

The Abridged USDA National Organic Program Regulation: Standards Applicable to Production Operations

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Subpart A—Definitions

§ 205.1 Meaning of words.

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

§ 205.2 Terms defined.

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

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

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

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

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

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

Agricultural Marketing Service (AMS). The Agricultural Marketing Service of the United States Department of Agriculture.

Allowed synthetic. A substance that is included on the National List of synthetic substances allowed for use in organic production or handling.

AMDUCA . The Animal Medicinal Drug Use Clarification Act of 1994 (Pub. L. 103–396).

Animal drug. Any drug as defined in section 201 of the Federal Food, Drug, and Cosmetic Act, as amended (21 U.S.C. 321), that is intended for use in livestock, including any drug intended for use in livestock feed but not including such livestock feed.

Annual seedling. A plant grown from seed that will complete its life cycle or produce a harvestable yield within the same crop year or season in which it was planted.

Area of operation. The types of operations: crops, livestock, wild-crop harvesting or handling, or any combination thereof that a certifying agent may be accredited to certify under this part.

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

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

Biologics. All viruses, serums, toxins, and analogous products of natural or synthetic origin, such as diagnostics, antitoxins, vaccines, live microorganisms, killed microorganisms, and the antigenic or immunizing components of microorganisms intended for use in the diagnosis, treatment, or prevention of diseases of animals.

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

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

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

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

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

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

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

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

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

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

Compost. The product of a managed process through which microorganisms break down plant and animal materials into more available forms suitable for application to the soil. Compost must be produced through a process that combines plant and animal materials with an initial C:N ratio of between 25:1 and 40:1. Producers using an in-vessel or static aerated pile system must maintain the composting materials at a temperature between 131 °F and 170 °F for 3 days. Producers using a windrow system must maintain the composting materials at a temperature between 131 °F and 170 °F for 15 days, during which time, the materials must be turned a minimum of five times.

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

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

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

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

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

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

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

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

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

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

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

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

Excipients . Any ingredients that are intentionally added to livestock medications but do not exert therapeutic or diagnostic effects at the intended dosage, although they may act to improve product delivery (e.g., enhancing absorption or controlling release of the drug substance). Examples of such ingredients include fillers, extenders, diluents, wetting agents, solvents, emulsifiers, preservatives, flavors, absorption enhancers, sustained-release matrices, and coloring agents.

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

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

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

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

(1) Diluted with other feeds when fed to livestock;

(2) Offered free choice with other parts of the ration if separately available; or

(3) Further diluted and mixed to produce a complete feed.

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

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

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

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

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

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

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

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

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

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

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

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

Inspection. The act of examining and evaluating the production or handling operation of an applicant for certification or certified operation to determine compliance with the Act and the regulations in this part.

Inspector. Any person retained or used by a certifying agent to conduct inspections of certification applicants or certified production or handling operations.

Label. A display of written, printed, or graphic material on the immediate container of an agricultural product or any such material affixed to any agricultural product or affixed to a bulk container containing an agricultural product, except for package liners or a display of written, printed, or graphic material which contains only information about the weight of the product.

Labeling. All written, printed, or graphic material accompanying an agricultural product at any time or written, printed, or graphic material about the agricultural product displayed at retail stores about the product.

Livestock. Any cattle, sheep, goat, swine, poultry, or equine animals used for food or in the production of food, fiber, feed, or other agricultural-based consumer products; wild or domesticated game; or other nonplant life, except such term shall not include aquatic animals or bees for the production of food, fiber, feed, or other agricultural-based consumer products.

Lot. Any number of containers which contain an agricultural product of the same kind located in the same conveyance, warehouse, or packing house and which are available for inspection at the same time.

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

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

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

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

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

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

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

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

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

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

Nonretail container. Any container used for shipping or storage of an agricultural product that is not used in the retail display or sale of the product.

Nontoxic. Not known to cause any adverse physiological effects in animals, plants, humans, or the environment.

Organic. A labeling term that refers to an agricultural product produced in accordance with the Act and the regulations in this part.

Organic matter. The remains, residues, or waste products of any organism.

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

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

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

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

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

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

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

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

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

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

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

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

Processing aid. (1) Substance that is added to a food during the processing of such food but is removed in some manner from the food before it is packaged in its finished form;

(2) a substance that is added to a food during processing, is converted into constituents normally present in the food, and does not significantly increase the amount of the constituents naturally found in the food; and

(3) a substance that is added to a food for its technical or functional effect in the processing but is present in the finished food at insignificant levels and does not have any technical or functional effect in that food.

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

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

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

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

Residue testing. An official or validated analytical procedure that detects, identifies, and measures the presence of chemical substances, their metabolites, or degradation products in or on raw or processed agricultural products.

Responsibly connected. Any person who is a partner, officer, director, holder, manager, or owner of 10 percent or more of the voting stock of an applicant or a recipient of certification or accreditation.

Retail food establishment. A restaurant; delicatessen; bakery; grocery store; or any retail outlet with an in-store restaurant, delicatessen, bakery, salad bar, or other eat-in or carry-out service of processed or prepared raw and ready-to-eat-food.

Routine use of parasiticide. The regular, planned, or periodic use of parasiticides.

Secretary. The Secretary of Agriculture or a representative to whom authority has been delegated to act in the Secretary's stead.

Sewage sludge. A solid, semisolid, or liquid residue generated during the treatment of domestic sewage in a treatment works. Sewage sludge includes but is not limited to: domestic septage; scum or solids removed in primary, secondary, or advanced wastewater treatment processes; and a material derived from sewage sludge. Sewage sludge does not include ash generated during the firing of sewage sludge in a sewage sludge incinerator or grit and screenings generated during preliminary treatment of domestic sewage in a treatment works.

Slaughter stock. Any animal that is intended to be slaughtered for consumption by humans or other animals.

Soil and water quality. Observable indicators of the physical, chemical, or biological condition of soil and water, including the presence of environmental contaminants.

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

State. Any of the several States of the United States of America, its territories, the District of Columbia, and the Commonwealth of Puerto Rico.

State certifying agent. A certifying agent accredited by the Secretary under the National Organic Program and operated by the State for the purposes of certifying organic production and handling operations in the State.

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

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

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

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

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

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

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

[65 FR 80637, Dec. 21, 2000, as amended at 72 FR 70484, Dec. 12, 2007]

Subpart B—Applicability

§ 205.100 What has to be certified.

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

(b) Any production or handling operation or specified portion of a production or handling operation that has been already certified by a certifying agent on the date that the certifying agent receives its accreditation under this part shall be deemed to be certified under the Act until the operation's next anniversary date of certification. Such recognition shall only be available to those operations certified by a certifying agent that receives its accreditation within 18 months from February 20, 2001.

(c) Any operation that:

(1) Knowingly sells or labels a product as organic, except in accordance with the Act, shall be subject to a civil penalty of not more than 3.91(b)(1)(xxxvii) of this title per violation.

(2) Makes a false statement under the Act to the Secretary, a governing State official, or an accredited certifying agent shall be subject to the provisions of section 1001 of title 18, United States Code.

[65 FR 80637, Dec. 21, 2000, as amended at 70 FR 29579, May 24, 2005]

§ 205.101 Exemptions and exclusions from certification.

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

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

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

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

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

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

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

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

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

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

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

(i) Are packaged or otherwise enclosed in a container prior to being received or acquired by the operation; and

(ii) Remain in the same package or container and are not otherwise processed while in the control of the handling operation.

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

(i) The requirements for the prevention of contact with prohibited substances as set forth in §205.272; and

(ii) The labeling provisions of §205.310.

(c) Records to be maintained by exempt operations. (1) Any handling operation exempt from certification pursuant to paragraph (a)(3) or (a)(4) of this section must maintain records sufficient to:

(i) Prove that ingredients identified as organic were organically produced and handled; and

(ii) Verify quantities produced from such ingredients.

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

§ 205.102 Use of the term, “organic.”

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

(a) Produced in accordance with the requirements specified in §205.101 or §§205.202 through 205.207 or §§205.236 through 205.240 and all other applicable requirements of part 205; and

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

§ 205.103 Recordkeeping by certified operations.

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

(b) Such records must:

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

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

§ 205.104 [Reserved]

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

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

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

§§ 205.106-205.199 [Reserved]

Subpart C—Organic Production and Handling Requirements

§ 205.200 General.

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

§ 205.201 Organic production and handling system plan.

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

- (1) A description of practices and procedures to be performed and maintained, including the frequency with which they will be performed;
 - (2) A list of each substance to be used as a production or handling input, indicating its composition, source, location(s) where it will be used, and documentation of commercial availability, as applicable;
 - (3) A description of the monitoring practices and procedures to be performed and maintained, including the frequency with which they will be performed, to verify that the plan is effectively implemented;
 - (4) A description of the recordkeeping system implemented to comply with the requirements established in §205.103;
 - (5) A description of the management practices and physical barriers established to prevent commingling of organic and nonorganic products on a split operation and to prevent contact of organic production and handling operations and products with prohibited substances; and
 - (6) Additional information deemed necessary by the certifying agent to evaluate compliance with the regulations.
- (b) A producer may substitute a plan prepared to meet the requirements of another Federal, State, or local government regulatory program for the organic system plan: *Provided*, That, the submitted plan meets all the requirements of this subpart.

§ 205.202 Land requirements.

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

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

§ 205.203 Soil fertility and crop nutrient management practice standard.

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

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

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

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

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

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

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

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

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

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

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

(3) Uncomposted plant materials.

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

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

(2) A mined substance of low solubility;

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

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

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

(e) The producer must not use:

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

(2) Sewage sludge (biosolids) as defined in 40 CFR part 503; and (3) Burning as a means of disposal for crop residues produced on the operation: *Except*, That, burning may be used to suppress the spread of disease or to stimulate seed germination.

§ 205.204 Seeds and planting stock practice standard.

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

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

(2) Nonorganically produced seeds and planting stock that have been treated with a substance included on the National List of synthetic substances allowed for use in organic crop production may be used to produce an organic crop when an equivalent organically produced or untreated variety is not commercially available;

(3) Nonorganically produced annual seedlings may be used to produce an organic crop when a temporary variance has been granted in accordance with §205.290(a)(2);

(4) Nonorganically produced planting stock to be used to produce a perennial crop may be sold, labeled, or represented as organically produced only after the planting stock has been maintained under a system of organic management for a period of no less than 1 year; and

(5) Seeds, annual seedlings, and planting stock treated with prohibited substances may be used to produce an organic crop when the application of the materials is a requirement of Federal or State phytosanitary regulations.

(b) [Reserved]

§ 205.205 Crop rotation practice standard.

The producer must implement a crop rotation including but not limited to sod, cover crops, green manure crops, and catch crops that provide the following functions that are applicable to the operation:

(a) Maintain or improve soil organic matter content;

(b) Provide for pest management in annual and perennial crops;

(c) Manage deficient or excess plant nutrients; and

(d) Provide erosion control.

§ 205.206 Crop pest, weed, and disease management practice standard.

(a) The producer must use management practices to prevent crop pests, weeds, and diseases including but not limited to:

- (1) Crop rotation and soil and crop nutrient management practices, as provided for in §§205.203 and 205.205;
- (2) Sanitation measures to remove disease vectors, weed seeds, and habitat for pest organisms; and
- (3) Cultural practices that enhance crop health, including selection of plant species and varieties with regard to suitability to site-specific conditions and resistance to prevalent pests, weeds, and diseases.

(b) Pest problems may be controlled through mechanical or physical methods including but not limited to:

- (1) Augmentation or introduction of predators or parasites of the pest species;
- (2) Development of habitat for natural enemies of pests;
- (3) Nonsynthetic controls such as lures, traps, and repellents.

(c) Weed problems may be controlled through:

- (1) Mulching with fully biodegradable materials;
- (2) Mowing;
- (3) Livestock grazing;
- (4) Hand weeding and mechanical cultivation;
- (5) Flame, heat, or electrical means; or
- (6) Plastic or other synthetic mulches: *Provided*, That, they are removed from the field at the end of the growing or harvest season.

(d) Disease problems may be controlled through:

- (1) Management practices which suppress the spread of disease organisms; or
- (2) Application of nonsynthetic biological, botanical, or mineral inputs.

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

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

§ 205.207 Wild-crop harvesting practice standard.

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

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

§§ 205.208-205.235 [Reserved]

§ 205.271 Facility pest management practice standard.

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

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

(2) Prevention of access to handling facilities; and

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

(b) Pests may be controlled through:

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

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

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

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

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

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

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

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

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

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

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

§§ 205.273-205.289 [Reserved]

Subpart D—Labels, Labeling, and Market Information

§ 205.300 Use of the term, “organic.”

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

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

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

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

§ 205.301 Product composition.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

§ 205.302 Calculating the percentage of organically produced ingredients.

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

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

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

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

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

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

§ 205.303 Packaged products labeled “100 percent organic” or “organic.”

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

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

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

(3) The term, “organic,” to identify the organic ingredients in multiingredient products labeled “100 percent organic”;

(4) The USDA seal; and/or

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

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

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

(2) On the information panel, below the information identifying the handler or distributor of the product and preceded by the statement, “Certified organic by * * *,” or similar phrase, identify the name of the certifying agent that certified the handler of

the finished product and may display the business address, Internet address, or telephone number of the certifying agent in such label.

§ 205.307 Labeling of nonretail containers used for only shipping or storage of raw or processed agricultural products labeled as “100 percent organic,” “organic,” or “made with organic (specified ingredients or food group(s)).”

(a) Nonretail containers used only to ship or store raw or processed agricultural product labeled as containing organic ingredients may display the following terms or marks:

(1) The name and contact information of the certifying agent which certified the handler which assembled the final product;

(2) Identification of the product as organic;

(3) Special handling instructions needed to maintain the organic integrity of the product;

(4) The USDA seal;

(5) The seal, logo, or other identifying mark of the certifying agent that certified the organic production or handling operation that produced or handled the finished product.

(b) Nonretail containers used to ship or store raw or processed agricultural product labeled as containing organic ingredients must display the production lot number of the product if applicable.

(c) Shipping containers of domestically produced product labeled as organic intended for export to international markets may be labeled in accordance with any shipping container labeling requirements of the foreign country of destination or the container labeling specifications of a foreign contract buyer: *Provided*, That, the shipping containers and shipping documents accompanying such organic products are clearly marked “For Export Only” and: *Provided further*, That, proof of such container marking and export must be maintained by the handler in accordance with recordkeeping requirements for exempt and excluded operations under §205.101.

§ 205.311 USDA Seal.

(a) The USDA seal described in paragraphs (b) and (c) of this section may be used only for raw or processed agricultural products described in paragraphs (a), (b), (e)(1), and (e)(2) of §205.301.

(b) The USDA seal must replicate the form and design of the example in figure 1 and must be printed legibly and conspicuously:

(1) On a white background with a brown outer circle and with the term, “USDA,” in green overlaying a white upper semicircle and with the term, “organic,” in white overlaying the green lower half circle; or

(2) On a white or transparent background with black outer circle and black “USDA” on a white or transparent upper half of the circle with a contrasting white or transparent “organic” on the black lower half circle.

(3) The green or black lower half circle may have four light lines running from left to right and disappearing at the point on the right horizon to resemble a cultivated field.



Figure 1

Subpart E—Certification

§ 205.400 General requirements for certification.

A person seeking to receive or maintain organic certification under the regulations in this part must:

- (a) Comply with the Act and applicable organic production and handling regulations of this part;
- (b) Establish, implement, and update annually an organic production or handling system plan that is submitted to an accredited certifying agent as provided for in §205.200;
- (c) Permit on-site inspections with complete access to the production or handling operation, including noncertified production and handling areas, structures, and offices by the certifying agent as provided for in §205.403;
- (d) Maintain all records applicable to the organic operation for not less than 5 years beyond their creation and allow authorized representatives of the Secretary, the applicable State organic program's governing State official, and the certifying agent access to such records during normal business hours for review and copying to determine compliance with the Act and the regulations in this part, as provided for in §205.104;
- (e) Submit the applicable fees charged by the certifying agent; and
- (f) Immediately notify the certifying agent concerning any:
 - (1) Application, including drift, of a prohibited substance to any field, production unit, site, facility, livestock, or product that is part of an operation; and
 - (2) Change in a certified operation or any portion of a certified operation that may affect its compliance with the Act and the regulations in this part.

§ 205.401 Application for certification.

A person seeking certification of a production or handling operation under this subpart must submit an application for certification to a certifying agent. The application must include the following information:

- (a) An organic production or handling system plan, as required in §205.200;

(b) The name of the person completing the application; the applicant's business name, address, and telephone number; and, when the applicant is a corporation, the name, address, and telephone number of the person authorized to act on the applicant's behalf;

(c) The name(s) of any organic certifying agent(s) to which application has previously been made; the year(s) of application; the outcome of the application(s) submission, including, when available, a copy of any notification of noncompliance or denial of certification issued to the applicant for certification; and a description of the actions taken by the applicant to correct the noncompliances noted in the notification of noncompliance, including evidence of such correction; and

(d) Other information necessary to determine compliance with the Act and the regulations in this part.

§ 205.402 Review of application.

(a) Upon acceptance of an application for certification, a certifying agent must:

(1) Review the application to ensure completeness pursuant to §205.401;

(2) Determine by a review of the application materials whether the applicant appears to comply or may be able to comply with the applicable requirements of subpart C of this part;

(3) Verify that an applicant who previously applied to another certifying agent and received a notification of noncompliance or denial of certification, pursuant to §205.405, has submitted documentation to support the correction of any noncompliances identified in the notification of noncompliance or denial of certification, as required in §205.405(e); and

(4) Schedule an on-site inspection of the operation to determine whether the applicant qualifies for certification if the review of application materials reveals that the production or handling operation may be in compliance with the applicable requirements of subpart C of this part.

(b) The certifying agent shall within a reasonable time:

(1) Review the application materials received and communicate its findings to the applicant;

(2) Provide the applicant with a copy of the on-site inspection report, as approved by the certifying agent, for any on-site inspection performed; and

(3) Provide the applicant with a copy of the test results for any samples taken by an inspector.

(c) The applicant may withdraw its application at any time. An applicant who withdraws its application shall be liable for the costs of services provided up to the time of withdrawal of its application. An applicant that voluntarily withdrew its application prior to the issuance of a notice of noncompliance will not be issued a notice of noncompliance. Similarly, an applicant that voluntarily withdrew its application prior to the issuance of a notice of certification denial will not be issued a notice of certification denial.

§ 205.403 On-site inspections.

(a) On-site inspections. (1) A certifying agent must conduct an initial on-site inspection of each production unit, facility, and site that produces or handles organic products and that is included in an operation for which certification is requested. An on-site inspection shall be conducted annually thereafter for each certified operation that produces or handles organic products for the purpose of determining whether to approve the request for certification or whether the certification of the operation should continue.

(2)(i) A certifying agent may conduct additional on-site inspections of applicants for certification and certified operations to determine compliance with the Act and the regulations in this part.

(ii) The Administrator or State organic program's governing State official may require that additional inspections be performed by the certifying agent for the purpose of determining compliance with the Act and the regulations in this part.

(iii) Additional inspections may be announced or unannounced at the discretion of the certifying agent or as required by the Administrator or State organic program's governing State official.

(b) Scheduling. (1) The initial on-site inspection must be conducted within a reasonable time following a determination that the applicant appears to comply or may be able to comply with the requirements of subpart C of this part: Except, That, the initial inspection may be delayed for up to 6 months to comply with the requirement that the inspection be conducted when the land, facilities, and activities that demonstrate compliance or capacity to comply can be observed.

(2) All on-site inspections must be conducted when an authorized representative of the operation who is knowledgeable about the operation is present and at a time when land, facilities, and activities that demonstrate the operation's compliance with or capability to comply with the applicable provisions of subpart C of this part can be observed, except that this requirement does not apply to unannounced on-site inspections.

(c) Verification of information. The on-site inspection of an operation must verify:

(1) The operation's compliance or capability to comply with the Act and the regulations in this part;

(2) That the information, including the organic production or handling system plan, provided in accordance with §§205.401, 205.406, and 205.200, accurately reflects the practices used or to be used by the applicant for certification or by the certified operation;

(3) That prohibited substances have not been and are not being applied to the operation through means which, at the discretion of the certifying agent, may include the collection and testing of soil; water; waste; seeds; plant tissue; and plant, animal, and processed products samples.

(d) Exit interview. The inspector must conduct an exit interview with an authorized representative of the operation who is knowledgeable about the inspected operation to confirm the accuracy and completeness of inspection observations and information gathered during the on-site inspection. The inspector must also address the need for any additional information as well as any issues of concern.

(e) Documents to the inspected operation. (1) At the time of the inspection, the inspector shall provide the operation's authorized representative with a receipt for any samples taken by the inspector. There shall be no charge to the inspector for the samples taken.

(2) A copy of the on-site inspection report and any test results will be sent to the inspected operation by the certifying agent.

§ 205.404 Granting certification.

(a) Within a reasonable time after completion of the initial on-site inspection, a certifying agent must review the on-site inspection report, the results of any analyses for substances conducted, and any additional information requested from or supplied by the applicant. If the certifying agent determines that the organic system plan and all procedures and activities of the applicant's operation are in compliance with the requirements of this part and that the applicant is able to conduct

operations in accordance with the plan, the agent shall grant certification. The certification may include requirements for the correction of minor noncompliances within a specified time period as a condition of continued certification.

(b) The certifying agent must issue a certificate of organic operation which specifies the:

(1) Name and address of the certified operation;

(2) Effective date of certification;

(3) Categories of organic operation, including crops, wild crops, livestock, or processed products produced by the certified operation; and

(4) Name, address, and telephone number of the certifying agent.

(c) Once certified, a production or handling operation's organic certification continues in effect until surrendered by the organic operation or suspended or revoked by the certifying agent, the State organic program's governing State official, or the Administrator.

§ 205.405 Denial of certification.

(a) When the certifying agent has reason to believe, based on a review of the information specified in §205.402 or §205.404, that an applicant for certification is not able to comply or is not in compliance with the requirements of this part, the certifying agent must provide a written notification of noncompliance to the applicant. When correction of a noncompliance is not possible, a notification of noncompliance and a notification of denial of certification may be combined in one notification. The notification of noncompliance shall provide:

(1) A description of each noncompliance;

(2) The facts upon which the notification of noncompliance is based; and

(3) The date by which the applicant must rebut or correct each noncompliance and submit supporting documentation of each such correction when correction is possible.

(b) Upon receipt of such notification of noncompliance, the applicant may:

(1) Correct noncompliances and submit a description of the corrective actions taken with supporting documentation to the certifying agent;

(2) Correct noncompliances and submit a new application to another certifying agent: Provided, That, the applicant must include a complete application, the notification of noncompliance received from the first certifying agent, and a description of the corrective actions taken with supporting documentation; or

(3) Submit written information to the issuing certifying agent to rebut the noncompliance described in the notification of noncompliance.

(c) After issuance of a notification of noncompliance, the certifying agent must:

(1) Evaluate the applicant's corrective actions taken and supporting documentation submitted or the written rebuttal, conduct an on-site inspection if necessary, and

- (i) When the corrective action or rebuttal is sufficient for the applicant to qualify for certification, issue the applicant an approval of certification pursuant to §205.404; or
 - (ii) When the corrective action or rebuttal is not sufficient for the applicant to qualify for certification, issue the applicant a written notice of denial of certification.
- (2) Issue a written notice of denial of certification to an applicant who fails to respond to the notification of noncompliance.
 - (3) Provide notice of approval or denial to the Administrator, pursuant to §205.501(a)(14).
- (d) A notice of denial of certification must state the reason(s) for denial and the applicant's right to:
- (1) Reapply for certification pursuant to §§205.401 and 205.405(e);
 - (2) Request mediation pursuant to §205.663 or, if applicable, pursuant to a State organic program; or
 - (3) File an appeal of the denial of certification pursuant to §205.681 or, if applicable, pursuant to a State organic program.
- (e) An applicant for certification who has received a written notification of noncompliance or a written notice of denial of certification may apply for certification again at any time with any certifying agent, in accordance with §§205.401 and 205.405(e). When such applicant submits a new application to a certifying agent other than the agent who issued the notification of noncompliance or notice of denial of certification, the applicant for certification must include a copy of the notification of noncompliance or notice of denial of certification and a description of the actions taken, with supporting documentation, to correct the noncompliances noted in the notification of noncompliance.
- (f) A certifying agent who receives a new application for certification, which includes a notification of noncompliance or a notice of denial of certification, must treat the application as a new application and begin a new application process pursuant to §205.402.
- (g) Notwithstanding paragraph (a) of this section, if a certifying agent has reason to believe that an applicant for certification has willfully made a false statement or otherwise purposefully misrepresented the applicant's operation or its compliance with the certification requirements pursuant to this part, the certifying agent may deny certification pursuant to paragraph (c)(1)(ii) of this section without first issuing a notification of noncompliance.

§ 205.406 Continuation of certification.

- (a) To continue certification, a certified operation must annually pay the certification fees and submit the following information, as applicable, to the certifying agent:
- (1) An updated organic production or handling system plan which includes:
 - (i) A summary statement, supported by documentation, detailing any deviations from, changes to, modifications to, or other amendments made to the previous year's organic system plan during the previous year; and
 - (ii) Any additions or deletions to the previous year's organic system plan, intended to be undertaken in the coming year, detailed pursuant to §205.200;
 - (2) Any additions to or deletions from the information required pursuant to §205.401(b);

(3) An update on the correction of minor noncompliances previously identified by the certifying agent as requiring correction for continued certification; and

(4) Other information as deemed necessary by the certifying agent to determine compliance with the Act and the regulations in this part.

(b) Following the receipt of the information specified in paragraph (a) of this section, the certifying agent shall within a reasonable time arrange and conduct an on-site inspection of the certified operation pursuant to §205.403: Except, That, when it is impossible for the certifying agent to conduct the annual on-site inspection following receipt of the certified operation's annual update of information, the certifying agent may allow continuation of certification and issue an updated certificate of organic operation on the basis of the information submitted and the most recent on-site inspection conducted during the previous 12 months: Provided, That, the annual on-site inspection, required pursuant to §205.403, is conducted within the first 6 months following the certified operation's scheduled date of annual update.

(c) If the certifying agent has reason to believe, based on the on-site inspection and a review of the information specified in §205.404, that a certified operation is not complying with the requirements of the Act and the regulations in this part, the certifying agent shall provide a written notification of noncompliance to the operation in accordance with §205.662.

(d) If the certifying agent determines that the certified operation is complying with the Act and the regulations in this part and that any of the information specified on the certificate of organic operation has changed, the certifying agent must issue an updated certificate of organic operation pursuant to §205.404(b).

§§ 205.407-205.499 [Reserved]

Subpart G—Administrative

The National List of Allowed and Prohibited Substances

§ 205.600 Evaluation criteria for allowed and prohibited substances, methods, and ingredients.

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

(a) Synthetic and 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).

§ 205.601 Synthetic substances allowed for use in organic crop production.

In accordance with restrictions specified in this section, the following synthetic substances may be used in organic crop production: *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 repellent only, no contact with soil or edible portion of crop.
- (e) As insecticides (including acaricides or mite control).
 - (1) Ammonium carbonate—for use as bait in insect traps only, no direct contact with crop or soil.
 - (2) Boric acid—structural pest control, no direct contact with organic food or crops.
 - (3) 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 oxychloride, includes products exempted from EPA tolerance, *Provided*, That, copper-based materials must be used in a manner that minimizes accumulation in the soil and shall not be used as herbicides.
 - (2) Copper sulfate—Substance must be used in a manner that minimizes accumulation of copper in the soil.

- (3) Hydrated lime.
 - (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]

[65 FR 80637, Dec. 21, 2000, as amended at 68 FR 61992, Oct. 31, 2003; 71 FR 53302 Sept. 11, 2006; 72 FR 69572, Dec. 10, 2007]

§ 205.602 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 fluoaluminat (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]

[68 FR 61992, Oct. 31, 2003]

§ 205.603 Synthetic substances allowed for use in organic livestock production.

In accordance with restrictions specified in this section the following synthetic substances may be used in organic livestock production:

- (a) As disinfectants, sanitizer, and medical treatments as applicable.
 - (1) Alcohols.
 - (i) Ethanol-disinfectant and sanitizer only, prohibited as a feed additive.
 - (ii) Isopropanol-disinfectant only.
 - (2) Aspirin-approved for health care use to reduce inflammation.
 - (3) Atropine (CAS #–51–55–8)—federal law restricts this drug to use by or on the lawful written or oral order of a licensed veterinarian, in full compliance with the AMDUCA and 21 CFR part 530 of the Food and Drug Administration regulations. Also, for use under 7 CFR part 205, the NOP requires:
 - (i) Use by or on the lawful written order of a licensed veterinarian; and
 - (ii) A meat withdrawal period of at least 56 days after administering to livestock intended for slaughter; and a milk discard period of at least 12 days after administering to dairy animals.
 - (4) Biologics—Vaccines.
 - (5) Butorphanol (CAS #–42408–82–2)—federal law restricts this drug to use by or on the lawful written or oral order of a licensed veterinarian, in full compliance with the AMDUCA and 21 CFR part 530 of the Food and Drug Administration regulations. Also, for use under 7 CFR Part 205, the NOP requires:
 - (i) Use by or on the lawful written order of a licensed veterinarian; and
 - (ii) A meat withdrawal period of at least 42 days after administering to livestock intended for slaughter; and a milk discard period of at least 8 days after administering to dairy animals.
 - (6) Chlorhexidine—Allowed for surgical procedures conducted by a veterinarian. Allowed for use as a teat dip when alternative germicidal agents and/or physical barriers have lost their effectiveness.
 - (7) Chlorine materials—disinfecting and sanitizing facilities and equipment. Residual chlorine levels in the water shall not exceed the maximum residual disinfectant limit under the Safe Drinking Water Act.
 - (i) Calcium hypochlorite.
 - (ii) Chlorine dioxide.
 - (iii) Sodium hypochlorite.
 - (8) Electrolytes—without antibiotics.
 - (9) Flunixin (CAS #–38677–85–9)—in accordance with approved labeling; except that for use under 7 CFR part 205, the NOP requires a withdrawal period of at least two-times that required by the FDA.

(10) Furosemide (CAS #–54–31–9)—in accordance with approved labeling; except that for use under 7 CFR part 205, the NOP requires a withdrawal period of at least two-times that required that required by the FDA.

(11) Glucose.

(12) Glycerine—Allowed as a livestock teat dip, must be produced through the hydrolysis of fats or oils.

(13) Hydrogen peroxide.

(14) Iodine.

(15) Magnesium hydroxide (CAS #–1309–42–8)—federal law restricts this drug to use by or on the lawful written or oral order of a licensed veterinarian, in full compliance with the AMDUCA and 21 CFR part 530 of the Food and Drug Administration regulations. Also, for use under 7 CFR part 205, the NOP requires use by or on the lawful written order of a licensed veterinarian.

(16) Magnesium sulfate.

(17) Oxytocin—use in postparturition therapeutic applications.

(18) Paraciticides. Ivermectin—prohibited in slaughter stock, allowed in emergency treatment for dairy and breeder stock when organic system plan-approved preventive management does not prevent infestation. Milk or milk products from a treated animal cannot be labeled as provided for in subpart D of this part for 90 days following treatment. In breeder stock, treatment cannot occur during the last third of gestation if the progeny will be sold as organic and must not be used during the lactation period for breeding stock.

(19) Peroxyacetic/peracetic acid (CAS #–79–21–0)—for sanitizing facility and processing equipment.

(20) Phosphoric acid—allowed as an equipment cleaner, *Provided*, That, no direct contact with organically managed livestock or land occurs.

(21) Poloxalene (CAS #–9003–11–6)—for use under 7 CFR part 205, the NOP requires that poloxalene only be used for the emergency treatment of bloat.

(22) Tolazoline (CAS #–59–98–3)—federal law restricts this drug to use by or on the lawful written or oral order of a licensed veterinarian, in full compliance with the AMDUCA and 21 CFR part 530 of the Food and Drug Administration regulations. Also, for use under 7 CFR part 205, the NOP requires:

(i) Use by or on the lawful written order of a licensed veterinarian;

(ii) Use only to reverse the effects of sedation and analgesia caused by Xylazine; and

(iii) A meat withdrawal period of at least 8 days after administering to livestock intended for slaughter; and a milk discard period of at least 4 days after administering to dairy animals.

(23) Xylazine (CAS #–7361–61–7)—federal law restricts this drug to use by or on the lawful written or oral order of a licensed veterinarian, in full compliance with the AMDUCA and 21 CFR part 530 of the Food and Drug Administration regulations. Also, for use under 7 CFR part 205, the NOP requires:

(i) Use by or on the lawful written order of a licensed veterinarian;

(ii) The existence of an emergency; and

(iii) A meat withdrawal period of at least 8 days after administering to livestock intended for slaughter; and a milk discard period of at least 4 days after administering to dairy animals.

(b) As topical treatment, external parasiticide or local anesthetic as applicable.

(1) Copper sulfate.

(2) Iodine.

(3) Lidocaine—as a local anesthetic. Use requires a withdrawal period of 90 days after administering to livestock intended for slaughter and 7 days after administering to dairy animals.

(4) Lime, hydrated—as an external pest control, not permitted to cauterize physical alterations or deodorize animal wastes.

(5) Mineral oil—for topical use and as a lubricant.

(6) Procaine—as a local anesthetic, use requires a withdrawal period of 90 days after administering to livestock intended for slaughter and 7 days after administering to dairy animals.

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

(c) As feed supplements—None.

(d) As feed additives.

(1) DL-Methionine, DL-Methionine—hydroxy analog, and DL-Methionine—hydroxy analog calcium (CAS #–59-51-8; 63-68-3; 348-67-4)—for use only in organic poultry production until October 1, 2010.

(2) Trace minerals, used for enrichment or fortification when FDA approved.

(3) Vitamins, used for enrichment or fortification when FDA approved.

(e) As synthetic inert ingredients as classified by the Environmental Protection Agency (EPA), for use with 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) [Reserved]

(f) Excipients, only for use in the manufacture of drugs used to treat organic livestock when the excipient is: Identified by the FDA as Generally Recognized As Safe; Approved by the FDA as a food additive; or Included in the FDA review and approval of a New Animal Drug Application or New Drug Application.

(g)–(z) [Reserved]

[72 FR 70484, Dec. 12, 2007, as amended at 73 FR 54059, Sept. 18, 2008]

§ 205.604 Nonsynthetic substances prohibited for use in organic livestock production.

The following nonsynthetic substances may not be used in organic livestock production:

(a) Strychnine.

(b)–(z) [Reserved]

§ 205.605 Nonagricultural (nonorganic) substances allowed as ingredients in or on processed products labeled as “organic” or “made with organic (specified ingredients or food group(s)).”

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

(a) *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.

Carrageenan.

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—made from grape wine.

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 (specific 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—made from malic 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.

(c)–(z) [Reserved]

[68 FR 61993, Oct. 31, 2003, as amended as 68 FR 62217, Nov. 3, 2003; 71 FR 53302, Sept. 11, 2006; 72 FR 58473, Oct. 16, 2007; 73 FR 59481, Oct. 9, 2008]

§ 205.606 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).

(4) Black currant juice color (pigment CAS #'s: 528-58-5, 528-53-0, 643-84-5, 134-01-0, 1429-30-7, and 134-04-3).

- (5) Black/Purple carrot juice color (pigment CAS #'s: 528-58-5, 528-53-0, 643-84-5, 134-01-0, 1429-30-7, and 134-04-3).
- (6) Blueberry juice color (pigment CAS #'s: 528-58-5, 528-53-0, 643-84-5, 134-01-0, 1429-30-7, and 134-04-3).
- (7) Carrot juice color (pigment CAS # 1393-63-1).
- (8) Cherry juice color (pigment CAS #'s: 528-58-5, 528-53-0, 643-84-5, 134-01-0, 1429-30-7, and 134-04-3).
- (9) Chokeberry—Aronia juice color (pigment CAS #'s: 528-58-5, 528-53-0, 643-84-5, 134-01-0, 1429-30-7, and 134-04-3).
- (10) Elderberry juice color (pigment CAS #'s: 528-58-5, 528-53-0, 643-84-5, 134-01-0, 1429-30-7, and 134-04-3).
- (11) Grape juice color (pigment CAS #'s: 528-58-5, 528-53-0, 643-84-5, 134-01-0, 1429-30-7, and 134-04-3).
- (12) Grape skin extract color (pigment CAS #'s: 528-58-5, 528-53-0, 643-84-5, 134-01-0, 1429-30-7, and 134-04-3).
- (13) Paprika color (CAS # 68917-78-2)—dried, and oil extracted.
- (14) Pumpkin juice color (pigment CAS # 127-40-2).
- (15) Purple potato juice (pigment CAS #'s: 528-58-5, 528-53-0, 643-84-5, 134-01-0, 1429-30-7, and 134-04-3).
- (16) Red cabbage extract color (pigment CAS #'s: 528-58-5, 528-53-0, 643-84-5, 134-01-0, 1429-30-7, and 134-04-3).
- (17) Red radish extract color (pigment CAS #'s: 528-58-5, 528-53-0, 643-84-5, 134-01-0, 1429-30-7, and 134-04-3).
- (18) Saffron extract color (pigment CAS # 1393-63-1).
- (19) Turmeric extract color (CAS # 458-37-7).
- (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 lupulus*).
- (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.

[72 FR 35140, June 27, 2007]

§ 205.607 Amending the National List.

(a) Any person may petition the National Organic Standard Board for the purpose of having a substance evaluated by the Board for recommendation to the Secretary for inclusion on or deletion from the National List in accordance with the Act.

(b) A person petitioning for amendment of the National List should request a copy of the petition procedures from the USDA at the address in §205.607(c).

(c) A petition to amend the National List must be submitted to: Program Manager, USDA/AMS/TMP/NOP, 1400 Independence Ave., SW., Room 4008–So., Ag Stop 0268, Washington, DC 20250.

[65 FR 80637, Dec. 21, 2000, as amended at 68 FR 61993, Oct. 31, 2003]

§ 205.642 Fees and other charges for certification.

Fees charged by a certifying agent must be reasonable, and a certifying agent shall charge applicants for certification and certified production and handling operations only those fees and charges that it has filed with the Administrator. The certifying agent shall provide each applicant with an estimate of the total cost of certification and an estimate of the annual cost of updating the certification. The certifying agent may require applicants for certification to pay at the time of application a

nonrefundable fee which shall be applied to the applicant's fees-for-service account. The certifying agent may set the nonrefundable portion of certification fees; however, the nonrefundable portion of certification fees must be explained in the fee schedule submitted to the Administrator. The fee schedule must explain what fee amounts are nonrefundable and at what stage during the certification process fees become nonrefundable. The certifying agent shall provide all persons inquiring about the application process with a copy of its fee schedule.

§§ 205.643-205.649 [Reserved]

Compliance

§ 205.660 General.

(a) The National Organic Program's Program Manager, on behalf of the Secretary, may inspect and review certified production and handling operations and accredited certifying agents for compliance with the Act or regulations in this part.

(b) The Program Manager may initiate suspension or revocation proceedings against a certified operation:

(1) When the Program Manager has reason to believe that a certified operation has violated or is not in compliance with the Act or regulations in this part; or

(2) When a certifying agent or a State organic program's governing State official fails to take appropriate action to enforce the Act or regulations in this part.

(c) The Program Manager may initiate suspension or revocation of a certifying agent's accreditation if the certifying agent fails to meet, conduct, or maintain accreditation requirements pursuant to the Act or this part.

(d) Each notification of noncompliance, rejection of mediation, noncompliance resolution, proposed suspension or revocation, and suspension or revocation issued pursuant to §205.662, §205.663, and §205.665 and each response to such notification must be sent to the recipient's place of business via a delivery service which provides dated return receipts.

§ 205.661 Investigation of certified operations.

(a) A certifying agent may investigate complaints of noncompliance with the Act or regulations of this part concerning production and handling operations certified as organic by the certifying agent. A certifying agent must notify the Program Manager of all compliance proceedings and actions taken pursuant to this part.

(b) A State organic program's governing State official may investigate complaints of noncompliance with the Act or regulations in this part concerning organic production or handling operations operating in the State.

§ 205.662 Noncompliance procedure for certified operations.

(a) *Notification.* When an inspection, review, or investigation of a certified operation by a certifying agent or a State organic program's governing State official reveals any noncompliance with the Act or regulations in this part, a written notification of noncompliance shall be sent to the certified operation. Such notification shall provide:

(1) A description of each noncompliance;

(2) The facts upon which the notification of noncompliance is based; and

(3) The date by which the certified operation must rebut or correct each noncompliance and submit supporting documentation of each such correction when correction is possible.

(b) *Resolution*. When a certified operation demonstrates that each noncompliance has been resolved, the certifying agent or the State organic program's governing State official, as applicable, shall send the certified operation a written notification of noncompliance resolution.

(c) *Proposed suspension or revocation*. When rebuttal is unsuccessful or correction of the noncompliance is not completed within the prescribed time period, the certifying agent or State organic program's governing State official shall send the certified operation a written notification of proposed suspension or revocation of certification of the entire operation or a portion of the operation, as applicable to the noncompliance. When correction of a noncompliance is not possible, the notification of noncompliance and the proposed suspension or revocation of certification may be combined in one notification. The notification of proposed suspension or revocation of certification shall state:

- (1) The reasons for the proposed suspension or revocation;
- (2) The proposed effective date of such suspension or revocation;
- (3) The impact of a suspension or revocation on future eligibility for certification; and
- (4) The right to request mediation pursuant to §205.663 or to file an appeal pursuant to §205.681.

(d) *Willful violations*. Notwithstanding paragraph (a) of this section, if a certifying agent or State organic program's governing State official has reason to believe that a certified operation has willfully violated the Act or regulations in this part, the certifying agent or State organic program's governing State official shall send the certified operation a notification of proposed suspension or revocation of certification of the entire operation or a portion of the operation, as applicable to the noncompliance.

(e) *Suspension or revocation*. (1) If the certified operation fails to correct the noncompliance, to resolve the issue through rebuttal or mediation, or to file an appeal of the proposed suspension or revocation of certification, the certifying agent or State organic program's governing State official shall send the certified operation a written notification of suspension or revocation.

(2) A certifying agent or State organic program's governing State official must not send a notification of suspension or revocation to a certified operation that has requested mediation pursuant to §205.663 or filed an appeal pursuant to §205.681, while final resolution of either is pending.

(f) *Eligibility*. (1) A certified operation whose certification has been suspended under this section may at any time, unless otherwise stated in the notification of suspension, submit a request to the Secretary for reinstatement of its certification. The request must be accompanied by evidence demonstrating correction of each noncompliance and corrective actions taken to comply with and remain in compliance with the Act and the regulations in this part.

(2) A certified operation or a person responsibly connected with an operation whose certification has been revoked will be ineligible to receive certification for a period of 5 years following the date of such revocation, *Except*, That, the Secretary may, when in the best interest of the certification program, reduce or eliminate the period of ineligibility.

(g) *Violations of Act*. In addition to suspension or revocation, any certified operation that:

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

§ 205.663 Mediation.

Any dispute with respect to denial of certification or proposed suspension or revocation of certification under this part may be mediated at the request of the applicant for certification or certified operation and with acceptance by the certifying agent. Mediation shall be requested in writing to the applicable certifying agent. If the certifying agent rejects the request for mediation, the certifying agent shall provide written notification to the applicant for certification or certified operation. The written notification shall advise the applicant for certification or certified operation of the right to request an appeal, pursuant to §205.681, within 30 days of the date of the written notification of rejection of the request for mediation. If mediation is accepted by the certifying agent, such mediation shall be conducted by a qualified mediator mutually agreed upon by the parties to the mediation. If a State organic program is in effect, the mediation procedures established in the State organic program, as approved by the Secretary, will be followed. The parties to the mediation shall have no more than 30 days to reach an agreement following a mediation session. If mediation is unsuccessful, the applicant for certification or certified operation shall have 30 days from termination of mediation to appeal the certifying agent's decision pursuant to §205.681. Any agreement reached during or as a result of the mediation process shall be in compliance with the Act and the regulations in this part. The Secretary may review any mediated agreement for conformity to the Act and the regulations in this part and may reject any agreement or provision not in conformance with the Act or the regulations in this part.

§ 205.664 [Reserved]

§ 205.665 Noncompliance procedure for certifying agents.

(a) *Notification.* When an inspection, review, or investigation of an accredited certifying agent by the Program Manager reveals any noncompliance with the Act or regulations in this part, a written notification of noncompliance shall be sent to the certifying agent. Such notification shall provide:

- (1) A description of each noncompliance;
- (2) The facts upon which the notification of noncompliance is based; and
- (3) The date by which the certifying agent must rebut or correct each noncompliance and submit supporting documentation of each correction when correction is possible.

(b) *Resolution.* When the certifying agent demonstrates that each noncompliance has been resolved, the Program Manager shall send the certifying agent a written notification of noncompliance resolution.

(c) *Proposed suspension or revocation.* When rebuttal is unsuccessful or correction of the noncompliance is not completed within the prescribed time period, the Program Manager shall send a written notification of proposed suspension or revocation of accreditation to the certifying agent. The notification of proposed suspension or revocation shall state whether the certifying agent's accreditation or specified areas of accreditation are to be suspended or revoked. When correction of a noncompliance is not possible, the notification of noncompliance and the proposed suspension or revocation may be combined in one notification. The notification of proposed suspension or revocation of accreditation shall state:

- (1) The reasons for the proposed suspension or revocation;
- (2) The proposed effective date of the suspension or revocation;
- (3) The impact of a suspension or revocation on future eligibility for accreditation; and
- (4) The right to file an appeal pursuant to §205.681.

(d) *Willful violations.* Notwithstanding paragraph (a) of this section, if the Program Manager has reason to believe that a certifying agent has willfully violated the Act or regulations in this part, the Program Manager shall send a written notification of proposed suspension or revocation of accreditation to the certifying agent.

(e) *Suspension or revocation.* When the accredited certifying agent fails to file an appeal of the proposed suspension or revocation of accreditation, the Program Manager shall send a written notice of suspension or revocation of accreditation to the certifying agent.

(f) *Cessation of certification activities.* A certifying agent whose accreditation is suspended or revoked must:

(1) Cease all certification activities in each area of accreditation and in each State for which its accreditation is suspended or revoked.

(2) Transfer to the Secretary and make available to any applicable State organic program's governing State official all records concerning its certification activities that were suspended or revoked.

(g) *Eligibility.* (1) A certifying agent whose accreditation is suspended by the Secretary under this section may at any time, unless otherwise stated in the notification of suspension, submit a request to the Secretary for reinstatement of its accreditation. The request must be accompanied by evidence demonstrating correction of each noncompliance and corrective actions taken to comply with and remain in compliance with the Act and the regulations in this part.

(2) A certifying agent whose accreditation is revoked by the Secretary shall be ineligible to be accredited as a certifying agent under the Act and the regulations in this part for a period of not less than 3 years following the date of such revocation.

§§ 205.666-205.667 [Reserved]

§ 205.669 [Reserved]

Inspection and Testing, Reporting, and Exclusion from Sale

§ 205.670 Inspection and testing of agricultural product to be sold or labeled "organic."

(a) All agricultural products that are to be sold, labeled, or represented as "100 percent organic," "organic," or "made with organic (specified ingredients or food group(s))" must be made accessible by certified organic production or handling operations for examination by the Administrator, the applicable State organic program's governing State official, or the certifying agent.

(b) The Administrator, applicable State organic program's governing State official, or the certifying agent may require preharvest or postharvest testing of any agricultural input used or agricultural product to be sold, labeled, or represented as "100 percent organic," "organic," or "made with organic (specified ingredients or food group(s))" when there is reason to believe that the agricultural input or product has come into contact with a prohibited substance or has been produced using excluded methods. Such tests must be conducted by the applicable State organic program's governing State official or the certifying agent at the official's or certifying agent's own expense.

(c) The preharvest or postharvest tissue test sample collection pursuant to paragraph (b) of this section must be performed by an inspector representing the Administrator, applicable State organic program's governing State official, or certifying agent. Sample integrity must be maintained throughout the chain of custody, and residue testing must be performed in an accredited laboratory. Chemical analysis must be made in accordance with the methods described in the most current edition of the *Official Methods of Analysis of the AOAC International* or other current applicable validated methodology determining the presence of contaminants in agricultural products.

(d) Results of all analyses and tests performed under this section:

(1) Must be promptly provided to the Administrator; *Except*, That, where a State organic program exists, all test results and analyses shall be provided to the State organic program's governing State official by the applicable certifying party that requested testing; and

(2) Will be available for public access, unless the testing is part of an ongoing compliance investigation.

(e) If test results indicate a specific agricultural product contains pesticide residues or environmental contaminants that exceed the Food and Drug Administration's or the Environmental Protection Agency's regulatory tolerances, the certifying agent must promptly report such data to the Federal health agency whose regulatory tolerance or action level has been exceeded.

§ 205.671 Exclusion from organic sale.

When residue testing detects prohibited substances at levels that are greater than 5 percent of the Environmental Protection Agency's tolerance for the specific residue detected or unavoidable residual environmental contamination, the agricultural product must not be sold, labeled, or represented as organically produced. The Administrator, the applicable State organic program's governing State official, or the certifying agent may conduct an investigation of the certified operation to determine the cause of the prohibited substance.

§ 205.672 Emergency pest or disease treatment.

When a prohibited substance is applied to a certified operation due to a Federal or State emergency pest or disease treatment program and the certified operation otherwise meets the requirements of this part, the certification status of the operation shall not be affected as a result of the application of the prohibited substance: *Provided*, That:

(a) Any harvested crop or plant part to be harvested that has contact with a prohibited substance applied as the result of a Federal or State emergency pest or disease treatment program cannot be sold, labeled, or represented as organically produced; and

(b) Any livestock that are treated with a prohibited substance applied as the result of a Federal or State emergency pest or disease treatment program or product derived from such treated livestock cannot be sold, labeled, or represented as organically produced: *Except*, That:

(1) Milk or milk products may be sold, labeled, or represented as organically produced beginning 12 months following the last date that the dairy animal was treated with the prohibited substance; and

(2) The offspring of gestating mammalian breeder stock treated with a prohibited substance may be considered organic: *Provided*, That, the breeder stock was not in the last third of gestation on the date that the breeder stock was treated with the prohibited substance.

§§ 205.673-205.679 [Reserved]

Adverse Action Appeal Process

§ 205.680 General.

(a) Persons subject to the Act who believe they are adversely affected by a noncompliance decision of the National Organic Program's Program Manager may appeal such decision to the Administrator.

(b) Persons subject to the Act who believe that they are adversely affected by a noncompliance decision of a State organic program may appeal such decision to the State organic program's governing State official who will initiate handling of the appeal pursuant to appeal procedures approved by the Secretary.

(c) Persons subject to the Act who believe that they are adversely affected by a noncompliance decision of a certifying agent may appeal such decision to the Administrator, *Except*, That, when the person is subject to an approved State organic program, the appeal must be made to the State organic program.

(d) All written communications between parties involved in appeal proceedings must be sent to the recipient's place of business by a delivery service which provides dated return receipts.

(e) All appeals shall be reviewed, heard, and decided by persons not involved with the decision being appealed.

§ 205.681 Appeals.

(a) *Certification appeals.* An applicant for certification may appeal a certifying agent's notice of denial of certification, and a certified operation may appeal a certifying agent's notification of proposed suspension or revocation of certification to the Administrator, *Except*, That, when the applicant or certified operation is subject to an approved State organic program the appeal must be made to the State organic program which will carry out the appeal pursuant to the State organic program's appeal procedures approved by the Secretary.

(1) If the Administrator or State organic program sustains a certification applicant's or certified operation's appeal of a certifying agent's decision, the applicant will be issued organic certification, or a certified operation will continue its certification, as applicable to the operation. The act of sustaining the appeal shall not be an adverse action subject to appeal by the affected certifying agent.

(2) If the Administrator or State organic program denies an appeal, a formal administrative proceeding will be initiated to deny, suspend, or revoke the certification. Such proceeding shall be conducted pursuant to the U.S. Department of Agriculture's Uniform Rules of Practice or the State organic program's rules of procedure.

(b) *Accreditation appeals.* An applicant for accreditation and an accredited certifying agent may appeal the Program Manager's denial of accreditation or proposed suspension or revocation of accreditation to the Administrator.

(1) If the Administrator sustains an appeal, an applicant will be issued accreditation, or a certifying agent will continue its accreditation, as applicable to the operation.

(2) If the Administrator denies an appeal, a formal administrative proceeding to deny, suspend, or revoke the accreditation will be initiated. Such proceeding shall be conducted pursuant to the U.S. Department of Agriculture's Uniform Rules of Practice, 7 CFR part 1, Subpart H.

(c) *Filing period.* An appeal of a noncompliance decision must be filed within the time period provided in the letter of notification or within 30 days from receipt of the notification, whichever occurs later. The appeal will be considered "filed" on the date received by the Administrator or by the State organic program. A decision to deny, suspend, or revoke certification or accreditation will become final and nonappealable unless the decision is appealed in a timely manner.

(d) *Where and what to file.* (1) Appeals to the Administrator must be filed in writing and addressed to: Administrator, USDA, AMS, c/o NOP Appeals Staff, Stop 0203, Room 302-Annex, 1400 Independence Avenue, SW., Washington, DC 20250-0203.

(2) Appeals to the State organic program must be filed in writing to the address and person identified in the letter of notification.

(3) All appeals must include a copy of the adverse decision and a statement of the appellant's reasons for believing that the decision was not proper or made in accordance with applicable program regulations, policies, or procedures.

[65 FR 80637, Dec. 21, 2000, as amended at 71 FR 53303, Sept. 11, 2006]

§§ 205.682-205.689 [Reserved]