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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.

Class of animal. A group of livestock that shares a similar stage of life or production. The classes of animals are those that are commonly listed on feed labels.

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. Pastures, cover crops, green manure crops, catch crops, or any plant or part of a plant intended to be marketed as an agricultural product, fed to livestock, or used in the field to manage nutrients and soil fertility.

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.

Dry lot. A fenced area that may be covered with concrete, but that has little or no vegetative cover.

Dry matter. The amount of a feedstuff remaining after all the free moisture is evaporated out.

Dry matter demand. The expected dry matter intake for a class of animal.

Dry matter intake. Total pounds of all feed, devoid of all moisture, consumed by a class of animals over a given period of time.

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.

Feedlot. A dry lot for the controlled feeding of livestock.

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.

Graze. (1) The consumption of standing or residual forage by livestock.

(2) To put livestock to feed on standing or residual forage.

Grazing. To graze.

Grazing season. The period of time when pasture is available for grazing, due to natural precipitation or irrigation. Grazing season dates may vary because of mid-summer heat/humidity, significant precipitation events, floods, hurricanes, droughts or winter weather events. Grazing season may be extended by the grazing of residual forage as agreed in the operation's organic system plan. Due to weather, season, or climate, the grazing season may or may not be continuous. Grazing season may range from 120 days to 365 days, but not less than 120 days per year.

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.

Inclement weather. Weather that is violent, or characterized by temperatures (high or low), or characterized by excessive precipitation that can cause physical harm to a given species of livestock. Production yields or growth rates of livestock lower than the maximum achievable do not qualify as physical harm.

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, goats, 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 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.

Residual forage. Forage cut and left to lie, or windrowed and left to lie, in place in the pasture.

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.

Shelter. Structures such as barns, sheds, or windbreaks; or natural areas such as woods, tree lines, large hedge rows, or geographic land features, that are designed or selected to provide physical protection or housing to all animals.

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.

Stage of life. A discrete time period in an animal's life which requires specific management practices different than during other periods (e.g., poultry during feathering). Breeding, freshening, lactation and other recurring events are not a stage of life.

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.

Temporary and Temporarily. Occurring for a limited time only (e.g., overnight, throughout a storm, during a period of illness, the period of time specified by the Administrator when granting a temporary variance), not permanent or lasting.

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.

Yards/Feeding pad. An area for feeding, exercising, and outdoor access for livestock during the non-grazing season and a high traffic area where animals may receive supplemental feeding during the grazing season.

[65 FR 80637, Dec. 21, 2000, as amended at 72 FR 70484, Dec. 12, 2007; 75 FR 7192, Feb. 17, 2010]

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.

[65 FR 80637, Dec. 21, 2000, as amended at 75 FR 7193, Feb. 17, 2010]

§ 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]



§ 205.236 Origin of livestock.



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

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

(2) *Dairy animals*. Milk or milk products must be from animals that have been under continuous organic management beginning no later than 1 year prior to the production of the milk or milk products that are to be sold, labeled, or represented as organic, *Except*,

(i) That, crops and forage from land, included in the organic system plan of a dairy farm, that is in the third year of organic management may be consumed by the dairy animals of the farm during the 12-month period immediately prior to the sale of organic milk and milk products; and

(ii) That, when an entire, distinct herd is converted to organic production, the producer may, *provided* no milk produced under this subparagraph enters the stream of commerce labeled as organic after June 9, 2007: (a) For the first 9 months of the year, provide a minimum of 80-percent feed that is either organic or raised from land included in the organic system plan and managed in compliance with organic crop requirements; and (b) Provide feed in compliance with §205.237 for the final 3 months.

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

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

(b) The following are prohibited:

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

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

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

[65 FR 80637, Dec. 21, 2000, as amended at 71 FR 32807, June 7, 2006]

§ 205.237 Livestock feed.



[top](#)

(a) The producer of an organic livestock operation must provide livestock with a total feed ration composed of agricultural products, including pasture and forage, that are organically produced and handled by operations certified to the NOP, except as provided in §205.236(a)(2)(i), except, that, synthetic substances allowed under §205.603 and nonsynthetic substances not prohibited under §205.604 may be used as feed additives and feed supplements, *Provided*, That, all agricultural ingredients included in the ingredients list, for such additives and supplements, shall have been produced and handled organically.

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

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

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

(3) Feed plastic pellets for roughage;

(4) Feed formulas containing urea or manure;

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

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

(7) Provide feed or forage to which any antibiotic including ionophores has been added; or

(8) Prevent, withhold, restrain, or otherwise restrict ruminant animals from actively obtaining feed grazed from pasture during the grazing season, except for conditions as described under §205.239(b) and (c).

(c) During the grazing season, producers shall:

(1) Provide not more than an average of 70 percent of a ruminant's dry matter demand from dry matter fed (dry matter fed does not include dry matter grazed from residual forage or vegetation rooted in pasture). This shall be calculated as an average over the entire grazing season for each type and class of animal. Ruminant animals must be grazed throughout the entire grazing season for the geographical region, which shall be not less than 120 days per calendar year. Due to weather, season, and/or climate, the grazing season may or may not be continuous.

(2) Provide pasture of a sufficient quality and quantity to graze throughout the grazing season and to provide all ruminants under the organic system plan with an average of not less than 30 percent of their dry matter intake from grazing throughout the grazing season: *Except*, That,

(i) Ruminant animals denied pasture in accordance with §205.239(b)(1) through (8), and §205.239(c)(1) through (3), shall be provided with an average of not less than 30 percent of their dry matter intake from grazing throughout the periods that they are on pasture during the grazing season;

(ii) Breeding bulls shall be exempt from the 30 percent dry matter intake from grazing requirement of this section and management on pasture requirement of §205.239(c)(2); *Provided*, That, any animal maintained under this exemption shall not be sold, labeled, used, or represented as organic slaughter stock.

(d) Ruminant livestock producers shall:

(1) Describe the total feed ration for each type and class of animal. The description must include:

(i) All feed produced on-farm;

(ii) All feed purchased from off-farm sources;

(iii) The percentage of each feed type, including pasture, in the total ration; and

(iv) A list of all feed supplements and additives.

(2) Document the amount of each type of feed actually fed to each type and class of animal.

(3) Document changes that are made to all rations throughout the year in response to seasonal grazing changes.

(4) Provide the method for calculating dry matter demand and dry matter intake.

[65 FR 80637, Dec. 21, 2000, as amended at 75 FR 7193, Feb. 17, 2010]

§ 205.238 Livestock health care practice standard.



[top](#)

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

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

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

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

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

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

(6) Administration of vaccines and other veterinary biologics.

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

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

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

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

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

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

(3) Administer hormones for growth promotion;

(4) Administer synthetic parasiticides on a routine basis;

(5) Administer synthetic parasiticides to slaughter stock;

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

(7) Withhold medical treatment from a sick animal in an effort to preserve its organic status. All appropriate medications must be used to restore an animal to health when methods acceptable to organic production fail. Livestock treated with a prohibited substance must be clearly identified and shall not be sold, labeled, or represented as organically produced.

§ 205.239 Livestock living conditions.



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

(1) Year-round access for all animals to the outdoors, shade, shelter, exercise areas, fresh air, clean water for drinking, and direct sunlight, suitable to the species, its stage of life, the climate, and the environment: Except, that, animals may be temporarily denied access to the outdoors in accordance with §§205.239(b) and (c). Yards, feeding pads, and feedlots may be used to provide ruminants with access to the outdoors during the non-grazing season and supplemental feeding during the grazing season. Yards, feeding pads, and feedlots shall be large enough to allow all ruminant livestock occupying the yard, feeding pad, or feedlot to feed simultaneously without crowding and without competition for food. Continuous total confinement of any animal indoors is prohibited. Continuous total confinement of ruminants in yards, feeding pads, and feedlots is prohibited.

(2) For all ruminants, management on pasture and daily grazing throughout the grazing season(s) to meet the requirements of §205.237, except as provided for in paragraphs (b), (c), and (d) of this section.

(3) Appropriate clean, dry bedding. When roughages are used as bedding, they shall have been organically produced in accordance with this part by an operation certified under this part, except as provided in §205.236(a)(2)(i), and, if applicable, organically handled by operations certified to the NOP.

(4) Shelter designed to allow for:

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

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

(iii) Reduction of potential for livestock injury;

(5) The use of yards, feeding pads, feedlots and laneways that shall be well-drained, kept in good condition (including frequent removal of wastes), and managed to prevent runoff of wastes and

contaminated waters to adjoining or nearby surface water and across property boundaries.

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

(1) Inclement weather;

(2) The animal's stage of life: Except, that lactation is not a stage of life that would exempt ruminants from any of the mandates set forth in this regulation;

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

(4) Risk to soil or water quality;

(5) Preventive healthcare procedures or for the treatment of illness or injury (neither the various life stages nor lactation is an illness or injury);

(6) Sorting or shipping animals and livestock sales: *Provided*, that, the animals shall be maintained under continuous organic management, including organic feed, throughout the extent of their allowed confinement;

(7) Breeding: Except, that, bred animals shall not be denied access to the outdoors and, once bred, ruminants shall not be denied access to pasture during the grazing season; or

(8) 4–H, Future Farmers of America and other youth projects, for no more than one week prior to a fair or other demonstration, through the event and up to 24 hours after the animals have arrived home at the conclusion of the event. These animals must have been maintained under continuous organic management, including organic feed, during the extent of their allowed confinement for the event.

(c) The producer of an organic livestock operation may, in addition to the times permitted under §205.239(b), temporarily deny a ruminant animal pasture or outdoor access under the following conditions:

(1) One week at the end of a lactation for dry off (for denial of access to pasture only), three weeks prior to parturition (birthing), parturition, and up to one week after parturition;

(2) In the case of newborn dairy cattle for up to six months, after which they must be on pasture during the grazing season and may no longer be individually housed: *Provided*, That, an animal shall not be confined or tethered in a way that prevents the animal from lying down, standing up, fully extending its limbs, and moving about freely;

(3) In the case of fiber bearing animals, for short periods for shearing; and

(4) In the case of dairy animals, for short periods daily for milking. Milking must be scheduled in a manner to ensure sufficient grazing time to provide each animal with an average of at least 30 percent DMI from grazing throughout the grazing season. Milking frequencies or duration practices cannot be used to deny dairy animals pasture.

(d) Ruminant slaughter stock, typically grain finished, shall be maintained on pasture for each day that the finishing period corresponds with the grazing season for the geographical location: Except, that, yards, feeding pads, or feedlots may be used to provide finish feeding rations. During the finishing period, ruminant slaughter stock shall be exempt from the minimum 30 percent DMI requirement from grazing. Yards, feeding pads, or feedlots used to provide finish feeding rations shall be large enough to allow all ruminant slaughter stock occupying the yard, feeding pad, or feed lot to feed simultaneously without crowding and without competition for food. The finishing period shall not exceed one-fifth (1/5) of the animal's total life or 120 days, whichever is shorter.

(e) The producer of an organic livestock operation must manage manure in a manner that does not contribute to contamination of crops, soil, or water by plant nutrients, heavy metals, or pathogenic organisms and optimizes recycling of nutrients and must manage pastures and other outdoor access areas in a manner that does not put soil or water quality at risk.

[65 FR 80637, Dec. 21, 2000, as amended at 75 FR 7193, Feb. 17, 2010]

§ 205.240 Pasture practice standard.



The producer of an organic livestock operation must, for all ruminant livestock on the operation, demonstrate through auditable records in the organic system plan, a functioning management plan for pasture.

(a) Pasture must be managed as a crop in full compliance with §§205.202, 205.203(d) and (e), 205.204, and 205.206(b) through (f). Land used for the production of annual crops for ruminant grazing must be managed in full compliance with §§205.202 through 205.206. Irrigation shall be used, as needed, to promote pasture growth when the operation has irrigation available for use on pasture.

(b) Producers must provide pasture in compliance with §205.239(a)(2) and manage pasture to comply with the requirements of: §205.237(c)(2), to annually provide a minimum of 30 percent of a ruminant's dry matter intake (DMI), on average, over the course of the grazing season(s); §205.238(a)(3), to minimize the occurrence and spread of diseases and parasites; and §205.239(e) to refrain from putting soil or water quality at risk.

(c) A pasture plan must be included in the producer's organic system plan, and be updated annually in accordance with §205.406(a). The producer may resubmit the previous year's pasture plan when no change has occurred in the plan. The pasture plan may consist of a pasture/rangeland plan developed in cooperation with a Federal, State, or local conservation office: *Provided*, that, the submitted plan addresses all of the requirements of §205.240(c)(1) through (8). When a change to an approved pasture plan is contemplated, which may affect the operation's compliance with the Act or the regulations in this part, the producer shall seek the certifying agent's agreement on the change prior to implementation. The pasture plan shall include a description of the:

(1) Types of pasture provided to ensure that the feed requirements of §205.237 are being met.

(2) Cultural and management practices to be used to ensure pasture of a sufficient quality and quantity is available to graze throughout the grazing season and to provide all ruminants under the organic system plan, except exempted classes identified in §205.239(c)(1) through (3), with an average of not less than 30 percent of their dry matter intake from grazing throughout the grazing season.

(3) Grazing season for the livestock operation's regional location.

(4) Location and size of pastures, including maps giving each pasture its own identification.

(5) The types of grazing methods to be used in the pasture system.

(6) Location and types of fences, except for temporary fences, and the location and source of shade and the location and source of water.

(7) Soil fertility and seeding systems.

(8) Erosion control and protection of natural wetlands and riparian areas practices.

[75 FR 7194, Feb. 17, 2010]

§§ 205.241-205.269 [Reserved]



§ 205.270 Organic handling requirements.



(a) Mechanical or biological methods, including but not limited to cooking, baking, curing, heating,

drying, mixing, grinding, churning, separating, distilling, extracting, slaughtering, cutting, fermenting, eviscerating, preserving, dehydrating, freezing, chilling, or otherwise manufacturing, and the packaging, canning, jarring, or otherwise enclosing food in a container may be used to process an organically produced agricultural product for the purpose of retarding spoilage or otherwise preparing the agricultural product for market.

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

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

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

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

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

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

§ 205.271 Facility pest management practice standard.



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

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

(2) Prevention of access to handling facilities; and

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

(b) Pests may be controlled through:

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

(2) Lures and repellents using 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]



§ 205.290 Temporary variances.



(a) Temporary variances from the requirements in §§205.203 through 205.207, 205.236 through 205.240 and 205.270 through 205.272 may be established by the Administrator for the following reasons:

(1) Natural disasters declared by the Secretary;

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

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

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

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

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

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

[65 FR 80637, Dec. 21, 2000, as amended at 75 FR 7194, Feb. 17, 2010]

§§ 205.291-205.299 [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.

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



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

- (1) The statement:
 - (i) “Made with organic (specified ingredients)”: *Provided*, That, the statement does not list more than three organically produced ingredients; or
 - (ii) “Made with organic (specified food groups)”: *Provided*, That, the statement does not list more than three of the following food groups: beans, fish, fruits, grains, herbs, meats, nuts, oils, poultry, seeds, spices, sweeteners, and vegetables or processed milk products; and, *Provided further*, That, all ingredients of each listed food group in the product must be organically produced; and
 - (iii) Which appears in letters that do not exceed one-half the size of the largest type size on the panel and which appears in its entirety in the same type size, style, and color without highlighting.
- (2) The percentage of organic ingredients in the product. The size of the percentage statement must not exceed one-half the size of the largest type size on the panel on which the statement is displayed and

must appear in its entirety in the same type size, style, and color without highlighting.

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

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

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

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

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

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



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

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

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

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

(1) The USDA seal; and

(2) Any certifying agent seal, logo, or other identifying mark which represents organic certification of a product or product ingredients.

§ 205.306 Labeling of livestock feed.



(a) Livestock feed products described in §205.301(e)(1) and (e)(2) may display on any package panel the following terms:

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

(2) The USDA seal;

(3) The seal, logo, or other identifying mark of the certifying agent which certified the production or handling operation producing the raw or processed organic ingredients used in the finished product, *Provided*, That, such seals or marks are not displayed more prominently than the USDA seal;

(4) The word, "organic," or an asterisk or other reference mark which is defined on the package to identify ingredients that are organically produced. Water or salt included as ingredients cannot be identified as organic.

(b) Livestock feed products described in §205.301(e)(1) and (e)(2) must:

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

(2) Comply with other Federal agency or State feed labeling requirements as applicable.

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



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

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

(2) Identification of the product as organic;

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

(4) The USDA seal;

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

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

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

§ 205.308 Agricultural products in other than packaged form at the point of retail sale that are sold, labeled, or represented as "100 percent organic" or "organic."



(a) Agricultural products in other than packaged form may use the term, "100 percent organic" or "organic," as applicable, to modify the name of the product in retail display, labeling, and display containers: *Provided*, That, the term, "organic," is used to identify the organic ingredients listed in the ingredient statement.

(b) If the product is prepared in a certified facility, the retail display, labeling, and display containers may use:

(1) The USDA seal; and

(2) The seal, logo, or other identifying mark of the certifying agent that certified the production or handling operation producing the finished product and any other certifying agent which certified operations producing raw organic product or organic ingredients used in the finished product: *Provided*, That, such seals or marks are not individually displayed more prominently than the USDA seal.

§ 205.309 Agricultural products in other than packaged form at the point of retail sale that are sold, labeled, or represented as “made with organic (specified ingredients or food group(s)).”



(a) Agricultural products in other than packaged form containing between 70 and 95 percent organically produced ingredients may use the phrase, “made with organic (specified ingredients or food group(s)),” to modify the name of the product in retail display, labeling, and display containers.

(1) Such statement must not list more than three organic ingredients or food groups, and

(2) In any such display of the product's ingredient statement, the organic ingredients are identified as “organic.”

(b) If prepared in a certified facility, such agricultural products labeled as “made with organic (specified ingredients or food group(s))” in retail displays, display containers, and market information may display the certifying agent's seal, logo, or other identifying mark.

§ 205.310 Agricultural products produced on an exempt or excluded operation.



(a) An agricultural product organically produced or handled on an exempt or excluded operation must not:

(1) Display the USDA seal or any certifying agent's seal or other identifying mark which represents the exempt or excluded operation as a certified organic operation, or

(2) Be represented as a certified organic product or certified organic ingredient to any buyer.

(b) An agricultural product organically produced or handled on an exempt or excluded operation may be identified as an organic product or organic ingredient in a multiingredient product produced by the exempt or excluded operation. Such product or ingredient must not be identified or represented as “organic” in a product processed by others.

(c) Such product is subject to requirements specified in paragraph (a) of §205.300, and paragraphs (f)(1) through (f)(7) of §205.301.

§ 205.311 USDA Seal.



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

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

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

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

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



Figure 1

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§§ 205.312-205.399 [Reserved]



Subpart E—Certification



§ 205.400 General requirements for certification.



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

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

§ 205.401 Application for certification.



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

- (a) An organic production or handling system plan, as required in §205.200;
- (b) The name of the person completing the application; the applicant's business name, address, and telephone number; and, when the applicant is a corporation, the name, address, and telephone number of the person authorized to act on the applicant's behalf;
- (c) The name(s) of any organic certifying agent(s) to which application has previously been made; the year(s) of application; the outcome of the application(s) submission, including, when available, a copy of any notification of noncompliance or denial of certification issued to the applicant for certification; and a description of the actions taken by the applicant to correct the noncompliances noted in the notification of noncompliance, including evidence of such correction; and
- (d) Other information necessary to determine compliance with the Act and the regulations in this part.

§ 205.402 Review of application.



- (a) Upon acceptance of an application for certification, a certifying agent must:
 - (1) Review the application to ensure completeness pursuant to §205.401;
 - (2) Determine by a review of the application materials whether the applicant appears to comply or may be able to comply with the applicable requirements of subpart C of this part;
 - (3) Verify that an applicant who previously applied to another certifying agent and received a notification of noncompliance or denial of certification, pursuant to §205.405, has submitted documentation to support the correction of any noncompliances identified in the notification of noncompliance or denial of certification, as required in §205.405(e); and
 - (4) Schedule an on-site inspection of the operation to determine whether the applicant qualifies for certification if the review of application materials reveals that the production or handling operation may be in compliance with the applicable requirements of subpart C of this part.
- (b) The certifying agent shall within a reasonable time:
 - (1) Review the application materials received and communicate its findings to the applicant;
 - (2) Provide the applicant with a copy of the on-site inspection report, as approved by the certifying agent, for any on-site inspection performed; and
 - (3) Provide the applicant with a copy of the test results for any samples taken by an inspector.
- (c) The applicant may withdraw its application at any time. An applicant who withdraws its application shall be liable for the costs of services provided up to the time of withdrawal of its application. An applicant that voluntarily withdrew its application prior to the issuance of a notice of noncompliance will not be issued a notice of noncompliance. Similarly, an applicant that voluntarily withdrew its application prior to the issuance of a notice of certification denial will not be issued a notice of certification denial.

§ 205.403 On-site inspections.



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

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

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

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

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

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

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

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

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

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

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

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

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

§ 205.404 Granting certification.



(a) Within a reasonable time after completion of the initial on-site inspection, a certifying agent must review the on-site inspection report, the results of any analyses for substances conducted, and any additional information requested from or supplied by the applicant. If the certifying agent determines that the organic system plan and all procedures and activities of the applicant's operation are in compliance with the requirements of this part and that the applicant is able to conduct operations in accordance with the plan, the agent shall grant certification. The certification may include requirements for the correction of minor noncompliances within a specified time period as a condition of continued certification.

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

(1) Name and address of the certified operation;

(2) Effective date of certification;

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

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

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

§ 205.405 Denial of certification.



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

(1) A description of each noncompliance;

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

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

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

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

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

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

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

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

(i) When the corrective action or rebuttal is sufficient for the applicant to qualify for certification, issue the applicant an approval of certification pursuant to §205.404; or

(ii) When the corrective action or rebuttal is not sufficient for the applicant to qualify for certification, issue the applicant a written notice of denial of certification.

(2) Issue a written notice of denial of certification to an applicant who fails to respond to the notification of noncompliance.

(3) Provide notice of approval or denial to the Administrator, pursuant to §205.501(a)(14).

(d) A notice of denial of certification must state the reason(s) for denial and the applicant's right to:

(1) Reapply for certification pursuant to §§205.401 and 205.405(e);

- (2) Request mediation pursuant to §205.663 or, if applicable, pursuant to a State organic program; or
- (3) File an appeal of the denial of certification pursuant to §205.681 or, if applicable, pursuant to a State organic program.
- (e) An applicant for certification who has received a written notification of noncompliance or a written notice of denial of certification may apply for certification again at any time with any certifying agent, in accordance with §§205.401 and 205.405(e). When such applicant submits a new application to a certifying agent other than the agent who issued the notification of noncompliance or notice of denial of certification, the applicant for certification must include a copy of the notification of noncompliance or notice of denial of certification and a description of the actions taken, with supporting documentation, to correct the noncompliances noted in the notification of noncompliance.
- (f) A certifying agent who receives a new application for certification, which includes a notification of noncompliance or a notice of denial of certification, must treat the application as a new application and begin a new application process pursuant to §205.402.
- (g) Notwithstanding paragraph (a) of this section, if a certifying agent has reason to believe that an applicant for certification has willfully made a false statement or otherwise purposefully misrepresented the applicant's operation or its compliance with the certification requirements pursuant to this part, the certifying agent may deny certification pursuant to paragraph (c)(1)(ii) of this section without first issuing a notification of noncompliance.

§ 205.406 Continuation of certification.



- (a) To continue certification, a certified operation must annually pay the certification fees and submit the following information, as applicable, to the certifying agent:
- (1) An updated organic production or handling system plan which includes:
- (i) A summary statement, supported by documentation, detailing any deviations from, changes to, modifications to, or other amendments made to the previous year's organic system plan during the previous year; and
- (ii) Any additions or deletions to the previous year's organic system plan, intended to be undertaken in the coming year, detailed pursuant to §205.200;
- (2) Any additions to or deletions from the information required pursuant to §205.401(b);
- (3) An update on the correction of minor noncompliances previously identified by the certifying agent as requiring correction for continued certification; and
- (4) Other information as deemed necessary by the certifying agent to determine compliance with the Act and the regulations in this part.
- (b) Following the receipt of the information specified in paragraph (a) of this section, the certifying agent shall within a reasonable time arrange and conduct an on-site inspection of the certified operation pursuant to §205.403: *Except*, That, when it is impossible for the certifying agent to conduct the annual on-site inspection following receipt of the certified operation's annual update of information, the certifying agent may allow continuation of certification and issue an updated certificate of organic operation on the basis of the information submitted and the most recent on-site inspection conducted during the previous 12 months: *Provided*, That, the annual on-site inspection, required pursuant to §205.403, is conducted within the first 6 months following the certified operation's scheduled date of annual update.
- (c) If the certifying agent has reason to believe, based on the on-site inspection and a review of the information specified in §205.404, that a certified operation is not complying with the requirements of the Act and the regulations in this part, the certifying agent shall provide a written notification of noncompliance to the operation in accordance with §205.662.
- (d) If the certifying agent determines that the certified operation is complying with the Act and the

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

§§ 205.407-205.499 [Reserved]



Subpart F—Accreditation of Certifying Agents



§ 205.500 Areas and duration of accreditation.



(a) The Administrator shall accredit a qualified domestic or foreign applicant in the areas of crops, livestock, wild crops, or handling or any combination thereof to certify a domestic or foreign production or handling operation as a certified operation.

(b) Accreditation shall be for a period of 5 years from the date of approval of accreditation pursuant to §205.506.

(c) In lieu of accreditation under paragraph (a) of this section, USDA will accept a foreign certifying agent's accreditation to certify organic production or handling operations if:

(1) USDA determines, upon the request of a foreign government, that the standards under which the foreign government authority accredited the foreign certifying agent meet the requirements of this part; or

(2) The foreign government authority that accredited the foreign certifying agent acted under an equivalency agreement negotiated between the United States and the foreign government.

§ 205.501 General requirements for accreditation.



(a) A private or governmental entity accredited as a certifying agent under this subpart must:

(1) Have sufficient expertise in organic production or handling techniques to fully comply with and implement the terms and conditions of the organic certification program established under the Act and the regulations in this part;

(2) Demonstrate the ability to fully comply with the requirements for accreditation set forth in this subpart;

(3) Carry out the provisions of the Act and the regulations in this part, including the provisions of §§205.402 through 205.406 and §205.670;

(4) Use a sufficient number of adequately trained personnel, including inspectors and certification review personnel, to comply with and implement the organic certification program established under the Act and the regulations in subpart E of this part;

(5) Ensure that its responsibly connected persons, employees, and contractors with inspection, analysis, and decision-making responsibilities have sufficient expertise in organic production or handling techniques to successfully perform the duties assigned.

(6) Conduct an annual performance evaluation of all persons who review applications for certification, perform on-site inspections, review certification documents, evaluate qualifications for certification, make

recommendations concerning certification, or make certification decisions and implement measures to correct any deficiencies in certification services;

(7) Have an annual program review of its certification activities conducted by the certifying agent's staff, an outside auditor, or a consultant who has expertise to conduct such reviews and implement measures to correct any noncompliances with the Act and the regulations in this part that are identified in the evaluation;

(8) Provide sufficient information to persons seeking certification to enable them to comply with the applicable requirements of the Act and the regulations in this part;

(9) Maintain all records pursuant to §205.510(b) and make all such records available for inspection and copying during normal business hours by authorized representatives of the Secretary and the applicable State organic program's governing State official;

(10) Maintain strict confidentiality with respect to its clients under the applicable organic certification program and not disclose to third parties (with the exception of the Secretary or the applicable State organic program's governing State official or their authorized representatives) any business-related information concerning any client obtained while implementing the regulations in this part, except as provided for in §205.504(b)(5);

(11) Prevent conflicts of interest by:

(i) Not certifying a production or handling operation if the certifying agent or a responsibly connected party of such certifying agent has or has held a commercial interest in the production or handling operation, including an immediate family interest or the provision of consulting services, within the 12-month period prior to the application for certification;

(ii) Excluding any person, including contractors, with conflicts of interest from work, discussions, and decisions in all stages of the certification process and the monitoring of certified production or handling operations for all entities in which such person has or has held a commercial interest, including an immediate family interest or the provision of consulting services, within the 12-month period prior to the application for certification;

(iii) Not permitting any employee, inspector, contractor, or other personnel to accept payment, gifts, or favors of any kind, other than prescribed fees, from any business inspected: *Except*, That, a certifying agent that is a not-for-profit organization with an Internal Revenue Code tax exemption or, in the case of a foreign certifying agent, a comparable recognition of not-for-profit status from its government, may accept voluntary labor from certified operations;

(iv) Not giving advice or providing consultancy services, to certification applicants or certified operations, for overcoming identified barriers to certification;

(v) Requiring all persons who review applications for certification, perform on-site inspections, review certification documents, evaluate qualifications for certification, make recommendations concerning certification, or make certification decisions and all parties responsibly connected to the certifying agent to complete an annual conflict of interest disclosure report; and

(vi) Ensuring that the decision to certify an operation is made by a person different from those who conducted the review of documents and on-site inspection.

(12)(i) Reconsider a certified operation's application for certification and, if necessary, perform a new on-site inspection when it is determined, within 12 months of certifying the operation, that any person participating in the certification process and covered under §205.501(a)(11)(ii) has or had a conflict of interest involving the applicant. All costs associated with a reconsideration of application, including onsite inspection costs, shall be borne by the certifying agent.

(ii) Refer a certified operation to a different accredited certifying agent for recertification and reimburse the operation for the cost of the recertification when it is determined that any person covered under §205.501(a)(11)(i) at the time of certification of the applicant had a conflict of interest involving the applicant.

(13) Accept the certification decisions made by another certifying agent accredited or accepted by USDA pursuant to §205.500;

(14) Refrain from making false or misleading claims about its accreditation status, the USDA accreditation program for certifying agents, or the nature or qualities of products labeled as organically produced;

(15) Submit to the Administrator a copy of:

(i) Any notice of denial of certification issued pursuant to §205.405, notification of noncompliance, notification of noncompliance correction, notification of proposed suspension or revocation, and notification of suspension or revocation sent pursuant to §205.662 simultaneously with its issuance; and

(ii) A list, on January 2 of each year, including the name, address, and telephone number of each operation granted certification during the preceding year;

(16) Charge applicants for certification and certified production and handling operations only those fees and charges for certification activities that it has filed with the Administrator;

(17) Pay and submit fees to AMS in accordance with §205.640;

(18) Provide the inspector, prior to each on-site inspection, with previous on-site inspection reports and notify the inspector of its decision regarding certification of the production or handling operation site inspected by the inspector and of any requirements for the correction of minor noncompliances;

(19) Accept all production or handling applications that fall within its area(s) of accreditation and certify all qualified applicants, to the extent of its administrative capacity to do so without regard to size or membership in any association or group; and

(20) Demonstrate its ability to comply with a State's organic program to certify organic production or handling operations within the State.

(21) Comply with, implement, and carry out any other terms and conditions determined by the Administrator to be necessary.

(b) A private or governmental entity accredited as a certifying agent under this subpart may establish a seal, logo, or other identifying mark to be used by production and handling operations certified by the certifying agent to indicate affiliation with the certifying agent: *Provided*, That, the certifying agent:

(1) Does not require use of its seal, logo, or other identifying mark on any product sold, labeled, or represented as organically produced as a condition of certification and

(2) Does not require compliance with any production or handling practices other than those provided for in the Act and the regulations in this part as a condition of use of its identifying mark: *Provided*, That, certifying agents certifying production or handling operations within a State with more restrictive requirements, approved by the Secretary, shall require compliance with such requirements as a condition of use of their identifying mark by such operations.

(c) A private entity accredited as a certifying agent must:

(1) Hold the Secretary harmless for any failure on the part of the certifying agent to carry out the provisions of the Act and the regulations in this part;

(2) Furnish reasonable security, in an amount and according to such terms as the Administrator may by regulation prescribe, for the purpose of protecting the rights of production and handling operations certified by such certifying agent under the Act and the regulations in this part; and

(3) Transfer to the Administrator and make available to any applicable State organic program's governing State official all records or copies of records concerning the person's certification activities in the event that the certifying agent dissolves or loses its accreditation; *Provided*, That, such transfer shall not apply to a merger, sale, or other transfer of ownership of a certifying agent.

(d) No private or governmental entity accredited as a certifying agent under this subpart shall exclude from participation in or deny the benefits of the National Organic Program to any person due to discrimination because of race, color, national origin, gender, religion, age, disability, political beliefs, sexual orientation, or marital or family status.

§ 205.502 Applying for accreditation.



(a) A private or governmental entity seeking accreditation as a certifying agent under this subpart must submit an application for accreditation which contains the applicable information and documents set forth in §§205.503 through 205.505 and the fees required in §205.640 to: Program Manager, USDA-AMS-TMP-NOP, Room 2945—South Building, P.O. Box 96456, Washington, DC 20090–6456.

(b) Following the receipt of the information and documents, the Administrator will determine, pursuant to §205.506, whether the applicant for accreditation should be accredited as a certifying agent.

§ 205.503 Applicant information.



A private or governmental entity seeking accreditation as a certifying agent must submit the following information:

(a) The business name, primary office location, mailing address, name of the person(s) responsible for the certifying agent's day-to-day operations, contact numbers (telephone, facsimile, and Internet address) of the applicant, and, for an applicant who is a private person, the entity's taxpayer identification number;

(b) The name, office location, mailing address, and contact numbers (telephone, facsimile, and Internet address) for each of its organizational units, such as chapters or subsidiary offices, and the name of a contact person for each unit;

(c) Each area of operation (crops, wild crops, livestock, or handling) for which accreditation is requested and the estimated number of each type of operation anticipated to be certified annually by the applicant along with a copy of the applicant's schedule of fees for all services to be provided under these regulations by the applicant;

(d) The type of entity the applicant is (e.g., government agricultural office, for-profit business, not-for-profit membership association) and for:

(1) A governmental entity, a copy of the official's authority to conduct certification activities under the Act and the regulations in this part,

(2) A private entity, documentation showing the entity's status and organizational purpose, such as articles of incorporation and by-laws or ownership or membership provisions, and its date of establishment; and

(e) A list of each State or foreign country in which the applicant currently certifies production and handling operations and a list of each State or foreign country in which the applicant intends to certify production or handling operations.

§ 205.504 Evidence of expertise and ability.



A private or governmental entity seeking accreditation as a certifying agent must submit the following documents and information to demonstrate its expertise in organic production or handling techniques; its ability to fully comply with and implement the organic certification program established in §§205.100 and 205.101, §§205.201 through 205.203, §§205.300 through 205.303, §§205.400 through 205.406, and §§205.661 and 205.662; and its ability to comply with the requirements for accreditation set forth in §205.501:

(a) *Personnel.* (1) A copy of the applicant's policies and procedures for training, evaluating, and supervising personnel;

(2) The name and position description of all personnel to be used in the certification operation, including administrative staff, certification inspectors, members of any certification review and evaluation committees, contractors, and all parties responsibly connected to the certifying agent;

(3) A description of the qualifications, including experience, training, and education in agriculture, organic production, and organic handling, for:

(i) Each inspector to be used by the applicant and

(ii) Each person to be designated by the applicant to review or evaluate applications for certification; and

(4) A description of any training that the applicant has provided or intends to provide to personnel to ensure that they comply with and implement the requirements of the Act and the regulations in this part.

(b) *Administrative policies and procedures.* (1) A copy of the procedures to be used to evaluate certification applicants, make certification decisions, and issue certification certificates;

(2) A copy of the procedures to be used for reviewing and investigating certified operation compliance with the Act and the regulations in this part and the reporting of violations of the Act and the regulations in this part to the Administrator;

(3) A copy of the procedures to be used for complying with the recordkeeping requirements set forth in §205.501(a)(9);

(4) A copy of the procedures to be used for maintaining the confidentiality of any business-related information as set forth in §205.501(a)(10);

(5) A copy of the procedures to be used, including any fees to be assessed, for making the following information available to any member of the public upon request:

(i) Certification certificates issued during the current and 3 preceding calendar years;

(ii) A list of producers and handlers whose operations it has certified, including for each the name of the operation, type(s) of operation, products produced, and the effective date of the certification, during the current and 3 preceding calendar years;

(iii) The results of laboratory analyses for residues of pesticides and other prohibited substances conducted during the current and 3 preceding calendar years; and

(iv) Other business information as permitted in writing by the producer or handler; and

(6) A copy of the procedures to be used for sampling and residue testing pursuant to §205.670.

(c) *Conflicts of interest.* (1) A copy of procedures intended to be implemented to prevent the occurrence of conflicts of interest, as described in §205.501(a)(11).

(2) For all persons who review applications for certification, perform on-site inspections, review certification documents, evaluate qualifications for certification, make recommendations concerning certification, or make certification decisions and all parties responsibly connected to the certifying agent, a conflict of interest disclosure report, identifying any food- or agriculture-related business interests, including business interests of immediate family members, that cause a conflict of interest.

(d) *Current certification activities.* An applicant who currently certifies production or handling operations must submit: (1) A list of all production and handling operations currently certified by the applicant;

(2) Copies of at least 3 different inspection reports and certification evaluation documents for production or handling operations certified by the applicant during the previous year for each area of operation for which accreditation is requested; and

(3) The results of any accreditation process of the applicant's operation by an accrediting body during the previous year for the purpose of evaluating its certification activities.

(e) *Other information.* Any other information the applicant believes may assist in the Administrator's evaluation of the applicant's expertise and ability.

§ 205.505 Statement of agreement.



(a) A private or governmental entity seeking accreditation under this subpart must sign and return a statement of agreement prepared by the Administrator which affirms that, if granted accreditation as a certifying agent under this subpart, the applicant will carry out the provisions of the Act and the regulations in this part, including:

(1) Accept the certification decisions made by another certifying agent accredited or accepted by USDA pursuant to §205.500;

(2) Refrain from making false or misleading claims about its accreditation status, the USDA accreditation program for certifying agents, or the nature or qualities of products labeled as organically produced;

(3) Conduct an annual performance evaluation of all persons who review applications for certification, perform on-site inspections, review certification documents, evaluate qualifications for certification, make recommendations concerning certification, or make certification decisions and implement measures to correct any deficiencies in certification services;

(4) Have an annual internal program review conducted of its certification activities by certifying agent staff, an outside auditor, or a consultant who has the expertise to conduct such reviews and implement measures to correct any noncompliances with the Act and the regulations in this part;

(5) Pay and submit fees to AMS in accordance with §205.640; and

(6) Comply with, implement, and carry out any other terms and conditions determined by the Administrator to be necessary.

(b) A private entity seeking accreditation as a certifying agent under this subpart must additionally agree to:

(1) Hold the Secretary harmless for any failure on the part of the certifying agent to carry out the provisions of the Act and the regulations in this part;

(2) Furnish reasonable security, in an amount and according to such terms as the Administrator may by regulation prescribe, for the purpose of protecting the rights of production and handling operations certified by such certifying agent under the Act and the regulations in this part; and

(3) Transfer to the Administrator and make available to the applicable State organic program's governing State official all records or copies of records concerning the certifying agent's certification activities in the event that the certifying agent dissolves or loses its accreditation; *Provided*, That such transfer shall not apply to a merger, sale, or other transfer of ownership of a certifying agent.

§ 205.506 Granting accreditation.



(a) Accreditation will be granted when:

(1) The accreditation applicant has submitted the information required by §§205.503 through 205.505;

(2) The accreditation applicant pays the required fee in accordance with §205.640(c); and

(3) The Administrator determines that the applicant for accreditation meets the requirements for accreditation as stated in §205.501, as determined by a review of the information submitted in accordance with §§205.503 through 205.505 and, if necessary, a review of the information obtained

from a site evaluation as provided for in §205.508.

(b) On making a determination to approve an application for accreditation, the Administrator will notify the applicant of the granting of accreditation in writing, stating:

- (1) The area(s) for which accreditation is given;
- (2) The effective date of the accreditation;
- (3) Any terms and conditions for the correction of minor noncompliances; and
- (4) For a certifying agent who is a private entity, the amount and type of security that must be established to protect the rights of production and handling operations certified by such certifying agent.

(c) The accreditation of a certifying agent shall continue in effect until such time as the certifying agent fails to renew accreditation as provided in §205.510(c), the certifying agent voluntarily ceases its certification activities, or accreditation is suspended or revoked pursuant to §205.665.

§ 205.507 Denial of accreditation.



(a) If the Program Manager has reason to believe, based on a review of the information specified in §§205.503 through 205.505 or after a site evaluation as specified in §205.508, that an applicant for accreditation is not able to comply or is not in compliance with the requirements of the Act and the regulations in this part, the Program Manager shall provide a written notification of noncompliance to the applicant. Such notification shall provide:

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

(b) When each noncompliance has been resolved, the Program Manager will send the applicant a written notification of noncompliance resolution and proceed with further processing of the application.

(c) If an applicant fails to correct the noncompliances, fails to report the corrections by the date specified in the notification of noncompliance, fails to file a rebuttal of the notification of noncompliance by the date specified, or is unsuccessful in its rebuttal, the Program Manager will provide the applicant with written notification of accreditation denial. An applicant who has received written notification of accreditation denial may apply for accreditation again at any time in accordance with §205.502, or appeal the denial of accreditation in accordance with §205.681 by the date specified in the notification of accreditation denial.

(d) If the certifying agent was accredited prior to the site evaluation and the certifying agent fails to correct the noncompliances, fails to report the corrections by the date specified in the notification of noncompliance, or fails to file a rebuttal of the notification of noncompliance by the date specified, the Administrator will begin proceedings to suspend or revoke the certifying agent's accreditation. A certifying agent who has had its accreditation suspended may at any time, unless otherwise stated in the notification of suspension, submit a request to the Secretary for reinstatement of its accreditation. The request must be accompanied by evidence demonstrating correction of each noncompliance and corrective actions taken to comply with and remain in compliance with the Act and the regulations in this part. A certifying agent whose accreditation is revoked will be ineligible for accreditation for a period of not less than 3 years following the date of such determination.

§ 205.508 Site evaluations.



(a) Site evaluations of accredited certifying agents shall be conducted for the purpose of examining the certifying agent's operations and evaluating its compliance with the Act and the regulations of this part. Site evaluations shall include an on-site review of the certifying agent's certification procedures, decisions, facilities, administrative and management systems, and production or handling operations certified by the certifying agent. Site evaluations shall be conducted by a representative(s) of the Administrator.

(b) An initial site evaluation of an accreditation applicant shall be conducted before or within a reasonable period of time after issuance of the applicant's "notification of accreditation." A site evaluation shall be conducted after application for renewal of accreditation but prior to the issuance of a notice of renewal of accreditation. One or more site evaluations will be conducted during the period of accreditation to determine whether an accredited certifying agent is complying with the general requirements set forth in §205.501.

§ 205.509 Peer review panel.



The Administrator shall establish a peer review panel pursuant to the Federal Advisory Committee Act (FACA) (5 U.S.C. App. 2 et seq.). The peer review panel shall be composed of not less than 3 members who shall annually evaluate the National Organic Program's adherence to the accreditation procedures in this subpart F and ISO/IEC Guide 61, General requirements for assessment and accreditation of certification/registration bodies, and the National Organic Program's accreditation decisions. This shall be accomplished through the review of accreditation procedures, document review and site evaluation reports, and accreditation decision documents or documentation. The peer review panel shall report its finding, in writing, to the National Organic Program's Program Manager.

§ 205.510 Annual report, recordkeeping, and renewal of accreditation.



(a) *Annual report and fees.* An accredited certifying agent must submit annually to the Administrator, on or before the anniversary date of the issuance of the notification of accreditation, the following reports and fees:

(1) A complete and accurate update of information submitted pursuant to §§205.503 and 205.504;

(2) Information supporting any changes being requested in the areas of accreditation described in §205.500;

(3) A description of the measures implemented in the previous year and any measures to be implemented in the coming year to satisfy any terms and conditions determined by the Administrator to be necessary, as specified in the most recent notification of accreditation or notice of renewal of accreditation;

(4) The results of the most recent performance evaluations and annual program review and a description of adjustments to the certifying agent's operation and procedures implemented or to be implemented in response to the performance evaluations and program review; and

(5) The fees required in §205.640(a).

(b) *Recordkeeping.* Certifying agents must maintain records according to the following schedule:

(1) Records obtained from applicants for certification and certified operations must be maintained for not less than 5 years beyond their receipt;

(2) Records created by the certifying agent regarding applicants for certification and certified operations must be maintained for not less than 10 years beyond their creation; and

(3) Records created or received by the certifying agent pursuant to the accreditation requirements of this subpart F, excluding any records covered by §§205.510(b)(2), must be maintained for not less than 5

years beyond their creation or receipt.

(c) *Renewal of accreditation.* (1) The Administrator shall send the accredited certifying agent a notice of pending expiration of accreditation approximately 1 year prior to the scheduled date of expiration.

(2) An accredited certifying agent's application for accreditation renewal must be received at least 6 months prior to the fifth anniversary of issuance of the notification of accreditation and each subsequent renewal of accreditation. The accreditation of certifying agents who make timely application for renewal of accreditation will not expire during the renewal process. The accreditation of certifying agents who fail to make timely application for renewal of accreditation will expire as scheduled unless renewed prior to the scheduled expiration date. Certifying agents with an expired accreditation must not perform certification activities under the Act and the regulations of this part.

(3) Following receipt of the information submitted by the certifying agent in accordance with paragraph (a) of this section and the results of a site evaluation, the Administrator will determine whether the certifying agent remains in compliance with the Act and the regulations of this part and should have its accreditation renewed.

(d) *Notice of renewal of accreditation.* Upon a determination that the certifying agent is in compliance with the Act and the regulations of this part, the Administrator will issue a notice of renewal of accreditation. The notice of renewal will specify any terms and conditions that must be addressed by the certifying agent and the time within which those terms and conditions must be satisfied.

(e) *Noncompliance.* Upon a determination that the certifying agent is not in compliance with the Act and the regulations of this part, the Administrator will initiate proceedings to suspend or revoke the certifying agent's accreditation.

(f) *Amending accreditation.* Amendment to scope of an accreditation may be requested at any time. The application for amendment shall be sent to the Administrator and shall contain information applicable to the requested change in accreditation, a complete and accurate update of the information submitted pursuant to §§205.503 and 205.504, and the applicable fees required in §205.640.

§§ 205.511-205.599 [Reserved]



Subpart G—Administrative



The National List of Allowed and Prohibited Substances



§ 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.



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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/demosers.

(8) Sodium carbonate peroxyhydrate (CAS #–15630–89–4)—Federal law restricts the use of this substance in food crop production to approved food uses identified on the product label.

(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) Aqueous potassium silicate (CAS #–1312–76–1)—the silica, used in the manufacture of potassium silicate, must be sourced from naturally occurring sand.

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

(4) 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.

(5) Elemental sulfur.

(6) Lime sulfur—including calcium polysulfide.

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

(8) Soaps, insecticidal.

(9) Sticky traps/barriers.

(10) 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) Aqueous potassium silicate (CAS #–1312–76–1)—the silica, used in the manufacture of potassium silicate, must be sourced from naturally occurring sand.
 - (2) 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.
 - (3) Copper sulfate—Substance must be used in a manner that minimizes accumulation of copper in the soil.
 - (4) Hydrated lime.
 - (5) Hydrogen peroxide.
 - (6) Lime sulfur.
 - (7) Oils, horticultural, narrow range oils as dormant, suffocating, and summer oils.
 - (8) Peracetic acid—for use to control fire blight bacteria.
 - (9) Potassium bicarbonate.
 - (10) Elemental sulfur.
 - (11) Streptomycin, for fire blight control in apples and pears only.
 - (12) Tetracycline, for fire blight control only and for use only until October 21, 2012.
- (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.
 - (9) Sulfurous acid (CAS # 7782–99–2) for on-farm generation of substance utilizing 99% purity elemental sulfur per paragraph (j)(2) of this section.
- (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—for use only 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; 75 FR 38696, July 6, 2010; 75 FR 77524, Dec. 13, 2010]

§ 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 fluoaluminate (mined).

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

(h) Strychnine.

(i) Tobacco dust (nicotine sulfate).

(j)–(z) [Reserved]

[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) Paraciticide. 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, 2012, at the following maximum levels of synthetic methionine per ton of feed: laying chickens—4 pounds; broiler chickens—5 pounds; turkeys and all other poultry—6 pounds.

(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; 75 FR 51924, Aug. 24, 2010]

§ 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 (Alginate; 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.

Gellan gum (CAS # 71010–52–1)—high-acyl form only.

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; 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; 75 FR 77524, Dec. 13, 2010]

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



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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) Fortified cooking wines.

(1) Marsala.

(2) Sherry.

(h) Fructooligosaccharides (CAS # 308066–66–2).

(i) Galangal, frozen.

(j) Gelatin (CAS # 9000–70–8).

(k) Gums—water extracted only (Arabic; Guar; Locust bean; and Carob bean).

(l) Hops (*Humulus lupulus*).

(m) Inulin-oligofructose enriched (CAS # 9005–80–5).

(n) Kelp—for use only as a thickener and dietary supplement.

(o) Konjac flour (CAS # 37220–17–0).

(p) Lecithin—unbleached.

(q) Lemongrass—frozen.

(r) Orange shellac-unbleached (CAS # 9000–59–3).

(s) Pectin (high-methoxy).

(t) Peppers (Chipotle chile).

(u) 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.

(v) Tragacanth gum (CAS #–9000–65–1).

(w) Turkish bay leaves.

(x) Wakame seaweed (*Undaria pinnatifida*).

(y) Whey protein concentrate.

[72 FR 35140, June 27, 2007, as amended at 75 FR 77524, Dec. 13, 2010]

§ 205.607 Amending the National List.



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(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]

§§ 205.608-205.619 [Reserved]



State Organic Programs



§ 205.620 Requirements of State organic programs.



(a) A State may establish a State organic program for production and handling operations within the State which produce and handle organic agricultural products.

(b) A State organic program must meet the requirements for organic programs specified in the Act.

(c) A State organic program may contain more restrictive requirements because of environmental conditions or the necessity of specific production or handling practices particular to the State or region of the United States.

(d) A State organic program must assume enforcement obligations in the State for the requirements of this part and any more restrictive requirements approved by the Secretary.

(e) A State organic program and any amendments to such program must be approved by the Secretary prior to being implemented by the State.

§ 205.621 Submission and determination of proposed State organic programs and amendments to approved State organic programs.



(a) A State organic program's governing State official must submit to the Secretary a proposed State organic program and any proposed amendments to such approved program.

(1) Such submission must contain supporting materials that include statutory authorities, program description, documentation of the environmental conditions or specific production and handling practices particular to the State which necessitate more restrictive requirements than the requirements of this part, and other information as may be required by the Secretary.

(2) Submission of a request for amendment of an approved State organic program must contain supporting materials that include an explanation and documentation of the environmental conditions or specific production and handling practices particular to the State or region, which necessitates the proposed amendment. Supporting material also must explain how the proposed amendment furthers and is consistent with the purposes of the Act and the regulations of this part.

(b) Within 6 months of receipt of submission, the Secretary will: Notify the State organic program's governing State official of approval or disapproval of the proposed program or amendment of an approved program and, if disapproved, the reasons for the disapproval.

(c) After receipt of a notice of disapproval, the State organic program's governing State official may submit a revised State organic program or amendment of such a program at any time.

§ 205.622 Review of approved State organic programs.



The Secretary will review a State organic program not less than once during each 5-year period following the date of the initial program approval. The Secretary will notify the State organic program's governing State official of approval or disapproval of the program within 6 months after initiation of the review.

§§ 205.623-205.639 [Reserved]



Fees



§ 205.640 Fees and other charges for accreditation.



Fees and other charges equal as nearly as may be to the cost of the accreditation services rendered under the regulations, including initial accreditation, review of annual reports, and renewal of accreditation, shall be assessed and collected from applicants for initial accreditation and accredited certifying agents submitting annual reports or seeking renewal of accreditation in accordance with the following provisions:

(a) *Fees-for-service.* (1) Except as otherwise provided in this section, fees-for-service shall be based on the time required to render the service provided calculated to the nearest 15-minute period, including the review of applications and accompanying documents and information, evaluator travel, the conduct of on-site evaluations, review of annual reports and updated documents and information, and the time required to prepare reports and any other documents in connection with the performance of service. The hourly rate shall be the same as that charged by the Agricultural Marketing Service, through its Quality Systems Certification Program, to certification bodies requesting conformity assessment to the International Organization for Standardization "General Requirements for Bodies Operating Product Certification Systems" (ISO Guide 65).

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

(3) Applicants for initial accreditation and renewal of accreditation must pay at the time of application, effective 18 months following February 20, 2001, a nonrefundable fee of \$500.00 which shall be applied to the applicant's fees-for-service account.

(b) *Travel charges.* When service is requested at a place so distant from the evaluator's headquarters that a total of one-half hour or more is required for the evaluator(s) to travel to such place and back to the headquarters or at a place of prior assignment on circuitous routing requiring a total of one-half hour or more to travel to the next place of assignment on the circuitous routing, the charge for such service shall include a mileage charge administratively determined by the U.S. Department of Agriculture and travel tolls, if applicable, or such travel prorated among all the applicants and certifying agents furnished the service involved on an equitable basis or, when the travel is made by public transportation (including hired vehicles), a fee equal to the actual cost thereof. Travel charges shall become effective for all

applicants for initial accreditation and accredited certifying agents on February 20, 2001. The applicant or certifying agent will not be charged a new mileage rate without notification before the service is rendered.

(c) *Per diem charges.* When service is requested at a place away from the evaluator's headquarters, the fee for such service shall include a per diem charge if the employee(s) performing the service is paid per diem in accordance with existing travel regulations. Per diem charges to applicants and certifying agents will cover the same period of time for which the evaluator(s) receives per diem reimbursement. The per diem rate will be administratively determined by the U.S. Department of Agriculture. Per diem charges shall become effective for all applicants for initial accreditation and accredited certifying agents on February 20, 2001. The applicant or certifying agent will not be charged a new per diem rate without notification before the service is rendered.

(d) *Other costs.* When costs, other than costs specified in paragraphs (a), (b), and (c) of this section, are associated with providing the services, the applicant or certifying agent will be charged for these costs. Such costs include but are not limited to equipment rental, photocopying, delivery, facsimile, telephone, or translation charges incurred in association with accreditation services. The amount of the costs charged will be determined administratively by the U.S. Department of Agriculture. Such costs shall become effective for all applicants for initial accreditation and accredited certifying agents on February 20, 2001.

§ 205.641 Payment of fees and other charges.



(a) Applicants for initial accreditation and renewal of accreditation must remit the nonrefundable fee, pursuant to §205.640(a)(3), along with their application. Remittance must be made payable to the Agricultural Marketing Service, USDA, and mailed to: Program Manager, USDA-AMS-TMP-NOP, Room 2945-South Building, P.O. Box 96456, Washington, DC 20090-6456 or such other address as required by the Program Manager.

(b) Payments for fees and other charges not covered under paragraph (a) of this section must be:

- (1) Received by the due date shown on the bill for collection;
- (2) Made payable to the Agricultural Marketing Service, USDA; and
- (3) Mailed to the address provided on the bill for collection.

(c) The Administrator shall assess interest, penalties, and administrative costs on debts not paid by the due date shown on a bill for collection and collect delinquent debts or refer such debts to the Department of Justice for litigation.

§ 205.642 Fees and other charges for certification.



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

§§ 205.643-205.649 [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 the amount specified in §3.91(b)(1)(xxxvii) of this title" 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.

[65 FR 80637, Dec. 21, 2000, as amended by 75 FR 17560, Apr. 7, 2010]

§ 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]



§ 205.668 Noncompliance procedures under State organic programs.



(a) A State organic program's governing State official must promptly notify the Secretary of commencement of any noncompliance proceeding against a certified operation and forward to the Secretary a copy of each notice issued.

(b) A noncompliance proceeding, brought by a State organic program's governing State official against a certified operation, shall be appealable pursuant to the appeal procedures of the State organic program. There shall be no subsequent rights of appeal to the Secretary. Final decisions of a State may be appealed to the United States District Court for the district in which such certified operation is located.

(c) A State organic program's governing State official may review and investigate complaints of noncompliance with the Act or regulations concerning accreditation of certifying agents operating in the State. When such review or investigation reveals any noncompliance, the State organic program's governing State official shall send a written report of noncompliance to the Program Manager. The report shall provide a description of each noncompliance and the facts upon which the noncompliance is based.

§ 205.669 [Reserved]



Inspection and Testing, Reporting, and Exclusion from Sale



§ 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]



Miscellaneous



§ 205.690 OMB control number.



The control number assigned to the information collection requirements in this part by the Office of Management and Budget pursuant to the Paperwork Reduction Act of 1995, 44 U.S.C. Chapter 35, is OMB number 0581-0191.

[65 FR 80637, Dec. 21, 2000, as amended at 75 FR 7195, Feb. 17, 2010]

§§ 205.691-205.699 [Reserved]



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Program Manual



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MOSA Program Manual

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I. Introduction to Midwest Organic Services Association

A. Welcome to MOSA!

Midwest Organic Services Association (MOSA) is a non-profit, non-stock corporation registered in the state of Wisconsin offering a third-party certification program and verification services to producers and handlers of organic products. MOSA was incorporated on March 24th, 1999, to respond to the growing demand for organic certification. MOSA provides knowledgeable and professional certification services to a broad and diverse range of organic operators.

This manual outlines the standards and policies of MOSA's program for certification of organic farms and handling operations. Contact MOSA with questions or requests for further information.

B. Quality Policy

Midwest Organic Services Association (MOSA) provides reliable and efficient verification and certification services to organic producers and handlers primarily in the Midwestern United States. MOSA's certification program is committed to maintaining a timely, courteous, accurate, transparent, and consistent approach throughout the program and on a day-to-day basis.

C. Scope of Certification Services

MOSA offers organic certification services to all interested parties for the following types of operations:

- **Crop**, including general crops and specialty crops such as mushrooms, greenhouse, sprouts, and maple syrup;
- **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);
- **Livestock** (slaughter, dairy or other livestock products, including apiculture);
- **Handler**, including processor, on-farm processor, contract handler, contract feed mill, contract meat processor (this arrangement is limited to three years), retailer, distributor, restaurant, and private label arrangement.

D. Verification of Transition to Organic

MOSA offers verification of transition to organic production for the purpose of enrollment in the Environmental Quality Incentives Program (EQIP) or other programs. Generally, individuals who apply for this service do not go through the entire certification process.

E. Additional Verifications

MOSA offers the following additional verification services:

- USDA Grassfed for ruminant slaughter stock only;
- EU 834/2007;
- US-Canadian Equivalence Arrangement;
- US Export Arrangements.

General requirements are described in the Certification Program Policies section of this manual. Contact us for details on other possible additional verification services.

F. Non-Discrimination Policy

MOSA administers its certification program in a non-discriminatory manner.

- MOSA's services are available to all applicants whose operations fall within the scope of MOSA's activities;

- MOSA does not deny participation in or benefits of the MOSA certification program to any person because of race, color, nationality, gender, religion, age, disability, political beliefs, sexual orientation, or family or marital status;
- MOSA confines its requirements, evaluations, and decisions on certification and verification to those matters specifically related to the type of certification or verification requested by the operator.

G. Confidentiality and Impartiality Policies

Confidentiality

MOSA ensures strict, confidential handling and appropriate use of all confidential and proprietary information and records. MOSA does not disclose confidential information, including the records obtained or generated in the course of certification activities except to federal and/or state Organic Program officials.

MOSA does NOT consider the following information to be confidential but renders it public:

- Certificates issued within the current and previous three calendar years;
- Products certified, effective date of certification and contact information for MOSA certified operations;
- The results of laboratory analyses for residues of prohibited substances conducted for the current and three previous calendar years, provided the results are not part of an ongoing compliance investigation;
- Other business information as specifically identified and permitted in writing by the operator.

All other information is considered confidential. If MOSA is required by law to release confidential or proprietary information or records, except to those engaged in MOSA's accreditation or financial audits, the affected person(s) or entities are informed of the release in writing.

Impartiality: Avoidance of Conflict of Interest

MOSA prevents conflict of interest at all stages of its certification process to ensure that the review, inspection, and certification decisions are carried out in an impartial manner, free from influences or pressures potentially affecting the outcome of the certification decision. Conflict of interest is a direct commercial, financial, consulting, or family interest, within the 24-month period prior to applying for certification, between personnel and an operation requesting MOSA certification. We prevent conflict of interest in the certification process through the following procedures:

- All personnel and those who are responsibly connected to MOSA are required to comply with MOSA's conflict of interest policy and procedures, including submitting a written declaration of interest prior to beginning work for MOSA and at least annually thereafter;
- All MOSA-endorsed inspectors sign a declaration of interest for each inspection they perform for MOSA, affirming that they have no conflict of interest with the operation being inspected;
- MOSA ensures that any certification personnel who have a direct conflict of interest with an operation are excluded from work, discussions, and decisions related to that operation through all stages of the certification process;
- MOSA prohibits all personnel or representatives from accepting payment (other than the appropriate fees for MOSA services) or gifts or favors beyond customary courtesies, from any Associate or Applicant requesting certification;
- MOSA prohibits all personnel or representatives from providing consulting services or advice regarding overcoming identified barriers to certification to any Associate or Applicant requesting certification;
- MOSA ensures that the decision concerning the certification of an operation is made by a different person than the one who conducted the initial review and the on-site inspection.

H. Accreditations

On April 29th, 2002, MOSA was among the first group of certifiers accredited by the USDA's National Organic Program (NOP). The NOP is the culmination of a 12-year federal rulemaking process, initiated by the Organic Foods Production Act (OFPA) of the 1990 Farm Bill. The OFPA mandated the creation of a unified set of production standards for the United States, a national materials list, and certification requirements. OFPA also called for regulatory oversight, through accreditation of state and private certification agencies such as MOSA. Mutual recognition of certification decisions made by NOP-accredited certifiers and access to international markets for certified products bearing the USDA organic seal are two of the main goals of the NOP.

MOSA has also obtained accreditation from the USDA for compliance with the International Organization for Standardization (ISO) Guide 65, providing additional oversight of MOSA's services and marketing opportunities for MOSA's clients. ISO Guide 65 accreditation is intended to ensure that certification bodies operate third-party certification systems in a consistent and reliable manner, thereby facilitating their acceptance on a national and international basis.

Although the definition of organic production has been widely debated in the past 25 years, the accepted NOP definition of organic production is as follows:

A production system that is managed in accordance with the regulations of a USDA accredited certification agent, including the ability to respond to site-specific conditions by integrating cultural, biological and mechanical practices that foster cycling of resources, promote ecological balance, and conserve biodiversity.

The National Organic Standards, including the National List (detailing materials that are allowed and prohibited for use), present the requirements for organic production and handling in the United States. MOSA-certified operations must follow all applicable National Organic Standards to obtain and maintain certification. MOSA informs Applicants and Associates of changes to the Standards or National List through *The Organic Cultivator* newsletter. When significant changes are made, MOSA sends updated paper or electronic versions of the Standards.

I. Newsletter and Website

The Organic Cultivator is a newsletter published by the MOSA office and distributed to all MOSA Associates. It contains program updates and reminders, articles of interest, information on resources and events, and classified ads. Associates are encouraged to submit items to *The Organic Cultivator* that might benefit or be of interest to others.

MOSA maintains a website, www.mosaorganic.org, which contains a directory of MOSA Associates, current and past newsletters, classified ads, information about the certification process, links to the National Organic Standards and other resources, as well as forms available for download.

J. Industry Affiliations

- MOSA is a member of the Organic Trade Association (OTA), the Accredited Certifiers Association (ACA), the Domestic Fair Trade Association (DFTA) and the International Federation of Organic Agriculture Movements (IFOAM);
- MOSA is a subscriber to and a supporter of the Organic Materials Review Institute (OMRI), a non-profit organization that provides professional review of both generic and brand name materials;
- MOSA works cooperatively with Midwest Organic & Sustainable Education Services (MOSES) and other organizations of comparable missions that support and promote organic agriculture.

II. Organizational Structure

A. Associates

MOSA's "Associates" are the individuals and business entities certified by MOSA. Associates must comply with the National Organic Standards and all other MOSA certification requirements described in this Program Manual in order to obtain and maintain MOSA certification.

B. Board of Directors

The MOSA Board of Directors is comprised of experienced and qualified individuals from the organic community. Directors must not be MOSA Applicants or Associates. The Board is the highest governing authority within the organization and seeks to pursue the best interests of the organization through its oversight and decision-making responsibilities.

Nominating Committee

The MOSA Nominating Committee is comprised of a minimum of one Board Member and one Associate. The Nominating Committee has the responsibility of recruiting and recommending qualified individuals to Associates for election to the Board. For more information concerning the composition, responsibilities, and activities of the Board of Directors and its Nominating Committee, refer to the MOSA Bylaws, available from the MOSA website or office.

C. Advisory Committee

Stakeholder groups represented on this Committee include crop producers, livestock producers, handlers, consumers, and organic industry technical experts. The responsibility of the Advisory Committee is to harmonize the diverse interests of MOSA Associates during their review of proposals for change to MOSA's policies. The Advisory Committee's recommendations on policy changes are presented to the Board of Directors for approval.

D. Personnel

Management

Oversight of MOSA's certification and administrative work is the responsibility of the Executive Director, in cooperation with the Management Team.

Certification Department

The Certification Department includes all staff responsible for the certification process.

Administrative Department

The Administrative Department includes all staff responsible for the organizational and office functions not related to certification decisions.

Inspectors

Staff inspectors and with independent inspectors perform on-site inspections of operations. Inspectors report their observations about an operation's compliance through Inspection Reports that are reviewed by Certification Specialists.

E. Administrative Services

Business Hours

The MOSA office, located at 122 West Jefferson Street, Viroqua, Wisconsin, maintains regular business hours Monday through Friday, 8 a.m. – 5 p.m. During this time the office staff is available to receive questions, concerns and general inquiries regarding MOSA and organic certification. The office is closed on holidays and weekends.

Communication with MOSA

Staff strives to respond to questions, concerns, and inquiries in a professional and timely manner:

- Mailing Address: PO Box 821, Viroqua, WI 54665
- Telephone: (608) 637-2526
- Fax machine: (608) 637-7032
- Email: mosa@mosaorganic.org
- Website: www.mosaorganic.org

F. Financial Structure

The MOSA certification program is financially self-sustaining. MOSA Applicants and Associates pay certification, inspection and user fees. The Board of Directors determines fees annually and MOSA's financial statements are available from the office upon request. Refer to the Fee Schedule for details on fees for certification, inspection and user fees.

III. General Requirements

Some operations may be exempt or excluded from the requirement to be certified. For a complete listing and explanation of all types of exempt and excluded operations, refer to National Organic Standards §205.101, *Exemptions and Exclusions from Certification*. Contact the office if you have any questions about whether your operation may be exempt or excluded.

Ingredients or livestock feed from exempt or excluded operations do not meet requirements for organic ingredients or feed used by certified operations. Livestock feed purchased for use during or after dairy transition or fed during the last third of gestation of livestock bearing slaughter offspring must be certified.

A. General Certification Requirements

Any operator seeking MOSA certification must submit an application and provide all information necessary for MOSA to determine the operation's compliance with the National Organic Standards and MOSA certification requirements. Prior to selling, labeling or representing a product as "100% organic," "organic," or "made with organic ingredients," an operation must sign an Associate Licensing Agreement, return it to MOSA and must receive formal notice of certification from MOSA.

After initial certification, operators must update their certification information as outlined in this manual and must provide all information requested by MOSA to determine the operation's continued compliance with the National Organic Standards and MOSA certification requirements. All operations seeking to obtain or maintain certification with MOSA must meet the following general requirements:

- Comply with all applicable MOSA certification requirements, as outlined in this Program Manual;
- Agree to all rights and responsibilities as outlined in the MOSA Associate Licensing Agreement;
- Disclose any prior notification of noncompliance or a notification of denial of certification received from another certification agency. If such prior notification(s) have been received, the operator must submit documented evidence of corrections;
- Comply with all applicable organic production and handling regulations stated in the National Organic Standards, including the National List;
- Establish, implement and annually update an Organic System Plan;

- Permit annual on-site inspections, and others as needed, with complete access to production and/or handling areas, structures, offices (including non-certified production and handling areas, structures and offices) and all applicable records;
- Maintain all applicable organic records for not less than 5 years beyond their creation. Records must fully disclose all activities and transactions of the operation in sufficient detail as to be readily understood and audited. The operator must allow MOSA as well as authorized federal and/or state Organic Program officials access to such records during normal business hours for review and copying to determine compliance;
- Notify MOSA promptly concerning any significant changes to your operation; see the section on Reporting Changes in Certification Program Policies for examples of what are considered to be significant changes;
- Submit applicable fees by stated deadlines.

B. Organic System Plans

The information provided to MOSA through forms and supporting documents makes up the **Organic System Plan**. It is important that operators keep copies of their documents. MOSA's Inspector visits the operation to verify that the Organic System Plan is accurate.

MOSA strongly recommends that Applicants submit their Organic System Plans on MOSA forms, as some information required by MOSA may not be adequately addressed by alternate documents. Additionally, the MOSA initial review, inspection and decision processes are based on the MOSA forms and operate most efficiently when those are used. However, in compliance with NOP regulations, MOSA does allow Applicants to submit their Organic System Plans in other formats, such as those designed to meet the requirements of another Federal, State, or local government regulatory program, provided that such forms and documents meet all the following requirements:

- A description of practices and procedures to be performed and maintained, including the frequency with which they will be performed;
- 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;
- A description of the monitoring practices and procedures to be performed and maintained, including the frequency with which they will be performed, in order to verify that the Organic System Plan is effectively implemented;
- A description of the record keeping system used to comply with MOSA's audit trail requirements;
- A description of the management practices and physical barriers established to prevent commingling of organic and non-organic products on a split operation and to prevent contact of organic production and handling operations and products with prohibited substances; and
- Additional information deemed necessary by MOSA.

C. Financial Requirements

Certification and inspection fees are required annually and fees for services are due as billed. User fees are to be paid on the sale of products represented as certified organic and a user fee minimum may apply. Late payments may incur late fees. Refer to MOSA's Fee Schedule for details. The payment of fees is required by National Organic Standard 205.400(e) and noncompliance proceedings may be instituted if financial requirements are not met in a timely manner.

IV. The Certification Process

Application and Fees You submit your annual Organic System Plan to MOSA. If fees are not included or paperwork is not complete, MOSA notifies you and your file may be put on hold until all items are received.

Initial Review A Certification Specialist or your Inspector reviews your Organic System Plan and notifies you of the results, including requests for any additional information needed and when such information must be addressed. If it appears that your organic plan is compliant with the certification requirements, your file moves on to inspection.

Inspection The inspector contacts you to schedule the inspection. Timing is based on inspector availability, your operation's location, seasonal observation needs of your operation, and your needs and availability. The inspector inspects your operation, completes an Inspection Report, and returns your certification file to MOSA.

Operator Review

MOSA sends you a copy of the Inspection Report. You are encouraged to submit comments or corrections to MOSA within 7 days of receiving the Report.

Notification of Decision The reviewer sends notification of the decision and/or a request for further information. Determination may include conditions for continued certification. The notification will state a deadline by which additional information needs and/or conditions must be addressed.

Certification Review and Decision

A Certification Specialist reviews your certification file and determines compliance. The reviewer may decide that additional information is needed before the certification decision can be made.

Certification Completed Upon successful completion of the certification process, MOSA sends you an organic certificate.

Annual Update To maintain certification you must update your organic plan information annually and as significant organic plan changes occur. MOSA sends update forms annually. Return them on time so inspectors can observe land, facilities and activities during an appropriate season to verify compliance.

V. Certification Details for New Applicants

A. Application Packet

Operations interested in certifying with MOSA are encouraged to obtain an application packet to begin the certification process. Go to the MOSA website, www.mosaorganic.org, or contact us by phone, fax, email or postal mail to request the appropriate application.

B. Deadlines for Submitting First-Time Applications

First-time applications for certification are accepted throughout the year. However, applications must be received in time so Inspectors can observe land, facilities, and activities during an appropriate season to verify compliance. First-time Applicants are strongly encouraged to submit applications as early as possible. Fees will be assessed based on the year in which the operation is inspected and certified, should it differ from the year in which the application was received.

C. Length of the Certification Process

Applicants should be aware that the certification process, from time of application through initial review, inspection, certification review and decision, to the point of notification, could require three to six months. A delay in an Applicant's response to an information request or in submitting required fees typically extends the certification process and can result in noncompliance notification.

D. Withdrawal from the Certification Process

An Applicant may voluntarily withdraw the application from MOSA at any time during the certification process prior to the issuance of the certificate. Applicants choosing to withdraw are liable for any costs incurred up to the point of withdrawal (see the Fee Schedule for refund policy). If withdrawal from the certification process takes place prior to the issuance of a notification of noncompliance or denial, MOSA will not issue these notifications.

VI. The Inspection Process

A. General Inspection Policy

Once an Applicant's application materials have successfully passed the initial review, MOSA conducts an initial on-site inspection of the operation. Thereafter, MOSA conducts an on-site inspection annually as part of the process of updating certification.

B. Purpose of the Inspection

The goal of the inspection is to verify compliance with the National Organic Standards and MOSA certification requirements and identify any points of noncompliance. The Inspector checks each facet of an operation and interviews the managers in order to verify the accuracy of the operation's Organic System Plan and supporting documents. The Inspector completes a written Inspection Report, which is sent to MOSA for use in the process of making the certification decision.

C. Inspector Endorsement

MOSA Inspectors may be employees staff Inspectors or independent contractors. MOSA maintains responsibility for all subcontracted work.

While Inspectors can answer questions related directly to the Standards for organic production and handling, all questions regarding MOSA's policies, production and processing inputs or certification status should be directed to the MOSA office, not to an Inspector. Inspectors do not make certification decisions, recommendations on sanctions or final determinations about the certification status of the operations they inspect.

MOSA aims to contract with or employ qualified, capable, and professional Inspectors. To this end, we have a rigorous endorsement process, provide annual evaluations and feedback, and provide training to Inspectors.

Operators may not request a particular Inspector but they do have the right to object to having a particular Inspector. In such a case, the Inspection Manager will gather more information about the objection and will make an alternate inspection assignment if appropriate. An Inspector evaluation form is sent to the operator when MOSA sends the Inspection Report. MOSA encourages operators to provide us information about the inspection experience as we use this feedback to improve our inspection system and when evaluating our Inspectors. All feedback about the inspection process is confidential and may be submitted anonymously. Any questions about Inspectors may be directed to MOSA's Inspection Manager.

D. Scheduling the Inspection

The Inspector contacts the operator by phone, mail, or email to schedule an inspection. Inspectors must schedule all announced inspections when an authorized, knowledgeable representative of the operation is present and at a time when it is possible to observe the land, facilities and activities needed to verify the operation's compliance with the National Organic Standards and MOSA certification requirements. The initial assignment of an operation's file to an Inspector may take up to 6 months in order for the inspection to be conducted at a time when land, facilities and activities can be observed to verify the capacity to comply.

E. Preparing for the Inspection

The Organic System Plan

The Inspector receives the operator's Organic System Plan as part of the operation's certification file and is required to verify the information submitted in the Plan, noting any changes or deviations. Therefore, an important part of the operator's preparation for inspection is getting ready to discuss details of the Plan with the Inspector and to address questions such as these during the inspection:

- Does the operator's Organic System Plan provide an accurate description of the operation? For example, do buffer zones and other measures taken to avoid contamination meet MOSA's requirements, and are field history and eligibility records accurate? For processing facilities, what are the organic control points and how are they monitored?
- What changes have been made since the Organic System Plan was last updated? Are any materials, facilities, or practices being used that were not noted in the Plan? Have some listed practices been discontinued?
- If applicable, how has the operator addressed previously identified noncompliances?

The Audit Trail

The "audit trail" is the part of the operation's record keeping system that allows verification of organic production practices, purchases, and sales. Organic certification requires that operators fully disclose all activities and transactions of the operation in sufficient detail as to be readily understood and audited and that records must verify the integrity of organic products from production through harvest, storage, transport, processing, handling, and sales.

The audit trail also serves as a tool for monitoring the effectiveness of the operator's organic plan in meeting organic standards and verifying that the plan is being implemented. As such, the audit trail is a major focus during an inspection and all audit trail documentation must be current and available for the Inspector. Applicants must describe their audit trail systems or present plans for implementing audit trail systems in their Organic Plans and they must make all related records and information available to the Inspector.

It is important for operators to ensure that all records are well organized and easily accessible prior to the arrival of the Inspector. For tips on organizing the records needed to support an audit trail, refer to the additional information included in this Manual's appendices.

Land, Livestock, and Facilities

During the inspection, the Inspector must be able to observe the land, facilities, and activities needed to verify the operation's compliance or capacity to comply with all applicable National Organic Standards and MOSA certification requirements. Operators must provide the Inspector with complete access to all production or processing/handling areas, structures, and offices.

Livestock operations must ensure that their animals are accessible for up-close observation by the Inspector.

Land, livestock and production or processing facilities used for conventional production must also be accessible to the Inspector.

F. Elements of the Inspection

Documents Used in the Inspection Process

Inspectors use the MOSA Inspection Report formats to customize interviews, assessments of the premises, and analysis of records.

After the inspection, the Inspector writes an Inspection Report and submits it to MOSA within 21 days of the site visit. The Inspection Report records the observations made by the Inspector at the time of the site visit regarding the operator's compliance or ability to comply with the National Organic Standards and MOSA certification requirements.

Each operation receives a copy of its Inspection Report within two weeks of MOSA's receipt of the Report. The operator has the right to submit comments about the Inspection Report to MOSA within 7 days of receiving the Report.

Inspecting the Premises

An inspection of the premises of a farm or processing operation includes inspection of each production unit, field, facility, and site that produces or handles organic products and that is included in an operation for which certification is requested. In the case of handling, equipment proposed for use must be in place and functional at the time of inspection.

Inspectors may also collect samples for the purpose of assessing whether there has been:

- Contamination by prohibited materials;
- Environmental pollution or the persistence of synthetic materials; and/or
- Fraud related to materials use or use of excluded methods.

Auditing the Operation's Records

MOSA audits an operation's records during each annual inspection. For first-time Applicants, this portion of the inspection serves to assess the Applicant's ability to comply with record keeping requirements. The operator must allow the Inspector access to all of the operation's records.

An important part of the assessment of an operation's records is a check of the audit trail. To accomplish this, the Inspector determines whether records of purchases, sales, and inventory are accurate and up-to-date. In addition, the Inspector assesses records to see if they demonstrate that:

- Quantities and types of products sold correspond with those produced and/or purchased by the operator;
- Amounts and types of products purchased by the operation correspond with those used by the operation; and
- The record keeping system allows products to be traced back to their origin.

The Exit Interview

The MOSA on-site inspection concludes with an “exit interview” between the authorized representative of the inspected operation and the MOSA Inspector. The purpose of this discussion is to confirm the accuracy and completeness of the information gathered during the inspection. The Inspector addresses the need for any additional information, as well as any issues of concern that have been identified during the inspection. The Inspector invites the operator to pose questions and to provide additional information about the topics that have been covered during the inspection. The Inspector may include additional issues in the Inspection Report as they may become evident while composing and writing the Report. All exit interview issues will be evaluated by Certification Specialists during the process of final review.

G. Additional Inspections

The Need for Additional Inspections

As deemed necessary, MOSA conducts on-site inspection(s) in addition to the annual inspection. Additional inspections may be required in cases where satisfactory assessment of compliance with the Standards and MOSA certification requirements cannot be determined without such assessment. Additional inspections may be used to:

- Implement routine surveillance activities for monitoring continued compliance of MOSA-certified operations;
- Investigate a complaint against an operation;
- Monitor an operation that has compliance issues that require on-site observation, including carrying out orders from an Organic Program official to gather more information via inspection about a suspected violation of organic standards.

Methods for Additional Inspections

MOSA follows its usual inspection policy and procedures when conducting additional inspections, except that the scope of the inspection may focus on specific topics and the inspection may not cover all aspects of the operation. Also, additional inspections may be unannounced.

Cost of Additional Inspections

Depending on the reason for conducting an additional inspection and the outcome of the inspection, the costs of an additional inspection are allocated either to MOSA or to the operation.

- MOSA is responsible for the costs of routine surveillance inspections unless, as a result of such inspection, MOSA determines that the operation has a major noncompliance, in which case the operator is billed for the inspection costs. Also, if the surveillance inspection is determined by MOSA to be sufficient enough in scope to replace the annual inspection, the operator is billed.
- If an additional inspection is required for investigation of a complaint, the cost of the additional inspection is the responsibility of the operator only if a major noncompliance is identified during the investigation. If a major noncompliance is not identified, MOSA bears all costs related to the additional inspection.
- The cost of an additional inspection that is called for as a condition of certification to monitor compliance is the responsibility of the operator, regardless of the outcome.

VII. Certification Communications

As part of the review process of certification, Certification Specialists may communicate with the operator regarding the need for additional information in order to verify compliance, or to describe a

noncompliance identified during the review process. The following are descriptions of types of situations that can arise during the review process:

A. Additional Information Needed

There may be a request for additional information that needs to be provided before a certification decision can be made.

B. Noncompliance Notifications

A **notification of noncompliance** contains a description of each noncompliance, the facts upon which the noncompliance is based, the date by which the operator must rebut or correct the noncompliance issue (if correction is possible), and the need for further testing, evaluation and additional inspection, if applicable.

A **minor noncompliance** is a violation of the National Organic Standards that, on its own, does not jeopardize the effectiveness of the operation's Organic System Plan or the organic integrity of the product. The correction of minor noncompliances is necessary for continued certification. Verification that minor noncompliances have been corrected is an important part of the continuing certification and inspection process.

A **major noncompliance** is a violation of the National Organic Standards or MOSA policy which results in a serious failure in the operation's Organic System Plan and requires notification of the National Organic Program. The following are examples of major noncompliances:

- A violation resulting in the loss of organic integrity of a product proposed for certification;
- Willful misuse of MOSA's name, the certification claim, and/or the MOSA certification seal (fraud);
- Multiple minor noncompliances related to the same topic may be considered a major noncompliance;
- Failure to meet time requirements set for submission of information required to evaluate compliance may be considered a major noncompliance.

Operators who disagree with a noncompliance notification have the right to rebut, request mediation or file an appeal of the decision within the time period given in the notification.

C. Rebuttals to Noncompliances

An operator who receives notification of noncompliance has the right to rebut the decision within the stated time period. MOSA may not issue a Notification of Proposed Suspension or Proposed Revocation if a rebuttal is pending. An Applicant may rebut MOSA's decision to deny certification and an Associate may rebut a decision to suspend or revoke its certification.

- A rebuttal must be submitted to the MOSA office in writing by the deadline stipulated and must outline in detail the nature of the disagreement with the certification decision.
- MOSA will review the rebuttal and notify the operator of the outcome within 30 days of MOSA's receipt of the rebuttal. If MOSA decides to uphold its decision, the related notification shall state a deadline by which the operator may request mediation or file an appeal of the decision. This stated deadline shall allow the required 30 days for filing an appeal.

D. Requesting Mediation

An Applicant who receives a Notification of Denial of Certification or an Associate who receives a Notification of Proposed Suspension or Revocation of Certification from MOSA has the right to request mediation under National Organic Program regulation §205.663. MOSA may not issue a Notification of Suspension or Revocation if mediation is pending.

A request for mediation must be submitted to the MOSA office in writing by the deadline stipulated. MOSA has the right to reject a request for mediation and informs the Applicant or Associate in writing

whether or not this request has been accepted or rejected. If the request for mediation is rejected by MOSA, the operator retains the right to file an appeal with the National Organic Program within 30 days.

Mediation requests must include the mediation deposit. Mediation costs include fees charged by the mediator and administrative fees charged by MOSA. Administrative fees for mediation are based on time spent by each MOSA staff member working on the mediation process. All costs incurred by the mediation procedures are assumed by the operator requesting the mediation as listed in the Fee Schedule.

If MOSA accepts the request, mediation is conducted within 30 days of the date of the acceptance notification, at a time and place mutually agreed upon by MOSA and the operator. Mediation is to be conducted by a qualified mediator who has adequate understanding of the subject of the dispute. The mediator is to be mutually agreed upon by both MOSA and the operator.

MOSA and the operator have a maximum of 30 days following the mediation session to reach an agreement. In conclusion of the mediation process, as outlined and facilitated by the chosen mediator, the mediator may emphasize points of agreement and identify areas of disagreement for more discussion. The mediator may suggest ideas for resolution, but has no authority to impose a solution on MOSA or the operator. If both parties agree to a resolution, the points of the settlement are written down and signed by the two parties and the mediator. MOSA sends written documentation to the operator outlining the agreement and issues any applicable certification documents. Any agreement reached during or as a result of the mediation process must be in compliance with the National Organic Program regulations and MOSA certification requirements.

If mediation is undertaken and an agreement is not reached, MOSA notifies the operator in writing of his/her right to file an appeal within 30 days with the National Organic Program.

E. Requesting an Appeal

An Applicant who receives a Notification of Denial of Certification or an Associate who receives a Notification of Proposed Suspension or Revocation from MOSA has the right to file an appeal with the Administrator within the time period provided in the notification or within 30 days from receipt of the notification, whichever occurs later.

Appeals are considered to be filed on the date they are received by the Administrator. Decisions become final if they are not appealed within the given time frame. MOSA may not issue a Notification of Suspension or Revocation if an appeal is pending. All appeals shall be reviewed, heard, and decided by persons not involved with the decision being appealed. Appeals filed with the National Organic Program must be submitted in writing and addressed to

Administrator – USDA – AMS
c/o NOP Appeals Staff
STOP 0203 Room 302-Annex
1400 Independence Ave. SW
Washington, DC 20250-0203

MOSA requests that operators notify MOSA of their intent to appeal and submit a copy of their written appeal to the MOSA office at the time of filing the appeal with the National Organic Program.

If the federal or state authority agrees with the operator's appeal, MOSA issues all required certification documents, as applicable. If the appeal is denied, a formal administrative proceeding is initiated to deny, suspend or revoke the operator's certification, pursuant to the U.S. Department of Agriculture's Uniform Rules of Practice.

F. Notification of Denial

If an *Applicant* fails to correct a major noncompliance through rebuttal or additional information provided within the given time period, does not file a request for mediation or appeal, or if the major noncompliance is deemed willful or uncorrectable, MOSA sends a **notification of denial**.

If MOSA 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 National Organic Standards and/or MOSA certification requirements, MOSA may deny certification without first issuing a notification of major noncompliance.

An *Applicant* who has received a noncompliance notification or a notice of denial of certification may apply for certification again at any time. If a certification application is submitted to a certifying agent other than MOSA, the application must include a copy of the noncompliance notification or notice of denial of certification and evidence demonstrating correction of each noncompliance issue.

G. Notification of Suspension or Revocation

If an *Associate* fails to correct a major noncompliance through rebuttal or additional information provided within the given time period, does not file a request for mediation or appeal of the proposed suspension or revocation of certification, or if the major noncompliance is deemed willful or uncorrectable, MOSA sends a **notification of suspension or revocation**.

An *Associate* whose certification has been suspended may at any time, unless otherwise stated in the suspension notification, submit a request to the US Secretary of Agriculture for reinstatement of 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 Organic Foods Production Act and the National Organic Program regulations.

An *Associate* or 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 revocation. However, the US Secretary of Agriculture, when in the best interest of the certification program, may reduce or eliminate the period of ineligibility.

H. Violations of the Organic Foods Production Act

In addition to suspension or revocation, any operation that knowingly sells or labels a product as organic, except in accordance with the Organic Foods Production Act, shall be subject to a civil penalty of not more than \$11,000 per violation. Also, any operation that makes a false statement under the Act to a federal and/or state Organic Program official shall be subject to the provisions of section 1001 of title 18, United States Code. Enforcement falls under the jurisdiction of the USDA.

VIII. Certification Update and Changes to Certification

A. Update Packets

Current Associates annually receive an update packet with the following items:

- Organic System Plan(s) and supplementary forms for the type(s) of certification granted the previous year, to be completed and returned to MOSA;
- National Organic Standards, including the National List of Allowed and Prohibited Substances, if updated from the previous year;
- MOSA Program Manual, if updated since the previous year;
- An invoice for fees and MOSA's Fee Schedule.

B. Deadlines for Producers

Applications for updating producer certification must be received by May 1st. MOSA will accept update applications after this date, but they are subject to late fees.

Producers who do not submit update applications by May 1st or who do not inform MOSA of their intent to surrender MOSA certification will be subject to major noncompliance proceedings.

C. Deadlines for Handlers

Applications for updating handler certification must be received at least 90 days prior to the anniversary of the effective date of their certification. MOSA will accept update applications after this date, but they are subject to late fees.

Handlers that do not submit update applications by their deadlines or inform MOSA of intent to surrender MOSA certification will be subject to major noncompliance proceedings.

D. Surrender of Certification

An Associate may surrender MOSA certification at any time. However, once a certification file has been reviewed and a certification decision made, MOSA must issue any resulting noncompliance notification. Upon surrender of certification, the terms and agreements of the Associate Licensing Agreement are terminated and the Associate must immediately cease all certification claims using MOSA's name and/or seal. Associates are liable for any costs incurred up to the point of surrender in accordance with the Fee Schedule.

E. Extending Certification

All Associates must update their certification information annually, by the specified deadline. Normally, Associates who choose not to update certification with MOSA must formally surrender their MOSA certification or be subject to procedures to suspend certification. However, an Associate may request a one-time extension of MOSA certification beyond the update deadline if either of the following conditions applies:

Transferring from MOSA to another Certification Agency

Associates that intend to continue to produce or sell products as organic must maintain their MOSA certification until certification has been granted by the new certification agency. Requests to MOSA for an extension during transfer of certification should be in writing and include a statement from the accredited certifier to which the Associate is transferring, verifying that:

- The Associate has submitted an appropriate and complete application for certification;
- If MOSA has identified a noncompliance in the Associate's operation and has not issued a letter of resolution confirming correction of the noncompliance, the other certifier must confirm that the Associate has disclosed these noncompliances during the process of applying for certification to their agency;
- The certifier is able to process the certification for the products the Associate has requested for certification.

Accommodating Sales of Inventory

Associates may request a one-time extension of MOSA certification beyond their operation's update deadline in order to allow for sales of the remaining inventory of certified product. Requests for extension must be in writing and must include:

- A description of the product(s) to be sold;
- How the product has been stored and organic integrity maintained;
- When the sale of the product will be completed.

A Certification Specialist reviews the extension request. A decision to grant extension and the length of extension varies with situational needs and most-recent inspection date. Extensions are generally less than 6 months.

Associates who are granted an extension must continue to pay all applicable user fees to MOSA during the extension period. MOSA may require additional organic plan update information or an additional inspection during the extension period if necessary to verify compliance.

F. Adding New Products or Handling

When an Associate wishes to add new products or handling *beyond* those currently certified, sufficient information must be provided so MOSA can verify that the new products or handling activities comply with all applicable National Organic Standards and MOSA certification requirements. The Associate must submit supporting documentation demonstrating compliance. Documentation must sufficiently describe the products to be added, and any related changes to the operation.

A Certification Specialist reviews this new information and a certification decision is made. Additional information, such as an updated Organic System Plan and/or an additional inspection may be required in order to complete the certification decision process.

No additional fees will be charged if the review for the added product or handling coincides with the scheduling of the annual certification update process. MOSA's fee for adding new products or handling activities to the certificate outside of the regular annual review process is an hourly administrative fee. MOSA bills the Associate for all work done by MOSA staff and Inspectors in processing and reviewing the request.

If certification is granted for the additional product or handling activity, MOSA sends appropriately revised certification documents.

G. Removing Products or Handling from the Certificate

When there are changes in an operation such that products listed on the certificate are no longer eligible to be certified, Associates must notify MOSA of these changes. We will issue amended certification documents to show the reduction of the operation's certified products or handling activities.

IX. Certification Program Policies

A. Commercial Availability Policy

"Commercially available" means 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 MOSA in the course of reviewing the Organic System Plan.

Seeds and Planting Stock

Applicants and Associates must provide evidence of due diligence in sourcing organic inputs in order for MOSA to approve the operator's use of the non-organic input.

MOSA Applicants and Associates must use organically grown seeds, annual seedlings and planting stock to obtain and maintain MOSA certification, with only the following exceptions:

- Non-organic untreated seeds and planting stock may be used to produce an organic crop when an equivalent organic variety is not commercially available, except that organically produced seed must be used for the production of edible sprouts;
- Non-organic seed and planting stock that have been treated with an approved synthetic substance included on the National List may be used to produce an organic crop when an equivalent organic or untreated variety is not commercially available;
- Non-organic seed and planting stock that have been treated with an approved synthetic substance included on the National List may be used during the operation's transition to organic production;
- Non-organically produced annual seedlings may be used to produce an organic crop when a temporary variance has been granted in accordance with §205.290(a)(2) of the National Organic Program regulations;
- Non-organically produced planting stock to be used to produce a perennial crop may be sold, labeled, or represented as organically produced only after the planting stock has been maintained under a system of organic management for a period of no less than 1 year;

- 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.

Ingredients in Processed Products

For all processed products labeled or represented as "organic," MOSA Applicants and Associates must use the organic form of an ingredient. Exceptions may be allowed for ingredients as specifically listed in National Organic Standard §205.606, if the operator provides adequate documentation to verify the product is not commercially available in organic form. Additionally, handlers must not include organic and non-organic forms of the same ingredient in a product labeled as "100 percent organic," "organic," or in ingredients identified as organic in a product's ingredient statement. For more details on product composition requirements, refer to National Organic Standard §205.301.

B. Evaluation of Materials Used in Organic

Materials used in the organic production of crops and livestock as well as those used in processing and handling organic products, must be allowed for use by the NOP's National List of Allowed and Prohibited Substances. Certification may be jeopardized by the use of products of indeterminate or incorrectly determined status. Therefore, the status of each material must be determined prior to the use of the material. If a material contains multiple ingredients, the status of each ingredient, including inert ingredients and processing aids, must be determined. If ingredients are not disclosed, MOSA considers the material prohibited.

Products and materials are reviewed based on the National List as:

- **Allowed:** materials and/or practices which may be used for the production of organic crops, livestock and processed/handled products, including regulated materials and/or practices with annotated restrictions;
- **Prohibited:** a substance or practice which is not allowed to be used in organic production or handling.

Operators should note that Inspectors are not authorized to make determinations on the status of materials.

MOSA accepts product status as outlined in Organic Materials Review Institute and Washington State Department of Agriculture lists. Product use must be described in the Organic System Plan and must be compliant with the National Organic Standards.

C. Amending the National List

Any person may petition the National Organic Standards Board for the purpose of having a substance evaluated by the Board for recommendation for inclusion on or deletion from the National List. A person petitioning for amendment to the National List should request a copy of the petition procedures from the USDA. Requests for petition procedures and submissions must be directed to:

Program Manager
USDA/AMS/TMP/NOP
1400 Independence Ave., SW
Room 4008-So., Ag Stop 0268
Washington, DC 20250

D. Residue Testing Policy and Exclusion from Organic Sale

MOSA may require residue testing when there is reason to believe any of the following conditions exist:

- Contamination by off-farm materials or genetically engineered organisms;
- Environmental pollution or persistence of synthetic materials in soil or water;

- Processing of agricultural products occurs in a facility or with equipment in which prohibited substances are used;
- Fraud related to materials use/use of genetically engineered organisms.

Associates and Applicants consent to the use of a subcontracted laboratory to conduct residue tests as part of their certification agreement with MOSA. Results of residue testing are shared with the operator and the National Organic Program and will be available for public access, unless the testing is part of an ongoing compliance investigation.

If a residue test detects a prohibited substance at levels that are greater than 5% of the Environmental Protection Agency's tolerance level, the agricultural product must not be sold, labeled or represented as organically produced. Organic officials may conduct an investigation of the certified operation to determine the cause of the prohibited substance.

E. Emergency Pest or Disease Treatment

When a prohibited substance is applied to a certified operation as a result of a Federal or State mandated emergency pest or disease treatment program, the certification status of the operator will not be affected, provided that:

- Any harvested crop or plant part that has contact with the prohibited substance cannot be represented as organic in any way;
- Any livestock that was treated with a prohibited substance or its products cannot be represented as organic in any way, except that milk products from treated animals may be sold, labeled or represented as organically produced after a 12 month withdrawal period; and
- 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.

F. Compliance with State Organic Programs

Although MOSA does not certify in states that have State Organic Programs at this time, MOSA fully implements all provisions of the NOP regulation that may require MOSA to interact with a State Organic Program such as compliance actions, testing, additional inspections, supplying information about certified parties, etc.

G. Variances to the National Organic Standards

Only the USDA may grant temporary variances to the National Organic Standards. However, at the requests of the operations they certify, State Organic Programs and accredited certifying agents may recommend temporary variances for consideration by the Administrator. Temporary variances may only be granted by the National Organic Program to certain production and handling standards, specifically §§205.203-205.207, 205.236-205.240, and 205.270-205.272. Temporary variances will not be granted for any practice, materials or procedure described under §205.105. In addition, temporary variances will only be granted for the following reasons:

- Natural disasters declared by the US Secretary of Agriculture;
- Damage caused by drought, wind, flood, or excessive moisture, hail, tornado, earthquake, fire, or other business interruption; and
- Practices used for the purpose of conducting research or trials of techniques, varieties or ingredients used in organic production or handling.

Operators wishing to suggest a variance for recommendation by MOSA to the Administrator must submit the following information in writing to the MOSA office:

- The variance that is suggested, including applicable Standards;
- The reasons for suggesting the variance and how the variance is justified by one of the three reasons allowed by the National Organic Program, as listed above;

- Documentation supporting the need for the variance.

MOSA considers all complete variance suggestions from operators and decides whether or not to recommend the variance to the Administrator. MOSA provides written notification of the decision to the operator who submitted the variance suggestion.

In the event that the USDA grants a temporary variance to certification standards or policies, MOSA will notify all operators potentially affected by the variance. Such a notification may be accomplished through a special mailing to operators and/or through information published in MOSA's newsletter. MOSA will also post information about the variance on its website. The information provided to operators will include a description of the variance and the length of time it is to be in effect.

H. The Transaction Certificate (TC) System

The organic certificate is proof of MOSA's certification of the operation's production or handling of the products listed on the certificate. MOSA also can provide Transaction Certificates (TCs), which provide buyers with additional assurance of certification for individual sales or shipments of product. In addition, TCs document in-depth sales information for use by buyers, sellers, and other certification agencies.

MOSA provides a blank Transaction Certificate Authorization (TCA) form and a sheet explaining the use of the TC System; this form is available on the website as well. A MOSA Associate wishing to have a Transaction Certificate (TC) issued to a buyer must submit a completed TCA to the MOSA office for review. If review verifies that TCA information is consistent with information in the certification file, MOSA sends a TC to the Associate and the buyer.

I. Additional Verifications

In cases where a buyer asks for verification of requirements not covered by the National Organic Standards, MOSA will assess compliance in order to provide such verification. Operators wishing to have verification of additional production or handling requirements should indicate this on their applications, describing each item for which they need additional verification. Additional fees as outlined in the Fee Schedule apply. MOSA strongly encourages that such requests be submitted with the annual Organic System Plan information, so that evaluation can occur during all stages of the certification process. Operators who make requests after submitting the annual Organic System Plan documents may have to provide additional information or undergo an additional inspection in order for MOSA to verify compliance with the requirements.

The National Organic Program has several types of country to country arrangements to facilitate trade and ensure a consistent supply of organic products for the U.S. Markets. Export Arrangements are agreements between the U.S. and a foreign country that allow U.S. organic products to be sold as organic in the receiving country, provided specific requirements are met. Equivalence agreements between two countries allow products produced and certified to either country's organic standards to be sold as organic in both countries.

Producers and handlers wanting to market organic crops or processed products in the European Union may obtain the necessary verification from MOSA. MOSA provides application forms for EU verification and a guidance document that explains EU organic certification requirements.

Upon request, MOSA is also able to verify compliance with the US-Canadian Equivalence Arrangement for all products destined for organic sales in Canada. MOSA also provides verification of compliance with the additional requirements of US Export Arrangements. Contact MOSA staff for a description of these requirements.

Producers of organic ruminant slaughter stock who wish to market as "USDA Grassfed" may do so if MOSA is able to verify that the USDA Grass (forage) Fed standard is met. This standard can be found on the MOSA website or may be requested from the MOSA office.

J. Private Label Policy

In most cases, companies using the MOSA logo, a MOSA certificate, or the claim “certified organic by MOSA” (or similar statement), must be MOSA-certified. However, through a Private Label Arrangement, MOSA may authorize use of MOSA’s logo, certificate, or name by an operation that is not MOSA-certified, but only for the operation’s marketing of product that was produced by a MOSA-certified operation. Typically, handling activities conducted by an operation distributing a private label product are excluded from mandatory certification by National Organic Standard §205.101.

Private Label Arrangements must be authorized by MOSA prior to the use of MOSA’s logo, certificate, or name on a private label product. To initiate a Private Label Arrangement, a MOSA Associate must submit completed forms and fees as described in the Fee Schedule.

K. Reporting Significant Changes in an Operation

In the event of significant changes to an operation – either one that is certified or one that is in the process of initial certification – MOSA needs to be informed about the changes. MOSA considers significant changes to be:

- Significant expansion or reduction in the number of acres farmed, the types or amounts of crops grown, or the number of animals managed;
- Addition or withdrawal of processes and/or products from certification;
- Application, including drift, of a prohibited substance to any field, production unit, site, facility, livestock, or product;
- Change in any portion of the operation that may affect its compliance with the National Organic Standards and/or MOSA certification requirements thereby require a change to the MOSA certificate, including but not limited to a change in product specifications, to the ownership of the operation, or of the person responsible for implementation of the Organic System Plan.

If your operation experiences significant changes, you must provide a detailed description of the changes, including relevant dates, to MOSA and withhold sale of affected products pending review by MOSA. You may be required to complete new documents in order for MOSA to reevaluate the operation and the changes to the Organic System Plan.

Based on the information provided by the operator, MOSA will determine whether an additional inspection is required. Once a certification decision has been made on the changes to the operation, MOSA notifies the operator of the decision, including approval or denial of the organic sale of any products produced under the changed procedures.

X. The Rights and Responsibilities of Certification

A. The Associate Licensing Agreement

The rights and responsibilities of both MOSA and its Associates are fully documented in the Associate Licensing Agreement (ALA). Completing the agreement is a precondition for MOSA certification.

The ALA, after being signed and dated by both the Applicant and by MOSA, establishes a contractual agreement. The signed ALA is binding for the duration of the Associate’s MOSA certification. If MOSA revises the text of the agreement both the Associate and MOSA must sign and date a copy of the revised version within a timeframe set by MOSA in order for the operation’s certification to remain in effect.

The following information is a general discussion of the rights and responsibilities detailed in the ALA. Refer to a copy of the Agreement for complete information on this topic.

B. Rights and Responsibilities of Associates and Applicants

Rights

MOSA Applicants and Associates have the right to:

- Service from MOSA that is fully compliant with the National Organic Program regulations, the MOSA Bylaws and Program Manual;
- Use of the MOSA certification mark and logo to identify their MOSA-certified products;
- Protection of confidential business information by MOSA;
- Participate in the process for amending or developing the Policies and Bylaws;
- Submit nominations to the Nominating Committee for available positions on the Board of Directors;
- Timely notification of changes to the National Organic Standards or MOSA certification requirements.

Responsibilities

MOSA Applicants and Associates have the responsibility to:

- Comply with the certification program, as outlined in the current National Organic Program regulations and MOSA Program Manual;
- Cooperate with the certification process by providing access to records as well as all information required for inspection including but not limited to land, facilities, and equipment;
- Pay all fees associated with certification within stated timelines, as outlined in the Program Manual;
- Only make certification claims that accurately reflect the type(s) of MOSA certification(s) granted;
- Ensure that certification claims are used in a manner that does not harm MOSA or make any unauthorized or misleading claims;
- Discontinue the use of all certification claims and return any documents required by MOSA, upon surrender or notification of suspension or revocation of MOSA certification;
- Use certification claims only to indicate that the operator's products are in compliance with MOSA's program;
- Refrain from assigning, transferring, allowing, or otherwise sublicensing the MOSA logo or name for use by any subsidiary organization not certified by MOSA, unless a MOSA-approved Private Label Arrangement is in force;
- Cooperate and assist in ascertaining the facts if it is reported that their products bearing the MOSA logo and name are not in compliance with the certification program, as outlined in the National Organic Standards and MOSA Program Manual;
- Indemnify MOSA against liability arising from the sales and use of the Associate's product(s) including reasonable fees and costs attending to any claims and/or lawsuits due to acts and omissions by the Associate relative to the terms and conditions of the Associate Licensing Agreement.
- Immediately cease all use of MOSA's logo and/or name upon termination or expiration of the operation's Associate Licensing Agreement.

C. Rights and Responsibilities of MOSA

Rights

MOSA has the right to:

- Publish identifying information about certified operations in its directory;

- Inspect all operations that apply for certification or continuation of certification on at least an annual basis;
- Amend its fees associated with certification at its sole discretion upon 30 days written notice to the Associate and provided that the fee changes have been filed with the National Organic Program;
- Conduct activities for continuing oversight of certified operations, including but not limited to residue testing, additional announced and unannounced inspections, and marketplace surveillance.

Responsibilities

MOSA has the responsibility to:

- Fully comply with its Quality System, as described in the MOSA Bylaws, and the Quality, Program, and Administrative Procedures Manuals;
- Provide Applicants and Associates (annually, unless no revisions are made) with a current Program Manual, National Organic Standards (including the National List of allowed and prohibited products) and any other information or documents required for use by the operator;
- Provide any Applicant or Associate with further information on or explanation of specific certification processes or services related to their operation;
- Provide any Applicant or Associate information requested about the MOSA certification program, unless the information is classified as confidential;
- Refrain, without the Associate's prior authorization in writing, from voluntarily disclosing to third parties the Associate's confidential information;
- Monitor the Associate's adherence to the certification program, as outlined in the current National Organic Standards and MOSA Program Manual;
- Solicit input on policy and Bylaws amendments and additions;
- Maintain all functions and responsibilities necessary to obtain and retain accreditation with the USDA's National Organic Program;
- Maintain responsibility for all subcontracted work.

XI. Disputes and Complaints

A. Disputes

The most common disputes are related to financial matters. Financial disagreements may arise through discrepancies in the financial records kept by operators and MOSA. Operators should bring such instances to the attention of the Accounts Manager.

- Operators must be prepared to verify their payments to MOSA by presenting a copy of the cancelled check or record of credit card payment. Upon receipt of such verification MOSA corrects its records of the operator's account;
- If items remain unpaid, the operation's certification application is put on hold.
- Continuing disputes as to charges for services may be resolved with the Executive Director.

B. Complaints Submitted to MOSA

MOSA has authority to act upon complaints received about Applicants or Associates if the complaint is related to compliance with the National Organic Standards, verification to other certification standards, or compliance with MOSA policies. Complaints about the organic integrity of MOSA Applicants' or Associates' operations are to be directed to the Executive Director.

MOSA also will investigate complaints about personnel or contracted parties if the complaint falls within the following areas of MOSA responsibility: disregard for MOSA's policies or operating procedures, arbitrary judgments, unprofessional or unethical behavior, financial mismanagement,

discrimination, deficiencies in the administering of services, violation of conflict of interest policy or procedure, or breach of confidentiality. Complaints about employees or contracted parties are to be made to the Executive Director. Complaints about Inspectors are to be directed to the Inspection Manager. The President of the Board is to receive complaints about the Executive Director and MOSA Board Members.

If you wish to make a formal complaint, it must be in writing and must provide:

- A complete explanation of the complaint including dates and names of those involved;
- Supporting evidence;
- The name, contact information and signature of the complainant.

Details of the formal complaint handling procedure will be provided upon receipt of formal complaints or as requested.

MOSA will also accept and consider verbal or anonymous complaints and all information provided is taken into consideration for either surveillance activities or for improvement in MOSA operations.

C. Complaints Received by Associates

MOSA requires Associates to record all complaints that are directed to their operations related to the compliance of their products with the relevant standards as required by ISO Guide 65 accreditation. An operation's complaint log must include:

- A description of the complaint;
- When it was received; and
- How it was handled.

The complaint log must be made available at the time of inspection. MOSA provides a sample complaint log as part of the record-keeping forms it supplies to operators.

XII. Amending Bylaws and Policies

MOSA encourages the participation of Associates and the organic community as a whole in the improvement and development of the MOSA program. The process of proposing amendments to Bylaws and policies is therefore open to participation by all interested parties. Bylaws are available on our website and upon request from the office and policies are as described in this manual. Changes to the MOSA program must be in compliance with the National Organic Program and ISO Guide 65.

A. Amending Bylaws

Submission Requirements

All proposals for amendment of Bylaws must be submitted in writing and received postmarked by the end of the first full business week in December.

- Mail to MOSA, PO Box 821, Viroqua, WI 54665
- Email to mosa@mosaorganic.org
- Fax to (608) 637-7032.

Review and Approval Process for Bylaws

The Quality Manager compiles proposals of amendments into a final list and submits the list for distribution with notice of the Annual Meeting. MOSA sends the notice to Associates at least 20 and not more than 40 days before the date of the Annual Meeting. MOSA also posts the list on its website to facilitate access to the information by all interested parties. Voting on amendments to the Bylaws is conducted according to the procedures outlined in the MOSA Bylaws, Article 10.

Notification of Changes

MOSA notifies Applicants and Associates of all approved changes to its Bylaws and their implementation dates through a mailing or via the newsletter.

B. Amending Policies

Submission Requirements

Proposals for amendments of MOSA's policies described in this Program Manual must be postmarked by November 1st. Exceptions to this schedule may be considered for amendments necessary for maintenance of MOSA's accreditations.

- Mail to MOSA, PO Box 821, Viroqua, WI 54665
- Email to mosa@mosaorganic.org
- Fax to (608) 637-7032.

Review and Approval Process for Policies

MOSA will process submissions that are postmarked before November 1st for review by the Advisory Committee. For the list of proposals for amendments slated for review by the Committee, contact the office after the end of the first full business week in November or check the website.

The Advisory Committee members review the proposals for policy amendments independently and then discuss them collectively in order to identify those to be recommended by the Committee to the Board of Directors for approval. Proposals may require editing, redrafting, or conceptual development by the Advisory Committee prior to being passed along to the Board. The Committee must finalize its recommendation to the Board by the end of the first full business week in December. For a copy of the Advisory Committee's recommendation to the Board regarding submitted proposals, contact the office after the end of the first full business week in December.

The Board of Directors has access to all the proposals originally reviewed by the Advisory Committee as well as the Committee's recommendations on policy changes. The Board evaluates this information, and may propose further editing, amendment, or clarification of the proposals. The Board reaches a final decision regarding the policy amendments by the end of the fourth full business week in December.

MOSA encourages Associates and interested parties to participate in the amendment process not only by submitting proposals, but also during the review and approval process through contacting members of the Advisory Committee and Board of Directors to discuss the amendments under review.

Notification of Changes

MOSA notifies Applicants and Associates of all approved changes to its policies and their implementation through a mailing or via the newsletter.

C. Requirements for Submitting Proposed Amendments

Persons submitting proposed amendments for MOSA's policies or Bylaws must supply the following information in order for their ideas to be included in the revision process:

- **Contact Information**

Name

Mailing Address

Other Contact Information (telephone number, fax number, email address)

Date

- **Statement of Proposed Amendment**

New Bylaw or policy — When submitting a proposal for a new Bylaw or policy, include the complete text that you propose for addition. Provide your suggestion for the proposed

placement of the new text, including the document, page, or section where you think it should be placed.

Changes to existing Bylaw or policy — When submitting a change to an existing Bylaw or policy, write out MOSA's current text and utilize ~~strikethrough~~ to reflect deletion and **bold** text or underline to reflect additions. Note the section or page of the document where the text occurs.

- **Purpose:** Provide a description of the purpose of the proposed amendment and a succinct summary of the argument(s) in support of the change.
- **Alternatives:** List alternatives to the proposed amendment. Describe the other options and discuss why the proposed amendment is preferable to these alternatives.
- **History:** Describe the history, if any, behind the development, existence, and application of the current policies or Bylaws related to the topic of the proposed amendment.
- **Research:** List and briefly describe any relevant research regarding the proposed amendment. Attach research documents that provide background information and more detail.

D. Voting and Reporting on Results

MOSA allows Associates to vote by mail or in person at the Annual Meeting on both the election of Board members and other matters which are slated for voting at a meeting of Associates. MOSA announces the results of votes at the Annual Meeting and also through the newsletter

XIII. Definitions

The following terms are defined as they are used in this manual. For more definitions, see the National Organic Standards.

Administrator – the Administrator of 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.

appeal – a process whereby an operator can request that the National Organic Program reconsider a certification decision made by MOSA.

Applicant – a producer or handler of agricultural products applying for initial certification with MOSA.

Associate – a producer or handler certified by MOSA.

audit trail –documentation sufficient to determine the source, transfer of ownership, transportation, and protection of integrity of organic products and/or ingredients, from production through harvest, storage, transport, processing, handling, and sale.

certificate – an annual written assurance provided by MOSA verifying that a production or handling operation is in compliance with the standards for which certification is requested.

certification – the annual procedure by which a certification agent gives written assurance that a clearly identified production or handling system has been methodically assessed and conforms to organic standards.

contract meat processor – a meat processing operation that is certified only to provide services for a specific MOSA-certified livestock producer. This arrangement is limited to three years.

contract handler – a person or entity that provides a handling service for a primary operator.

denial – the refusal by MOSA to grant initial certification to an Applicant due to major noncompliance(s).

distributor – a handler that purchases product under its own name, usually from a shipper, processor, or another distributor. Distributors may or may not take physical possession of the merchandise. A distributor is required to be certified as a processor if they substantially transform, process, repackage, or re-label organic products.

handle – to sell, process, package or store agricultural products.

handler – a person or entity who engages in the business of handling food or feed products.

loss of organic integrity – contamination of an organic product by commingling with a non-organic product or by contact with prohibited substances.

major noncompliance – a violation of the National Organic Standards or MOSA policies resulting in a serious failure in the operation's Organic System Plan.

minor noncompliance – a violation of the National Organic Standards that, on its own, does not jeopardize the effectiveness of the operation's Organic System Plan or the organic integrity of the product.

on-farm processing – processing and/or handling of crop or livestock products by the farm operation on which these products were grown or produced.

operator – a person who owns, directs, or manages a production or handling enterprise.

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 as called for by the National Organic Standards.

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 of food in a container.

processor – a person or entity who engages in the business of processing food or feed products.

producer – a person or entity who engages in the business of growing or producing food, feed, fiber crops, livestock and other agricultural-based consumer products.

revocation – the termination by MOSA of an Associate's certification resulting in the loss of the ability of the Associate to market products as "organic," and/or as certified by MOSA.

surrender – the voluntary termination by an Associate of his/her own certification resulting in the loss of the Associate's ability to market products as "organic," and/or as certified by MOSA.

suspension – the action taken by MOSA resulting in an Associate's temporary loss of the ability to market products as certified by MOSA.

withdrawal – an Applicant's purposeful termination of the certification process prior to the issuance of the MOSA certificate.

XIV. Appendices

A. Inspection Guide for Producers

Please make every effort to be available for your inspector's schedule. In order to keep your travel costs down, inspectors must also schedule other nearby producers during the same day or in the same trip.

The inspector will verify the accuracy of your organic farm plan, look at your fields, crops, equipment and storage and verify that your record keeping system is complete. Inspectors report on your operation and identify issues of concern. Areas of concern are those that can have potential for contamination or commingling, like buffer areas, split production, or equipment also used in conventional farming.

If you are prepared, well organized and have a fairly straight-forward operation, your inspection should take 2-4 hours. Allow more time for your first inspection, or if you have a complex operation (livestock, split production, or distant fields or facilities).

CROP PRODUCERS:

- Be prepared to update the inspector regarding any changes to fields, maps, current crop plan, seeds, fertility, pest or disease control inputs. Have available total acreages and projected yields for each crop. If you received an Initial Review Letter, see if further information is needed for the inspection.
- Records your inspector will want to look at:
 - Receipts for all seeds used and a tag or bag for each variety.
 - Tags or documentation for seed inoculants.
 - Organic Seed Search form if non-organic seed was purchased, documentation of untreated and non-GMO status for non-organic seed.
 - Receipts for all other crop inputs—fertilizers; pest, disease and weed control products; soil mixes.
 - Product labels and ingredients statements for inputs not previously approved by MOSA.
 - Field activity records documenting field work from planting through harvest for each field.
 - Equipment, storage and truck cleaning records.
 - Storage inventory records.
 - Harvest and sales records—the inspector will audit TCs and sales from the previous year.
 - National Organic Standards and MOSA Program Manual.
 - Complaint log.

LIVESTOCK PRODUCERS:

- If there are changes in what livestock you have on your operation since your livestock application was submitted, have updated information available.
- Your inspector will observe your animals, living areas and pasture. They will look at the following records:
 - Feed rations and records for each type of livestock you are certifying.
 - Receipts and certification documentation for all purchased feed and supplements.
 - Updated individual herd health records for dairy animals, herd health records or flock records for slaughter or egg operations.
 - Certification documentation for purchased livestock. Receipts for all livestock inputs. Livestock inputs include everything except feed that goes into or onto your organic livestock.
 - Pasturing & confinement records.

B. Recordkeeping Requirements for Producers

Your audit trail refers to the records you keep that can trace a certified product from seed to market shelf. Creating and maintaining these records is required for certification. All records are to be maintained for 5 years and available at the time of your inspection.

MAPS OF LAND AND CROP STORAGE OR LIVESTOCK FACILITIES

Maps can be hand drawn or “official” (FSA/NRCS). Field maps need to have field numbers, acreages, boundaries, and adjoining land use clearly labeled. Indicate all areas that will require a buffer with a colored pencil or highlighter. Have maps for all fields under your management including conventional or transitional fields, both rented and owned. A separate map is preferred showing all facilities for crop/feed storage and livestock areas (both indoors and outdoors), but this may be indicated on the field maps if it can be clearly understood.

FIELD HISTORIES/PRIOR LAND USE DECLARATIONS

You need to have information in your file for the past three years’ inputs on land you’re requesting for certification. If you’re a new Applicant and have managed the land for the past 3 years, you need to complete the Three Year Field History form. A Current Year Field Plan is needed. Conventional and transitional fields should be listed on all field documents. If you’re requesting certification for crops grown on land that has not been under your management for 3 years and the land was certified by another agency or no seeds were planted or off-farm inputs applied, a Prior Land Use Declaration may be used to describe the past 3 years of field histories. Pastures must be included on field histories.

FIELD ACTIVITY LOG

Field activity logs will vary depending on the type of operation you are managing. Logs should include all field activities with dates (plowing, soil preparation, planting and cultivation), application of inputs such as fertilizers, foliar feedings, pesticides, manure (with dates and rates); harvests and amounts harvested; and general observations on crops. Calendars, daily planners, notebooks or computers all work – whatever you prefer to keep the necessary information.

BUFFER MANAGEMENT RECORDS

If you harvest in a buffer zone, you need to keep a record of when, amount and what you do with the buffer harvest. This can be done as part of a Field Activity Log or by using the Non-organic Crop Usage form. If no prohibited applications are currently used on the cropped, pastured, or residential land adjacent to your organic cropland or pasture, and your neighbor signs a Verification of Adjoining Land Use form, no buffer is needed.

CROPS/INPUTS

A crop input is anything besides seeds, on-farm manure, or compost that is applied to land or crop, whether as fertilizer, inoculants, potting mix, foliar applications, lime or other minerals, or any product used on stored crops or feed. You need to provide MOSA with a Crop Input Inventory listing all products used. List the exact brand name and manufacturer’s name for each input listed on your input inventory. If a product has not been approved by MOSA, ingredients information needs to be provided prior to use. For fertilizers, we need an ingredients list, not analysis. Have all purchase records for inputs available at inspection. Keep a copy of your Crop Input Inventory for your records, updating as necessary.

CLEANING DOCUMENTATION

If any equipment or storage is used for both organic and non-organic crops, you need to record how, when and who cleaned or purged before organic use or storage. This documentation must be completed for any buffer harvests and transportation of organic feed or crops. Your Field Activity Log or Cleaning Log may be used.

STORAGE DOCUMENTATION

If you sell crops or feed your crops to livestock and also have conventional or transitional crops on the farm, a system must be used to identify the areas in which crops are stored on the farm and to keep track of quantities in storage. All bins, cribs, bunkers or other storage areas should have an identification (ID) number, letter or name, and be indicated on the farm maps and on the Organic System Plan. If many different crops are being stored in bins over the course of a season, the storage records should identify the field or fields from which the crops originated. A Bin Register form is provided in your packet for your use. If you only raise organic crops for your own organic livestock, you also need to have all storage areas identified on your facility maps. Your harvest records should be sufficient to document how much feed went into storage. Have a feed inventory available at inspection time.

LOT NUMBER SYSTEM

If you sell crops, you need a lot numbering system. Lot numbers assigned by you are used on your field or storage records, sales records and outgoing documents to maintain the tracking of your crop from seed to sale. The lot number should clearly identify the year of production, your initials, the last location of the crop (field # if sold directly from a field, or bin ID# if sold from a storage bin), the crop and the date it was shipped. If more than one load is shipped in a day, this could also be indicated. The lot number should be used on all weigh tickets, bills of lading, invoices and Transaction Certificates. Here is an example of a lot number which includes this information: 08-JD-5-C-1114-2

08	JD	5	C	1114	2
Year of Production	Producer Initials	Storage Bin or Field #	Crop = Corn	Shipped = Nov 14	Load #

SALES RECORDS

Sales records should include sales receipts, clean transportation verification, bills of lading (BOL) and Transaction Certificates. Receipts and BOL should include the date of transaction, your name or farm name and the type of crops sold. Be sure to distinguish between organic crops and non-organic crops. The receipt should also include the dollar amount for which the crop sold. You need to keep sales records for all crops grown in split production. This means you must keep sales records on conventional and transitional crops as well as the organic crop. The Audit Control Register form may be helpful in keeping these records.

LIVESTOCK/LIVESTOCK PRODUCTS

The records you keep must be able to trace an individual animal's lineage and verify everything that goes in or on that animal.

INDIVIDUAL HERD HEALTH RECORDS

Individual herd health records must be established for each dairy animal that receives treatment. An index card or page in a notebook with corresponding animal ID (number, photo or name) can be used to record all lineage information, treatments, reproductive information, general comments, and ship or cull dates. These records are to be established at birth and kept for 5 years after the animal leaves the farm. Slaughter stock must have health records with reproductive information and specific treatments noted for individually identified animals or group treatment or events. Whole herd treatments such as vaccinations, physical alterations, and treatments given at the same stage of lactation or development can be recorded as whole herd health events.

POULTRY

Poultry operations should maintain records of hatching dates and source of chicks, proof of organic certification for purchased birds, batch records with corresponding batch number, vaccination schedule, treatments, mortality, production records and dates of provision for outdoor access.

FEED RATION

Record your overall rations and supplements and note when ration changes are made. Use seasonal feeding records to document pasture intake. Keep, and have available at inspection, all records of purchased feed.

LIVESTOCK PURCHASES

Keep records of, and have available at inspection, any purchases of livestock for organic production. If you have split production of livestock or livestock products (such as both organically and conventionally raised slaughter animals of the same type), record any conventional purchases as well.

LIVESTOCK INPUTS

A livestock input is anything, besides the feed you grow or purchase, that goes in or on your livestock. This includes feed supplements, minerals, additives or inoculants; pest treatments; wound treatments; health treatments or preventatives; or cleaning products. Provide MOSA with ingredients information for any product used. List the exact brand name and manufacturer's name for each input listed on your input inventory. If a product has not been approved by MOSA, ingredients information needs to be provided prior to use. Keep a copy of the Livestock Input Inventory for your records and keep it up-to-date.

LIVESTOCK SALES

Keep all sales records for organic livestock and livestock products and have available for inspection. If you sell anything both organically and conventionally, keep records for both. When you sell an animal that was treated with a prohibited substance, keep records of these sales and remember to contact the office to report use.

C. Inspection Guide for Handlers

Review this checklist to help you understand the process and organize your documentation for the inspector. If you're prepared, it will save you time and money!

Inspectors verify the accuracy of your processing/handling Organic System Plan. They look at product profiles and ingredients, processing product flow, quality control, sanitation system and materials, pest control operations and raw and finished product storage. They look at packaging, lot numbering and organic labeling. In addition, inspectors do a sample audit of your organic production and will also tour the production facilities.

Inspectors report on your operation and identify issues of concern. Areas of concern for inspectors are those that have potential for contamination or commingling in receiving, raw ingredient storage, sanitation, pest control, process scheduling and organic process production.

If you're well organized and have a fairly straightforward operation, plan on a 3 to 5 hour inspection. Personnel who are responsible for various aspects of the organic operation should be available on the day of inspection. Allow more time for your first inspection or if you have a complex operation (wide variety of organic products, complex procedures, distant facilities).

Review and outline changes to previously submitted forms and documents (maps, product profiles, ingredients, equipment and product flow descriptions). This includes changes in suppliers. Be prepared to update the inspector on such changes.

Have verification/documentation on how the previous year's conditions/requirements set by MOSA or any other organic certification agent have been addressed.

Be prepared to respond to any Initial Review letter items needing attention at inspection.

For Product Profiles: have labels, receipts, ingredient information, organic certification verification or affidavits for all inputs including organic ingredients, non-organic ingredients, non-agricultural ingredients, flavors and processing aids.

Have audit trail documentation accessible, showing how products are tracked from ingredient receiving through processing/handling, storage, product sale and shipping. Personnel that keep documentation at each stage of production need to be available to the inspector.

Have support documentation available: pest management, complaint, and employee training logs; quality assurance protocols and procedures; sales invoices; and composition and source information for pest control products, boiler chemicals, cleansers and sanitizers. Have verification of current organic certification for all certified organic ingredients and organic products received for further handling.

Have current verification to show compliance with any National List restrictions for any non-organic ingredients or processing aids. For example, non-organic agricultural ingredients used in organic products must be listed at National Organic Standards section 205.606, must be shown to be non-GMO, non-irradiated, and not produced using sewage sludge, and must be shown to be commercially unavailable in organic form.

If organic and non-organic products are handled in the same operation (parallel or split production), have records that show there is no commingling or contamination.

- Have current versions of the National Organic Standards and the MOSA Program Manual.
- Be prepared with the total dollar amounts of net sales (gross sales less cost of organic goods) made on MOSA-certified products or services (does not apply for first MOSA inspections).
- Have current or proposed retail and non-retail labels for all products making an organic claim.
- Have current licenses and/or permits as required by other regulatory authorities.

D. Recordkeeping Requirements for Handlers

AUDIT TRAIL

An audit trail refers to records that track a certified product from receiving ingredients to shipping finished product to the marketplace. Developing and maintaining these records is required for certification, and enables a faster inspection and file review, saving time and money. Read the following for tips on maintaining effective records, which must be maintained for 5 years and be available at inspection. The audit trail elements described below are not necessarily the only records you need; records must be adapted to your operation. Formats may differ, but records must demonstrate a complete and unbroken audit trail.

LOT NUMBERING SYSTEM

All organic products must be traceable back to their origin. **Lot numbering systems** are commonly used to meet this requirement. Incoming product/ingredient lot numbers should be noted and linked to any new lot number you assign. Lot numbers are utilized in receiving, production, storage and sales records, and on outgoing retail products and shipping documents to maintain traceability of a product and its components throughout the entire process.

INSPECTOR SAMPLE AUDIT

At your inspection, the inspector will conduct a sample audit to test your audit trail system. This sample audit could take different forms. A *trace-back* audit starts with a finished product and traces the audit trail back to the raw organic ingredients. A *trace-forward* audit does the reverse, with the inspector deciding what quantity of raw product to trace forward. A *balance in-balance out* audit will look at ingredients coming into the system and finished product going out of the system over a time period chosen by the inspector. Batch records may be compared to Organic Product Profiles submitted. Sample audits can be randomly selected from any organic production date and are not chosen prior to the inspection.

INGREDIENTS DOCUMENTATION

The *Ingredients Monitoring Spreadsheet* helps you monitor current certification or other compliance verification for various ingredients, especially if you have a large number of ingredients to track.

Organic Ingredients

Proof of current certification for all organic ingredients is required. A copy of the supplier's annual organic certificate, a Transaction Certificate (TC), or a statement from the supplier's organic certifier must be kept on hand to verify organic status. The verification of current certification should clearly identify the ingredient by name.

Non-Organic Agricultural Ingredients

When non-organic *agricultural* ingredients are used in organic processing, **non-organic ingredient compliance documentation** must be obtained to verify the ingredients were not derived from genetically modified organisms (GMOs), produced using sewage sludge as a fertilizer, or treated with

ionizing radiation. MOSA's *Non-GMO Verification* form may be used for this purpose. Also, for products labeled "organic," any non-organic agricultural ingredients used must be on the National List at section 205.606, and an **organic ingredient search** must be conducted and documented to verify that organic ingredients were not commercially available.

Non-Agricultural Ingredients

Non-agricultural ingredient compliance documentation must be obtained to verify ingredients' compliance with National Organic Standards annotations. Documentation requirements vary depending on the type of ingredient, so check the National List or the OMRI listing for specific compliance verifications needed.

OTHER AUDIT TRAIL RECORDS REQUIRED FOR CERTIFIED OPERATIONS

Purchase records: The purchase dates and quantities of ingredients and processing aids used in your organic processing operation must be documented. Keep invoices, receipts, BOLs, contracts, and other purchase records.

Receiving log: A receiving summary log should list product lot numbers as well as receiving dates and quantities for all incoming ingredients.

Production records: Track the amounts and lot numbers for ingredients used in organic products and link specific ingredients to their final product. MOSA's Audit Control Summary Sheet may be used to track ingredients.

Sales records: These include sales invoices, BOLs, purchase orders, and/or TCs. Sales records should include date of transaction, product lot number, operation's name, type of product sold, and purchase price. Describe the product as "organic" on the BOL and invoice. To track net sales for calculating user fees, records must show gross organic sales (including fees charged for organic processing services), and your cost for certified organic ingredients used as inputs. You must keep sales records that show the inspector and reviewer that organic products are not commingled with the same conventional product you manufacture, and that conventional product is not sold as organic.

EQUIPMENT, STORAGE, AND TRANSPORT DOCUMENTATION

Equipment cleaning before organic product contact occurs must be documented, especially if equipment is used for non-organic production. Sanitation logs may be used to document cleaning prior to organic production, or the *Cleaning Log* form may be used. Documentation of clean transportation, such as **clean truck affidavits** both for incoming ingredients and outgoing product, should be maintained. MOSA's *Off-Site Transportation Cleaning Affidavit* may be used for this purpose. If any transport units are used during the production process (such as tubs or carts) and are not dedicated for organic use, they must also be documented as clean.

Storage inventory records must be maintained and at minimum should include: storage unit identification for bulk raw product, product lot number, amount and date of incoming product, amount and date of outgoing product, the disposition or destination of the product, and current balance of product. If bulk storage units or silos are not dedicated organic, they must be cleaned before storing organic products, and cleaning needs to be documented on a **storage cleaning log or sanitation log** that indicates the date, storage unit ID, method of cleaning, and signature or initials of the person responsible for the cleaning.

DOCUMENTATION OF MATERIALS USED IN ORGANIC PRODUCTION

Materials include pesticides, cleansers, boiler additives, or other products necessary for processing. **Materials records** used to verify compliance include all labels, receipts, and ingredient listings for these types of inputs. Labels or receipts should provide the supplier's name and contact information, and a complete ingredient listing. MOSA's *Handler Materials Inventory* form can be used to list these materials and how they're used. **Input usage logs** include sanitation and pest control logs in a form suited to your operation. They must contain complete information on application and use. **Monitoring records** should also be kept as part of the audit trail. Monitoring records include water tests and other product quality tests.

If cleaners/sanitizers will be in contact with organic product, they may contain only active ingredients that are allowed on the National List. Other cleaners and sanitizers may be used if you can document that these materials do not contact organic product or food contact surfaces, or that there is an intervening event sufficient to remove residues. Sufficient intervening events include rinsing or allowing the material to dry, followed by documented residue testing indicating no residues remain. Materials such as quaternary ammonia that leave a persistent residue are more problematic but may be allowed if you can verify, such as through residue testing, that these materials do not contaminate organic product.

For pest control, follow the steps outlined in National Organic Standards section 205.271. Preventive management practices must be used first. If those practices are shown to be ineffective, you may use materials that are allowed in the Standards. Use of pest control materials that are prohibited in the Standards are only allowed if you can document that preventive practices and allowed materials are insufficient to control pests, and if the use of such materials is part of your approved organic pest management plan .

OTHER SUPPORTING DOCUMENTATION

Develop a **facility map** with all areas of the operation clearly labeled. Facility maps should identify all features of importance (such as equipment, receiving areas, storage locations). Be sure to show all areas under your management on the facility maps, including all conventional areas.

Develop a complete written description or schematic product **flow chart** that shows the movement of all organic products, from incoming/receiving through production to outgoing/shipping. Indicate where ingredients are added and/or processing aids are used. All equipment and storage areas must be identified. Organic Control Points (OCPs) should be noted on the processing flow chart. OCPs are points in a production system where the integrity of the organic product may be compromised if proper management is not in place. Examples include improper cleaning of equipment prior to running organic product, resulting in commingling with non-organic products left in the equipment, or use of a prohibited pesticide when organic product is present, resulting in contamination by a prohibited substance.

Facility pest maps should indicate the locations of all traps, bait stations, and other pesticide applications.

All operations certified by MOSA are required to keep a **complaint log**, even if no complaints are received. MOSA's *Complaint Log* form can be used for tracking complaints and how they were addressed.

LABELING REQUIREMENTS

All organic product retail labels must be reviewed and approved by MOSA prior to use in the marketplace. Retail labels must include the statement "Certified organic by MOSA" or similar phrase, placed below or immediately next to the information identifying your company; and identify all organic ingredients in the ingredients statement with the word "organic" or with an asterisk or other reference mark and the word "organic." All non-retail labels must include the lot number. Other label elements are optional, provided they follow guidelines in the Standards, including specifics related to the category of product ("100% Organic," "Organic," or "Made with Organic...").

MOSA PROCESSOR/HANDLER FEE SCHEDULE

The cost of certification includes base certification fees, inspection fees and user fees.

Base Certification Fees *due with application*

First year processor/handler, distributor, retail or restaurant certification	\$450 per location
Update processor/handler, distributor, retail or restaurant certification	\$400 per location
Private label arrangements	Billed at \$60/hour minimum \$200/arrangement

Late Fees *due with application*

Update application received after due date	\$100/month
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Inspection Fee Deposit *due with application*

Inspection fee deposit	\$300 per location
Inspection fee balance <i>includes inspector's actual charges for service, mileage and lodging and will be billed following the inspection, minus the Inspection Fee Deposit</i>	Varies with actual charges

User Fees *Organic sales are reported quarterly and user fees due quarterly unless other arrangements are made. A minimum user fee amount of \$200/year is required. Any balance due will be billed at the beginning of the following year.*

Processor/Handler User Fee (cap=\$75,000 annually)

For annual net sales* \$0–2.2 million	.5%
For additional net sales over \$2.2 million	.1%

Distributor User Fee for those who *take title of product* (cap=\$75,000 annually)

For annual net sales* \$0–2 million	.1%
For additional net sales* \$2 million-50 million	.05%
For additional net sales* \$50 million-100 million	.025%
For additional net sales* \$100 million and over	.0025%

Distributor User Fee for those who *do not take title of product* (cap=\$75,000 annually)

For gross organic sales resulting in commissions totaling up to \$2 million	.1%
For additional commissions of \$2 million-50 million	.05%
For additional commissions of \$50 million-100 million	.025%
For additional commissions over \$100 million	.0025%

*Net sales are gross organic sales or organic handling charges less the cost of certified organic ingredients.

Retailer/Restaurant (Flat User Fee)

Certified departments totaling less than 7,500 square feet	\$750
Certified departments of 7,500 sq. ft. to 18,000 sq. ft.	\$1500
Certified departments greater than 18,000 sq. ft.	\$2500

Additional Services and Fees billed at \$60/hour, minimums apply

Additional verification: EU, US Export Arrangements with Japan or Taiwan, Canadian Equivalence or other	\$75 minimum
Adding products or services to certificate outside of the annual review process	\$60 minimum
Extending certification during transfer to another agency or to accommodate sales of inventory	\$60 minimum
Reinstatement	\$100 minimum
Mediation costs in addition to Mediator's fees	\$300 deposit required with request
Additional administrative or certification services	

Refunds If an application is withdrawn or certification surrendered prior to initial review and inspection assignment MOSA will refund cert fees and inspection deposit minus a \$60 administrative fee. If an application is withdrawn or certification surrendered after initial review but before inspection, the inspection deposit will be refunded. No refunds will be made for withdrawals or surrender of certification after inspection.