Worm castings

Beneficial organisms
- Algae
- Bacteria [including *Bacillus thuringiensis* (Bt)]
- Fungi
- Higher animals
- Higher plants
- Insects
- Microbial soil, compost, plant and seed inoculants
- Mites
- Nematodes
- Protozoa
- Viruses

Fermented or bio-processed substances and composts (see animal, plant and mineral categories for compost feed stocks):
- Alcohol-from natural sources only (Ethyl)
- Biodynamic preparations
- Compost
- Compost tea
- Gibberellic acid
- Leaf mold
- Mushroom compost
- Vinegar

Mined minerals and other mined substances:
- Basalt
- Borate and boron products
- Calcium sulfate (gypsum)
- Chilean nitrate (sodium nitrate, nitrate of soda)
- Clays
- Colloidal phosphate
- Cryolite (sodium fluoaluminate)
- Diatomaceous earth
- Dolomite
- Feldspar
- Granite dust
- Greensand
- Humates, mined sources
- Humic acid derivatives
- Kieserite
- Lignite
- Limestone
- Marl
- Muriate of potash
- Niter (potassium nitrate)
- Peat moss
- Perlite
- Phosphate rock, raw
- Potassium sulfate
- Pumice
- Rock dust
- Sand
- Sulfur
- Sulphate of potash magnesia (langbeinite)
- Sodium bicarbonate
- Vermiculite

Plant substances or byproducts:
- Alfalfa pellets, or meal
- Aquatic plant extracts
- Citrus products
- Citrus oil
- Cocoa bean hulls
- Cotton gin trash
- Cottonseed meal
- Food processing wastes
- Garlic
- Grape and other pomaces
- Herbal preparations
- Hay
- Kelp or seaweed, unprocessed, meal, extracts or other derivatives
- Leaves
- Molasses
- Neem and Neem extracts
- Peanut meal
- Peanut hulls
- Plant extracts
- Propolis
- Pyrethrums
- Rice hulls and other residues
- Rotenone
- Ryania
- Sabadilla
- Saw dust, bark, wood chips and other wood wastes
- Soybean meal
- Straw
- Tobacco, and tobacco by-products
- Wood ash
- Vegetable waste, cannery waste

We consider a non-synthetic substance that is an industrial by-product to be synthetic only if the substance becomes chemically altered as a result of a manufacturing process. This is consistent with section 2103(21) of the OFPA (7 U.S.C. 6502(21)) which defines a synthetic substance as one that is formulated or manufactured by a chemical process or by a process that chemically changes the substance. Examples of industrial by-products that are synthetic substances are: paper

manufacturing wastes, kiln dust, and leather meal. Whey solids and sawdust are examples of industrial by-products that are not chemically altered and are therefore non-synthetic.

We do not consider non-synthetic substances that have been treated with a s ynthetic substance, but which have not been chemically altered by a manufacturing process, to be synthetic under the definition given in the Act. This is because the residues of synthetic substances that may be present in these materials do not chemically combine with or change the chemical composition of the original substance. Additionally, the presence of these residues has no significant effect on biological and chemical interactions in the agroecosystem, including physiological effects on soil organisms, crops and livestock, nor would the residues cause measurable degradation to soil or water quality. The synthetic residues therefore are not considered to be active synthetic ingredients or substances under the definition we have proposed. Examples of non-synthetic substances that may have been treated with a synthetic substance, but not chemically altered, include municipal yard wastes and processing wastes from non-organically produced crops, such as cotton gin trash or cocoa hulls.

We also do not consider certain categories of substances that are delineated in section 2118(c)(1)(B)(i) of the OFPA (7 U.S.C. 6517(c)(1)(B)(i)), which provides one set of criteria for substances which may be included on the National List of synthetic substances allowed for use in organic farming and handling, as synthetic substances according to the definition of synthetic given in the Act. We are therefore proposing to allow the use of the following substances in organic production and handling without being included in the National List of active synthetic substances allowed for use in organic farming.

Toxins derived from bacteria are not synthetic and the use of non-synthetic toxins as pest control substances in organic crop production would be regulated under section 205.9(e)(1). We note, however, that toxins derived from genetically engineered microorganisms are included in this document as a separate listing on the proposed National List of active synthetic substances allowed for use in crop production, as set forth in section 205.22(d) of subpart B. We have included toxins derived from genetically engineered bacteria on the proposed National List primarily so that we can receive comment on the proper classification of these substances, and on whether they should be allowed, prohibited, or approved on a case-by-case basis.

Fish emulsions are non-synthetic, although they may contain synthetic preservatives or stabilizers. These preservatives or stabilizers would be considered as inert ingredients, as defined in section 205.2, because they are not active ingredients in the formulated product. Also, these preservatives or stabilizers do not chemically alter the non-synthetic fish emulsion; therefore, their presence in a formulated product would not make the fish emulsion synthetic under the definition in the Act. However, if the level of a synthetic stabilizer in the fish emulsion is higher than necessary to stabilize the product, the stabilizer would then be considered as a synthetic fertilizer and thus prohibited under section 2109(b)(1) of the OFPA (7 U.S.C. 6508(b)(1)).

Treated seed, i.e., seed treated with pesticides, itself is not a synthetic substance because seed is an agricultural product and the treatment does not chemically alter or combine with the seed. When a treated seed is used as permitted in proposed section 205.8(a), the seed treatment does not function as an active ingredient for its intended use, nor do we consider it as causing measurable degradation of soil or water quality; therefore, the seed treatment is incidental or inconsequential when treated seed is used in organic production.

The second category, proposed in paragraph (b)(2) of this section, includes those substances or devices that are not active synthetic ingredients or substances, as defined in section 205.2, in a system of organic farming and handling. This category encompasses certain production aids used in crop and livestock production, such as plastics or other synthetic materials used as mechanical devices, treatments used for structures, and substances that otherwise do not enter into chemical interactions in the agroecosystem under normal conditions of use. It also includes certain production aids and other substances used in handling that are considered to be incidental additives, as is consistent with FDA and FSIS regulations governing ingredients that must be included on product labels.

The following list of substances or categories of substances have been determined by us to fall into this category because they are aids, devices, or incidental additives that do not contain active synthetic ingredients and do not meet the proposed definition of active ingredient or substance, and are therefore permitted for use in organic production or handling without inclusion on the National List. Included in this listing are some categories of substances delineated in section 2118(c)(1)(B)(i) of the OFPA (7 U.S.C. 6517(c)(1)(B)(i)), which establishes one set of criteria for substances that may be included on the National List, as well as additional substances that were considered by the NOSB for inclusion on the National List. This discussion is not intended to be an all-inclusive listing of non-active substances that may be used in organic production or handling.

Production aids such as netting; tree wraps and seals; sticky barriers; row covers; equipment cleaners; flocculants; pelletizers; adjuvants; and surfactants and other substances added to water to change its physical properties do not contain or function as active ingredients under our proposed definition of active ingredient because proper use of these substances has no consequential effects on biological and chemical interactions in the agroecosystem and does not cause measurable degradation of soil or water quality. Agricultural plastics, whether used as insect barriers, mulch, irrigation pipe, season extenders, or similar purposes, cannot be said to enter into chemical interactions in the agroecosystem. Substances used to adjust the texture of dry materials (e.g., flocculants or pelletizers) or to change the physical qualities of water (e.g., adjuvants or surfactants) are considered to be inconsequential additives rather than active ingredients in fertilizer, pest control, tank mixes, or other types of product formulations.

Synthetic substances used in insect or rodent traps are not active synthetic ingredients because they are not integrated into an organic production or handling system and do not interact chemically with any element of the agroecosystem. They are, additionally, prohibited from directly contacting an organic product or crop and therefore would not affect the integrity of an organic product.

We do not consider wood that is treated with synthetic preservatives and used in buildings, trellises and fences to have a significant potential to cause degradation of soil or water quality because the wood preservatives do not chemically interact with, or affect the integrity of, any aspect of the agroecosystem when used for structures, even structures that are used in contact with the soil. However, in certain situations, treatments used to preserve wood have been shown to have effects on biological and chemical interactions in the agroecosystem that would cause the treated wood to be considered an

active substance under our proposed definition. These situations are conditions that bring the wood into prolonged contact with soil that has a very high organic content, as is commonly found in compost bins and containers used for greenhouse potting mixes. We therefore would consider treated wood to be an active synthetic substance in any such situation, and thus prohibited for use in conditions of prolonged contact with soil that has a very high organic content. Further, as discussed in the supplementary information for section 205.21, if treated wood were to be used as a bin or container for an organic product, its use would be prohibited under section 2111(a)(5) of the OFPA (7 U.S.C. 6510(a)(5)), which prohibits the use for the handling of organic products of any storage containers or bins that contain synthetic fungicides, preservatives or fumigants.

An incidental additive used in the processing of agricultural products, which we define as an additive present in an agricultural product at an insignificant level and that does not have any technical or functional effect in the product, does not therefore meet our definition of an active ingredient. As discussed in the supplementary information for section 205.26, incidental additives may be used in organic handling without inclusion on the National List, but their use is regulated in section 205.17(a).

In section 205.20(b)(3), we propose that formulated products containing inert ingredients may be used in a certified organic farming operation if the formulated product does not contain an active synthetic ingredient that is prohibited for use in organic farming, and any synthetic inert ingredient contained in the formulation is not classified by EPA as an inert of toxicological concern. In order for a formulated product to be used in organic crop production, each active ingredient it contains must be a substance that is permitted under the Act and subpart B of part 205.

Additionally, the Act in section 2118(c)(1)(B)(ii) of the OFPA (7 U.S.C. 6517(c)(1)(B)(ii)) specifically prohibits products containing substances classified by EPA as inerts of toxicological concern. We have determined that this prohibition applies only to EPA List 1 inerts (Inerts of Toxicological Concern), as explained in the supplementary information for section 205.21(d). Accordingly, formulations containing synthetic inert substances included on EPA List 2, Potentially Toxic Inerts; EPA List 3, Inerts of Unknown Toxicity; and EPA List 4, Inerts of Minimal Concern would be permitted in organic production under our proposal.

General Rules for Categories of Substances and Ingredients Prohibited for Use in Organic Farming and Handling—Section 205.21

Section 205.21 delineates five general categories of substances that would be prohibited for any use in organic production or handling. The first of these, proposed in paragraph (a) of this section, would be an active synthetic substance that is not included as an active synthetic substance permitted for use in either organic crop or livestock production in sections 205.22 or 205.24 of the National List. This category is proposed, as stated previously, in accordance with sections 2105(1) and 2118(c)(1)(B)(i) of the OFPA (7 U.S.C. 6504(1) and 6517(c)(1)(B)(i)) which prohibit the use of any active synthetic substance in organic production unless it is on the National List. Our proposed category specifically includes any synthetic carbon based substance that has a cytotoxic mode of action, as defined in section 205.2. These synthetic carbon based substances are discussed in the supplementary information for section 205.9(f). They are not one of the categories of substances that is identified in section 2118(c)(1)(B)(i) of the OFPA (7 U.S.C. 6517(c)(1)(B)(i)) as a possible category of synthetic substances that may be put on the National List, thus allowing their use. It should be noted that any active synthetic substance that does not belong to any of the categories of substances identified in this section of the Act could not be included on the National List and thus could not be permitted for use in organic farming or handling.

Paragraph (b) of this section would prohibit the use of a non-agricultural substance used as an ingredient in or on a processed product that is labeled as organic or as made with certain organic ingredients if the substance is not included in section 205.26 as an allowed non-agricultural substance. This category, as previously discussed, is proposed in accordance with section 2118(c)(1)(B)(iii) of the OFPA (7 U.S.C. 6517(c)(1)(B)(iii)), which permits the use of a non-organically produced ingredient in handling an organic product only if the substance is included on the National List.

The third category, proposed in paragraph (c) of this section, would include any prohibited non-synthetic substance included in either sections 205.23 or 205.25. The absence of any prohibited non-synthetic substances in this proposal is discussed in the supplementary information for proposed section 205.23.

The fourth category of substances prohibited under this proposal, in section 205.21(d), is in accordance with section 2118(c)(1)(B)(ii) of the OFPA (7 U.S.C. 6517(c)(1)(B)(ii)), which prohibits the use of formulated products that contain any synthetic inert ingredient that is classified by the Administrator of the EPA as an inert of toxicological concern. Inert ingredients of toxicological concern are those inert ingredients included on the EPA List 1 Inerts of Toxicological Concern (54 FR 48314, November 22, 1989). Our proposed provision would prohibit the use of any formulation containing an inert ingredient included on the EPA List 1, even if that product contained an active ingredient that was otherwise allowed in this subpart. Formulated pesticidal products that contain EPA List 1 inerts can be identified by organic producers and handlers because the EPA requires the phrase ‘‘This product contains the toxic inert ingredient . . .’’ to appear on the label of such products.

Paragraph (e) of this section would prohibit the use of any fertilizer or commercially blended fertilizer that contains an active synthetic ingredient not allowed for use in crop production as provided for in section 205.22, or that contains an active prohibited substance. This prohibition is consistent with section 2109(b)(1) of the OFPA (7 U.S.C. 6508(b)(1)) and would apply in this proposal only to substances or products which meet the definition of fertilizer which we propose in section 205.2. Under our proposal, the provisions of paragraph (e) of this section would not apply to substances used as micronutrients, foliar nutrients, soil cation balancing agents, soil conditioners, or substances with similar functions which do not meet our proposed definition of fertilizer as a single or blended substance applied to the soil to supply any of the three primary plant nutrients, nitrogen (N), phosphorus (P) and potassium (K), needed for the growth of plants. Micronutrients and these substances with similar functions are permitted for use in organic crop production in most of the existing organic programs we have reviewed, and to include them within the category of synthetic fertilizers, which are prohibited under the Act, would unnecessarily restrict the options available to organic farmers for providing essential plant nutrients and maintaining soil fertility.

The National List of Active Synthetic Substances Allowed for Use in Organic Crop Production—Section 205.22

This section of the proposed regulation lists the active synthetic substances that have been reviewed for use in organic crop production and which the Secretary proposes be allowed for such use because each meets the criteria in the Act that permits their use. These substances have been reviewed by the NOSB as required by the Act, and have been determined by the Secretary to contain or function as an active ingredient in one of the categories the Act permits for inclusion on the National List as a substance permitted for use.

Any synthetic substance included on the National List appears only according to its generic or most commonly used name. In some cases, we have indicated other commonly-known terms for certain substances, such as horticultural oils. A farmer or handler is expected to request clarification from the applicable certifying agent in the case of uncertainty about the generic name of a particular brand-name substance, or about the use of any substance for which there might be any other questions.

Section 205.22, the list of active synthetic substances allowed for use in organic crop production, is organized into groups according to the functions for which the substances may be used. These groups are: horticultural oils used as insect pest smothering or suffocating agents; soaps used as insecticides, algicides, de-mossers, large animal repellants, and herbicides; production aids; toxins derived from genetically engineered bacteria (that are not released live into the agroecosystem) for use as pesticides; copper and sulfur compounds used as pesticides; minerals used as micronutrients; and minerals used as defoliants in fiber production.

Most of the substances included in this section of the National List are proposed in accordance with the recommendations provided by the NOSB. There are, however, a few cases in which we have determined it necessary to amend the NOSB recommendations concerning a particular substance in consideration of the Act, public input, and other information, including evaluations by the technical advisory panels. The following are substances for which the NOSB recommendations differ from our proposed list in section 205.22.

The NOSB recommended restricting the use of herbicidal soaps (proposed in section 205.22(b)) to non-field applications. We determined, however, that the uses of herbicidal soaps allowed by EPA would not be harmful to human health or the environment and are consistent with the other criteria provided by the Act, and thus do not need to be restricted to non-field applications. The available evidence suggests that these soaps are not persistent in the agroecosystem and would not cause measurable degradation of soil or water quality or have discernable effects on biological and chemical interactions in the agroecosystem.

The NOSB recommended allowing certain specific antibiotics as pesticides in crop production, but did not recommend to allow others for this use, particularly Avermectin. Based on a review of the technical information for these substances, we determined that all the antibiotics labeled for use as pesticides by EPA are of equally minimal consequence in their effects on biological and chemical interactions in the agroecosystem and would not cause measurable degradation of soil or water quality when properly used according to label instruction and use restrictions, and there are no other criteria specified in the Act that any specific substance in this category fails to meet.

The synergist piperonyl butoxide (PBO) (proposed in section 205.22(c)(9)) was not recommended by the NOSB for inclusion on the National List; the vote to approve PBO failed by only one vote to achieve the two-thirds majority required for approval. PBO is extracted from a non-synthetic substance, but is modified synthetically in the process of extraction and refining; it does not appear to persist in the environment or otherwise have significant effects on biological and chemical interactions in the agroecosystem or cause measurable degradation of soil or water quality, and is consistent with the other criteria specified in the Act. It also functions in a manner that significantly reduces the amounts required of some botanical pesticides that may be applied. In consideration of the benefits of reducing the amount of botanical pesticides used in an organic farming operation, which the scientific evidence clearly indicates is more likely to effect biological and chemical interactions in the agroecosystem than the PBO, we have determined that PBO should appear as an allowed synthetic substance on the proposed National List.

The NOSB did not recommend to include on the proposed National List killed microbial pesticides (toxins derived from genetically engineered bacteria that are not released live into the agroecosystem), such as the *Bacillus thuringiensis* toxin (proposed in section 205.22(d)). However, several technical experts to the NOSB reviewed these substances positively, and did not raise concerns about their effects on biological and chemical interactions in the agroecosystem when these substances are properly used. We have included toxins derived from genetically engineered bacteria that are not released live into the agroecosystem on the proposed National List.

Our research indicates that the genetically engineered bacteria from which the toxins proposed for inclusion on the National List in section 205.22(d) are derived are not released live into the agroecosystem and therefore do not have the potential to reproduce. Our research, however, indicates that the toxins themselves if overused may have the potential to induce accelerated resistance of pest populations. In this regard, we would like to receive public comment and technical and scientific data as to the effects of the use of toxins derived from genetically engineered bacteria that are not released live into the agroecosystem on the biological and chemical interactions in the agroecosystem.

The NOSB recommended that minerals used as defoliants in organic fiber production (proposed in section 205.22(g)) should be restricted according to their use and source because of their potential to cause measurable degradation of soil and water quality. However, technical information we reviewed about the use of these substances indicates that they are unlikely to result in measurable degradation of soil and water quality in the amounts applied for the defoliation of fiber crops. We have, therefore, listed calcium chloride, magnesium chloride, sodium chlorate, and sodium chloride as allowed synthetic substances used to defoliate fiber crops. In accordance with proposed section 205.3(b)(2), a non-synthetic substance, such as sodium chloride extracted from brine, would have to be chosen in preference to any synthetic defoliant, whenever possible. However, we determined that all four substances reviewed should appear on the National List because they are relatively indistinguishable with respect to their potential for measurable degradation of soil and water quality. In addition, all these minerals are available in both synthetic and non-synthetic forms that are not readily distinguishable, and thus would have to appear on the National List in order to be permitted for use.

The NOSB has reviewed amino acids (proposed in section 205.22(b)(5)) but has not yet made a recommendation as to whether to include them on the

National List as allowed synthetic crop production substances. However, the NOSB did vote to allow the use of certain vitamins, which are similar to amino acids in their use as a crop production aid and their effects on soil and water quality. We did not find any scientific evidence that amino acids, which are synthetically derived but chemically identical to substances that are normally found in soil organic matter, pose any concern for measurable degradation of soil and water quality and they meet all the other criteria established in the Act. We therefore have included amino acids on the proposed National List for use as an organic crop production aid.

The NOSB recommended the following substances for inclusion on the National List of allowed synthetic substances, but we have not included them on the proposed National List because we determined that they were non-synthetic. Therefore, they may be used in organic farming without being included on the National List.

Fish products, aquatic plant extracts, and humic acid and its derivatives are not included because, as discussed previously, we determined that they are non-synthetic. Although the NOSB also had concerns about synthetic extractants used to produce these non-synthetic substances, we determined that the extraction methods for substances used in crop production are inconsequential in their effects on biological and chemical interactions in the agroecosystem or to measurable degradation of soil and water quality. Additionally, the addition of small amounts of synthetic stabilizers or preservatives to these products is of minimal concern and, as discussed in the supplementary information for section 205.20 of this proposal, the inclusion in a formulated product of synthetic inert ingredients that are not of toxicological concern does not cause the product to be prohibited for use in organic production. However, we are aware that synthetic stabilizers sometimes may be added to such products at levels higher than necessary to stabilize the formulation in order to increase its fertilizer value. In such cases, the stabilizers would be considered to be synthetic fertilizers, which are prohibited for use in organic production by section 2109(b)(1) of the OFPA (7 U.S.C. 6508(b)(1)) and proposed section 205.7(d)(1). A certified producer or handler is expected to request clarification from the certifying agent in the case of uncertainty about whether a specific product would be prohibited according to this definition.

Elemental sulfur also was recommended by the NOSB for inclusion in proposed section 205.21. However, we consider elemental sulfur to be non-synthetic regardless of its source.

Potassium nitrate (niter) was reviewed by the NOSB as a synthetic substance and was not recommended for inclusion as an allowed synthetic substance for organic crop production. However, we reviewed information that potassium nitrate also exists as a natural mineral deposit that may be mined for agricultural use. Although we agree with the NOSB and do not consider synthetic potassium nitrate to meet the criteria for inclusion as a synthetic substance on the National List, niter in the form of a non-synthetic mined product would be allowed for use in organic production under the Act and the proposed regulations in subpart B of this part.

The following substances were recommended by the NOSB for inclusion as allowed synthetic substances for organic crop production. We have not included them on the National List because we consider them not to be active substances or ingredients in the applications for which they are used and therefore, as previously discussed, are substances that may be used in a certified organic operation without inclusion on the National List:

Plastic mulches and row covers do not interact chemically with the agroecosystem and are specifically permitted under section 2109(c)(2) of the OFPA (7 U.S.C. 6508(c)(2)) if they are removed at the end of each harvest season.

Disinfectants, such as alcohols, hydrogen peroxide and chlorine bleach that are used to clean equipment; sticky traps and barriers; and ammonium carbonate used as bait in traps are not used directly on soil or crops and thus are not active because they have no significant consequence to the organic production system.

Lignin sulfonate, which is used as a dust suppressant or as a chelating agent, is not active in either use because, in the former instance it is not applied to soil used for crop production and, in the latter instance, it is not an active ingredient in a formulated (micronutrient) product.

Detergents and other emulsifiers used as surfactants or adjuvants often are added in very small quantities directly to tank mixes used for spraying and are considered to be non-active, just as inert ingredients within a formulated product are. Similar considerations apply to sodium silicate and other substances used to affect the surface tension of water, as is sometimes done to improve the buoyancy of tree fruit during packing.

The NOSB also recommended that lumber treated with arsenates not be included on the National List as an allowed synthetic substance. However, as previously discussed, we determined that a substance used to treat lumber that is used for such purposes as buildings, fences and trellises cannot be considered to be an active ingredient under our definition of an active ingredient. However, evidence we have reviewed indicates that arsenates and other synthetic lumber preservatives may become active when in contact with soil having a very high organic content, such as soil used in greenhouse beds or compost bins. Because arsenates and other synthetic substances used to preserve lumber are not proposed by us to be included on the National List as active synthetic substance, and because section 2109(c)(1) of the OFPA (7 U.S.C. 6508(c)(1)) specifically prohibits the use of arsenic or lead salts in organic crop production, the use of arsenates and other synthetic lumber preservatives in any manner that might be considered an active use would be prohibited under the Act and this proposal. Furthermore, section 2111(a)(5) of the OFPA (7 U.S.C. 6510(a)(5)) prohibits the use of storage containers or bins that contain any synthetic fungicides or preservatives in handling organic products and this would include bins constructed of arsenate treated lumber.

Finally, the NOSB recommended that biosolids, or municipal sludge, should be classified as synthetic and were not appropriate for use in organic crop production. The EPA defines biosolids as the primarily organic residuals, produced by current wastewater treatment processes that treat domestic sewage, that can be beneficially recycled. Under current EPA regulations, such recycling can include land application of biosolids to provide primary plant nutrients and micronutrients to crops and vegetation produced in agriculture and to improve soil characteristics by providing necessary moisture and/or organic matter to enhance soil tilth. Over the years, EPA, USDA, and FDA have issued joint policy statements that have endorsed the beneficial utilization of biosolids on land for purposes that include the production of fruits and vegetables. However, to prevent potential problems, the guidance contains steps that must be taken relative to issues such as the amount of cadmium and lead that can be applied to the soil, the amount of PCBs in the biosolids, and the relative accumulation

of heavy metals into edible plant parts. Under these and other restrictions contained in 40 CFR Part 503, biosolids can be safely used in conventional agriculture. However, we are requesting comments to assess the extent to which biosolids may be used in organic production. The USDA specifically invites comments on whether the use of biosolids (municipal sludge) should be permitted or prohibited in organic production. The USDA also invites comments on the classification of biosolids as a synthetic rather than a non-synthetic substance. Comments should detail the basis for the commenter's recommendation, including the agricultural, policy, technical, or scientific factors.

The National List of Non-Synthetic (Natural) Substances Prohibited for Use in Organic Crop Production—Section 205.23

The NOSB has recommended that the rodenticide strychnine, the fertilizer ingredient manure ash, and the pesticide sodium fluoaluminate, which are non-synthetic (natural) substances, be prohibited for use in organic farming and handling. As stated previously, in order for the Secretary to prohibit the use of a non-synthetic (natural) substance in an organic farming or handling operation, it must be determined that the use of such substance both would be harmful to human health and the environment and inconsistent with organic farming or handling. Further, the Secretary of HHS and the Administrator of EPA must be consulted.

The Secretary of HHS and the Administrator of EPA, respectively, have the authority to regulate crop production substances according to human health and safety and environmental protection. These two agencies have the responsibility to review and establish appropriate restrictions on the use of any substance as a pest control, food, feed or drug, and the applicable agency must determine that allowed use of the substance poses no threat to human health and the environment before permitting a substance to be used in agricultural production or handling. In consulting with these agencies, they concluded that their review of these substances showed that, when used according to the requirements established by these agencies, the substances do not meet the criteria in the Act for inclusion on the National List of prohibited non-synthetic (natural) substances. In concurrence with this conclusion, we have determined that there can be no non-synthetic substance that meets both of the OFPA criteria for being designated as a prohibited non-synthetic substance, and we did not accept the NOSB's recommendation for the prohibition of strychnine, manure ash, and sodium fluoaluminate. We only include sections 205.23 and 205.25 in our proposal so that appropriate substances may be included on the National List in the future should this be determined to be necessary.

The National List of Active Synthetic Substances Allowed for Use in Organic Livestock Production—Section 205.24

The substances proposed for inclusion in this section of the National List are listed as the following six categories: trace minerals; nutrients and dietary supplements; feed additives (provided they are also included in section 205.26); animal drugs and other animal health care substances; vaccines and biologics; and pest control substances (provided they also are included in section 205.22).

This section would permit any active synthetic substance permitted by FDA, EPA and USDA in the specified categories to be allowed for use in organic livestock production when used in accordance with the restrictions specified by the approving agency and the restrictions specified in this section. We have proposed these active synthetic substances to be permitted for use after reviewing the NOSB recommendations for livestock substances to be included on the National List, and their recommendations for the use of vitamins, minerals, inoculants, vaccines, antibiotics and parasiticides in livestock production. Our proposed list is consistent with sections 2110 and 2118 of the OFPA (7 U.S.C. 6509 and 6517), which delineate feeding and health care practices to be used in organic livestock production and the categories of synthetic substances related to livestock production that may be included in the National List.

Section 2110(d) of the OFPA (7 U.S.C. 6509(d)) prohibits certain uses of veterinary medications, specifically subtherapeutic doses of antibiotics and routine administration of synthetic internal parasiticides, in organic livestock production. The use of other veterinary medications, except vaccines, is prohibited only in the absence of illness. This indicates that therapeutic doses of antibiotics, non-routine use of synthetic internal parasiticides, any use of vaccines, and administration of any veterinary medication to treat an illness are all permitted under the Act, without the need to include these substances on the National List of synthetic substances permitted to be used. However, because livestock parasiticides and medicines are also included among the categories of active synthetic substances in section 2118(c)(1)(B)(i) of the OFPA (7 U.S.C. 6517(c)(1)(B)(i)) that would need to be included on the National List in order to be permitted to be used, we have included animal drugs (veterinary medications) in this section of the proposed National List in order to clarify that their use is permitted.

All of the categories proposed for inclusion in this section of the National List, other than animal drugs and other animal health care substances and vaccines and biologics, have been explicitly reviewed by the NOSB itself and proposed for inclusion as either crop production substances in section 205.22 or as ingredients allowed in processed products in section 205.26. We are including the categories of animal drugs and animal health care substances and vaccines and biologics in the National List because these substances have already been evaluated by the applicable regulatory agency that approves them for general use by criteria similar to those in section 2119(m) of the OFPA (7 U.S.C. 6518(m)) that are to be used by the NOSB in evaluating a substance.

A representative of the FDA's Center of Veterinary Medicine (CVM) addressed the NOSB in Rohnert Park, California, in October 1994, to explain in detail the review process conducted by CVM in reviewing veterinary drugs and establishing withdrawal times. The NOSB voted at its meeting in Austin, Texas, on October 31, 1995, to accept the FDA evaluations of antibiotics, parasiticides, vitamins and minerals and the USDA evaluations of inoculants and vaccines as equivalent to the substance review process established for the NOSB in sections 2119(k), (l) and (m) of the OFPA (7 U.S.C. 6518 (k), (l) and (m)). However, in doing so, the NOSB did indicate that it would: defer the initial technical advisory panel review of synthetic vitamins and minerals for a period of two years unless a specific vitamin or mineral is identified in the interim as being in conflict with organic principles and therefore requires an immediate review; defer the initial review of vaccines and inoculants for a period of two years, except in the case of a substance that may be in conflict with organic principles and therefore requires an immediate review; and establish a priority ranking of antibiotics and parasiticides to be used by producers when administering animal drugs. To date, the NOSB has not yet established a priority ranking for preferred use of the antibiotics and parasiticides approved by FDA.

The National List of Non-Synthetic Substances Prohibited for Use in Organic Livestock Production—Section 205.25

As previously discussed with reference to proposed section 205.23, no substances are proposed in this section because we have determined that no non-synthetic substances meet the criteria provided in section 2118(c)(2) of the OFPA (7 U.S.C. 6517(c)(2)) for prohibiting their use.

The National List of Non-agricultural Substances Allowed as Ingredients in or on Processed Products Labeled as Organic or Made With Certain Organic Ingredients—Section 205.26

We propose in § 205.26 the National List category of non-agricultural substances allowed as ingredients in or on processed products labeled as organic or made with certain organic ingredients. As discussed previously, this section of the National List is proposed to satisfy the provision in section 2118(c)(1)(B)(iii) of the OFPA (7 U.S.C. 6517(c)(1)(B)(iii)) that a non-organically produced substance used in handling be evaluated as if it were synthetic, and therefore the use of such a substance is prohibited unless it appears on the National List.

The inclusion of both synthetic and non-synthetic non-agricultural substances in this category is necessary because, as was indicated in the NOSB's deliberations, it is often very difficult to decisively classify many non-agricultural ingredients as synthetic or non-synthetic. For example, citric acid is a naturally occurring substance that may be obtained from citrus fruits. However, after reviewing and discussing the process by which virtually all commercially available citric acid is formulated, the NOSB was almost evenly divided in its vote as to whether or not this process rendered the substance synthetic under the definition provided in section 2103 of the OFPA (7 U.S.C. 6502).

We have not, however, proposed to include in this section of the National List any substance (ingredient) that does not meet our definition of an active ingredient. Substances that are not active ingredients are considered to be incidental additives, and such substances are not consistent with the FDA and FSIS requirements for substances that must be listed on a product label. As previously discussed, because incidental additives are not active ingredients, they are not otherwise prohibited by the Act and may thus be used in handling organic products without having to be included on the National List. We are accordingly including only substances that do meet the definition of an active ingredient, and that therefore are required by the FDA and FSIS to be listed on a product label, in the National List of non-agricultural substances allowed as ingredients in or on processed organic products.

Proposed § 205.26 contains an alphabetical listing of the generic name of the non-agricultural substances which meet the Act's criteria for inclusion on the National List as substances permitted to be used. These substances have been reviewed by the NOSB and included in recommendations made by them to the Secretary regarding substances to be included on the proposed National List. In most cases, substances are listed individually, such as ammonium bicarbonate or lactic acid, but in many cases categories of substances, such as cultures (dairy, non-synthetic) or nutrient supplements, are listed. When a category is listed, the use of any substance that belongs to that category is allowed.

This section diverges from certain recommendations provided by the NOSB. As discussed with respect to allowed synthetic substances used in crop production, proposed in § 205.22, certain substances that the NOSB recommended be included on the National List of substances allowed for use as ingredients in or on processed organic products are not active, and are thus not included in this section. These substances, which may be used without inclusion on the National List, are diatomaceous earth, clays including kaolin and bentonite, nitrogen, oxygen, ozone, chlorine bleach, perlite, sodium hydroxide, ethylene, hydrogen peroxide, and potassium hydroxide.

Kelp was reviewed and recommended by the NOSB as a permitted non-agricultural substance in processed products. We have not included kelp as a non-agricultural substance permitted for use because kelp and other seaweeds are plants harvested from the wild, and so are considered agricultural products as opposed to non-agricultural products when used as ingredients in processed organic products. Kelp also might be considered a nutrient supplement when used as a source of iodine in food meant for human consumption and as a source of iodine and trace minerals in livestock feed.

The NOSB recommended the plant derived waxes carnauba wax and wood rosin for inclusion on the proposed National List. (Wood rosin also is referred to as lac-resin, shellac-based wax, or resin). We have included carnauba wax and wood rosin in this proposed section and additionally propose to include candelilla wax and beeswax as allowed non-agricultural substances. Candelilla wax is a plant derived wax that is commonly used, as is beeswax, in coatings for fresh produce. We consider both waxes to be necessary to the handling of agricultural products and as meeting the other requirements of section 2118(a) of the OFPA (7 U.S.C. 6517(a)) that must be met before such substances may be permitted to be used. In accordance with section 2111(a)(5) of the OFPA (7 U.S.C. 6510(a)(5)), which prohibits the use of any packaging materials that contain synthetic fungicides or preservatives, any wax used as a coating on fresh produce could not contain synthetic preservatives or fungicides.

The NOSB recommended the inclusion of unmodified cornstarch as a permitted substance and postponed a decision on other unmodified starches. Unmodified starches are agricultural ingredients because they are manufactured from agricultural products through methods that do not meet the Act's definition of synthetic. Their use would therefore be permitted as non-organic agricultural ingredients in proposed § 205.27.

The NOSB reviewed whey protein and did not recommend it for inclusion on the National List of allowed non agricultural ingredients. We consider whey protein to be necessary to the handling of certain agricultural products because of the unavailability of wholly natural products, which use is then provided for in section 2118(c)(1)(A)(ii) of the OFPA (7 U.S.C. 6517(c)(1)(A)(ii)). This substance also meets the other criteria in the Act for inclusion on the National List, and we accordingly propose that it be included as an allowed non-agricultural ingredient as part of our category whey and its fractions.

The NOSB also recommended not to include magnesium carbonate, potassium phosphate, magnesium stearate, and potassium iodide on their proposed National List of non-agricultural ingredients allowed in agricultural products labeled as organic. However, the NOSB recommended that these four substances be permitted in products labeled as made with certain organic ingredients. Because our proposed National List is applicable to both types of labeled products, we propose to include magnesium carbonate, potassium phosphate, magnesium stearate and potassium iodide in this section and allow their use in products labeled organic and made with certain organic ingredients.

(Potassium iodide is not listed separately because it is included within the nutrient supplement category).

Chymosin is an enzyme that occurs naturally in animals and currently is being produced through genetically engineered microorganism in quantities suitable for cheese production. The NOSB recommended that chymosin not be included on the proposed National List of non-agricultural substances because it is derived from a genetically engineered microorganism. We have included chymosin on the proposed National List so as to solicit public comment.

The NOSB recommended that enzymes derived from bacteria which were not genetically engineered are appropriate for use as non agricultural ingredients in agricultural products labeled as organic or made with certain organic ingredients. Although the NOSB has not completed its review of sources of non-synthetic enzymes, such as plant, animal, and micro-organisms other than bacteria, we have included the category of enzymes, non-synthetic in this section of the proposed National List for the purpose of receiving comment during the period that the NOSB completes its review and develops its recommendation. When they have completed their review, appropriate notice will be provided. We would consider animal-derived rennet to be included in the category of non-synthetic enzymes.

The NOSB classified calcium sulfate as synthetic and did not recommend it for inclusion on the proposed National List of non-agricultural substances permitted to be used. However, we are aware of at least one source of mined gypsum (non-synthetic) that is refined to food grade calcium sulfate. Also, we received comments from some manufacturers of tofu who stated their preference for calcium sulfate over other coagulants. Non-synthetic calcium sulfate could serve in some cases as a wholly natural alternative to the use of synthetic tofu coagulants, and otherwise meets the Act's criteria for inclusion on the National List of non-agricultural substances permitted to be used. We have therefore included calcium sulfate in this section of the proposed National List.

Some substances included in this proposed section 205.26 as non-agricultural substances are manufactured from feed stocks that are agricultural products, such as corn. Some persons may thus consider these substances to be agricultural products, and therefore not appropriate for inclusion in this section of the National List. We have included these substances because they are not easily recognizable as agricultural products, or because there is some likelihood that the processing methods used to purify these substances would render them synthetic as defined under the Act. The inclusion of these substances in this section is based on our definition of a non-agricultural ingredient (proposed in section 205.2) as a substance that is extracted, isolated from, or is a fraction of an agricultural product, so that the identity of the agricultural product is unrecognizable in the extract, isolate or fraction. Examples of these proposed substances include: ascorbic acid, beeswax, citric acid, candelilla wax, carnauba wax, carrageenan, non-synthetic colors, lactic acid, lecithin, mono and diglycerides, pectin, potassium acid tartrate, tartaric acid and whey and its fractions. Since many of these substances originate from agricultural products, it is possible that these substances could be available in the future as organic agricultural products.

Non-organically Produced Agricultural Products Allowed as Ingredients In or On Processed Products Labeled as Organic or Made With Organic Ingredients—Section 205.27

Non-organically produced agricultural ingredients are permitted for use in processed organic products under section 2111(a)(4) of the OFPA (7 U.S.C. 6510(a)(4)), provided that they comprise less than five percent by weight of the finished product, exclusive of water and salt, and are included on the National List. Section 2118(c)(1)(B)(iii) of the OFPA (7 U.S.C. 6517(c)(1)(B)(iii)) requires non-organically produced substances to be evaluated according to the same criteria used for active synthetic ingredients in order to be permitted for use as ingredients in organic products. In its review of non-organically produced agricultural products, the NOSB concluded that all agricultural products, considered as a category, meet the criteria for including substances on the National List, as set forth in sections 2118(c)(1)(A) and 2119(m) of the OFPA (7 U.S.C. 6517(c)(1)(A) and 6518(m)). In concurrence with the NOSB, we are proposing in this section that all non-organically produced agricultural products be allowed as ingredients in organic processed products. Under this proposal, any agricultural product could be used if such use complied with the provisions proposed in section 205.16.

Amending the National List—Section 205.28

Section 2119(n) of the OFPA (7 U.S.C. 6518(n)) requires the establishment of a petition procedure by which interested parties may request the NOSB to evaluate substances for inclusion on the National List. We accordingly have proposed in section 205.28 a process by which an interested party may petition the NOSB to review a substance and make a recommendation as to whether the substance should be included in the National List as an allowed active synthetic substance, a prohibited non-synthetic substance, or a non-agricultural substance allowed to be used as an ingredient in or on processed organic products.

This section also proposes the information that, to the extent it is available to the petitioner, should be included in the petition to assist the NOSB review of the substance and the Secretary's determination as to its inclusion on the National List. The information requested by proposed paragraph (d) of this section would provide information relevant to the issues that are to be examined when considering placing a substance on the National List. This would include information that would enable the Secretary to determine whether a substance functions as, or contains, an active synthetic ingredient, and whether it falls into one of the categories of active synthetic substances that may be included on the National List of approved substances. This would also include information needed to evaluate the health, environmental, and agroecosystem effects of the substance.

This proposed section also would require regulatory information, such as registration of the substance in question with EPA or FDA. Other required information would include a description of the manufacturing process of the substance, product characteristics, safety information relating to the substance, and bibliographies of scientific literature relating to the substance that may be available to the petitioner to be submitted. The petitioner would be requested to submit information that describes alternative substances or alternative cultural methods that could be utilized in place of the substance, and that summarizes the effects on the environment, human health, and farm ecosystem that might support the use of the substance. This information is needed to help determine whether a substance is an active synthetic ingredient in one of the categories that the Act, in section 2118(c)(1)(B)(i) of the

OFPA (7 U.S.C. 6517(c)(1)(B)(i)), permits to be used if it is on the National List and whether allowance of a synthetic substance is justified by the lack of a suitable non-synthetic or cultural alternative, as required under section 2118(c)(1)(A)(ii) of the OFPA (7 U.S.C. 6517(c)(1)(A)(ii)). Other information required to be submitted is needed to determine whether a non-synthetic substance will be prohibited for use under the criteria specified in section 2118(c)(2) of the OFPA (7 U.S.C. 6517(c)(2)).

Section 2118(d) of the OFPA (7 U.S.C. 6517(d)) includes provision for the procedure by which amendments may be made to the National List. Following receipt of a petition, as proposed in this section, the Secretary would determine whether the substance is within one of the categories of the National List. If the substance is within one of the defined categories, it would be reviewed by the NOSB in accordance with the criteria provided in the Act.

After the NOSB submits its recommendations concerning a petitioned substance to the Secretary, the Secretary would then determine whether the substance satisfies the criteria listed in section 2118(c) of the OFPA (7 U.S.C. 6517(c)) regarding the inclusion of substances on the National List as an allowed or prohibited substance. If the Secretary determines that the substance does meet these criteria, the addition of the substance to the National List would then be proposed as an amendment to the National List according to the procedure established in section 2118(d) of the OFPA (7 U.S.C. 6517 (d)), which includes publication in the **Federal Register** of a proposed amendment to the National List and an opportunity for public comment.

As provided for in section 2118(e) of the OFPA (7 U.S.C. 6517(e)), the NOSB also would review any substance on the National List within five years of the substance being allowed or prohibited for use, and would provide the Secretary with recommendations as to whether the substance should remain on the National List. The Secretary would decide whether to renew each allowance or prohibition in order for an allowed or prohibited substance to remain on the National List. The Secretary's decisions concerning this then would be published in the **Federal Register**.

Subpart C—Labels, Labeling, and Market Information

Sections 2106(a)(1)(A) and (B) of the OFPA (7 U.S.C. 6505(a)(1)(A) and (B)) state that persons may sell or label agricultural products as organically produced only in accordance with the Act, and that persons may affix a label to and provide other market information concerning organically produced agricultural products only when the products are produced and handled in accordance with the Act.

In accordance with the Act, we are proposing in subpart C of this part provisions regarding labels, labeling, and marketing information for agricultural products that are organically produced and for any agricultural products that contain organically produced ingredients. Additionally, provisions also are included for the use of the USDA seal on labels, labeling, and other market information as authorized by section 2106(a)(2) of the OFPA (7 U.S.C. 6505(a)(2)), and this subpart also addresses the use of products that originate from operations that sell no more than $5,000 annually in value of agricultural products. These operations are exempt from certain provisions of the Act.

Agricultural Products in Packages Sold, Labeled, or Represented as Organic—Section 205.100

In accordance with section 2106 of the OFPA (7 U.S.C. 6505) which provides for selling and labeling a product as organically produced, we propose in section 205.100 of this subpart our labeling provisions for agricultural products in packages described in section 205.16(a) that are sold, labeled, or represented as organic. These are finished products that contain at least 95 percent organically produced ingredients, by weight, excluding water and salt, hereafter referred to as ''products that contain at least 95 percent organic ingredients''. The percentage of the product that is not organic must be made of some combination of non-agricultural ingredients and/or non-organically produced agricultural products included on the National List. Packages are defined in our proposal as a container or wrapping that bears a label and which encloses an agricultural product, except for agricultural products in bulk containers, shipping containers, or shipping cartons.

In paragraph (a) of this section, we propose the terms that may be used on agricultural products described in section 205.16(a) that are sold, labeled, or represented as organic, (i.e., products that contain at least 95 percent organic ingredients). We propose to allow the term organic to be used on the principal display panel to modify the name of the product and in the ingredients statement to modify the name of each ingredient organically produced and handled in accordance with the Act and the regulations in this part. We have defined the principal display panel to be that part of a label that is most likely to be displayed, presented, shown or examined under customary conditions of display for retail sale. The ingredients statement is defined as the listing of the ingredients contained in a product listed by their common or usual names in the descending order of predominance. The ingredients statement is usually located on the information panel of products other than meat and poultry products and is often located on the principal display panel of meat and poultry products, but may be placed on other package panels because of package restrictions.

We are proposing to allow the term organic to appear on the principal display panel to ensure a clear, consistent and conspicuous identification of organically produced agricultural products for consumers. Examples of the use of this term are organic grapes, organic beef, organic peppermint tea, organic vegetable soup, organic whole wheat bread, and organic ice cream. We are proposing to allow the term organic to be used in the ingredients statement to modify the name of each organically produced ingredient in order to provide consumers with a means of knowing which ingredients have been organically produced. Many consumers would consider information about the specific organic ingredients contained in a product to be essential information to have as a part of their purchasing decision.

Section 2106(a)(2) of the OFPA (7 U.S.C. 6505(a)(2)) provides for products that meet USDA standards for organic production to incorporate the USDA seal on such agricultural products. Additionally, section 2108 of the OFPA (7 U.S.C. 6507) provides for a State to establish a State organic program that meets the requirements of the national organic program. If a State does so, and its program is approved by USDA, we believe it is appropriate to allow the State to have a seal representing its program, and to allow agricultural products produced under such a State program to bear a State seal. Accordingly, we propose in paragraph (a)(3) of this section that a USDA seal, and a State seal that represents a State organic program approved by the Secretary, as provided for in section 205.402 of subpart F, may be used on the principal display panel of packages of agricultural products labeled as organic. These seals would reflect that

the product was produced and handled in accordance with the Act and the regulations in this part, and if applicable, the requirements of a State organic program approved by the Secretary.

We think that the terms and marks used on the principal display panel, which is the most visible panel, should be those terms and marks which simply and clearly present information about the organic nature of the agricultural product and its compliance with the national organic program requirements and, if applicable, the requirements of an approved State organic program. This is consistent with the purposes stated in sections 2102(2) and (3) of the OFPA (7 U.S.C. 6501(2) and (3)) to assure consumers that organically produced products meet a consistent standard and to facilitate commerce.

We propose in paragraph (a)(4) of this section the terms and marks which may appear on the information panel of products in packages that are sold, labeled, or represented as organic (i.e., products that contain at least 95 percent organic ingredients). We have defined the information panel to be that part of the label immediately contiguous and to the right of the principal display panel as observed by an individual facing the principal display panel, unless an allowance has to be made for another section of the label to be designated as the information panel because of size or other limitations. Many meat and poultry products do not have an information panel.

Most of the terms and marks proposed to be permitted to be used on the information panel of products that contain at least 95 percent organic ingredients are the same terms and marks previously proposed to be allowed to be used on the principal display panel: the term organic, the USDA seal, and a State seal representing a State organic program approved by the Secretary. Additionally, we propose to permit on the information panel the use of a certifying agent's name, seal, logo or other identification which represents that the farm, wild crop harvesting, or handling operation that produced or handled the finished product is a certified operation. We are proposing here to allow only the identification of the certifying agent that certified the operation that produced or handled the finished product. We believe that allowance of the use of multiple identification of certifying agents who certify any operation involved in the production or handling of the product would be unwieldy and confusing to the consumer. We invite comments on this issue.

The NOSB received some public comment which requested that identification of a certifying agent on product labels be prohibited. Other public comments, however, indicated that the identification of a certifying agent should be required on product labels to inform consumers of the specific organization that performed the certification of the operation. Additionally, some public comments requested that the identification of a certifying agent be optional, so that each individual producer and handler could decide whether to include this identification on their label.

After evaluating the public comments, we agree that the decision as to whether to include the certifying agent's identification on a label should be optional. We believe that inclusion of the identification of the certifying agent who certified the operation that made the finished product is not essential. Therefore, we have included this identification of a certifying agent in our proposal as optional information that may be included on the information panel of a label of products that contain at least 95 percent organic ingredients.

We propose to allow the placement of the identification of the certifying agent on the information panel, but not on the principal display panel, because we want the principal display panel to include only those terms or marks that would be important to everyone, i.e., those terms or marks that present information about the organic nature of the agricultural product, its compliance with the national organic program requirements and, if applicable, the requirements of an approved State organic program; we do not feel that the identification of a certifying agent is this type of information. We propose to allow the placement of the identification of the certifying agent on the information panel, rather than restricting its use to other less prominent panels, because we agree with the public input we received that stated that this information would be important to some consumers in their purchasing decisions.

In paragraph (a)(5) of this section, we propose that the terms or marks that may appear on the information panel for products sold, labeled, or represented as organic (i.e., products that contain at least 95 percent organic ingredients) also may be used on any package panels of the product, excluding the principal display panel. Additionally, we are proposing that these same terms and marks may be used on the product's labeling and on market information about the product. We have defined labeling to be written, printed or graphic material accompanying a product at any time or displayed about the product at the retail store. Market information has been defined to be any written, printed, audio-visual or graphic information, including advertising, pamphlets, flyers, catalogues, posters, and signs, that are used to assist in the sale or promotion of a product. This provision is consistent with section 2106(a)(1)(B) of the OFPA (7 U.S.C. 6505(a)(1)(B)), which provides for labels and market information to be provided for and affixed on agricultural products that are produced and handled in accordance with the Act and the regulations in this part.

Agricultural Products in Packages Sold, Labeled, or Represented as Made With Certain Organic Ingredients—Section 205.101

Section 2106(c)(1) of the OFPA (7 U.S.C. 6505(c)(1)) authorizes the Secretary, in consultation with the NOSB and the Secretary of Health and Human Services, to allow the use of the word organic on the principal display panel of an agricultural product that contains at least 50 percent organically produced ingredients by weight, excluding water and salt, only for the purpose of describing the organically produced ingredients. Our proposed section 205.16(b) makes it clear that this type of product is one containing at least 50 percent, but less than 95 percent, organically produced ingredients. The Secretary has consulted with the Secretary of Health and Human Services and reviewed the NOSB recommendations for this matter. We are proposing to allow the word organic to appear on the principal display panel of products described in section 205.16(b) as discussed below, hereafter referred to as ''products that contain between 50 and 95 percent organic ingredients''.

We propose, in paragraph (a) of this section, the terms that must be used on agricultural products sold in packages, described in section 205.16(b), that are sold, labeled, or represented as made with certain organic ingredients, (i.e., products that contain between 50 and 95 percent organic ingredients). We propose in paragraph (a)(1) of this section that the statement made with certain organic ingredients must be used on the principal display panel of a product described in section 205.16(b). We believe that allowing the word organic to appear on the principal display panel of these products only when used within the statement made with certain organic ingredients would enable consumers to easily distinguish this type of product from a product that

contains at least 95 percent organic ingredients, on which the term organic must appear on the principal display panel to modify the name of the product.

We request comments from industry, consumers, consumer interest groups, and all other interested persons on our proposed use of the statement made with certain organic ingredients on the principal display panel of products that contain between 50 and 95 percent organic ingredients. We are soliciting information as to whether there are alternative label proposals, and if so, a description of them, that would accomplish our purpose of clearly distinguishing on the principal display panel between products that contain at least 95 percent organic ingredients and those that contain between 50 and 95 percent organic ingredients.

We also propose in paragraph (a)(2) of this section to require that the term organic be used in the ingredients statement to modify organically produced ingredients. We are proposing this in order to provide consumers with a means of knowing which ingredients have been organically produced.

We propose in paragraph (b) of this section the terms and marks that may, but that are not required to, be used on agricultural products described in section 205.16(b) that are sold, labeled, or represented as made with certain organic ingredients (i.e., products that contain between 50 and 95 percent organic ingredients). In paragraph (b)(1) of this section, we propose to allow the statement made with certain organic ingredients to appear on the information panel. We believe this would further assist consumers in readily identifying products that contain between 50 and 95 percent organic ingredients, and additionally may be useful in certain retail display situations where the view of the principal display panel may be obscured from the consumer. We also propose in paragraph (b)(1) of this section to allow the identification on the information panel of the certifying agent who certified the farm, wild crop harvesting, or handling operation that produced or handled the finished product. Our reasons for allowing the optional inclusion of the certifying agent's identification on the information panel and the prohibition of its placement on the principal display panel for these type of products, are the same ones we previously discussed with regard to products that contain at least 95 percent organic ingredients.

In paragraph (b)(2) of this section, we propose that any of the terms and marks proposed to be allowed to be used on the information panel may also be used on labeling, market information and any package panel, excluding the principal display panel, of products labeled as made with certain organic ingredients. The allowed terms or marks would be the statement made with certain organic ingredients and the certifying agent's identification. This provision is consistent with section 2106(a)(1)(B) of the OFPA (7 U.S.C. 6505(a)(1)(B)), which provides for labels and market information to be provided for and affixed on agricultural products that are produced and handled in accordance with the Act and the regulations in this part.

Multi-ingredient Agricultural Products That Only Represent the Organic Nature of Such Ingredients in the Ingredients Statement—Section 205.102

Section 2106(c)(2) of the OFPA (7 U.S.C. 6505(c)(2)) authorizes the Secretary, in consultation with the NOSB and the Secretary of Health and Human Services, to allow products that contain less than 50 percent organically produced ingredients by weight of the finished product, excluding water and salt, to include the word organic on the ingredient listing panel to describe those ingredients that are organically produced. The Secretary has consulted with the Secretary of Health of Human Services and reviewed the NOSB recommendations on this matter. We propose the following provisions for the use of the word organic in the ingredients statement of multi-ingredient agricultural products that only represent the organic nature of such ingredients in the ingredients statement.

We propose in section 205.102 that the term organic may be used in the ingredients statement of this type of product to modify the name of an ingredient organically produced and handled in accordance with the Act and the regulations in this part. We also propose in section 205.102 that agricultural products that are composed of more than one ingredient may represent in an ingredients statement that the ingredients are organic without the finished product having to be produced and handled in a certified operation, if certain conditions are met. One of the conditions that must be met is that the producer or handler of the finished product would have to maintain certain records that are required for non-certified operations. The second condition that must be met is that the only representation made about the organic nature of the product is a statement in the ingredients statement that identifies organic ingredients.

We also propose in paragraph (b) of this section that the term organic may be used on labeling, marketing information and package panels of labels other than the principal display panel and information panel, to describe the organic ingredients in products discussed above. We are permitting the identification of organic ingredients under these conditions for a variety of organic products in order to allow the organic industry flexibility in the production and marketing of organic products.

Use of Terms or Statements That Directly or Indirectly Imply That a Product is Organically Produced and Handled—Section 205.103

Section 2106(a)(1)(B) of the OFPA (7 U.S.C. 505(a)(1)(B)) provides that a person may affix or provide a label or other market information about an agricultural product, including an ingredient, that directly or indirectly implies that the product is organically produced and handled only when the product has been produced and handled using organic methods in accordance with the Act. Accordingly, we propose in this section that labels, labeling or market information that directly or indirectly imply organic production and handling practices may be provided for or affixed only on agricultural products produced and handled in accordance with the Act and the regulations in this part.

Our proposed regulations would authorize the use on a label, labeling, or market information of the term organic and other terms and phrases that directly or indirectly imply that the product was organically produced and handled. Therefore, under our proposal, any terms or phrases that directly or indirectly imply that a product has been organically produced or handled would be prohibited from being used on the label, labeling, or market information of products that are not produced in accordance with the Act and the regulations in this part.

We considered putting in our proposed requirement a specific list of the terms and phrases that we believe would directly or indirectly imply that a product was organically produced and handled. We have not done this because we are uncertain as to what terms and phrases should appropriately be placed on such a list. We request comment from the public as to what terms or phrases, other than organic or made with certain organic ingredients, they believe could directly or indirectly imply that a product was organically produced and handled and the rationale for the allowance of their use. Examples

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

Informational Statements Prohibited—Section 205.104

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

The USDA Seal—Section 205.107

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

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

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

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

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

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

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

SUBPART C—LABELS, LABELING, AND MARKET INFORMATION

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

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

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

Subpart D—Certification

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

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

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

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

Synopsis of Proposed Certification Program

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

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

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

What Has to be Certified—Section 205.201

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

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

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

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

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

Exemptions and Exclusions—Section 205.202

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

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

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

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

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

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

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

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

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

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

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

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

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

sought to provide additional exemptions from certification.

General Requirements for Certification—Section 205.203

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

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

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

Applying for Certification—Section 205.204

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

Organic Plan—Section 205.205

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Statement of Compliance—Section 205.206

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

Preliminary Evaluation of an Application for Certification—Section 205.207

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

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

Arranging for Inspections—Section 205.208

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

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

Verification of Information—Section 205.210

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

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

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

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

Post-inspection Conference—Section 205.211

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

Reporting to the Certifying Agent—Section 205.212

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

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

Additional Inspections—Section 205.213

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

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

Approval of Certification—Section 205.214

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

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

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

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

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

Denial of Certification—Section 205.215

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

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

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

Recordkeeping—Section 205.216

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

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

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

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

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

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

Continuation of Certification—Section 205.217

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

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

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

Notification of Non-compliance With Certification Requirements—Section 205.218

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

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

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

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

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

Termination of Certification—Section 205.219

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

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

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

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

Notification of Certification Status—Section 205.220

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

SUBPART D—WHAT HAS TO BE CERTIFIED

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

SUBPART D—WHAT HAS TO BE CERTIFIED—Continued

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

Subpart E—Accreditation of Certifying Agents

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

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

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

Synopsis of Proposed Accreditation Program

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

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

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

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

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

Distinctions Between Certifying Agents

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

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

Areas of Accreditation—Section 205.300

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

General Requirements for Accreditation—Section 205.301

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

provided under the Act and the regulations in this part.

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

Applying for Accreditation—Section 205.302

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

Information to be Submitted by an Accreditation Applicant—Section 205.303

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

determine whether conflicts of interest may exist.

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

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

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

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

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

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

Approval of Accreditation—Section 205.306

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

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

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

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

Denial of Accreditation—Section 205.307

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

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

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

Maintaining Accreditation—Section 205.308

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

Site Evaluations—Section 205.309

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

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

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

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

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

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

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

Peer Review Panel—Section 205.311

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

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

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

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

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

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

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

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

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

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

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

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

Confirmation of Accreditation—Section 205.312

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

Denial of Confirmation—Section 205.313

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

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

Continued Accreditation—Section 205.314

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

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

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

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

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

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

Notification of Non-Compliance With Accreditation Requirements—Section 205.315

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

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

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

Termination of Accreditation—Section 205.316

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

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

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

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

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

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

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

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

Subpart F—Additional Regulatory Functions

State Programs

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

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

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

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

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

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

Requirements of State Programs—Section 205.401

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

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

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

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

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

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

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

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

Approval of State Programs and Program Amendments—Section 205.402

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

Review of Approved Programs—Section 205.403

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

Fees

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

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

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

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

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

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

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

Fees for Accreditation Applicants and Accredited Certifying Agents—Section 205.421

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Fees for Certified Operations—Section 205.422

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

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

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

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

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

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

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

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

Fees for Import Programs—Section 205.423

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

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

Payment of Fees and Other Charges—Section 205.424

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

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

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

ESTIMATED NATIONAL ORGANIC PROGRAM FEES

[Based on 1994 data]

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

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

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

Compliance Review and Other Testing

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

Compliance Review—Section 205.430

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

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

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

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

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

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

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

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

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

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

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

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

Preharvest Tissue Testing—Section 205.431

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

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

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

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

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

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

Emergency Pest or Disease Treatment—Section 205.432

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

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

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

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

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

Reporting the Application of a Prohibited Substance—Section 205.433

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

Appeals

General—Section 205.452

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

Equivalency of Imported Organic Products

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

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

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

Determination of the Equivalency of Foreign Programs—Section 205.481

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

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

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

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

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

Process for Establishing Equivalency of Foreign Programs—Section 205.482.

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

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

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

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

Maintenance of Eligibility for Importation—Section 205.483

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

List of Subjects in 7 CFR Part 205

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

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

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

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

SUBCHAPTER M—ORGANIC FOODS PRODUCTION ACT PROVISIONS

PART 205—NATIONAL ORGANIC PROGRAM

Subpart A—Definitions

Sec.
205.1 Meaning of words.
205.2 Terms defined.

Subpart B—Organic Crop and Livestock Production and Handling Requirements

205.3 Applicability.
205.4 [Reserved]

Organic Crop Production Requirements

205.5 Land requirements.
205.6 Crop rotation.
205.7 Soil fertility and crop nutrient management.
205.8 Selection and use of seeds, seedlings and planting stock.
205.9 Prevention and control of crop pests, weeds, and diseases.
205.10 [Reserved]
205.11 Wild crop harvesting.

Organic Livestock Production Requirements

205.12 Origin of livestock.
205.13 Livestock feed.
205.14 Livestock health care.
205.15 Livestock living conditions and manure management.

Organic Handling Requirements

205.16 Product composition.
205.17 Processing practices.
205.18 Prevention and control of facility pests.
205.19 Prevention of commingling and contact with prohibited substances.

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

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

The National List of Allowed and Prohibited Substances

205.22 Active synthetic substances allowed for use in organic crop production.
205.23 Non-synthetic substances prohibited for use in organic crop production.
205.24 Active synthetic substances allowed for use in organic livestock production.
205.25 Non-synthetic substances prohibited for use in organic livestock production.
205.26 Non-agricultural (non-organic) substances allowed as ingredients in or on processed products labeled as organic or made with certain organic ingredients.
205.27 Non-organically produced agricultural products allowed as ingredients in or on processed products labeled as organic or made with certain organic ingredients.
205.28 Amending the National List.
205.29—205.99 [Reserved]

Subpart C—Labels, Labeling, and Market Information

205.100 Agricultural products in packages sold, labeled or represented as organic.
205.101 Agricultural products in packages sold, labeled or represented as made with certain organic ingredients.
205.102 Multi-ingredient agricultural products that only represent the organic nature of such ingredients in the ingredients statement.
205.103 Use of terms or statements that directly or indirectly imply that a product is organically produced and handled.
205.104 Informational statements prohibited.
205.105 Agricultural products in a form other than packages that are sold, labeled or represented as organic or made with certain organic ingredients.
205.106 Agricultural products produced on an exempt farm or handling operation.
205.107 The USDA seal.
205.108—205.200 [Reserved]

Subpart D—Certification

205.201 What has to be certified.
205.202 Exemptions and exclusions from certification.
205.203 General requirements for certification.
205.204 Applying for certification.
205.205 Organic plan.
205.206 Statement of compliance.
205.207 Preliminary evaluation of an application for certification.
205.208 Arranging for inspections.
205.209 [Reserved]
205.210 Verification of information.
205.211 Post-inspection conference.
205.212 Reporting to the certifying agent.
205.213 Additional inspections.
205.214 Approval of certification.
205.215 Denial of certification.
205.216 Recordkeeping.
205.217 Continuation of certification.
205.218 Notification of non-compliance with certification requirements.
205.219 Termination of certification.
205.220 Notification of certification status.
205.221—205.299 [Reserved]

Subpart E—Accreditation of Certifying Agents

205.300 Areas of accreditation.
205.301 General requirements for accreditation.
205.302 Applying for accreditation.
205.303 Information to be submitted by an accreditation applicant.
205.304 Evidence of expertise and ability to be submitted by an accreditation applicant.
205.305 Statement of agreement to be submitted by an accreditation applicant.
205.306 Approval of accreditation.
205.307 Denial of accreditation.
205.308 Maintaining accreditation.
205.309 Site evaluations.
205.310 [Reserved]
205.311 Peer review panel.
205.312 Confirmation of accreditation.
205.313 Denial of confirmation.

205.314 Continued accreditation.
205.315 Notification of non-compliance with accreditation requirements.
205.316 Termination of accreditation.
205.317—205.400 [Reserved]

Subpart F—Additional Regulatory Functions

State Programs

205.401 Requirements of State programs.
205.402 Approval of State programs and program amendments.
205.403 Review of approved programs.
205.404–205.420 [Reserved]

Fees

205.421 Fees for accreditation applicants and accredited certifying agents.
205.422 Fees for certified operations.
205.423 Fees for import programs.
205.424 Payment of fees and other charges.
205.425–205.429 [Reserved]

Compliance Review and Other Testing

205.430 Compliance review.
205.431 Preharvest tissue testing.
205.432 Emergency pest or disease treatment.
205.433 Reporting the application of a prohibited substance.
205.434–205.451 [Reserved]

Appeals

205.452 General.
205.453–205.479 [Reserved]

Equivalency of Imported Organic Products

205.480 Equivalency of agricultural products for importation into the United States.
205.481 Determination of the equivalency of foreign programs.
205.482 Process for establishing equivalency of foreign programs.
205.483 Maintenance of eligibility for importation.
205.484–205.999 [Reserved]

Authority: 7 U.S.C. 6501–6522.

PART 205—NATIONAL ORGANIC PROGRAM

Subpart A—Definitions

§ 205.1 Meaning of words.

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

§ 205.2 Terms defined.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Fungicide. Any substance that kills fungi or molds.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Subpart B—Organic Crop and Livestock Production and Handling Requirements

§ 205.3 Applicability.

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

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

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

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

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

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

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

§ 205.4 [Reserved]

Organic Crop Production Requirements

§ 205.5 Land requirements.

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

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

(2) Have clearly defined and identifiable boundaries.

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

§ 205.6 Crop rotation.

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

§ 205.7 Soil fertility and crop nutrient management.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

(2) Mechanical or physical controls; or

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

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

(1) Mulching with fully biodegradable materials;

(2) Livestock grazing;

(3) Mechanical, heat or electrical means; or

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

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

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

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

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

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

§ 205.10 [Reserved]

§ 205.11 Wild crop harvesting.

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

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

Organic Livestock Production Requirements

§ 205.12 Origin of livestock.

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

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

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

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

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

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

(i) At any stage of life for bees;

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

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

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

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

(2) The use of hormones for breeding purposes.

§ 205.13 Livestock feed.

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

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

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

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

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

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

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

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

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

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

(i) Antibiotics or other animal drugs;

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

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

§ 205.14 Livestock health care.

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

(1) Providing diverse feedstuffs;

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

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

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

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

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

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

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

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

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

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

(3) The subtherapeutic use of antibiotics.

§ 205.15 Livestock living conditions and manure management.

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

(1) Protection from the elements;

(2) Space for movement;

(3) Clean and dry living conditions;

(4) Access to outside; and

(5) Access to food and clean water.

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

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

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

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

(3) Optimizes recycling of nutrients; and

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

Organic Handling Requirements

§ 205.16 Product composition.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

§ 205.17 Processing practices.

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

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

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

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

(3) The use of a volatile synthetic solvent.

§ 205.18 Prevention and control of facility pests.

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

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

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

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

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

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

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

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

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

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

§ 205.19 Prevention of commingling and contact with prohibited substances.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

The National List of Allowed and Prohibited Substances

Crop Production Substances

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

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

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

(1) Dormant oils;

(2) Suffocating oils; and

(3) Summer oils.

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

(c) Production aids may be used as follows:

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

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

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

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

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

(6) Antibiotics may be used as pesticides;

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

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

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

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

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

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

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

(1) Bordeaux mixes;

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

(3) Lime sulfur, including calcium polysulphide, and

(4) Sulfur dioxide.

(f) Micronutrient minerals as follows may be used:

(1) Chelated micronutrients;

(2) Soluble boron products; and

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

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

(1) Calcium chloride;

(2) Magnesium chloride;

(3) Sodium chlorate; and

(4) Sodium chloride.

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

None.

Livestock Production Substances

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

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

(a) Trace minerals;

(b) Nutrients and dietary supplements;

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

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

(e) Vaccines and biologics; and

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

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

None.

Processed Product Substances

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

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

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

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

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

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

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

§ 205.28 Amending the National List.

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

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

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

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

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

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

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

(1) Background information about the following:

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

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

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

(iv) Current or intended use of the substance;

(v) Sources from which the substance is derived;

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

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

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

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

(ii) Food and Drug Administration registration;

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

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

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

(3) Research, characteristics, and safety information:

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

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

(B) Toxicity and persistence in the environment;

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

(D) Effects on human health; and

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

(ii) Bibliographies of pertinent research on the substance;

(iii) Material Safety Data Sheet (MSDS);

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

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

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

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

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

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

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

§§ 205.29 through 205.99 [Reserved]

Subpart C—Labels, Labeling, and Market Information

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

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

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

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

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

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

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

provided for in § 205.402 of subpart F; and

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

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

(ii) The USDA seal described in § 205.107;

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

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

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

(b) [Reserved]

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

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

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

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

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

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

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

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

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

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

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

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

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

§ 205.104 Informational statements prohibited.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

§ 205.107 USDA seal.

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

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

Figure 1

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

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

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

§§ 205.108 through 205.200 [Reserved]

Subpart D—Certification

§ 205.201 What has to be certified.

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

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

§ 205.202 Exemptions and exclusions from certification.

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

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

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

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

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

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

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

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

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

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

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

(ii) The agricultural product offered to the consumer:

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

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

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

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

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

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

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

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

§ 205.203 General requirements for certification.

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

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

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

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

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

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

(f) Immediately notify the certifying agent concerning:

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

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

§ 205.204 Applying for certification.

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

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

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

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

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

§ 205.205 Organic plan.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

commingling of organic and non-organic products, and contact of organic field units, storage areas and packaging to be used for organic products, and organic products, including livestock, with prohibited substances.

(d) *Wild crop harvesting operations.* The following information shall be submitted concerning a wild crop harvesting operation:

(1) A map(s) of each area from which wild crops are designated to be harvested in the certification year;

(2) Information about the ownership of, and evidence of permission to harvest from, the area from which wild crops are designated to be harvested;

(3) A history of each designated area so as to demonstrate that no prohibited substance has been applied within three years prior to the initial harvest of a wild crop to be sold, labeled or represented as organically produced;

(4) A list of each species of plant(s) to be harvested, including: its botanical name(s); the part of the plant to be harvested (e.g., roots, flowers, fruits); the quantity expected to be harvested in the certification year; dates of the harvest season; and any available information on the impact of the intended harvest on the environment and on the growth and production of the wild crop;

(5) A list of each type of wild product to be sold or represented as an organic product, indicating the anticipated quantity of each type; and

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

(e) *Handling operations.* The following information shall be submitted concerning a handling operation:

(1) A brief, general description of the type of handling operation and the processing, manufacturing, or other handling procedures used and intended to be used;

(2) A list of the structural pest management methods used or intended to be used;

(3) A list, including the quantity, of each product intended to be handled and sold or represented as organic, and as made with certain organic ingredients;

(4) A list of each non-organically produced product or type of product, if any, intended to be handled or sold;

(5) The measures that will be used to prevent the commingling of organic and non-organic products and ingredients and the contact of storage areas and packaging to be used for organic products, and organic products, with prohibited substances; and

(6) A list of each ingredient, incidental additive, and type of packaging material intended to be used as a production input in the handling of organic products specifying for each item listed, as applicable:

(i) Whether it is an organic agricultural product, a non-organic agricultural product, or a non-agricultural ingredient;

(ii) The estimated quantity to be used;

(iii) The source or manufacturer;

(iv) The country of origin for each imported organic agricultural product or ingredient; and

(v) The source of water used as an ingredient in any organic product, specifying whether it meets the Safe Drinking Water Act requirements (42 U.S.C. 300(f) *et seq.*).

§ 205.206 Statement of compliance.

A person seeking certification of a farm, wild crop harvesting or handling operation shall submit to the certifying agent a statement agreeing to comply with the Act and the regulations of this part, including the requirements for receiving and maintaining certification delineated in § 205.203 of this subpart.

§ 205.207 Preliminary evaluation of an application for certification.

A certifying agent shall, with respect to any applicant for certification:

(a) Make a preliminary evaluation of the operation's compliance and ability to comply with the applicable requirements of subpart B of this part;

(b) Verify that an applicant who previously applied to another certifying agent and received a notification of non-compliance, pursuant to § 205.215(a) of this subpart, has submitted documentation to support the correction of any deficiencies identified in such notification, as required in § 205.215(b) of this subpart; and

(c) Arrange to conduct an on-site inspection of the operation if the preliminary evaluation reveals that the farm, wild crop harvesting or handling operation may be in compliance with the applicable requirements of subpart B of this part.

§ 205.208 Arranging for inspections.

(a) A certifying agent shall arrange to conduct an initial on-site inspection of each farm, facility, and site that is included in an operation for which certification is requested, and an on-site inspection of each certified operation annually thereafter, for the purpose of determining whether to approve the request for certification or determining whether the certification of the operation should continue.

(b) The initial on-site inspection shall be conducted within a reasonable time following a favorable preliminary evaluation of an application for certification in accordance with § 205.207.

(c) The on-site inspection shall be scheduled at such time that:

(1) Land, facilities, and activities that demonstrate the operation's compliance with or capability to comply with the applicable provisions of subpart B of this part may be observed; and

(2) The applicant or an authorized representative of the applicant who is knowledgeable about the operation will be present during the inspection.

§ 205.209 [Reserved].

§ 205.210 Verification of information.

The inspection of an operation shall be sufficient to verify the operation's compliance, or ability to comply, with the Act and the regulations in this part, including verification that the information, including the organic plan, provided in accordance with §§ 205.204 or 205.217, and § 205.205, accurately reflects the practices used or to be used by the applicant for certification or by the certified operation and, in the case of an on-site inspection to evaluate continuation of certification, that the provisions of the organic plan are being implemented.

§ 205.211 Post-inspection conference.

The inspector shall conduct a post-inspection conference with an authorized representative of the inspected operation, and discuss observations made by the inspector regarding the compliance, or ability of the operation to comply, with the Act and the regulations in this part.

§ 205.212 Reporting to the certifying agent.

The certifying agent shall require that the inspector prepare and submit to the certifying agent, within thirty days of completing an inspection, a written report that describes the inspector's observations and assessments of the inspected operation's compliance, or ability to comply, with the Act and the regulations in this part.

§ 205.213 Additional inspections.

(a) In addition to the annual on-site inspection, required in § 205.208(a), a certifying agent may conduct an inspection of any farm, facility, or site used by a certified operation or an applicant for certification when necessary to determine compliance with the Act and the regulations in this part.

(b) The Secretary may require that additional inspections be performed for the purpose of determining compliance

with the Act and the regulations in this part.

§ 205.214 Approval of certification.

(a) Within a reasonable time after completion of the initial on-site inspection, a certifying agent shall review the inspection report, together with the application materials submitted pursuant to §§ 205.204 through 205.206 or § 205.217, as applicable, and shall request the applicant for certification to submit any additional information and documentation needed to determine if the certification applicant is complying, or is able to comply, with the Act and the regulations in this part.

(b) Following the receipt of any additional information and documentation submitted in accordance with paragraph (a) of this section, the certifying agent shall approve the application for certification upon a determination that:

(1) The practices and substances used or intended to be used by the applicant for certification are consistent with a system of organic farming and handling, as set forth in § 205.2 of subpart A, and comply with the applicable organic production and handling requirements, as set forth in §§ 205.3, 205.5 through 205.9, and §§ 205.11 through 205.28 of subpart B;

(2) The applicant has satisfied the general requirements for certification set forth in § 205.203;

(3) The organic plan satisfies the applicable requirements of the Act and the regulations in subpart B of this part; and

(4) The records and recordkeeping system maintained by the applicant satisfy the applicable requirements of § 205.216.

(c) Upon determining, pursuant to paragraph (b) of this section, to approve an application for certification, a certifying agent shall provide a written notification to the certification applicant's place of business, indicating in such notification restrictions or requirements, if any, imposed as a condition of certification.

(d) A notice of approval of certification sent to a certification applicant pursuant to paragraph (c) of this section shall include a certificate that states:

(1) The name of the certified operation;

(2) The effective date of the certification; and

(3) The category(ies), type(s) of products, and crop years, if applicable, covered by the certification.

§ 205.215 Denial of certification.

(a) If the certifying agent has reason to believe, based on a review of the information specified in § 205.214(a), that an applicant for certification is not able to comply, or is not in compliance, with the requirements of the Act and the regulations in this part, the certifying agent shall provide a written notification of non-compliance to the applicant in accordance with § 205.218(a) of this part.

(b) Following the correction of deficiencies identified in the notification issued in accordance with paragraph (a) of this section, the applicant may submit a new application for certification to any accredited certifying agent. If a new application is submitted to a certifying agent other than the agent who issued the notification of non-compliance, the certification applicant shall simultaneously inform the certifying agent who issued the notification of non-compliance that a new application has been submitted and shall identify the new certifying agent to whom it was submitted. The new application shall include documentation of actions taken by the applicant to correct the deficiencies delineated in the notification of non-compliance.

(c) If a certification applicant who receives a notification pursuant to paragraph (a) of this section does not correct the deficiencies or does not notify the certifying agent that it has submitted a new application, as provided for in paragraph (b) of this section, within the time specified in the notice of non-compliance, the certifying agent shall submit to the Administrator a notice of its recommendation to deny certification to the applicant. Upon receipt of a notice of a recommendation to deny certification, the Administrator may institute proceedings to deny certification.

§ 205.216 Recordkeeping.

(a) A certified operation shall maintain records concerning the production, harvesting, and handling of agricultural products that are or that are intended to be, sold, labeled or represented as organic or made with certain organic ingredients for a period of five years sufficient to demonstrate compliance with the Act and regulations in the part, and shall make such records available to authorized representatives of the Secretary, the applicable governing State official, and the certifying agent.

(b) The records that shall be maintained by the certified operation in accordance with paragraph (a) of this section shall include, but are not limited to:

(1) A list of all substances applied to fields and land that are part of the certified operation for a period of no less than three years preceding the intended or actual time of harvest of an organic crop from such fields or land;

(2) The name and address of any person, including the operator of the certified operation and employees of the certified operation, who applies and who has applied any substance to any part of the farm and any livestock or other agricultural product, including the name of the substance, and the date(s), location(s), rate(s) and method(s) of application;

(3) For each animal (or livestock management unit, such as a poultry flock or bee colony) that is, or whose products are, intended to be sold, labeled or represented as organic livestock or organic livestock products in accordance with the livestock production standards set forth in §§ 205.12 through 205.15 of subpart B:

(i) The source of the animal or livestock management unit and the date it entered the certified operation;

(ii) The amounts and sources of all animal drugs administered;

(iii) All feeds and feed supplements fed; and

(iv) The location of the field, farm unit, or facility where it is maintained, as applicable.

(4) Any information submitted to the certifying agent as part of the application for certification or as part of continuation of certification in accordance with § 205.204 or § 205.217 of this subpart, respectively; and

(5) Records sufficient to show the quantities, source of, production and handling methods used for, transfer of ownership of, and transportation of, any agricultural product, including livestock, sold, labeled or represented as organic or as made with certain organic ingredients, that is received by or shipped from the certified operation, sufficient to establish an audit trail.

(c) A farm, wild crop harvesting, handling, or other operation that is exempt or excluded from certification under §§ 205.202(a) or (b) shall maintain records as provided for in § 205.202(c).

§ 205.217 Continuation of certification.

(a) A certified operation shall annually submit the following information, as applicable, to the certifying agent:

(1) Any additions and changes to the information about the operation submitted in the previous year;

(2) Any amendments to the organic plan, including a description of any

activities undertaken in the previous year, and intended to be undertaken in the coming year, to implement the provisions of the organic plan;

(3) A statement that the certified operation will remain in compliance with the Act and the regulations in this part; and

(4) Any other information requested by the certifying agent, in accordance with § 205.214(a) of this subpart.

(b) Following the receipt of the information specified in paragraph (a), the certifying agent shall arrange and conduct an on-site inspection of the certified operation, pursuant to §§ 205.208 through 205.211.

(c) If the certifying agent has reason to believe, based on the on-site inspection and a review of the information specified in § 205.214(a), that a certified operation is not complying with the requirements of the Act and the regulations in this part, the certifying agent shall provide a written notification of non-compliance to the operation in accordance with § 205.218(a) of this subpart.

§ 205.218 Notification of non-compliance with certification requirements.

(a) A written notification of non-compliance shall be sent by certified mail to the place of business of the certification applicant or the certified operation and shall contain the following information:

(1) A description of each deficiency in compliance and each possible violation of the Act and the regulations in this part that the certifying agent has reason to believe has occurred;

(2) The evidence on which the notification is based; and

(3) The date by which the operation must correct each deficiency in compliance and each possible violation delineated in the notification, and submit documentation to the certifying agent to support such corrections.

(b) If the documentation received by the certifying agent from an operation it has certified, pursuant to paragraph (a)(3) of this section, is not adequate to demonstrate that each deficiency in compliance and each possible violation has been corrected, the certifying agent shall:

(1) Conduct an additional inspection of the certified operation, as provided for in § 205.213, if the certifying agent determines that an additional inspection is necessary to determine whether the operation is complying with, or has violated, the Act or the regulations in this part;

(2) Review the status of the certified operation to determine whether the operation or any portion of the operation has ceased to comply with, or has violated, the Act or the regulations in this part; and

(3) *Notification of determination or recommendation.* (i) If, following the review specified in paragraph (b)(2) of this section, the certifying agent determines that the operation is in compliance with the Act and the regulations in this part, the certifying agent shall notify the certified operation in writing of its determination.

(ii) If, following the review specified in paragraph (b)(2) of this section, the certifying agent has reason to believe that the certified operation or any portion of the operation is not in compliance with the Act and the regulations in this part, the certifying agent shall submit to the Administrator a notice of its recommendation to terminate the certification of the certified operation or any portion of the certified operation that the certifying agent believes to have ceased to comply with the Act and the regulations in this part.

§ 205.219 Termination of certification.

(a) A certifying agent shall follow the procedures in accordance with § 205.218 of this subpart if the certifying agent has reason to believe that a certified operation or a person responsibly connected with a farm, wild crop harvesting, or handling operation it has certified has:

(1) Made a false statement;

(2) Attempted to have a label indicating that an agricultural product is organically produced affixed to such product when such product was produced or handled in a manner that is not in accordance with the Act and the regulations in this part; or

(3) Otherwise violated the purposes of the certification program established in Subpart D of this part.

(b) Notwithstanding paragraph (a) of this section, if a certifying agent has reason to believe that a certified operation or a person responsibly connected with an operation that has been certified by the certifying agent has wilfully violated the Act and the regulations in this part, the certifying agent shall submit to the Administrator a notice of its recommendation to terminate the certification of the certified operation or any portion of the certified operation that the certifying agent believes to have ceased to comply with the Act and the regulations in this part. A notice of recommendation to terminate certification shall list the names of any persons the certifying agent believes to have violated the Act and the regulations in this part.

(c) Upon receipt by the Administrator of a notification of a recommendation to terminate the certification of an operation or any portion of an operation, submitted pursuant to paragraph (b) of this section or § 205.218(b)(3)(ii) of this subpart, as applicable, the Administrator may institute the proceedings to terminate certification.

(d) *Ineligibility and waiver.* (1) A certified farm, wild crop harvesting, or handling operation, or a person responsibly connected with such an operation, that violates the Act and the regulations in this part, as determined following the proceedings instituted pursuant to paragraph (c) of this section, shall not be eligible to receive certification for any farm, wild crop harvesting, or handling operation in which such operation or person has an interest for a period of 5 years from the occurrence of such violation.

(2) Notwithstanding paragraph (d)(1) of this section, the Secretary may waive ineligibility for certification if it is in the best interests of the certification program established under subpart D of this part.

§ 205.220 Notification of certification status.

A certifying agent shall submit to the Administrator:

(a) A copy of any notification of non-compliance, sent pursuant to § 205.218, simultaneously with its issuance to the certification applicant or the certified operation; and

(b) On a quarterly calendar basis, the name of each operation whose application for certification has been approved.

§§ 205.221 through 205.299 [Reserved]

Subpart E—Accreditation of Certifying Agents

§ 205.300 Areas of accreditation.

The Secretary shall accredit a qualified applicant in the areas of crops, livestock, wild crops, or handling, or any combination thereof, to certify a farm, wild crop harvesting operation, or handling operation as a certified organic farm, certified organic wild crop harvesting operation, or certified organic handling operation.

§ 205.301 General requirements for accreditation.

(a) A private person or governing State official accredited as a certifying agent under this subpart shall:

(1) Have sufficient expertise in organic farming and handling techniques to fully comply with and implement the terms and conditions of

the organic certification program established under the Act and the regulations in this part;

(2) Demonstrate the ability to fully comply with the requirements for accreditation set forth in this subpart;

(3) Carry out the provisions of the Act and the regulations in this part, including the provisions of §§ 205.207 through 205.214 of subpart D, and § 205.430 of subpart F.

(4) Use a sufficient number of adequately trained personnel, including inspectors and certification review personnel, to comply with and implement the organic certification program established under the Act and the regulations in subpart D of this part;

(5) Conduct an annual performance review for each inspector used by the certifying agent, and implement measures to correct any possible defects in compliance with the Act and the regulations in this part identified in each review conducted;

(6) Have an annual internal evaluation review conducted of its certification activities, and implement measures to correct any possible defects in compliance with the Act and the regulations in this part identified in each review conducted;

(7) Provide sufficient information to persons seeking certification to enable an applicant for certification to comply with the applicable requirements of the Act and the regulations in this part;

(8) Maintain records and permit access to records as follows:

(i) Maintain all records concerning its activities under the Act and the regulations in this part for a period of not less than 10 years from the date of creation of the record; and

(ii) Allow representatives of the Secretary and the applicable governing State official access to any and all records concerning the certifying agent's activities under the Act and the regulations in this part;

(9) Maintain strict confidentiality with respect to its clients under the applicable organic certification program and not disclose to third parties (with the exception of the Secretary or the applicable governing State official) any business related information concerning any client obtained while implementing the regulations in this part, except as provided for in § 205.304(b)(5);

(10) Prevent conflict of interest by not:

(i) Certifying an operation if the certifying agent or a responsibly connected party of such certifying agent has or has held a commercial interest in the operation, including the provision of consultancy services, within the 12 month period prior to the application for certification, and by not certifying an operation through the use of any employee that has or has held a commercial interest in the operation, including the provision of consultancy services, within the 12 month period prior to the application for certification;

(ii) Assigning an inspector to perform an inspection of an operation if the inspector has or has held a commercial interest in the operation, including the provision of consultancy services, within the 12 months prior to conducting the inspection;

(iii) Permitting any employee, inspector, or other personnel to accept payment, gifts, or favors of any kind, other than prescribed fees, from any business inspected; and

(iv) Providing advice concerning organic practices or techniques to any certification applicant or certified organic farm or handling operation for a fee, other than as part of the fees established under the applicable certification program established under the Act;

(11) Accept the certification decisions made by another USDA accredited certifying agent as equivalent to its own;

(12) Refrain from making false or misleading claims about its accreditation status, the USDA accreditation program for certifying agents, or the nature or qualities of products labeled as organically produced;

(13) Charge only such fees to applicants for certification and operations it certifies that the Secretary determines are reasonable;

(14) Pay and submit fees to AMS in accordance with §§ 205.421 and 205.422(b) of subpart F of this part; and

(15) Comply with and implement such other terms and conditions deemed necessary by the Secretary.

(b) A private person or governing State official accredited as a certifying agent under this subpart may establish a seal, logo or other identifying mark to be used by farms, wild crop harvesting operations, and handling operations certified by the certifying agent to denote affiliation with the certifying agent, *Provided,* That the certifying agent:

(1) Does not require as a condition of certification by it the display of its identifying mark on any product sold, labeled or represented as organically produced; and

(2) Does not require as a condition of use of its identifying mark compliance with any farming or handling requirements other than those provided for in the Act and the regulations in this part.

(c) A private person accredited as a certifying agent shall:

(1) Hold the Secretary harmless for any failure on the part of the certifying agent to carry out the provisions of the Act and the regulations in this part;

(2) Furnish reasonable security, in an amount and according to such terms as the Secretary may by regulation prescribe, for the purpose of protecting the rights of farms, wild crop harvesting operations, and handling operations certified by such certifying agent under the Act and the regulations in this part; and

(3) Transfer to the Secretary, and make available to any applicable governing State official, all records or copies of records concerning the person's certification activities in the event that the certifying agent dissolves or loses its accreditation.

§ 205.302 Applying for accreditation.

(a) A private person or governing State official seeking accreditation as a certifying agent under this subpart shall submit an application for accreditation which contains the applicable information and documents set forth in §§ 205.303 through 205.305 and the fees required in § 205.421(a) of subpart F to: Program Manager, USDA–AMS–TM–NOP, Room 2945–S, P.O. Box 96456, Washington, D.C. 20090–6456.

(b) Following the receipt of the information and documents, the Administrator will determine according to the provisions set forth in § 205.306 whether the applicant for accreditation should be accredited as a certifying agent.

§ 205.303 Information to be submitted by an accreditation applicant.

A private person or governing State official seeking accreditation as a certifying agent shall submit the following information:

(a) The name, primary office location, mailing address, and contact numbers (telephone, fax, and Internet address) of the applicant; additionally, for an applicant who is a private person, the name of the person designated to control its day-to-day operations, and its taxpayer identification number;

(b) The name, office location, mailing address, and contact numbers (telephone, fax, and Internet address) for each of its organizational units, such as chapters or subsidiary offices, and the name of a contact person for each unit;

(c) Each area of operation (crops, wild crops, livestock or handling) for which accreditation is requested and the estimated numbers of each type of operation anticipated to be certified annually by the applicant;

(d) The type of entity the applicant is (e.g. State government agricultural

office, for-profit business, not-for-profit membership association); and, in addition, for:

(1) A governing State official, a copy of the official's authority to conduct certification activities under the Act and the regulations in this part; and

(2) A private person, documentation of its entity's status and organizational purpose, such as articles of incorporation and by-laws, ownership or membership provisions, and its date of establishment; and

(e) A list of each State in which the applicant currently certifies farms and handling operations, and, in addition, a list of each State in which the applicant intends to certify farms or handling operations.

§ 205.304 Evidence of expertise and ability to be submitted by an accreditation applicant.

A private person or governing State official seeking accreditation as a certifying agent shall submit the following documents and information to demonstrate its expertise in organic farming and handling techniques, its ability to fully comply with and implement the organic certification program established in §§ 205.201 through 205.220 of subpart D of this part, and its ability to comply with the requirements for accreditation set forth in § 205.301 of this subpart:

(a) *Personnel.* (1) A description of the applicant's policies and procedures for training, evaluating and supervising personnel;

(2) The name and functions of all personnel intended to be used in the certification operation, including administrative staff, certification inspectors, members of any certification review and internal evaluation committees, and all parties responsibly connected to the certification operation;

(3) A description of the qualifications, including past experience, training, and education in agriculture, including organic farming and handling, for:

(i) Each inspector intended to be used by the applicant; and

(ii) Each person designated or to be designated by the applicant to review or evaluate applications for certification; and

(4) A description of any training that the applicant has provided or intends to provide to personnel to ensure that they can comply with and implement the requirements of the Act and the regulations in this part.

(b) *Administrative policies and procedures.* (1) A description of the procedure to be used to evaluate certification applicants, make certification decisions and issue certification certificates;

(2) A description of the procedures to be used for reviewing compliance of certified farm, wild crop harvesting, and handling operations with the Act and the regulations in this part and the reporting of violations of the Act and the regulations in this part to the Administrator;

(3) A description of the procedures to be used for complying with the recordkeeping requirements set forth in § 205.301(a)(8);

(4) A description of the procedures to be used for maintaining the confidentiality of any business related information, as set forth in § 205.301(a)(9) of this subpart;

(5) A description of the procedures to be used for making the following information available to any member of the public upon request:

(i) A list of producers and handlers whose operations it has certified, and the effective dates of the certifications, during the ten year period preceding the receipt of the request from the public;

(ii) The organic agricultural products produced by each certified operation;

(iii) The results of laboratory analyses for residues of pesticides and other prohibited substances conducted during the ten year period preceding the request from the public; and

(iv) Other non-confidential business information as permitted by the producer or handler and approved by the Secretary.

(c) *Financial policies and procedures.* A description of the applicant's policies and procedures for the collection and disbursement of funds, and documents that identify anticipated sources of income, including all fees to be collected from producers and handlers in accordance with § 205.301(a)(13) of this subpart and § 205.422(a) of subpart F.

(d) *Conflict of interest.* (1) A description of procedures intended to be implemented to prevent the occurrence of conflicts of interest, as delineated in § 205.301(a)(10); and

(2) For each person identified in § 205.304(a)(2), the identification of any food and agriculture-related business interests, including business interests of immediate family members, that may cause a conflict of interest.

(e) *Current certification activities.* An applicant who currently certifies farms, wild crop harvesting, or handling operations may additionally submit:

(1) A list of all farms, wild crop harvesting, and handling operations currently certified by the applicant;

(2) Copies of the inspection reports and certification evaluation documents for farms, wild crop harvesting, or handling operations certified by the applicant during the previous year; and

(3) The results of an accreditation process, if any, conducted of the applicant's operation by an accrediting body during the previous year for the purpose of evaluating its certification activities; and

(f) *Other information.* Any other information the applicant believes may support the Secretary's evaluation of the applicant's expertise and ability.

§ 205.305 Statement of agreement to be submitted by an accreditation applicant.

(a) A private person or a governing State official seeking accreditation under this subpart shall submit a statement which affirms that, if granted accreditation as a certifying agent under this subpart, the applicant will:

(1) Carry out the provisions of the Act and the regulations in this part;

(2) Accept the certification decisions made by another USDA accredited certifying agent as equivalent to its own;

(3) Refrain from making false or misleading claims about its accreditation status, the USDA accreditation program for certifying agents, or the nature or qualities of products labeled as organically produced;

(4) Conduct an annual performance review for each inspector to be used and implement measures to correct any possible defects in compliance with the Act and the regulations in this part identified in each review conducted;

(5) Have an annual internal evaluation review conducted of its certification activities and implement measures to correct any possible defects in compliance with the Act and the regulations in this part identified in each review conducted;

(6) Pay and submit fees to AMS in accordance with §§ 205.421 and 205.422(b) of subpart F of this part; and

(7) Implement and carry out any other terms and conditions determined by the Secretary to be necessary.

(b) A private person who seeks accreditation as a certifying agent under this subpart shall additionally agree to:

(1) Hold the Secretary harmless for any failure on the part of the certifying agent to carry out the provisions of the Act and the regulations in this part;

(2) Furnish reasonable security, in an amount and according to such terms as the Secretary may by regulation prescribe, for the purpose of protecting the rights of the farming and handling operations certified by such certifying agent under the Act and the regulations in this part; and

(3) Transfer to the Secretary and make available to the applicable governing

State official all records or copies of records concerning the person's certification activities in the event that the certifying agent dissolves or loses its accreditation.

§ 205.306 Approval of accreditation.

(a) Accreditation will be approved if:

(1) The accreditation applicant has submitted the information required by §§ 205.303 through 205.305 of this subpart;

(2) The accreditation applicant pays the required fee in accordance with § 205.421(c) of subpart F of this part; and

(3) The Administrator determines that the applicant for accreditation meets or is capable of meeting the general requirements for accreditation as stated in § 205.301 of this subpart, as applicable, as determined by a review of the information submitted in accordance with §§ 205.303 through 205.305 and, if necessary, a review of the information obtained from a site visit as provided for in § 205.309.

(b) On making a determination to approve an application for accreditation, the Administrator shall notify the applicant of approval of accreditation in writing, stating:

(1) The area(s) for which accreditation is given;

(2) The effective date of the accreditation; and

(3) For a certifying agent who is a private person, the amount and type of security that must be established to protect the rights of farm, wild crop harvesting, and handling operations certified by such certifying agent.

§ 205.307 Denial of accreditation.

(a) If the Administrator has reason to believe, based on a review of the information specified in §§ 205.303 through 205.305 of this subpart, that an applicant for accreditation is not able to comply or is not in compliance with the requirements of the Act and the regulations in this part, including § 205.301 of this subpart, the Administrator shall provide a written notification of non-compliance to the applicant in accordance with § 205.315(a) of this subpart.

(b) Following the correction of deficiencies identified in the notification issued in accordance with paragraph (a) of this section, the applicant may submit a new application for accreditation to the Administrator. The new application shall include documentation of actions taken by the applicant to correct the deficiencies delineated in the notification of non-compliance.

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

§ 205.308 Maintaining accreditation.

To maintain accreditation, an accredited certifying agent must continue to satisfy the requirements of the Act and the regulations in this part throughout the duration of its accreditation, and pay and submit fees in accordance with §§ 205.421 and 205.422(b) of Subpart F of this part.

§ 205.309 Site evaluations.

(a) An initial site evaluation of the operation of each certifying agent shall be performed for the purpose of verifying its compliance with the Act and the regulations in this part within a reasonable period of time after the date on which the agent's notice of approval of accreditation is issued, as set forth in § 205.306 of this subpart, and after the agent has conducted sufficient certification activities for the Administrator to examine its operations and evaluate its compliance with § 205.301 of this subpart.

(b) A site evaluation of an accreditation applicant or certifying agent's operation and performance may be conducted at any time to determine whether an accreditation applicant can comply with the general requirements set forth in § 205.301 of this subpart or to evaluate the certifying agent's operation and performance under the Act and the regulations in this part.

§ 205.310 [Reserved].

§ 205.311 Peer review panel.

(a) *Peer review panel(s).* (1) A peer review panel shall review the accreditation status of a certifying agent after any site evaluation performed pursuant to §§ 205.309(a) and 205.314(b) of this subpart.

(2) The Administrator may convene a peer review panel at any time for the purpose of evaluating a certifying agent's activities under the Act and the regulations in this part.

(3) The Administrator shall consider the reports received from each individual member of a peer review panel when making a determination whether to confirm the accreditation of a certifying agent, or when making a determination whether to renew the accreditation of a certifying agent.

(b) *Composition of peer review panels.* (1) The Administrator shall convene a peer review panel, which shall consist of between three and five persons selected from the established peer review panel pool, with the following membership requirements:

(i) One member shall be personnel of AMS who shall be responsible for presiding over the convened panel; and

(ii) At least two members shall not be personnel of AMS or an approved State program.

(2) Each convened peer review panel shall include no less than one member who possesses sufficient expertise, as determined by the Administrator, in the areas of accreditation delineated in the notice of approval of accreditation, pursuant to § 205.306(a) of this subpart, for each certifying agent whose operations and performance are to be reviewed.

(3) No person participating on a convened peer review panel shall be, or shall have been, associated with a certifying agent being reviewed by the panel in a manner that would constitute a known or perceived conflict of interest, as determined by the Administrator.

(c) *Duties and responsibilities of panel members.* (1) Each person on a convened peer review panel shall individually review the site evaluation report prepared by the Administrator and any other information that may be provided by the Administrator relevant to confirming or renewing the accreditation status of a certifying agent;

(2) Information about the certifying agent received as part of the review process is confidential information, and peer reviewers shall not release, copy, quote, or otherwise use material from the information received, other than in the report required to be submitted;

(3) Each peer reviewer must agree, specifically, to treat the information received for review as confidential; and

(4) Each person on a convened peer review panel shall provide an individual written report to the Administrator regarding a certifying agent's ability to conduct and perform certification activities.

(d) *Optional meeting or conference call procedure for a convened peer review panel.* (1) The Administrator may convene a peer review panel meeting or conference call if necessary for evaluating the accreditation status of a certifying agent or at the request of at least one peer review panel member. The Administrator may include the certifying agent being evaluated, or a representative of the agent, for the purpose of providing additional information. Any meeting or conference call shall be conducted in a manner that will ensure that the actions of panel members are carried out on an individual basis with any opinions and

recommendations by a member being individually made.

(2) Copies of the peer review panel reports may be provided to the certifying agent and written responses from the certifying agent may be submitted for consideration by the Administrator.

(e) *Peer review panel reports.* Each person who participates in a peer review panel shall provide a written report to the Administrator which shall contain the person's recommendations concerning confirmation or renewal of the accreditation for each agent reviewed and the basis for each recommendation.

§ 205.312 Confirmation of accreditation.

(a) *Notice of confirmation.* The Administrator shall issue a written notice of confirmation of accreditation to a certifying agent if the Administrator determines the agent is in compliance with the requirements of the Act and the regulations in this part. The notice of confirmation will set forth any terms and conditions that must be addressed by the certifying agent before submitting a request for renewal of accreditation.

(b) *Duration of accreditation.* The accreditation of a certifying agent shall continue in effect until such time as the certifying agent fails to renew accreditation as delineated in § 205.314, voluntarily ceases its certification activities, or accreditation is suspended or terminated pursuant to § 205.316.

§ 205.313 Denial of confirmation.

(a) If the Administrator has reason to believe, based on a review of the information specified in §§ 205.303 through 205.305 and the results of a site evaluation and the reports submitted by the peer review panel, pursuant to §§ 205.309 and 205.311(e) of this subpart, that the certifying agent is not complying with the requirements of the Act and the regulations in this part, the Administrator shall provide a written notification of non-compliance to the certifying agent in accordance with § 205.315(a) of this subpart.

(b) If a certifying agent who receives a notification pursuant to paragraph (a) of this section corrects the deficiencies identified within the time specified in the notice of non-compliance, in accordance with § 205.315(a)(3) of this subpart, the Administrator shall issue a notice of confirmation of accreditation to the certifying agent, pursuant to § 205.312(a).

(c) If a certifying agent who receives a notification pursuant to paragraph (a) of this section does not correct the deficiencies identified within the time specified in the notice of non-compliance, the Administrator may institute proceedings to deny confirmation of accreditation.

§ 205.314 Continued accreditation.

(a) *Annual report and fees.* An accredited certifying agent shall submit annually to the Administrator on or before the anniversary date of the issuance of the notice of confirmation of accreditation, pursuant to § 205.312(a) of this subpart, the following reports and fees:

(1) A complete and accurate update of information submitted pursuant to §§ 205.303 and 205.304;

(2) Information supporting any changes being requested in the areas of accreditation delineated in § 205.300;

(3) The measures that were implemented in the previous year, and any measures to be implemented in the coming year, to satisfy any terms and conditions determined by the Administrator to be necessary as specified in the most recent notice of confirmation of accreditation, in accordance with § 205.312(a) of this subpart, or notice of renewal of accreditation, in accordance with paragraph (c) of this section;

(4) The results of the most recent inspector performance reviews and internal evaluation review, and adjustments to the certifying agent's operation and procedures implemented, and intended to be implemented, in response to the reviews; and

(5) The fees required in § 205.421(a) of subpart F.

(b) *Renewal of accreditation.* An accredited certifying agent shall request renewal of accreditation on or before the fifth anniversary of issuance of the notice of confirmation of accreditation and each subsequent renewal of accreditation. Following receipt of the information submitted by the certifying agent in accordance with paragraph (a) of this section and the results of a site evaluation and the reports submitted by the peer review panel, pursuant to §§ 205.309 and 205.311(e) of this subpart, the Administrator shall determine whether the certifying agent remains in compliance with the Act and the regulations of this part.

(c) *Notice of renewal of accreditation.* Upon a determination that the certifying agent continues to comply with the Act and the regulations of this part, the Administrator shall issue a notice of renewal of accreditation. The notice of renewal shall specify any terms and conditions that must be addressed by the certifying agent and the time within which those terms and conditions must be satisfied.

(d) *Non-compliance.* Upon a determination that there is reason to believe that the certifying agent is not in compliance with the Act and the regulations of this part, the Administrator shall initiate the procedure delineated in § 205.315 of this subpart.

§ 205.315 Notification of non-compliance with accreditation requirements.

(a) A written notification of non-compliance shall be sent by certified mail to the place of business of the accreditation applicant or the certifying agent, as applicable, and shall contain the following information:

(1) A description of each deficiency in compliance and each violation of the Act and the regulations in this part that the Administrator has reason to believe has occurred;

(2) The evidence on which the notification is based; and

(3) The date by which the accreditation applicant or the certifying agent, as applicable, must correct each deficiency and each violation delineated in the notification, and submit documentation to the Administrator to support such corrections.

(b) If the documentation received by the Administrator, pursuant to paragraph (a)(3) of this section, is not adequate to demonstrate that each deficiency in compliance and each violation has been corrected by the date indicated in the written notification, the Administrator may conduct a site evaluation, as provided for in § 205.309, to determine whether the certifying agent is complying with, or has violated, the Act or the regulations in this part.

(c) *Notification of determination or recommendation.* (1) If, following the procedure pursuant to paragraphs (a) and (b) of this section, the Administrator determines that the certifying agent is in compliance with the Act and the regulations in this part, the Administrator shall notify the certifying agent in writing of this determination.

(2) If, following the procedure pursuant to paragraphs (a) and (b) of this section, the Administrator has reason to believe that the certifying agent is not in compliance with the Act and the regulations in this part, the Administrator may institute a proceeding to suspend or terminate the accreditation of the certifying agent.

§ 205.316 Termination of accreditation.

(a) The Administrator shall follow the procedures prescribed in § 205.315 of this subpart if the Administrator has reason to believe that an accredited certifying agent or a person responsibly

connected with an accredited certifying agent has ceased to comply with or has violated the Act or the regulations in this part.

(b) Notwithstanding paragraph (a) of this section, if the Administrator has reason to believe that an accredited certifying agent or a person responsibly connected with an accredited certifying agent has wilfully violated the Act and the regulations in this part, the Administrator may institute a proceeding to suspend or terminate the accreditation of the certifying agent.

(c) A private person or a governing State official whose accreditation as a certifying agent is suspended or terminated shall:

(1) Cease any certification activity in each area of accreditation and in each State for which its accreditation is suspended; or

(2) In the case of a private person whose accreditation is terminated, cease all certification activities; and

(3) Transfer to the Secretary and make available to any applicable governing State official all records concerning its certification activities that were suspended or terminated, so that the Secretary may promptly determine whether farms or handling operations certified by such certifying agent may retain their organic certification.

(d) A private person or a governing State official whose accreditation as a certifying agent is suspended by the Secretary under this section may at any time submit a new request for accreditation, pursuant to § 205.302 of this subpart. The request shall be accompanied by documentation that demonstrates that appropriate corrective actions have been taken to comply with and remain in compliance with the Act and the regulations in this part.

(e) A private person whose accreditation as a certifying agent is terminated shall be ineligible to be accredited as a certifying agent under the Act and the regulations in this part for a period of not less than three years following the date of such determination.

§§ 205.317 through 205.400 [Reserved].

Subpart F—Additional Regulatory Functions

State Programs

§ 205.401 Requirements of State programs.

(a) A State may establish a State organic certification program for producers and handlers of agricultural products that have been produced within the State using organic methods as provided for in the Act and the regulations in part 205.

(b) The State program shall meet the requirements of the Act and the regulations in part 205.

(c) A State program may contain more restrictive requirements governing the certification of organic farms and handling operations and the production and handling of agricultural products that are to be sold or labeled as organically produced than are contained in the National Organic Program established by the Secretary, *Provided, That* such additional requirements:

(1) Further the purposes of the Act and the regulations in part 205;

(2) Are consistent with the provisions of the Act and the regulations in part 205;

(3) Do not discriminate towards agricultural commodities organically produced in other States in accordance with the Act and the regulations in part 205; and

(4) Are approved by the Secretary prior to being implemented.

§ 205.402 Approval of State programs and program amendments.

(a) A governing State official shall submit to the Secretary a proposed State program, and proposed substantive amendment(s) to a State program, and shall obtain the Secretary's approval prior to implementation of the proposed program and any proposed substantive amendments thereto.

(b) The Secretary will notify the governing State official within six months after the receipt of the proposed State program and proposed substantive amendment to the State program, as to whether the program or substantive amendment is approved or disapproved, and if disapproved, the reasons for the disapproval. After receipt of a notice of disapproval, the State may reapply at any time.

§ 205.403 Review of approved programs.

The Secretary will review a State organic certification program not less than once during each five-year period following the date of the initial approval of such program. The Secretary will notify the governing State official within six months after the initiation of the review, whether the program is approved or disapproved, and if disapproved, the reasons for the disapproval.

§§ 205.404 through 205.420 [Reserved].

Fees

§ 205.421 Fees for accreditation applicants and accredited certifying agents.

(a) *Application fees.* (1) Each applicant for accreditation and each accredited certifying agent shall submit a non-refundable fee of $640 simultaneous with the submission of each application for accreditation or annual report, as applicable. Payment shall be made by certified check or money order made payable to Agricultural Marketing Service and sent with the application or annual report to: Program Manager, USDA/AMS/TM/NOP, Room 2945–S, P.O. Box 96456, Washington, D.C., 20090–6456.

(2) An applicant or an accredited certifying agent whose organizational structure consists of chapters or subsidiary offices also shall include a non-refundable fee of $160 for each chapter or subsidiary office, simultaneous with the submission of each application for accreditation or annual report, as applicable.

(b) *Site evaluation fees and related travel and per diem expenses.* Each applicant or accredited certifying agent for whom a site visit is conducted shall submit a non-refundable payment for the following fees and expenses related to a site evaluation visit conducted, pursuant to § 205.309 of subpart E, within 30 days following issuance of a bill from AMS for the cost of the site evaluation visit which shall include payment of:

(1) An hourly fee of $40 per hour, calculated to the nearest fifteen minute period, for each AMS evaluator to conduct the site evaluation visit, including travel time to and from the evaluator's duty station; and

(2) Travel expenses and per diem allowances for each AMS evaluator.

(c) *Administrative fee.* Each accredited certifying agent shall submit a non-refundable administrative fee of $2,000, and an additional non-refundable administrative fee of $300 for each chapter or subsidiary office belonging to the certifying agent, within 30 days following issuance of a notification of approval of accreditation pursuant to § 205.306(b) of subpart E; within 30 days following the issuance of a subsequent notification of confirmation of accreditation, pursuant to § 205.312(a) of subpart E; or with the submission of each annual report, pursuant to § 205.314(a) of subpart E.

§ 205.422 Fees for certified operations.

(a) Each farm or wild crop harvesting operation shall submit to the certifying agent a non-refundable fee of $50 and each handling operation shall submit to the certifying agent a non-refundable fee of $500 by money order or certified check made payable to the Agricultural Marketing Service within 15 days of the date of the issuance by a certifying agent

of a notice of approval of certification pursuant to § 205.214(c) of subpart D.

(b) Each certifying agent shall submit to AMS, according to the instructions provided by the Administrator, all fees collected pursuant to paragraph (a) of this section within 15 days following the date of receipt by the certifying agent.

§ 205.423 Fees for import programs.

(a) Each foreign certification program, other than those operated by a foreign country itself, that wants AMS to determine whether its program is equivalent to the AMS organic certification program shall submit, as authorized by the Independent Offices Appropriations Act (31 U.S.C. 9701 *et seq.*), a non-refundable payment in the amount stated in the AMS notice of intent to acknowledge equivalency sent to them by AMS. The payment required will be based on an hourly charge of $40 per hour for review time plus any travel and per diem expenses incurred.

(b) No determination of equivalency of such a program shall be final and effective until such payment is made.

(c) The payment required shall be submitted by certified funds to AMS within 30 days following issuance of a bill from AMS according to the instructions provided with the notice of intent to acknowledge equivalency sent by AMS.

§ 205.424 Payment of fees and other charges.

(a) All fees shall be submitted in the form of a certified check or money order made payable to the Agricultural Marketing Service and sent according to the billing instructions.

(b) All fees submitted later than the time indicated in the applicable section shall be subject to interest, penalties and administrative costs, as provided in the Debt Collection Act of 1982 (31 U.S.C 3717), and may result in the loss of or failure to obtain certification, accreditation, or equivalency status.

§§ 205.425 through 205.429 [Reserved].

Compliance Review and Other Testing

§ 205.430 Compliance review.

(a) A certifying agent shall arrange for periodic sampling and residue testing, not less frequently than every five years, of agricultural products produced on certified organic farms or wild crop harvesting operations and handled through certified handling operations certified by that agent to determine if an agricultural product contains a detectable residue level of a pesticide or other prohibited substance. To the extent that certifying agents are aware of a violation of applicable laws relating to food safety, they are required to report such violation to the appropriate health agencies (Federal, State, and local).

(b) The Secretary or the applicable governing State official shall arrange for sampling and residue testing of agricultural products sold, labeled, or represented as organic, at any point of production or distribution, and may require the certifying agent to conduct sampling and residue testing of such products originating from operations certified by that agent in order to determine if such products contain a detectable residue level of a pesticide or other prohibited substance.

(c) *Sample collection.* (1) Each product sample collected pursuant to paragraphs (a) and (b) of this section shall be collected by an inspector representing the Secretary, certifying agent, or applicable governing State official and submitted for analysis to a laboratory accredited for the product test, in accordance with Subchapter 400 of the Food and Drug Administration ''Investigations Operations Manual,'' available from the FDA, Division of Emergency and Investigation Operations, 5600 Fishers Lane, Rockville MD 20857.

(2) The analytical methods used to test each product sample shall be selected as appropriate from:

(i) The FDA ''Pesticide Analytical Manual,'' Volumes I and II, available from the FDA, Department of Health, Education and Welfare, 200 C Street S.W., Washington, DC 20204;

(ii) The ''FSIS Residue Chemistry Guidebook'', available by request from: FSIS Quality Systems Branch, Room 516–A, Annex Building, 300 12th Street S.W., Washington, DC 20250–3700, or

(iii) The ''Official Methods of Analysis'' of the Association of Official Analytical Chemists International (AOACI), available by request from: AOACI, 481 North Frederick Ave., Suite 500, Gaithersburg, MD 20877.

(3) The results of all sampling and testing performed pursuant to paragraphs (a) and (b) of this section for each product sample shall be reported to the certifying agent or applicable governing State official, and to the Secretary, *Provided, That* if any test result indicates that the product sample contains a residue level of a pesticide or other prohibited substance that exceeds the EPA tolerance level [1] or the FDA action level,[2] as applicable, for that substance, the certifying agent, governing State official, or the Secretary also shall inform the appropriate health agencies of the results of the residue test.

(d) *Residue test investigations.* (1) If the results of the testing and sampling performed pursuant to paragraphs (a) and (b) of this section indicate that the product sample contains a detectable residue level of a pesticide or other prohibited substance, the certifying agent, the applicable governing State official, or the Secretary shall conduct an investigation of the certified operation that produced or harvested the product represented by the sample to determine the cause of the detectable residue level, and may require the producer or handler of such product to prove that any prohibited substance was not applied to such product.

(2) If the certifying agent, applicable governing State official, or the Secretary, determines as a result of the investigation that the detectable residue level of the pesticide or other prohibited substance exceeds the unavoidable residual environmental contamination level for the detected pesticide or other prohibited substance, or that the detected pesticide or other prohibited substance was the result of an intentional application, then the agricultural products represented by the sample shall not be sold or labeled as organically produced, and the Administrator may institute proceedings to terminate certification of the operation, or portion of an operation, from which the agricultural products represented by the sample originated, as provided for in § 205.219 of subpart D.

§ 205.431 Preharvest tissue testing.

(a) *General.* The Secretary, the applicable governing State official, or the certifying agent may require a preharvest tissue test of any crop to be sold or labeled as organically produced that is grown on soil suspected by the Secretary, the applicable governing State official, or the certifying agent of harboring a contaminant.

(b) *Preharvest tissue test sample collection.* (1) The preharvest tissue test sample collection conducted pursuant to paragraph (a) of this section shall be performed by an inspector representing the Secretary, certifying agent, or applicable governing State official and shall be collected and submitted for testing in accordance with Subchapter 400 of the ''FDA Investigations

[1] 40 CFR parts 180, 185, and 186.

[2] The FDA action levels are published in the FDA publication entitled ''Action Levels for Poisonous or Deleterious Substances in Human Food and Animal Feed.'' Single copies of this booklet are available fron: Industry Activities Section (HHF–326), CFSN/FDA, 200 C Street S.W., Washington, DC 20204.

Operations Manual'' to a laboratory accredited for the product test.

(2) The analytical methods used to determine whether a preharvest tissue test sample contains a residue of a contaminant shall be selected as appropriate from the FDA ''Pesticide Analytical Manual,'' Volumes I and II, or the ''Official Methods of Analysis'' of the Association of Official Analytical Chemists.

(c) *Reporting of preharvest tissue test results.* The results of each preharvest tissue test shall be reported to the Secretary and, *Provided, That* if the test result indicates that the residue level of a contaminant in the organically produced crop exceeds the EPA tolerance or FDA action level, the certifying agent or applicable official also shall report the results to the appropriate regulatory agency.

§ 205.432 Emergency pest or disease treatment.

If a pesticide or other prohibited substance is applied to a certified organic farm, wild crop harvesting, or handling operation due to a Federal or State emergency pest eradication or disease treatment program, and the certified operation otherwise meets the requirements of this part, the certification status of the operation shall not be affected as a result of the application of the pesticide or other prohibited substance, *Provided, That:*

(a) Any harvested crop or plant part to be harvested that has contact with a prohibited substance applied as the result of a Federal or State emergency pest eradication or disease treatment program is not sold or labeled as organically produced; and

(b) Any livestock that are treated with a prohibited substance applied as the result of a Federal or State emergency pest or disease treatment program, or product derived from such treated livestock, shall not thereafter be labeled or sold as organically produced, except that:

(1) Milk or milk products may be labeled or sold as organically produced beginning 12 months following the last date that the dairy animal was treated with the prohibited substance; and

(2) The offspring of gestating mammalian breeder stock treated with a prohibited substance may be considered organic *Provided, That* the breeder stock was not in the last third of gestation on the last date that the breeder stock was treated with the prohibited substance.

§ 205.433 Reporting the application of a prohibited substance.

A producer or handler shall immediately report any instance of application of a prohibited substance on their certified operation to their certifying agent and shall inform the agent of the reason for, or the cause of, the application.

§§ 205.434 through 205.451 [Reserved].

Appeals

§ 205.452 General.

Any person subject to the Act who believes that he or she is adversely affected by a decision of a member of the National Organic Program staff or by a certifying official may appeal such decision to the Administrator.

§§ 205.453 through 205.479 [Reserved].

Equivalency of Imported Organic Products

§ 205.480 Eligibility of agricultural products for importation into the United States.

Any agricultural product imported into the United States that is labeled or sold as organic or that contains an ingredient represented as organic shall have been produced and handled under an organic certification program that the Secretary has determined provides safeguards and guidelines governing the production and handling of such products that are at least equivalent to the requirements of the Act and the regulations set forth in part 205.

§ 205.481 Determination of the equivalency of foreign programs.

The determination of the equivalency to the Act and regulations in part 205 of a foreign organic certification program will be based on an evaluation of the following components of the program's provisions for organically produced and handled agricultural products:

(a) The standards of production and handling for agricultural products;

(b) The list of substances allowed and prohibited for use in the production and handling of agricultural products and the criteria for establishing the allowance or prohibition of substances used in organic production and handling;

(c) The requirements for, and process by which, farms and handling operations are inspected and certified as operating under a system of organic farming and handling, including the requirements for documentation of the practices and substances used;

(d) The measures identified to provide adequate enforcement for, and protection against, violations of the program requirements;

(e) The requirements for and process by which agents are evaluated and accredited by an agency of the government as being qualified to certify organic farm, wild crop harvesting, or handling operations; and

(f) Any other information relevant to the production and certification of organically produced products including the administration of the foreign organic certification program.

§ 205.482 Process for establishing equivalency of foreign programs.

(a) A foreign organic certification program that wants a determination of the equivalency of its program, as provided for in § 205.481, shall submit to the Secretary a complete and accurate description of its program, including any of the laws and applicable requirements upon which the program is based and any information requested by the Secretary.

(b) The foreign organic certification program shall be notified of the determination as follows:

(1) A foreign organic certification program that the Secretary determines to have safeguards and guidelines equivalent to the Act and regulations in part 205, the program's representative shall be notified in writing of the date upon which agricultural products produced and handled under that program may begin to be imported into the United States and sold or labeled as organically produced; and

(2) A foreign organic certification program that the Secretary determines does not have guidelines and safeguards equivalent to the Act and the regulations in part 205, the program's representative shall be notified in writing of the basis for such determination. After receipt of the notice, the program representative may reapply at any time.

(c) If at any time the Secretary determines that a foreign program is not equivalent, the Secretary may withdraw the equivalency status. Termination of the equivalency status will be effective upon receipt of the notice.

§ 205.483 Maintenance of eligibility for importation.

(a) Maintenance of eligibility for importation of agricultural products into the United States that are to be sold or labeled as organic will depend on the results of periodic reviews by the Secretary of the foreign organic certification program under which the products are produced and handled, and the timely submission of documents and other information necessary to reevaluate the equivalency status of the foreign organic certification program, as requested by the Secretary, including any amendments made to the foreign

organic certification program's requirements.

(b) For agricultural products imported into the United States to continue to be eligible to be sold or labeled as organic, the program representative of the program under which they were produced and handled must notify the Secretary of any amendments made to the program requirements prior to their implementation.

§§ 205.484—205.999 [Reserved]

PARTS 206—209 [RESERVED]

Dated: December 5, 1997.

Michael V. Dunn,

Assistant Secretary, Marketing and Regulatory Programs.

Note: The following Attachment will not appear in the Code of Federal Regulations.

Attachment—Regulatory Impact Assessment for Proposed Rules Implementing the Organic Foods Production Act of 1990

The Need for the Proposed Action

The Organic Foods Production Act (OFPA) of 1990, Title XXI of the Food, Agriculture, Conservation and Trade Act of 1990 (Farm Bill), U.S.C. Title 7, mandates that the Secretary of Agriculture develop a national organic program. The OFPA states that the Secretary shall establish an organic certification program for farmers, wild crop harvesters and handlers of agricultural products that have been produced using organic methods as provided for in the OFPA. In addition, section 6514 of the OFPA requires the Secretary to establish and implement a program to accredit a governing State official or any private person, who meets the requirements of the Act, as a certifying agent to certify that farm, wild crop harvesting or handling operations are in compliance with the standards set out in the regulation. As mandated by the OFPA in section 6501, the regulations are proposed for the following purposes: (1) to establish national standards governing the marketing of certain agricultural products as organically produced products; (2) to assure consumers that organically produced products meet a consistent standard; and (3) to facilitate interstate commerce in fresh and processed food that is organically produced. The purposes of the OFPA are similar to those of the quality grading programs currently provided by USDA for many agricultural products.

The following regulatory assessment is provided to fulfill the requirements of Executive Order 12866. This assessment consists of a statement of the need for the proposed action, an examination of alternative approaches, and an analysis of the benefits and costs. The analysis is necessarily descriptive of the anticipated impacts of the proposed rule. In the absence of basic market data on the prices and quantities of organic goods and services and the costs of organic production, it is not possible to provide quantitative estimates of the benefits and costs of the proposed rule, except for the cost of fees and recordkeeping proposed by the USDA. Consequently, the analysis does not contain an estimate of net benefits. Rather, it describes the developments leading up to the passage of the OFPA, outlines current market conditions and recent trends, and identifies the types of benefits and costs suggested by the changes in market conditions that the rule is expected to produce.

The OFPA was introduced at the request of the organic community after it experienced a number of problems in the marketing of organic products. Because many consumers are willing to pay price premiums for organic food, producers (farmers and wild crop harvesters) and handlers have an economic incentive to label their products organic. But one problem is that organic products cannot be distinguished from conventionally produced products by sight inspection; hence, consumers rely on verification methods, such as certification by private entities or verification by retailers. To the extent that consumers cannot verify organic product claims and are therefore vulnerable to fraud from the mislabeling of organic products, implementation of uniform organic standards and mandatory certification can be presumed to be beneficial.

A second problem is the lack of uniformity in various aspects of standards defining organic production. As organic production became established in the 1980's, certifying agencies were formed and some States passed laws establishing standards for organic production. However, many standards for production, processing and labeling of organic products were different to some degree, causing disagreements between certifiers over whose standards would apply to ingredients used in multi-ingredient organic processed products. Disagreements about standards also created sourcing problems for handlers of these multi-ingredient products, which at times resulted in losses for producers of organic ingredients.

Producers, handlers and certifiers appear to pay the costs resulting from the lack of uniformity in standards, which interferes with efficient resource allocation. However, whether these costs are significant is an empirical question. The data needed to estimate the effect of disagreements between certifiers on producer and handler costs would have to be collected. The costs of negotiating and maintaining reciprocity agreements among certifiers would provide one cost measure. These reciprocity agreements, which specify the conditions under which certifiers recognize each others' standards, would be unnecessary within a uniform national standards program. The costs of private accreditation or shipment-by-shipment certification, required to gain access to some foreign markets such as the European Union (EU), offer another indirect measure of the burden of the current system of variable standards. Certifiers would need to be surveyed to estimate these costs.

The lack of uniformity in various aspects of organic standards potentially reduces consumer welfare by creating confusion over the meaning of organic. However, the existence of different standards for organic production may provide consumers with a choice of products which they may not have under a program with a uniform standard. Our review of the literature did not find results of surveys of consumers' perceptions of the characteristics of organic foods. Consumer surveys focusing specifically on the meaning of organic and consumer preferences for organic standards would need to be conducted to determine more precisely the nature and extent of consumer confusion with, and level of confidence in, the status quo.

A third problem is the constraint on market growth resulting from the prohibition on labeling meat and poultry products as organic. The USDA Food Safety and Inspection Service (FSIS) has withheld approval for the use of organic labels on these products pending the outcome of this rulemaking. Industry data indicate the existence of a small market for ''natural'' meat, measured as sales of meat from natural foods stores, but no data are available on what proportion of these sales might be represented by organic meat. The data also are lacking with which to estimate the demand for organic meat and processed products containing organic meat. Consumer surveys indicating the degree of interest in these products would provide a measure of demand.

Alternatives to the Proposed Rule

Status Quo: The Organic Market in the Absence of Regulation

Sales of organic food products produced under a wide variety of protocols have grown at approximately 20 percent per year since 1990, the year the OFPA was passed (Table 1). Annual sales data are not available prior to 1990, but sales growth was approximately 10 percent from 1980 to 1989. Although the growth in the organic industry since 1989 has occurred without direct involvement of the Federal government, the establishment of national standards and accreditation could have been anticipated by the industry since 1990, when Congress passed the OFPA. Economic theory suggests the hypothesis that investments in production, new product development, and marketing during this period may have incorporated expectations for OFPA implementation. It has not been possible to test this hypothesis or to separate out the effect of these expectations from other forces on industry growth.

The EU is the largest market for organic food outside the United States. Valued at approximately $1.7 billion in 1990, the European market has been projected to grow at a rate of 25 percent per year, reaching approximately $14 billion by the year 2000 (Tate, p. 72). The EU regulations establishing the basis for equivalency in organic production among EU members and for imports from outside the EU were adopted in 1991 (Council Regulation 2092/91) (Byng, p. 21). These rules are being implemented by EU Member Countries, many of whom already have been operating under their own nationally recognized and mandated standards of production and inspection. The EU regulations allow for imports from non-EU countries whose national standards have been recognized as equivalent to the EU standards (Commission Regulation 94/92).

International access to domestic organic products may be very influential on development of the organic industry in the United States. In the absence of national standards, U.S. organic producers have been able to access European markets only by obtaining specific product permissions granted to individual importers by organic regulatory authorities in an EU Member State (Byng, p. 27–28). This process requires the importer to satisfy the authorities, through documentation and possible site inspection, that the product in question has been certified to have been produced under equivalent standards of production and inspection. It was intended as a temporary arrangement to accommodate non-EU countries that had not yet established government systems regulating organic production and certification. Growth in the trade of organic products, particularly exports, may be affected if equivalency between the EU and the United States is not established.

In the absence of a national program, the use of the term organic may be affected by the policies and regulations of other regulatory bodies. For example, FSIS currently does not approve the use of an organic label on meat and poultry, and without national standards they may continue their current restrictions, thus limiting growth in the sales of organic meat and poultry. The Food and Drug Administration (FDA) has allowed organic labeling for all other food products with the expectation that standards will be forthcoming. In the absence of a national standard, FDA's future position on organic labeling is uncertain. Additionally, in the absence of a national program, certifying agents would not be required to recognize another certifier's standards as equivalent. A lack of reciprocity between certifiers also may stifle the growth in trade of organic products for reasons previously discussed in the section of this assessment which discusses the need for this proposed action.

A Pure Food Model

Some consumers expect organic food to be pure food: that is, food which is completely free of synthetic chemicals (Burros, p. C–1). A pure food standard could be defined either as one which would not allow any exceptions to the prohibition on the use of synthetic substances, including the proposed use of some substances in emergency situations, or as one which would require that food test completely free of chemical residues. Such a standard could be posed as an alternative to the proposed rule; however, it would be more restrictive than the standard outlined in the OFPA, and would require an amendment to the OFPA.

Residue free food may be more restrictive than the standards of production and handling currently adopted by the organic industry itself. Standards based on residue testing have been rejected by the industry because: (1) residue testing focuses on the end product rather than the production process; (2) not all synthetic chemicals used in production are detectable as residues; and (3) some residues may appear in a product that has been produced organically because of unavoidable contamination in the soil, drift, or for other reasons which are beyond the farmer's control.

Establishing organic standards to meet a pure food definition could be expected to increase marginal costs, causing the supply curve to shift in and prices to increase, ceteris paribus. Some consumers, such as chemically sensitive persons or those who advocate pure food, likely would be willing to pay for a more restrictive definition for organic food. Other consumers would find the higher prices likely to result from a pure food standard beyond their willingness to pay for organic products and, therefore, may choose not to purchase organic products.

The niche market for pure food could be supplied by organic producers and handlers within the context of the regulations and restrictions contained in the final rule. Individual farmers and handlers would continue to have the option of putting additional information about their production methods on labeling materials of organic products, or otherwise meeting the product specifications of a pure food model, as long as these were not inconsistent with the national standards. Such additional information is subject to the same truth in labeling requirements as applied to all products. A certifier would be able to supply verification of additional product claims as a service to its clients, without requiring that all of its certified clients meet such product specifications.

Exemption of Small Certifiers From Accreditation

As explained below in the section entitled ''Costs of the Proposed Rule'' and as demonstrated in Table 5, the smallest certifiers (those with annual revenues of $25,000 or less) may not have the resources to meet all of the requirements of the rule, such as accreditation fees, administrative and personnel requirements, and conflict of interest restrictions, based on their current structure and revenues. Therefore, exempting the smallest certifiers from the accreditation requirement, similar to small producers being exempt from certification requirements, could mitigate the adverse impact of the rule on this group. This option, however, would require a legislative amendment to the OFPA.

The exemption of the smaller certifiers from accreditation would carry with it many of the limitations resulting from the absence of Federal oversight. International trade would likely be limited to products certified by accredited certifiers. Protecting domestic consumers from inappropriate organic claims on the labels of products certified by exempt certifiers would likely lead to greater confusion over labels in the marketplace. Federal enforcement agencies such as FDA, the Bureau of Alcohol, Tobacco and Firearms (ATF), and FSIS might wish to distinguish accredited certifiers from those certifiers who are exempt, perhaps by requiring accredited certifiers' clients to include the USDA seal on their product labels.

One of the purposes of the OFPA described in the statute is to assure consumers that organically produced products meet a consistent standard. Without Federal oversight of certifiers, it would be difficult to ensure that one national standard of production and handling for agricultural products would be employed. The result could be the continuation of reciprocity agreements between small, exempt certifiers and large accredited ones. This could result in a cost for small entities, while providing less benefit to certified producers and handlers than would be provided them by accreditation of all certifiers.

Benefits of the Proposed Rule

There are three points to note regarding the following discussion of benefits. First, while the costs of the rule may initially fall on certifiers, the benefits should be more widely distributed. The expected growth in the demand for organic products should create benefits for consumers, producers, handlers and certifiers. Second, not all benefits that may arise from the rule are primarily economic or quantifiable. Potential benefits which are neither quantifiable, such as increased protection for consumers producers and handlers, nor economic, such as greater communication among program participants and the NOP staff, are discussed here along with the economic benefits. Third, where economic data are available, they are generally not adequate to quantify economic benefits.

Consumer Benefits

Two potential benefits may accrue to consumers as a result of the proposed rule: protection from false and misleading organic food labels and a choice of a wider variety of organic foods.

Without a national standard, consumers can be mislead by labels on processed products claiming to contain organic ingredients, when in fact some of the ingredients may not be organically produced or individual ingredients may be certified under different standards of organic production. The proposed organic standards and USDA accreditation of certifiers might benefit consumers by providing assurance of the authenticity of organic claims. However, without additional data, it is not possible to quantify this benefit.

Establishing a national standard for the organic label is expected to increase the supply and variety of organic products, especially organic meat and poultry, available to consumers in the market. The organic label on meat and poultry products, including processed foods such as soups and entrees containing meat and poultry, would likely account for the bulk of new items that would enter the market following implementation.

Producer and Handler Benefits

As previously discussed, the proposed rule addresses the problem of existing certifying agents using different standards and not granting reciprocity to other certifying agents. By accrediting certifiers, the rule would establish the requirements and enforcement mechanism that would protect producers and handlers from inconsistent certification services, lack of reciprocity between certifiers, and competition from fraudulent products, all of which can increase costs or reduce revenues. In the absence of a system of accreditation, the certifier of a final

product is not required to recognize the certification of an intermediate product. Thus, both primary farmers and food handlers face a risk of being unable to sell certified organic product when more than one certifier is involved. The monitoring activities of accreditation should reduce the risk of restricted market access, and ensure that certifiers are using consistent criteria for certification and that certification personnel are knowledgeable and free from conflicts of interest.

The lack of a national standard for the organic label may present a barrier to marketing organic food products in the United States and abroad. Current data show organic sales growing at the rate of about 20 percent per year. It is unclear whether the growth rate will continue, increase, or decrease as a result of regulating the organic industry. In the absence of technical barriers to increasing production, implementation of the rule is expected to result in an increase in the rate of growth for organic exports and organic meat and poultry.

It is expected that national standards would create the conditions necessary for increased access to international markets. Despite restricted access to the European market, the United States is the most important non-EU supplier of organic products to EU countries (Foreign Agriculture Service (FAS), 1995). Import authorizations have been granted for a number of raw and processed commodities, including sunflowers, buckwheat, beans, sugar and apples. Demand is strong throughout the European Union, and the organic market share has been projected to reach 2.5 percent of total food consumption expenditures by 1998. Austria expects its organic market share to equal one third of all food sales by the year 2000 (FAS, Austria). In 1994, France and Germany combined had total retail sales of organic foods equal to that of the United States (approximately $2 billion) (FAS, France and Germany). Japan's retail sales for that year were estimated to be $688 million (SRI International, p. 15). Other EU countries report growth rates equal to or greater than the current growth rate in the United States of about 20 percent per year. Upon recognition of equivalency by the EU and the removal of the trade restrictions expected to follow implementation of the final rule, larger growth in exports of organic food products might be anticipated.

Increased access to international markets also implies that imports of organic products to the U.S. may increase. Currently, there are no restrictions on importing organic products to the U.S. in addition to those regulations applying to conventional products. Data are needed on the current trade balance in organic products to establish a baseline from which to measure changes in trade following implementation. The U.S. Customs Agency does not collect trade data that distinguish organic from conventional goods.

The impact of national organic standards on domestic production depends on increasing demand and on whether producers and handlers can lower their unit costs through expansion of their economies of scale of operations. Increasing demand may also create an incentive for new producers to enter the organic market. Input costs also may decline if economies of scale are achieved in input industries producing for the organic market. These conclusions are necessarily speculative given the lack of information on costs and production relationships for organic goods. However, such expectations are consistent with economic theory and experiences in other industries. Gains to organic producers and handlers may be partially offset by a decrease in the demand for comparable non-organically produced agricultural products, causing conventional producers and handlers to lose market share.

With the introduction of national standards to regulate labeling of organic products, processed organic products would acquire commercial item descriptions which are currently used by the food industry to identify conventional products. Adopting bar codes and industry accounting practices which identify organic goods would make sales information more accessible for research and marketing purposes.

Certifier Benefits

Certifiers might experience benefits from the rule through reductions in their administrative costs, greater exchange of information, and an increase in demand for certification resulting from an increased demand for organic products and from an expansion of the organic market due to new products entering the market.

There are several ways in which certifiers' administrative costs may be reduced as a result of the rule. First, increased assurance through accreditation might reduce certifiers' costs of maintaining access to organic markets for their clients. Costs associated with establishing reciprocity between certifiers could be eliminated. Accreditation and national standards would remove the need to negotiate individual reciprocity agreements with other certifiers, and would simplify the process of certifying multiple ingredient products, thus reducing certification costs. The responsibility for meeting production and certification requirements of each ingredient would rest with the certified producers and accredited certifiers of the individual ingredients.

Second, certifiers would no longer would have to pay private organizations for the accreditation required to gain access to some international markets. This would be of particular benefit to the smaller certifiers who may have been unable to enter these markets because of the high cost of international accreditation. A portion of the administrative fees paid by each certifying agent would support USDA activities to negotiate equivalency of organic standards in world markets so that producer clients of all USDA accredited certifiers could have access to these markets.

Third, in the long run, uniform standard of production, certification and accreditation should reduce the cost of training certification staff. Industry-wide training costs may increase initially, but should decline as the pool of trained certifiers and certification personnel increases and the corresponding cost of training new certification personnel decreases, especially in those instances where personnel transfer from one certifier to another. Standardized materials, such as compliance guides and training manuals, also should contribute to a reduction in the cost of training certification staff. In addition, USDA accreditation of certifiers would present opportunities for sharing information about standards, practices and the general requirements of the program through the National Organic Program staff. This information is most frequently provided in Small Entity Compliance Guides and other printed material.

The contribution of national standards to increasing domestic demand and opening international markets to U.S. organic products provides opportunities for growth in certification services. Certifiers' average costs of operation may decline as fixed costs are spread over a growing number of producers.

Costs of the Proposed Rule

Direct Program Costs

The proposed rule would impose direct costs on certifiers in the form of a fee paid to the Federal government for USDA accreditation, which the OFPA requires of all certifiers of organic food products in the United States. Certifiers, in turn, generate revenue by charging producers and handlers a certification fee. Although the proposed rule does not regulate the amount of certification fees, the OFPA does require that food products labeled organic be certified, and that the fees which certifiers collect from producers and handlers for this service be reasonable.

The OFPA also provides for the collection of reasonable fees by USDA from producers and handlers who participate in the national program. The following analysis of costs thus considers both fees to be charged to certifiers and fees to be charged to producers and handlers to recover other program costs.

Certifiers' costs of accreditation are assumed to be passed on to producers and handlers through an increase in certification fees. Currently, supply and demand for certification services determine the fees charged in most areas. Some States charge minimal fees for certification and instead subsidize operating costs from general revenues. The majority of certifiers structure their fee schedules on a sliding scale based on a measure of size, usually represented by the client's gross sales of organic products.

Direct national program costs would equal the cost of the accreditation program plus the costs of other functions carried out by the organic program staff (salaries, overhead, materials review, compliance costs, etc.). These costs are estimated at approximately $1 million for the first year that the program is in full operation (Table 2). In future years, direct national program costs would depend upon the number of accreditation applicants, annual reports received from certifiers, and the number of producers, handlers and certifiers who participate in the program. Data collected by AMS indicate that the number of organic farmers increased about 12 percent per year and the number of organic handlers increased at about 11 percent per year during the period 1990 to 1994. There

is no indication that the rate of growth has continued, or that the implementation of the organic program would cause an increase in the number of organic operations; however, growth in retail sales, the addition of meat and poultry to organic production, and the possibility of increased exports suggest that the number of operations may increase.

At the current (1995) level of retail sales, the $1 million program costs imply an additional consumer cost from the regulation of approximately .04 cents per dollar. If the known current 44 certifiers were to be accredited and assume the total program cost of $1 million, annual average costs per certifier would be $22,727. Assuming these costs are passed on to the estimated number of 4,600 existing certified organic farmers and handlers, and assuming that these certified farmers and handlers continue in business, certification costs for these 4,600 farmers and handlers would increase by an average of $217 per year as a result of the organic program. This increase may be smaller if more than 4,600 farmers and handlers are certified. Although the current fees are based on the anticipated certification of 4,600 farmers and handlers, we considered for purposes of estimating the reporting and recordkeeping burdens of the proposed rule that the actual total number of certified farmers and handlers who may participate in the national program during the first three years of the program may approximate 12,000 total farmers and handlers combined. These distributions of direct program costs are shown in Table 3. The actual distribution of program costs will be a function of the elasticity of demand for organic goods. The more inelastic the demand, the greater the portion of costs paid by consumers. If demand is elastic, producers and handlers will share a larger portion of the cost, and supply will be affected.

Producers and handlers would be required to produce and handle products in accordance with the standards set forth in the rule, and supply the information necessary to certifiers to verify certification requirements. These requirements are not expected to impose additional costs on those currently certified. Certified farmers and handlers of organic products are currently complying with certification requirements which are not substantially different from those in the proposed rule. Organic producers and handlers who currently are not certified, and new entrants to organic production and handling, would face higher costs.

The type of government fee structure largely would determine how program costs are distributed among certifiers and, secondarily, among producers and handlers. The impact of program costs on certifiers also would depend on the basis for the fees certifiers charge their customers, and on their customers' characteristics.

The provisions for assessing fee for direct services presented in the proposed rule set fixed application and administrative fees of $640 and $2,000, respectively, to be paid by certifiers, with the bulk of accreditation costs billed to certifiers on a time rate for direct services to conduct site visits. The level of these fixed fees, plus the variable fee for direct services, sets a lower bound on the size at which a certifier could operate and be economically viable. A certifier would have to collect enough revenue from the clients it certifies to cover these fees plus operating costs. Due to the fixed components of the fees, larger certifiers would have the ability to spread their costs over a greater number of farmers/handlers. Additionally, as required by the OFPA, a private certifying agent would have to furnish reasonable security for the purpose of protecting the rights of farms and handling operations certified by the certifying agent. The amount and type of security would be established through future rulemaking.

Under the fee for direct services provisions, labor hours, travel and per diem costs for the site inspection required for accreditation would be included in the variable fee for direct services. This practice is used by other USDA agencies that conduct inspection programs. The AMS estimates the average cost to conduct each accreditation site visit to be $3,500 per visit. The frequency of site-evaluations for each certifying agent could be expected to decrease as the operator becomes more familiar with the program regulations. Pre-accreditation site valuations might be necessary to enable the certifier to become accredited, and an evaluation would be required for confirmation of accreditation and thereafter for renewal of accreditation, which occurs every 5 years.

The travel cost component of this figure would vary based on the certifier's distance from Washington, D.C., because site visits will be conducted by the organic program staff headquartered there. An alternative method of distributing travel costs would be to estimate an average annual cost per trip, given the expected number of trips and the geographic distribution of all certifiers, and charge that amount for all site visits, regardless of location.

A measure of size is incorporated into the fee structure, i.e., the time spent conducting each accreditation by organic program staff. The variable portion of the fee would distribute program costs among certifiers according to the resources actually consumed in providing the accreditation service. The more complex and larger the certifier, the more time required to conduct an evaluation and the larger their fee for accreditation. However, imposing an hourly rate for accreditation services introduces a subjective measure in the determination of fees. With several national program staff conducting accreditation evaluations, disputes over the time required to complete a specific accreditation process would be difficult to resolve on an objective basis.

If program costs were distributed uniformly among existing certifiers, the smallest certifiers, those with annual revenues of $25,000 or less, may not have the financial capacity to continue to operate within the requirements of the regulation, based on their current revenues. Distributing program costs based on a measure of size would permit more small certifiers to stay in business, provided that they met other qualifications for accreditation. Generally, a fee structure proportionate to size would result in certifiers contributing to the costs of the program in proportion to the gains they accrue from it, their revenues being based largely on the share of total organic output produced by the operations they certify.

An additional feature of the proposed fees for direct services is that it attempts to distribute program costs according to a simplified measure of size through a variable fee charged directly to farmers and handlers who are certified by an accredited certifying agent. Under the proposed rule, a farmer would pay USDA an annual fee of $50 and a handler would pay $500 per year. The difference between farmer and handler fees is designed to account for the difference in staff time AMS estimates will be devoted to handler and processed food issues relative to farmer and raw product issues. Half of the total program cost of $1 million is assumed to be covered by these fees.

Administrative Requirements and Associated Costs

The proposed rule also would impose administrative costs, such as submission of information, recordkeeeping, and access to records that may constitute an additional burden. The actual amount of the additional administrative costs that would be imposed by the final rule is expected to be different for those entities who would begin their activities only after the national program is implemented. Certifiers, farmers, wild crop harvesters and handlers who currently are active in the organic industry already perform most of these administrative functions; therefore, the additional costs to them would depend upon the extent to which their current practices are different from the requirements of the final regulation. The following list describes several proposed administrative requirements or optional submissions and the probable resources required for compliance:

1. A list of farmers, wild crop harvesters and handlers currently certified. This information could be compiled from existing records. After implementation, certifiers would be required to submit on a quarterly basis a list of operations certified during that quarter.

2. A description of the certification decision process, compliance review procedures, a plan for allowing public access to records, and measures taken to prevent conflicts of interest. These policies may have to be created or modified to conform to the regulation.

3. Documentation of financial capacity and compliance with other administrative requirements (e.g., fee structure, recordkeeping capability, income sources, and business relationships showing absence of conflicts of interest). Some of this information would be compiled from existing records (e.g., income sources and fee schedules), and some may be generated from other sources.

4. Retention of certification documents for 10 years. This activity requires records and database management capabilities and resources (storage space, file cabinets, electronic storage, etc.). In an informal inquiry, AMS found that most existing certifiers currently retain records for at least 10 years, and use both electronic and paper storage. We believe that this requirement

would not pose an additional burden on existing certifiers.

The Act also requires producers and handlers to retain their records for a minimum of five years. According to the same informal AMS inquiry, the industry generally requires records to be kept for three years. Overall, producer and handler operation records required by the proposed regulation are extensions of, or modifications to, documents already maintained under normal industry practice, and therefore this requirement would have minimal impact on operations currently certified.

5. Public access would have to be provided to certification records, such as a list of certified farmers and handlers, their dates of certification, products produced, and the results of pesticide residue tests. This requirement would have minimal impact given the requirements for retaining records.

6. Certifiers are required to supply program information to certification applicants. To comply with this requirement, certifiers may need to modify existing standards and practice.

The criteria for qualified personnel required in the proposed rule may likely result in an increase in labor costs for some existing certifiers and, initially, an increase in training costs. The amount of additional costs to these certifiers would depend on the level of expertise among current certification agency staff, the extent to which certifiers currently rely on volunteers, and the current costs of training certification staff.

Our proposed inspector training requirements conform closely to current established practice in the industry and are not expected to impose an additional burden on most existing certifiers. Training programs are currently offered by the Independent Organic Inspectors Association (IOIA), an organization of approximately 165 organic certification inspectors, and by some of the larger certifiers (IOIA, p. 1).

Costs to existing certifiers to provide additional training to other staff are difficult to measure in the absence of information on current staff skill levels or the existence of formal training other than inspector training. Some agencies rely on volunteer staff who may have had no formal training, but the extent of this practice is unknown. AMS intends to offer assistance to certifiers, producers and handlers by providing guide books and other printed material that would enable participants to better understand the regulations. In addition, AMS intends to continue open and frequent communication with certifiers and inspectors to provide as much information as possible to aid them in fulfilling the requirements of the regulations.

Table 5 estimates the total initial costs for an applicant to become accredited as a certifying agent under the NOP, and the estimated total initial costs for a producer or handler to become certified. The costs presented in Table 5 are the upper-bound estimates for participation in the National Organic Program for new organic certifiers, farmers and handlers.

State Program Costs of the Proposed Rule

The proposed rule is based on the OFPA, a review of State and private certification programs, National Organic Standards Board (NOSB) recommendations, EU regulations, and foreign organic program provisions. Table 4 compares many general provisions of the proposed rule to existing State and private certification programs and the NOSB recommendations. The proposed rule encompasses most of the principles of existing State programs, with specific requirements modified to be performance-based rather than design-based. For example, the proposed standards for housing poultry require that farmers provide adequate light and space, rather than requiring a particular method of housing. With a performance-based rule, certifiers are free to exercise their judgement regarding how farmers meet the standards. Thus, the proposed rule provides greater flexibility than is provided by many existing programs in determining how a particular standard can be met.

In many cases, the proposed rule provides standards where many existing State programs are silent. For example, according to AMS data, only two of the eleven State agencies and 16 of the 33 private agencies certified livestock in 1994. In the same year, only six of the eleven States and 15 of the 33 private agencies certified processors or handlers.

There are 27 States with some standards governing the production or handling of organic food, and comparing features of State standards to the provisions of the proposed rule provides a means of examining the potential impact of the rule on existing State programs. There are two situations in which implementation of a national program may impose additional costs on States by requiring changes in their existing programs. First, where State standards are below Federal standards or where elements of the Federal standards are missing from a State program, these States would be required to make changes in their programs that they might otherwise not make. Second, where State standards exceed the Federal standards and the differences are not approved by the USDA, States also would be required to make changes in their programs. States without organic standards or whose current standards either would conform to those of the national program or would be approved by the Secretary would not incur additional costs resulting from required changes. In States with existing organic standards but no certification program, such as California, the national standards would apply to private certifiers operating within the State and, therefore, they also are relevant to indicating the degree of impact a national program would have on existing State programs. An analysis of selected aspects of specific standards follows:

Transition period. The transition period, which would specify the time period during which prohibited materials cannot be applied before a field can be certified as organic, is included in most State organic standards. The OFPA specifies a required transition period of three years before certifying a field. Existing certifiers and farmers will have had several years prior to implementation to conform with this requirement and its impact is expected to be minimal. In fact, a required transition period of three years is currently in effect in 20 out of 23 States.

Animal drug use. Another common feature of organic standards is the restricted use of animal drugs for livestock. Where livestock standards have been adopted by existing State programs, most prohibit the use of animal drugs except for the treatment of a specific disease condition. Use of animal drugs is generally prohibited within 90 days prior to slaughter, or the sale of milk or eggs as organic. The standards in the proposed rule would impose a more restrictive time period for drug use in animals for slaughter, but do not differ from most existing State standards in prohibiting the use of drugs on healthy animals.

Materials list. Lists of approved synthetic materials, including soil amendments and pesticides, vary from one State program to another. A detailed analysis of specific differences in the various existing materials lists shows them to be overlapping in most cases, but mutually exclusive in others. The impact of the national program would not be determined by how the national standards differ from current certification standards, but rather by how the national standards differ from actual practice. Data on materials currently used in organic production are not available to make this comparison.

Non-Quantifiable Costs

Some certifiers have identified the loss of independence in setting certification standards within a uniform national standard program as imposing a cost. Certification to a national standard has been described as ''forced reciprocity,'' that is, compelling certifiers to recognize as equal in value a product certified by a competitor. A national accreditation program would preclude a certifier of an end product from refusing to accept a different certification of an ingredient used in the end product. A lack of reciprocity can, in fact, impose costs on manufacturers in the form of lost product (Natural Foods Merchandiser, April 1995). Other certifiers welcome the enforcement of uniform national standards and view mandatory accreditation as a benefit because it would eliminate the risk of potentially costly reciprocity disputes. What appears to be at stake is the determination of market shares among certifiers: losses to one certifier would constitute gains to others.

Another possible cost of the rule may result from the requirement that certifiers provide access to records. The Secretary and the applicable governing State official would have access to all records and certifiers would have to provide public access to laboratory analyses and certification documents other than confidential business information. While not quantifiable, this requirement may represent a substantial change in the way some certifiers currently operate and interact with producers, other certifiers, government agencies, and the public.

Conclusion

Ideally, the net benefits of the proposed rule would be estimated by employing a welfare analysis. In a welfare model, the quantitative assessment of benefits would be represented by net changes in consumer and producer surplus, i.e., the difference between

the willingness to pay (or firm cost structure in the case of producers) and the market price of organic food. These net changes would be estimated using information about the cost structure of the industry, the demand for organic food, and projected shifts in supply and demand resulting from the various factors discussed in the assessment. Although researchers have conducted numerous small-scale studies to determine consumers' willingness to pay for certain organic products (primarily fresh produce) and to identify reasons why conventional food buyers do not choose organic food products (Hammitt, 1990 and 1993; Jolly; Misra et al.; Park and Lohr; Weaver et al.), the available data are insufficient to support a quantitative assessment of this type.

USDA has identified the entities that may be affected by the proposed rule and has analyzed the anticipated impacts of the rule on them based on our knowledge of the industry and limited data. However, USDA lacks data to thoroughly and quantitatively describe the existing organic industry and quantitatively analyze the effects of the proposed rule. To assist in the assessment of comments on the rule and to better report to the public the effects of the rule, USDA welcomes responses in the following areas. USDA is particularly interested in data and analyses that are nationally representative.

1. To establish a baseline, USDA requests data on the number of farmers producing and marketing organic goods, the number of handlers of organic goods, and the number of organic farmers, wild crop harvesters and handlers who are operating with third party certification, and the number who operating without third party certification..

2. To establish a baseline, USDA requests data on the number of entities certifying organic farmers and handlers and the number of organic certifiers who currently are accredited.

3. To establish a baseline, USDA requests data to characterize the costs of organic production and revenues from organic farming.

4. To assess the impact of the proposed program, USDA requests data on fees currently paid by organic producers and handlers for certification services and on fees currently paid by organic certifiers for accreditation.

5. To assess the impacts of the proposed program and to better project the costs of operating the National Organic Program (which will be recovered by fees), USDA requests information to project the number of organic producers and handlers who would apply for certification under the National Organic Program. USDA also requests information to project the number of entities which would seek USDA accreditation as an organic certifying agent.

6. The regulatory impact assessment for the proposed rule considers that cost may be incurred by fraudulent labeling of organic products. To what extent does mislabeling of non-organically produced products as organic occur and what are the market impacts in terms of quantities of organic goods sold and the prices for organic goods?

7. This rule would permit the marketing of meat and poultry products as organic, which is not currently permitted. USDA requests data and analyses which would support projections of the demand for organic meat and poultry.

8. The regulatory impact assessment for this rule reports that sales of organic goods have been growing at an annual rate of 20 percent. Are there data to support a different rate?

9. We estimate that the organic industry may grow after program implementation due to the introduction of organic meat and poultry and increased exports of organic agricultural products. Are there data to estimate the impact that this rule is likely to have on overall industry growth?

10. The organic industry and consumers of organic goods may benefit if industry growth results in economies of scale, and production and marketing efficiencies. What has been the industry experience in this area and do industry participants anticipate such benefits from this rule?

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TABLE 1.—ORGANIC SALES, 1980–1995

Year	Sales (in $ millions)
1980	178
1989	631
1990	1,000
1991	1,250
1992	1,540

TABLE 1.—ORGANIC SALES, 1980–1995—Continued

Year	Sales (in $ millions)
1993	1,890
1994	2,310
1995	2,800

Source: Emerich, p. 23.

TABLE 2.—BREAKDOWN OF PROJECTED NATIONAL ORGANIC PROGRAM COSTS

[Total Program Costs]

Salaries and Benefits	$644,000
Operating Costs*	180,617
Agency Overhead**	100,403
Division Overhead**	74,980
Total	1,000,000
Total Staffing	12

*Operating costs include travel, printing, training, equipment, supplies, rent and other services.

**Agency and Division overhead includes administrative support, contract and other fees for services, rent, heat, communications, and major equipment purchases.

Source: AMS.

TABLE 3.—DISTRIBUTION OF DIRECT ANNUAL PROGRAM COSTS FOR OFPA

[In dollars]

Direct program costs	$1,000,000
Costs per dollar sales ($2.8 billion)	0.00036 (.036¢)
Costs per certifier (44 certifiers)	22,727
Costs per farmer/handler (4,600 farmers/handlers)	217

Source: AMS data; Emerich, p. 23.

TABLE 4.—COMPARISON OF THE PROPOSED NATIONAL ORGANIC PROGRAM REGULATIONS WITH THE NOSB RECOMMENDATIONS AND REPRESENTATIVE STATE AND PRIVATE PROGRAMS

USDA provision in the proposed rule	NOSB recommendation	State programs	Private programs
PRODUCTION AND HANDLING:			
Standards based on identified organic principles	Recommended principles which USDA used in the proposed rule.	Similar principles	Similar principles.
Management includes long-range planning, such as an organic plan	Similar	Similar	Similar.
Preventive measures and mechanical or biological methods, as opposed to substances, used to control pests, weeds, and disease in crops and livestock.	Similar	Similar; few States have livestock standards.	Similar; few programs have livestock standards.
Organic planting stock, livestock, and ingredients used in preference to non-organic.	Similar	Similar	Similar.
Livestock may be fed non-organic feed under certain circumstances	Similar	Similar	Similar.
Prevention of prohibited substances contacting organic products	Similar	Similar	Similar.
Allowed use of specific synthetic substances	Proposed National List reflects almost all of the NOSB recommendations.	Similar; lists vary among States.	Similar; lists vary among programs.
Criteria for list of allowed synthetic substances	Similar	General criteria are similar.	General criteria are similar.
Mechanical or biological methods, as opposed to substances, used in handling operations.	Similar	Similar; few States have handling standards.	Similar; few programs have handling standards.
Allowed use of non-organic agricultural ingredients in processed organic food.	Similar	Similar	Similar.
Allowed use of specific non-agricultural ingredients in processed organic food.	Proposed National List reflects almost all of the NOSB recommendations.	Similar, but few States have handling standards; lists differ.	Similar, but few programs have handling standards; lists differ.
CERTIFICATION:			
Products labeled organic must originate from certified operations	Similar	Few States do their own certification but generally producers and handlers are certified.	Private programs generally certify.
Certification performed by a third-party in a prescribed manner	Similar	Similar for States that require certification.	Similar.
Annual certification with verification by inspection of site and records	Similar	Similar for States that require certification.	Similar.
All certifications granted by accredited certifiers are to be considered equivalent.	Similar	Equivalency granted on a case-by-case basis.	Equivalency granted on a case-by-case basis.
ACCREDITATION:			

TABLE 4.—COMPARISON OF THE PROPOSED NATIONAL ORGANIC PROGRAM REGULATIONS WITH THE NOSB RECOMMENDATIONS AND REPRESENTATIVE STATE AND PRIVATE PROGRAMS—Continued

USDA provision in the proposed rule	NOSB recommendation	State programs	Private programs
All certifiers must be accredited by USDA	Similar	Very few States accredit or register certifiers.	Very few programs are accredited by private organizations.
Certifiers evaluate and train inspectors and certification personnel	Similar	Similar; differs among States.	Similar; differs among programs.
Recordkeeping requirements, public access requirements, and safeguard requirements for confidential information.	Similar	Similar	Similar.
Measures enforced to prevent conflict of interest by certifier	Similar	Similar, as part of State's general requirements.	Similar, but may not be monitored.
Certifier performance reviewed by peers	Similar	Similar in any State accrediting certifiers.	Similar for the purpose of establishing reciprocity.
OTHER ELEMENTS:			
Site-specific unavoidable residual environmental contamination level used to determine organic status.	Predetermined unavoidable residual environmental contamination level should be used to determine organic status.	Similar, but some States also use a predetermined specified residue level to determine organic status.	Similar, but some programs also use a predetermined specified residue level to determine organic status.
Enforcement by Federal government	Similar	Intra-State enforcement of existing State regulations.	Enforcement of individual program policies.
Access to international markets	Not applicable	Individually acquired agreements.	Individually acquired agreements.
Evaluation of foreign programs to determine equivalency	Similar	Not applicable	Not applicable.

Source: AMS.

TABLE 5.—ESTIMATED UPPER-BOUND COSTS OF ACCREDITATION AND CERTIFICATION

ESTIMATED COST TO CERTIFIERS FOR INITIAL ACCREDITATION	
Accreditation application fee	$640
Site evaluation fee*	3,500
USDA Administrative fee	2,000
Total fees	6,140
Paperwork reporting burden	23,931 (for new organic certifiers)
Paperwork recordkeeping burden	60
Total reporting and recordkeeping	23,991
ESTIMATED TOTAL COST FOR INITIAL ACCREDITATION	30,131
ESTIMATED COST TO PRODUCERS FOR INITIAL CERTIFICATION	
Certification fee**	$413
USDA fee	50
Total fees	463
Paperwork reporting burden	381 (for new organic producers)
Paperwork recordkeeping burden	34
Total reporting and recordkeeping	415
ESTIMATED TOTAL COST TO PRODUCERS FOR INITIAL CERTIFICATION	878
ESTIMATED COST TO HANDLERS FOR INITIAL CERTIFICATION	
Certification fee**	943
USDA fee	500
Total fees	1,443
Paperwork reporting burden	433 (for new organic handlers)
Paperwork recordkeeping burden	34
Total reporting and recordkeeping	467

TABLE 5.—ESTIMATED UPPER-BOUND COSTS OF ACCREDITATION AND CERTIFICATION—Continued

ESTIMATED TOTAL COST TO HANDLERS FOR INITIAL CERTIFICATION	1,910

*Each certifying agent would have a site-evaluation to confirm accreditation, and thereafter a subsequent renewal evaluation at least every 5 years following confirmation of accreditation. In some cases, a pre-confirmation site visit may be necessary. We anticipate that the frequency of site evaluation would be based on the performance of the certifying agent and would be higher during the initial years of the program.

**The estimated certification fee is based on the average of fees charged by a representative group of certifying agents: private non-profit, private for-profit and a State agency. Most certifying agents in our representative group include the cost of inspection and, if applicable, required laboratory testing in the certification fee.

Source: AMS.

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