Subpart B - Applicability

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

Description of Regulations

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

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

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

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

Exempt and Excluded Operations

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

Exempt Operations

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

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

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

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

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

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

Excluded Operations

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

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

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

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

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

**Recordkeeping Requirements for Certified Operations**

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

**Examples of Records**

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

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

Allowed and Prohibited Substances

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

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

Description of Regulations

General Requirements

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

Production and Handling (General)

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

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

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

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

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

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

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

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

The fifth element which must be included in an organic system plan pertains to split production or handling operations. This provision requires an operation that produces both organic and nonorganic products to describe the management practices and physical barriers established to prevent commingling of organic and nonorganic products. This requirement addresses contact of organic products, including livestock, organic field units, storage areas, and packaging to be used for organic products, with prohibited substances.
The specific requirements to be included in an organic system plan are not listed here. The accreditation process provides an assurance that certifying agents are competent to determine the specific documentation they require to review and evaluate an operation's organic system plan. Section 205.200(a)(6) allows a certifying agent to request additional information needed to determine that an organic system plan meets the requirements of this subpart. The site-specific nature of organic production and handling necessitates that certifying agents have the authority to determine whether specific information is needed to carry out their function.

Crop Production

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

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

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

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

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

The producer must use preventive practices to manage crop pests, weeds, and diseases, including but not limited to crop rotation, soil and crop nutrient management, sanitation measures, and cultural practices that enhance crop health. Such cultural practices include the selection of plant species and varieties with regard to suitability to site-specific conditions and resistance to prevalent pests, weeds, and diseases. Mechanical and biological methods that do not entail application of synthetic substances may be used as needed to control pest, weed, and disease problems that may occur. Pest control practices include augmentation or introduction of pest predators or parasites; development of habitat for natural enemies; and nonsynthetic controls such as lures, traps, and repellents. Weed management practices include mulching with fully biodegradable materials; mowing; livestock grazing; hand weeding and mechanical cultivation; flame, heat, or electrical techniques; and plastic or other synthetic mulches, provided that they are removed from the field at the end of the growing or harvest season. Disease problems may be controlled through management practices which suppress the spread of disease organisms and the application of nonsynthetic biological, botanical, or mineral inputs. When these practices are insufficient to prevent or control crop pests, weeds, and diseases, a biological or botanical substance or a synthetic substance that is allowed on the National List may be used provided that the conditions for using the substance are documented in the organic system plan. The producer must not use lumber treated with arsenate or other prohibited materials for new installations or replacement purposes that comes into contact with soil or livestock.

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

Livestock Production
[Deleted]

Handling

Mechanical or biological methods can be used to process an agricultural product intended to be sold, labeled, or represented as "100 percent organic," "organic," or "made with organic ingredients" for the purpose of retarding spoilage or otherwise preparing the agricultural product for market. Processed multi-ingredient products labeled "100 percent organic," may only use wholly organic ingredients, pursuant to paragraph (a) of section 205.301. Nonagricultural substances that are allowed for use on the National List and nonorganically produced agricultural products may be used in or on "organic" and "made with..." products pursuant to paragraphs (b) and (c) of section 205.301, respectively. Documentation of commercial availability of each substance to be used as a nonorganic ingredient in products labeled "organic" must be listed in the organic handling system plan in accordance with section 205.201.

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

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

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

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

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

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

Section 205.272 provides additional practice standards that must be followed by an organic handling operation to prevent the commingling of organic and nonorganic products and to protect organic products from contact with prohibited substances. An organic handling operation must not use packaging materials and storage containers or bins that contain a synthetic fungicide, preservative, or fumigant in handling an organic product. The operation also must not use or reuse any storage bin or container that was previously in contact with any prohibited substance unless the reusable bin or container has been thoroughly cleaned and poses no risk of prohibited materials contacting the organic product.

**Temporary Variances**

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

The proposed rule inadvertently omitted the SOP's governing State official as having authority to recommend a temporary variance to the Administrator. We have added that authority in paragraph (b) of section 205.290.
Upon notification by the Administrator that a temporary variance has been established, the certifying agent must inform each production and handling operation it certifies that may be affected by the temporary variance. For example, if a drought causes a severe shortage of organically produced hay, a dairy operation may be permitted to substitute some nonorganic hay for a portion of the herd's diet to prevent liquidation of the herd. The producer must keep records showing the source and amount of the nonorganic hay used and the timeframe needed to restore the total feed ration to organic sources. The certifying agent may require that the next organic plan include contingency measures to avoid the need to resort to nonorganic feed in case of a future shortage.

Subpart D - Labels, Labeling, and Market Information

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

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

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

Under the National Organic Program (NOP), the assembly, packaging, and labeling of multiingredient organic products are considered handling activities. The certification of handling operations is covered in subpart C of this regulation. No claims, statements, or marks using the term, "organic," or display of certification seals, other than as provided in this regulation, may be used. Based on comments received, several important labeling changes from the proposed rule are made in this final rule. (1) The term, "organic," cannot be used in an agricultural product name if it modifies an ingredient that is not organically produced (e.g., "organic chocolate ice cream" when the chocolate flavoring is not organically produced). (2) The 5 percent or less of nonorganic ingredients in products labeled "organic" must be determined not "commercially available" in organic form. (3) Display of a product's organic percentage is changed from required to optional for "organic" and "made with ..." products. (4) The minimum organic content for "made with..." products is increased from 50 percent to 70 percent. (5) In addition to listing individual ingredients, the "made with..." label may identify a food group on the label ("made with organic fruit"). (6) A new section is added to provide labeling of livestock feed that is organically produced. (7) Finally, a revised design for the USDA seal is established. In addition to these changes, we have made a few changes in the regulatory text for clarity and consistency purposes. These do not change the intent of the regulation.
Once a handler makes a decision to market a product as organic or containing organic ingredients, the handler is required to follow the provisions in this subpart regarding use, display, and location of organic claims and certification seals. Handlers who produce and label organic ingredients and/or assemble multiingredient products composed of 70 percent or more organic ingredients must be certified as an organic handling operation. Handlers of products of less than 70 percent organic ingredients do not have to be certified unless the handler actually produces one or more of the organic ingredients used in the product. Repackers who purchase certified organic product from other entities for repackaging and labeling must be certified as an organic operation. Entities which simply relabel an organic product package are subject to recordkeeping requirements which show proof that the product purchased prior to relabeling was, indeed, organically produced and handled. Distributors which receive and transport labeled product to market are not subject to certification or any labeling requirements of this regulation.

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

**Description of Regulations**

**General Requirements**

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

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

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

**Categories of Organic Content**

Section 205.301 establishes the organic content requirements for different labeling provisions specified under this program. The type of labeling and market information that can be used and its placement on different panels of consumer packages and in market information is based on the percentage of organic ingredients in the product. The percentage must reflect the actual weight or fluid volume (excluding water and salt) of the organic ingredients in the product. Four categories of organic content are established: 100 percent organic; 95 percent or more organic; 70 to 95 percent organic; and less than 70 percent organic.

**100 Percent Organic**

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

Organic

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

Made with Organic Ingredients

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

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

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

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

Product With Less Than 70 Percent Organic Ingredients

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

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

Livestock feed
[Deleted]

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

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

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

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

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

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

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

Labeling "100 Percent Organic" and "Organic" Products
Section 205.303 includes optional, required, and prohibited practices for labeling agricultural products that are "100 percent organic" or "organic." Products that are composed of wholly organic ingredients may be identified with the label statement, "100 percent organic," on any package panel. Products composed of between 95 and 100 percent organic ingredients may be identified with the label statement "organic" on any package panel, and the handler must identify each organic ingredient in the ingredient statement.
The handler may display the following information on the pdp, the information panel, and any other part of the package and in market information representing the product: (1) the term, "100 percent organic" or "organic," as applicable to the content of the product; and (2) for products labeled "organic," the percentage of organic ingredients in the product. The size of the percentage statement must not exceed one-half the size of the largest type size on the panel on which the statement is displayed. It also must appear in its entirety in the same type size, style, and color without highlighting; (3) the USDA seal; and (4) the seal, logo, or other identifying mark of the certifying agent (hereafter referred to as "seal or logo") which certified the handler of the finished product. The seals or logos of other certifying agents which certified organic raw materials or organic ingredients used in the product also may be displayed, at the discretion of the finished product handler. If multiple organic ingredients are identified on the ingredient statement, the handler of the finished product that combined the various organic ingredients must maintain documentation, pursuant to subpart B of this regulation.

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

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

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

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

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

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

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

Display of the "made with..." statement on other panels must be similarly consistent with the size of print used on those panels. These restrictions are in accordance with FDA labeling requirements and similar to the recommendations of the National Organic Standards Board (NOSB). This provision helps assure that the "made with..." statement is not displayed in such a manner as to misrepresent the actual organic composition of the product.
The USDA seal may not be displayed on the pdp of products labeled "made with organic ingredients." However, at the handler's option and consistent with any contract agreement between the organic producer or handler and the certifying agent, the certifying agent's seal or logo may be displayed on the pdp and other package panels.

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

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

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

**Labeling Products with Less Than 70 Percent Organic Ingredients**

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

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

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

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

**Misrepresentation in Labeling of Organic Products.**

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

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

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

Labeling Organically Produced Livestock Feed Products

Labeling of Products Shipped in International Markets

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

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

Labeling Nonretail Containers

Section 205.307 provides for labeling nonretail containers used to ship or store raw or processed organic
agricultural products that are labeled "100 percent organic," "organic," and "made with organic..." Labeling
nonretail containers as containing organically produced product should provide for easy identification of
the product to help prevent commingling with nonorganic product or handling of the product which would
destroy the organic nature of the product (fumigation, etc.). These labeling provisions are not intended for
shipping or storage containers that also are used in displays at the point of retail sale. Retail containers
must meet labeling provisions specified in section 205.307.

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

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

Labeling Products at the Point of Retail Sale
Section 205.308 applies to organically produced “100 percent organic” and “organic” products that are not packaged prior to sale and are presented in a manner which allows the consumer to select the quantity of the product purchased.

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

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

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

**Labeling Products Produced in Exempt or Excluded Operations**

Section 205.310 provides limited organic labeling provisions for organic product produced or handled on exempt and excluded operations. Such operations would include retail food establishments, certain manufacturing facilities, and production and handling operations with annual organic sales of less than $5,000. These operations are discussed more thoroughly in subpart B, Applicability.

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

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

**USDA Organic Seal**

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

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

**State Organic Programs**

The Act provides that each State may implement an organic program for agricultural products that have been produced and handled within the State, using organic methods that meet the requirements of the Act and these regulations. The Act further provides that a State organic program (SOP) may contain more restrictive requirements for organic products produced and handled within the State than are contained in the National Organic Program (NOP). All SOP's and subsequent amendments thereto must be approved by the Secretary.

A State may have an SOP but not have a State certifying agent. A State may have a State certifying agent but no SOP. Finally, a State may have an SOP and a State certifying agent. In all cases, the SOP's must be approved by the Secretary. In all cases, the State certifying agent must apply for and receive accreditation to certify organic production or handling operations pursuant to subpart F.

In States with an approved SOP, the SOP's governing State official is responsible for administering a compliance program for enforcement of the NOP and any more restrictive requirements contained in the SOP. The SOP governing State officials may review and investigate complaints of noncompliance involving organic production or handling operations operating within their State and, when appropriate, initiate suspension or revocation of certification. The SOP governing State officials may also review and investigate complaints of noncompliance involving accredited certifying agents operating within their State. They must report the findings of any review and investigation of a certifying agent to the NOP Program Manager along with any recommendations for appropriate action. States that do not have an SOP will not be responsible for compliance under the NOP, except that an accredited State certifying agent operating within such State will have compliance responsibilities under the NOP as a condition of its accreditation.

The sections covering SOP's, beginning with section 205.620, establish: (1) the requirements for an SOP and amending such a program and (2) the process for approval of an SOP and amendments to the SOP's. Review and approval of an SOP will occur not less than once during each 5-year period. Review related to compliance matters may occur at any time.

**Description of Regulations**

**State Organic Program Requirements**

A State may establish an SOP for production and handling operations within the State that produces and handles organic agricultural products. The SOP and supporting documentation must demonstrate that the SOP meets the requirements for organic programs specified in the Act.

An SOP may contain more restrictive requirements governing the production and handling of organic products within the State. Such requirements must be based on environmental conditions or specific production or handling practices particular to the State or region of the United States, which necessitates the more restrictive requirement. More restrictive requirements must be justified and shown to be consistent with and to further the purposes of the Act and the regulations in this part. Requirements necessitated by an environmental condition that is limited to a specific geographic area of the State should only be required of organic production and handling operations operating within the applicable geographic area. If approved by the Secretary, the more restrictive requirements will become the NOP regulations for organic producers and handlers in the State or applicable geographical area of the State. All USDA-accredited certifying agents planning to operate within a State with an SOP will be required to demonstrate their ability to comply with the SOP's more restrictive requirements.

No provision of an SOP shall discriminate against organic agricultural products produced by production or handling operations certified by certifying agents accredited or accepted by USDA pursuant to section
205.500. Specifically, an SOP may not discriminate against agricultural commodities organically produced in other States in accordance with the Act and the regulations in this part. Further, an SOP may not discriminate against agricultural commodities organically produced by production or handling operations certified by foreign certifying agents operating under: (1) standards determined by USDA to meet the requirements of this part or (2) an equivalency agreement negotiated between the United States and a foreign government.

To receive approval of its SOP, a State must assume enforcement obligations in the State for the requirements of this part and any more restrictive requirements included in the SOP and approved by the Secretary. Specifically, the State must ensure compliance with the Act, the regulations in this part, and the provisions of the SOP by certified production and handling operations operating within the State. The SOP must include compliance and appeals procedures equivalent to those provided for under the NOP.

An SOP and any amendments thereto must be approved by the Secretary prior to implementation by the State.

State Organic Program Approval Process

An SOP and subsequent amendments thereto must be submitted to the Secretary by the SOP's governing State official for approval prior to implementation. A request for approval of an SOP must contain supporting materials that include statutory authorities, program descriptions, documentation of environmental or ecological conditions or specific production and handling practices particular to the State which necessitate more restrictive requirements than the requirements of this part, and other information as may be required by the Secretary. A request for amendment of an approved SOP must contain supporting materials that include an explanation and documentation of the environmental or ecological conditions or specific production practices particular to the State or region, which necessitate the proposed amendment. Supporting material also must explain how the proposed amendment furthers and is consistent with the purposes of the Act and the regulations in this part.

Each request for approval of an SOP or amendment to an SOP and its supporting materials and documentation will be reviewed for compliance with the Act and these regulations. Within 6 months of receiving the request for approval, the Secretary will notify the SOP's governing State official of approval or disapproval. A disapproval will include the reasons for disapproval. A State receiving a notice of disapproval of its SOP or amendment to its SOP may submit a revised SOP or amendment to its SOP at any time.

Review of State Organic Programs

SOP's will be reviewed at least once every 5 years by the Secretary as required by section 6507(c)(1) of the Act. The Secretary will notify the SOP's governing State official of approval or disapproval of the program within 6 months after initiation of the review.

Inspection and Testing, Reporting, and Exclusion from Sale

This portion of subpart G sets forth the inspection and testing requirements for agricultural products that have been produced on organic production operations or handled through organic handling operations.

Residue testing plays an important role in organic certification by providing a means for monitoring compliance with the National Organic Program (NOP) and by discouraging the mislabeling of agricultural products. This testing program provides State organic programs' (SOP) governing State officials and certifying agents with a tool for ensuring compliance with three areas for testing: (1) preharvest residue testing, (2) postharvest residue testing, and (3) testing for unavoidable residual environmental contamination levels.

Description of Regulations

General Requirements

Under the residue testing requirements of the NOP, all agricultural products sold, labeled, or represented as organically produced must be available for inspection by the Administrator, SOP's governing State official, or certifying agent. Organic farms and handling operations must be made available for inspection under subpart E, Certification. In addition, products from the aforementioned organic operations may be
required by the SOP's governing State official or certifying agent to undergo preharvest or postharvest testing when there is reason to believe that agricultural inputs used in organic agriculture production or agricultural products to be sold or labeled as organically produced have come into contact with prohibited substances or have been produced using excluded methods. The cost of such testing will be borne by the applicable certifying agent and is considered a cost of doing business. Accordingly, certifying agents should make provisions for the cost of preharvest or postharvest residue testing when structuring certification fees.

**Preharvest and Postharvest Residue Testing**

The main objectives of the residue testing program are to: (1) ensure that certified organic production and handling operations are in compliance with the requirements set forth in this final rule and (2) serve as a means for monitoring drift and unavoidable residue contamination of agricultural products to be sold or labeled as organically produced. Any detectable residues of a prohibited substance or a product produced using excluded methods found in or on samples during analysis will serve as a warning indicator to the certifying agent.

The Administrator, SOP's governing State official, or certifying agent may require preharvest or postharvest testing of any agricultural input used in organic agricultural production or any agricultural product to be sold or labeled as "100 percent organic," "organic," or "made with organic (specified ingredients or food group(s))." It is based on the Administrator's, SOP's governing State official's, or certifying agent's belief that an agricultural product or agricultural input has come into contact with one or more prohibited substances or has been produced using excluded methods. Certifying agents do not have to conduct residue tests if they do not have reason to believe that there is a need for testing. Certifying agents must ensure, however, that certified organic operations are operating in accordance with the Act and the regulations set forth in this part.

The "reason to believe" could be triggered by various situations, for example: (1) the applicable authority receiving a formal, written complaint regarding the practices of a certified organic operation; (2) an open container of a prohibited substance found on the premises of a certified organic operation; (3) the proximity of a certified organic operation to a potential source of drift; (4) suspected soil contamination by historically persistent substances; or (5) the product from a certified organic operation being unaffected when neighboring fields or crops are infested with pests. These situations do not represent all of the possible occurrences that would trigger an investigation. Preharvest or postharvest residue testing will occur on a case-by-case basis.

In each case, an inspector representing the Administrator, SOP's governing State official, or certifying agent or will conduct sampling. According to subpart F, Accreditation, private or State entities accredited as certifying agents under the NOP must ensure that its responsibly connected persons, employees, and contractors with inspection, analysis, and decision-making responsibilities have sufficient expertise to successfully perform the duties assigned. Therefore, all inspectors employed by certifying agents to conduct sampling must have sufficient expertise in methods of chain-of-custody sampling. Moreover, testing for chemical residues must be performed in an accredited laboratory. When conducting chemical analyses, the laboratory must incorporate the analytical methods described in the most current edition of the Official Methods of Analysis of the AOAC International or other current applicable validated methodology for determining the presence of contaminants in agricultural products. Results of all analyses and tests performed under section 205.670 must be promptly provided to the Administrator, except that, where an SOP exists, all test results and analyses should be provided to the SOP's governing State official by the applicable certifying party that requested testing. Residue test results and analyses must also be, according to section 205.403(e)(2), provided to the owner of the certified organic operation whose product was tested. All other parties desiring to obtain such information must request it from the applicable certifying agent.

OFPA requires certifying agents, to the extent of their awareness, to report violations of applicable laws relating to food safety to appropriate health agencies such as EPA and FDA. When residue testing indicates that an agricultural product contains pesticide residues or environmental contaminants that exceed either the EPA tolerance level or FDA action level, as applicable, the certifying agent must promptly report data revealing such information to the Federal agency whose regulatory tolerance or action level has been exceeded.
Residue Testing and Monitoring Tools

When testing indicates that an agricultural product to be sold or labeled as organically produced contains residues of prohibited substances, certifying agents will compare the level of detected residues with 5 percent of the Environmental Protection Agency (EPA) tolerance for the specific residue detected on the agricultural product intended to be sold as organically produced. This compliance measure, 5 percent of EPA tolerance for the detected prohibited residue, will serve as a standard for the Administrator, SOP's governing State officials, and certifying agents to assist in monitoring for illegal use violations.

In addition, we intend to establish levels of unavoidable residual environmental contamination (UREC) for crop-and site-specific agricultural commodities to be sold, labeled, or represented as "100 percent organic," "organic," or "made with..." These levels will represent limits at which USDA may take compliance action to suspend the use of a contaminated area for organic agricultural production. Currently, USDA is seeking scientifically sound principles and measures by which it can establish UREC levels to most effectively address issues of unavoidable residual environmental contamination with respect to this rule. However, in the interim, UREC will be defined as the Food and Drug Administration's (FDA) action levels for poisonous or deleterious substances in human food or animal feed. UREC levels will be initially set for persistent prohibited substances (aldrin, dieldrin, chlordane, DDE, etc.) in the environment. They may become more inclusive of prohibited residues as additional information becomes available. Unavoidable residual environmental contamination levels will be based on the unavoidability of the chemical substances and do not represent permissible levels of contamination where it is avoidable.

Analyses and test results will be available for public access unless the residue testing is part of an ongoing compliance investigation. Information relative to an ongoing compliance investigation will be confidential and restricted to the public.

Detection of Prohibited Substances or Products Derived from Excluded Methods

In the case of residue testing and the detection of prohibited substances in or on agricultural products to be sold, labeled, or represented as "100 percent organic," "organic," or "made with..." products with detectable residues of prohibited substances that exceed 5 percent of the EPA tolerance for the specific residue or UREC cannot be sold or labeled as organically produced. When such an agricultural crop is in violation of these requirements, the certification of that crop will be suspended for the period that the crop is in production. Certifying agents must follow the requirements specified in sections 205.662 and 205.663 of subpart G, Compliance.

The "5 percent of EPA tolerance" standard is considered a level above which an agricultural product cannot be sold as organic, regardless of how the product may have come into contact with a potential prohibited substance. This standard has been established to: (1) satisfy consumer expectations that organic agricultural products will contain minimal chemical residues and (2) respond to the organic industry's request to implement a standard comparable to current industry practices. However, the "5 percent of EPA tolerance" standard cannot be used to automatically qualify agricultural products as organically produced, even if the level of chemical residues detected on an agricultural product is below 5 percent of the EPA tolerance for the respective prohibited substance. This final rule is a comprehensive set of standards and regulations that determines whether a product can or cannot be considered to carry the specified organic labeling terms in subpart D, Labeling. Therefore, in addition to this section of subpart G, Administrative, all other requirements of this part must be met by certified organic operations to have an agricultural product considered "organically produced."

When residue testing detects the presence of any prohibited substance, whether above or below 5 percent of the EPA tolerance for the specific pesticide or UREC, the SOP's governing State official or certifying agent may conduct an investigation of the certified organic operation to determine the cause of the prohibited substance or product in or on the agricultural product to be sold or labeled as organically produced. The same shall occur if testing detects a product produced using excluded methods. If the investigation reveals that the presence of the prohibited substance or product produced using excluded methods in or on an agricultural product intended to be sold as organically produced is the result of an intentional application of a prohibited substance or use of excluded methods, the certified organic operation shall be subject to suspension or revocation of its organic certification. In addition, any person
who knowingly sells, labels, or represents an agricultural product as organically produced in violation of the Act or these regulations shall be subject to a civil penalty of not more than $10,000 per violation.

Emergency Pest or Disease Treatment Programs

When a prohibited substance is applied to an organic production or handling operation due to a Federal or State emergency pest or disease treatment program and the organic handling or production operation otherwise meets the requirements of this final rule, the certification status of the operation shall not be affected as a result of the application of the prohibited substance, except that: (1) any harvested crop or plant part to be harvested that has contact with a prohibited substance applied as the result of a Federal or State emergency pest or disease treatment program cannot be sold, labeled, or represented as “100 percent organic,” “organic,” or “made with...” and (2) any livestock that are treated with a prohibited substance applied as the result of a Federal or State emergency pest or disease treatment program or product derived from such treated livestock cannot be sold, labeled, or represented as “100 percent organic,” “organic,” or “made with...”

However, milk or milk products may be labeled or sold as organically produced beginning 12 months following the last date that the dairy animal was treated with the prohibited substance. Additionally, the offspring of gestating mammalian breeder stock treated with a prohibited substance may be considered organic if the breeder stock was not in the last third of gestation on the date that the breeder stock was treated with the prohibited substance.

Subpart G - Fees

This portion of subpart G sets forth the regulations on fees and other charges to be assessed for accreditation and certification services under the National Organic Program (NOP). These regulations address the kinds of fees and charges to be assessed by the U.S. Department of Agriculture (USDA) for the accreditation of certifying agents, the level of such fees and charges, and the payment of such fees and charges. These regulations also address general requirements to be met by certifying agents in assessing fees and other charges for the certification of producers and handlers as certified organic operations. Finally, these regulations address the Secretary's oversight of a certifying agent's fees and charges for certification services.

Description of Regulation

Fees and Other Charges for Accreditation

Fees and other charges will be assessed and collected from applicants for initial accreditation and accredited certifying agents submitting annual reports or seeking renewal of accreditation. Such fees will be equal as nearly as may be to the cost of the accreditation services rendered under these regulations. Fees-for-service will be based on the time required to render the service provided calculated to the nearest 15-minute period. Activities to be billed on the basis of time used include the review of applications and accompanying documents and information, evaluator travel, the conduct of on-site evaluations, review of annual reports and updated documents and information, and the preparation of reports and any other documents in connection with the performance of service. The hourly rate will be the same as that charged by the Agricultural Marketing Service (AMS), through its Quality System Certification Program, to certification bodies requesting conformity assessment to the International Organization for Standardization "General Requirements for Bodies Operating Product Certification Systems" (ISO Guide 65).

Applicants for initial accreditation and accredited certifying agents submitting annual reports or seeking renewal of accreditation during the first 18 months following the effective date of subpart F will receive service without incurring an hourly charge for such service.

Applicants for initial accreditation and renewal of accreditation must pay at the time of application, effective 18 months following the effective date of subpart F, a nonrefundable fee of $500.00. This fee will be applied to the applicant's fees-for-service account.

When service is requested at a place so distant from the evaluator's headquarters that a total of one-half hour or more is required for the evaluator(s) to travel to such a place and back to the headquarters or from a place of prior assignment on circuitous routing requiring a total of one-half hour or more to travel to
the next place of assignment on the circuitous routing, the charge for such service will include all applicable travel charges. Travel charges may include a mileage charge administratively determined by USDA, travel tolls, or, when the travel is made by public transportation (including hired vehicles), a fee equal to the actual cost thereof. If the service is provided on a circuitous routing, the travel charges will be prorated among all the applicants and certifying agents furnished the service involved. Travel charges will become effective for all applicants for initial accreditation and accredited certifying agents on the effective date of subpart F. The applicant or certifying agent will not be charged a new mileage rate without notification before the service is rendered.

When service is requested at a place away from the evaluator's headquarters, the fee for such service shall include a per diem charge if the employee(s) performing the service is paid per diem in accordance with existing travel regulations. Per diem charges to applicants and certifying agents will cover the same period of time for which the evaluator(s) receives per diem reimbursement. The per diem rate will be administratively determined by USDA. Per diem charges shall become effective for all applicants for initial accreditation and accredited certifying agents on the effective date of subpart F. The applicant or certifying agent will not be charged a new per diem rate without notification before the service is rendered.

When costs, other than fees-for-service, travel charges, and per diem charges, are associated with providing the services, the applicant or certifying agent will be charged for these costs. Such costs include but are not limited to equipment rental, photocopying, delivery, facsimile, telephone, or translation charges incurred in association with accreditation services. The amount of the costs charged will be determined administratively by USDA. Such costs will become effective for all applicants for initial accreditation and accredited certifying agents on the effective date of subpart F.

**Payment of Fees and Other Charges**

Applicants for initial accreditation and renewal of accreditation must remit the nonrefundable fee along with their application. Remittance must be made payable to the Agricultural Marketing Service, USDA, and mailed to: Program Manager, USDA-AMS-TMP-NOP, Room 2945-South Building, P.O. Box 96456, Washington, DC 20090-6456 or such other address as required by the Program Manager. All other payments for fees and other charges must be received by the due date shown on the bill for collection, made payable to the Agricultural Marketing Service, USDA, and mailed to the address provided on the bill for collection. The Administrator will assess interest, penalties, and administrative costs on debts not paid by the due date shown on a bill for collection and collect delinquent debts or refer such debts to the Department of Justice for litigation.

**Fees and Other Charges for Certification**

Fees charged by a certifying agent must be reasonable, and a certifying agent may charge applicants for certification and certified production and handling operations only those fees and charges that it has filed with the Administrator. The certifying agent must provide each applicant with an estimate of the total cost of certification and an estimate of the annual cost of updating the certification. The certifying agent may require applicants for certification to pay at the time of application a nonrefundable fee that must be applied to the applicant's fees-for-service account. A certifying agent may set the nonrefundable portion of certification fees; however, the nonrefundable portion of certification fees must be explained in the fee schedule submitted to the Administrator. The fee schedule must explain what fee amounts are nonrefundable and at what stage during the certification process the respective fees become nonrefundable. The certifying agent must provide all persons inquiring about the application process with a copy of its fee schedule.
Evaluation criteria for allowed and prohibited substances, methods, and ingredients.

The following criteria will be utilized in the evaluation of substances or ingredients for the organic production and handling sections of the National List:

(a) Synthetic and nonsynthetic substances considered for inclusion on or deletion from the National List of allowed and prohibited substances will be evaluated using the criteria specified in the Act (7 U.S.C. 6517 and 6518).

(b) In addition to the criteria set forth in the Act, any synthetic substance used as a processing aid or adjuvant will be evaluated against the following criteria:

(1) The substance cannot be produced from a natural source and there are no organic substitutes;

(2) The substance's manufacture, use, and disposal do not have adverse effects on the environment and are done in a manner compatible with organic handling;

(3) The nutritional quality of the food is maintained when the substance is used, and the substance, itself, or its breakdown products do not have an adverse effect on human health as defined by applicable Federal regulations;

(4) The substance's primary use is not as a preservative or to recreate or improve flavors, colors, textures, or nutritive value lost during processing, except where the replacement of nutrients is required by law;

(5) The substance is listed as generally recognized as safe (GRAS) by Food and Drug Administration (FDA) when used in accordance with FDA's good manufacturing practices (GMP) and contains no residues of heavy metals or other contaminants in excess of tolerances set by FDA; and

(6) The substance is essential for the handling of organically produced agricultural products.

(c) Nonsynthetics used in organic processing will be evaluated using the criteria specified in the Act (7 U.S.C. 6517 and 6518).

Synthetic substances allowed for use in organic crop production.

In accordance with restrictions specified in this section, the following synthetic substances may be used in organic crop production: Provided, That, use of such substances do not contribute to contamination of crops, soil, or water. Substances allowed by this section, except disinfectants and sanitizers in paragraph (a) and those substances in paragraphs (c), (j), (k), and (l) of this section, may only be used when the provisions set forth in §205.206(a) through (d) prove insufficient to prevent or control the target pest.

(a) As algicide, disinfectants, and sanitizer, including irrigation system cleaning systems.

(1) Alcohols.

(i) Ethanol.

(ii) Isopropanol.

(2) Chlorine materials—Except, That, residual chlorine levels in the water shall not exceed the maximum residual disinfectant limit under the Safe Drinking Water Act.

(i) Calcium hypochlorite.

(ii) Chlorine dioxide.

(iii) Sodium hypochlorite.

(3) Copper sulfate—for use as an algicide in aquatic rice systems, is limited to one application per field during any 24-month period. Application rates are limited to those which do not increase baseline soil test values for copper over a timeframe agreed upon by the producer and accredited certifying agent.

(4) Hydrogen peroxide.

(5) Ozone gas—for use as an irrigation system cleaner only.
(6) Peracetic acid—for use in disinfecting equipment, seed, and asexually propagated planting material.

(7) Soap-based algicide/demossers.

(b) As herbicides, weed barriers, as applicable.

(1) Herbicides, soap-based—for use in farmstead maintenance (roadways, ditches, right of ways, building perimeters) and ornamental crops.

(2) Mulches.

(i) Newspaper or other recycled paper, without glossy or colored inks.

(ii) Plastic mulch and covers (petroleum-based other than polyvinyl chloride (PVC)).

(c) As compost feedstocks—Newspapers or other recycled paper, without glossy or colored inks.

(d) As animal repellents—Soaps, ammonium—for use as a large animal repellant only, no contact with soil or edible portion of crop.

(e) As insecticides (including acaricides or mite control).

(1) Ammonium carbonate—for use as bait in insect traps only, no direct contact with crop or soil.

(2) Boric acid—structural pest control, no direct contact with organic food or crops.

(3) Copper sulfate—for use as tadpole shrimp control in aquatic rice production, is limited to one application per field during any 24-month period. Application rates are limited to levels which do not increase baseline soil test values for copper over a timeframe agreed upon by the producer and accredited certifying agent.

(4) Elemental sulfur.

(5) Lime sulfur—including calcium polysulfide.

(6) Oils, horticultural—narrow range oils as dormant, suffocating, and summer oils.

(7) Soaps, insecticidal.

(8) Sticky traps/barriers.

(9) Sucrose octanoate esters (CAS #s—42922–74–7; 58064–47–4)—in accordance with approved labeling.

(f) As insect management. Pheromones.

(g) As rodenticides.

(1) Sulfur dioxide—underground rodent control only (smoke bombs).

(2) Vitamin D₃.

(h) As slug or snail bait. Ferric phosphate (CAS # 10045–86–0).

(i) As plant disease control.

(1) Coppers, fixed—copper hydroxide, copper oxide, copper oxycholoride, includes products exempted from EPA tolerance, Provided, That, copper-based materials must be used in a manner that minimizes accumulation in the soil and shall not be used as herbicides.

(2) Copper sulfate—Substance must be used in a manner that minimizes accumulation of copper in the soil.

(3) Hydrated lime.

(4) Hydrogen peroxide.

(5) Lime sulfur.

(6) Oils, horticultural, narrow range oils as dormant, suffocating, and summer oils.
(7) Peracetic acid—for use to control fire blight bacteria.
(8) Potassium bicarbonate.
(9) Elemental sulfur.
(10) Streptomycin, for fire blight control in apples and pears only.
(11) Tetracycline (oxytetracycline calcium complex), for fire blight control only.
(j) As plant or soil amendments.
(1) Aquatic plant extracts (other than hydrolyzed)—Extraction process is limited to the use of potassium hydroxide or sodium hydroxide; solvent amount used is limited to that amount necessary for extraction.
(2) Elemental sulfur.
(3) Humic acids—naturally occurring deposits, water and alkali extracts only.
(4) Lignin sulfonate—chelating agent, dust suppressant, floatation agent.
(5) Magnesium sulfate—allowed with a documented soil deficiency.
(6) Micronutrients—not to be used as a defoliant, herbicide, or desiccant. Those made from nitrates or chlorides are not allowed. Soil deficiency must be documented by testing.
(i) Soluble boron products.
(ii) Sulfates, carbonates, oxides, or silicates of zinc, copper, iron, manganese, molybdenum, selenium, and cobalt.
(7) Liquid fish products—can be pH adjusted with sulfuric, citric or phosphoric acid. The amount of acid used shall not exceed the minimum needed to lower the pH to 3.5.
(8) Vitamins, B₁, C, and E.
(k) As plant growth regulators. Ethylene gas—for regulation of pineapple flowering.
(l) As floating agents in postharvest handling.
(1) Lignin sulfonate.
(2) Sodium silicate—for tree fruit and fiber processing.
(m) As synthetic inert ingredients as classified by the Environmental Protection Agency (EPA), for use with nonsynthetic substances or synthetic substances listed in this section and used as an active pesticide ingredient in accordance with any limitations on the use of such substances.
(1) EPA List 4—Inerts of Minimal Concern.
(2) EPA List 3—Inerts of Unknown Toxicity allowed:
(i) Glycerine Oleate (Glycerol monooleate) (CAS #s 37220–82–9)—for use only until December 31, 2006.
(ii) Inerts used in passive pheromone dispensers.
(n) Seed preparations. Hydrogen chloride (CAS # 7647–01–0)—for delinting cotton seed for planting.
(o)–(z) [Reserved]

**Nonsynthetic substances prohibited for use in organic crop production.**
The following nonsynthetic substances may not be used in organic crop production:
(a) Ash from manure burning.
(b) Arsenic.
(c) Calcium chloride, brine process is natural and prohibited for use except as a foliar spray to treat a physiological disorder associated with calcium uptake.

(d) Lead salts.

(e) Potassium chloride—unless derived from a mined source and applied in a manner that minimizes chloride accumulation in the soil.

(f) Sodium fluoaluminate (mined).

(g) Sodium nitrate—unless use is restricted to no more than 20% of the crop's total nitrogen requirement; use in spirulina production is unrestricted until October 21, 2005.

(h) Strychnine.

(i) Tobacco dust (nicotine sulfate).

(j)–(z) [Reserved]

Synthetic substances allowed for use in organic livestock production.

[Deleted]

Nonsynthetic substances prohibited for use in organic livestock production.

[Deleted]

The following nonagricultural substances may be used as ingredients in or on processed products labeled as “organic” or “made with organic (specified ingredients or food group(s))” only in accordance with any restrictions specified in this section.

(a) Nonsynthetics allowed:

Acids (Alginic; Citric—produced by microbial fermentation of carbohydrate substances; and Lactic).

Agar-agar.

Animal enzymes—(Rennet—animals derived; Catalase—bovine liver; Animal lipase; Pancreatin; Pepsin; and Trypsin).

Bentonite.

Calcium carbonate.

Calcium chloride.

Calcium sulfate—mined.

Carageenan.

Dairy cultures.

Diatomaceous earth—food filtering aid only.

Egg white lysozyme (CAS # 9001–63–2)

Enzymes—must be derived from edible, nontoxic plants, nonpathogenic fungi, or nonpathogenic bacteria.

Flavors, nonsynthetic sources only and must not be produced using synthetic solvents and carrier systems or any artificial preservative.

Glucono delta-lactone—production by the oxidation of D-glucose with bromine water is prohibited.

Kaolin.

L-Malic acid (CAS # 97–67–6).

Magnesium sulfate, nonsynthetic sources only.

Microorganisms—any food grade bacteria, fungi, and other microorganism.
Nitrogen—oil-free grades.
Oxygen—oil-free grades.
Perlite—for use only as a filter aid in food processing.
Potassium chloride.
Potassium iodide.
Sodium bicarbonate.
Sodium carbonate.
Tartaric acid.
Waxes—nonsynthetic (Carnauba wax; and Wood resin).
Yeast—nonsynthetic, growth on petrochemical substrate and sulfite waste liquor is prohibited (Autolysate; Bakers; Brewers; Nutritional; and Smoked—nonsynthetic smoke flavoring process must be documented).

(b) *Synthetics allowed:*
Activated charcoal (CAS #s 7440–44–0; 64365–11–3)—only from vegetative sources; for use only as a filtering aid.
Alginates.
Ammonium bicarbonate—for use only as a leavening agent.
Ammonium carbonate—for use only as a leavening agent.
Ascorbic acid.
Calcium citrate.
Calcium hydroxide.
Calcium phosphates (monobasic, dibasic, and tribasic).
Carbon dioxide.
Cellulose—for use in regenerative casings, as an anti-caking agent (non-chlorine bleached) and filtering aid.
Chlorine materials—disinfecting and sanitizing food contact surfaces, *Except,* That, residual chlorine levels in the water shall not exceed the maximum residual disinfectant limit under the Safe Drinking Water Act (Calcium hypochlorite; Chlorine dioxide; and Sodium hypochlorite).
Cyclohexylamine (CAS # 108–91–8)—for use only as a boiler water additive for packaging sterilization.
Diethylaminoethanol (CAS # 100–37–8)—for use only as a boiler water additive for packaging sterilization.
Ethylene—allowed for postharvest ripening of tropical fruit and degreening of citrus.
Ferrous sulfate—for iron enrichment or fortification of foods when required by regulation or recommended (independent organization).
Glycerides (mono and di)—for use only in drum drying of food.
Glycerin—produced by hydrolysis of fats and oils.
Hydrogen peroxide.
Lecithin—bleached.
Magnesium carbonate—for use only in agricultural products labeled “made with organic (specified ingredients or food group(s)),” prohibited in agricultural products labeled “organic”.
Magnesium chloride—derived from sea water.
Magnesium stearate—for use only in agricultural products labeled “made with organic (specified ingredients or food group(s)),” prohibited in agricultural products labeled “organic”.

Nutrient vitamins and minerals, in accordance with 21 CFR 104.20, Nutritional Quality Guidelines For Foods.

Octadecylamine (CAS # 124–30–1)—for use only as a boiler water additive for packaging sterilization.

Ozone.

Pectin (low-methoxy).

Peracetic acid/Peroxyacetic acid (CAS # 79–21–0)—for use in wash and/or rinse water according to FDA limitations. For use as a sanitizer on food contact surfaces.

Phosphoric acid—cleaning of food-contact surfaces and equipment only.

Potassium acid tartrate.

Potassium carbonate.

Potassium citrate.

Potassium hydroxide—prohibited for use in lye peeling of fruits and vegetables except when used for peeling peaches during the Individually Quick Frozen (IQF) production process.

Potassium iodide—for use only in agricultural products labeled “made with organic (specified ingredients or food group(s)),” prohibited in agricultural products labeled “organic”.

Potassium phosphate—for use only in agricultural products labeled “made with organic (specified ingredients or food group(s)),” prohibited in agricultural products labeled “organic”.

Silicon dioxide.

Sodium acid pyrophosphate (CAS # 7758–16–9)—for use only as a leavening agent.

Sodium citrate.

Sodium hydroxide—prohibited for use in lye peeling of fruits and vegetables.

Sodium phosphates—for use only in dairy foods.

Sulfur dioxide—for use only in wine labeled “made with organic grapes,” Provided, That, total sulfite concentration does not exceed 100 ppm.

Tartaric acid.

Tetrasodium pyrophosphate (CAS # 7722–88–5)—for use only in meat analog products.

Tocopherols—derived from vegetable oil when rosemary extracts are not a suitable alternative.

Xanthan gum.

Nonorganically produced agricultural products allowed as ingredients in or on processed products labeled as “organic.”

Only the following nonorganically produced agricultural products may be used as ingredients in or on processed products labeled as “organic,” only in accordance with any restrictions specified in this section, and only when the product is not commercially available in organic form.

(a) Casings, from processed intestines.

(b) Celery powder.

(c) Chia (Salvia hispanica L.).

(d) Colors derived from agricultural products.

(1) Annatto extract color (pigment CAS # 1393–63–1)—water and oil soluble.
(2) Beet juice extract color (pigment CAS # 7659–95–2).
(3) Beta-carotene extract color, derived from carrots (CAS # 1393–63–1).
(7) Carrot juice color (pigment CAS # 1393–63–1).
(13) Paprika color (CAS # 68917–78–2)—dried, and oil extracted.
(14) Pumpkin juice color (pigment CAS # 127–40–2).
(18) Saffron extract color (pigment CAS # 1393–63–1).
(e) Dillweed oil (CAS # 8006–75–5).
(f) Fish oil (Fatty acid CAS #'s: 10417–94–4, and 25167–62–8)—stabilized with organic ingredients or only with ingredients on the National List, §§205.605 and 205.606.
(g) Fructooligosaccharides (CAS # 308066–66–2).
(h) Galangal, frozen.
(i) Gelatin (CAS # 9000–70–8).
(j) Gums—water extracted only (Arabic; Guar; Locust bean; and Carob bean).
(k) Hops (Humulus luplus).
(l) Inulin-oligofructose enriched (CAS # 9005–80–5).
(m) Kelp—for use only as a thickener and dietary supplement.
(n) Konjac flour (CAS # 37220–17–0).
(o) Lecithin—unbleached.
(p) Lemongrass—frozen.
(q) Orange shellac-unbleached (CAS # 9000–59–3).
(r) Pectin (high-methoxy).
(s) Peppers (Chipotle chile).
(t) Starches.
(1) Cornstarch (native).
(2) Rice starch, unmodified (CAS # 977000–08–0)—for use in organic handling until June 21, 2009.
(3) Sweet potato starch—for bean thread production only.
(u) Turkish bay leaves.
(v) Wakame seaweed (Undaria pinnatifida).
(w) Whey protein concentrate.