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Tuesday  
December 16, 1997

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**Part II**

**Department of  
Agriculture**

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**Agricultural Marketing Service**

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**7 CFR Part 205  
National Organic Program; Proposed Rule**

**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 timetable 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
<b>Total fees .....</b>	<b>463</b>
Paperwork reporting burden .....	<sup>1</sup> 381
Paperwork record-keeping burden .....	34
<b>Total reporting and recordkeeping ....</b>	<b>415</b>

ESTIMATED COST TO FARMERS AND WILD CROP HARVESTERS FOR INITIAL CERTIFICATION .....	\$878
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**Estimated Cost to Handlers for Initial Certification**

Certification fee * .....	\$943
USDA fee .....	500
<b>Total fees .....</b>	<b>1,443</b>
Paperwork reporting burden .....	<sup>2</sup> 433
Paperwork record-keeping burden .....	34
<b>Total reporting and recordkeeping ....</b>	<b>467</b>

ESTIMATED TOTAL COST TO HANDLERS FOR INITIAL CERTIFICATION .....	\$1,910
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\* 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.

<sup>1</sup> For new organic producers.  
<sup>2</sup> 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
<b>Total fees .....</b>	<b>6,140</b>
Paperwork reporting burden .....	<sup>1</sup> 23,931
Paperwork record-keeping burden .....	60
<b>Total reporting and recordkeeping ....</b>	<b>23,991</b>

ESTIMATED TOTAL COST FOR INITIAL ACCREDITATION .....	\$30,131
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\*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.

<sup>1</sup> 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 misled 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 of 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 inquiries 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) <sup>1</sup> .....	Farmers .....	7,049	14.75	103,972.75	1,039,730
Farms with livestock <sup>2</sup> .....	Farmers .....	3,525	3.00	10,575.00	105,750
Split farms <sup>2</sup> .....	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 <sup>2</sup> .....	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 <sup>3</sup> .....	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 <sup>4</sup> .....	Certifying agents .....	12,769	0.85	10,848.20	216,960
Accreditation requirements (other than record-keeping) <sup>5</sup> .	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 <sup>6</sup> .....	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

<sup>1</sup> 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.

<sup>2</sup> 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.

<sup>3</sup> 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.

<sup>4</sup> 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.

<sup>5</sup> 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.

<sup>6</sup> 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 allelopathic 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 supplementary 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 synthetic 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 defoliant 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 defoliant 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 fluoaluminat, 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 fluoaluminat. 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. 6505(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