USDA National Organic Program Regulations

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NOFA-NY Certified Organic, LLC Guidance and Policy Manuals

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FOREWARD

NATIONAL ORGANIC PROGRAM REGULATIONS

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NOFA-NY CERTIFIED ORGANIC, LLC POLICY MANUAL
FORWARD

Organic certification is voluntary, third party verification of organic production practices. Those who choose organic certification of their operation make an agreement and commitment to operate according to the USDA National Organic Program (NOP) Regulations, which allows them to represent their products as organic. Certification is obtained through an Accredited Certification Agency, rather than through the NOP.

The NOP Regulations were originally published in the Federal Register on December 21, 2000, based on the principles of the Organic Foods Production Act of 1990. This manual includes the Regulations as written in the Federal Register as of November 29, 2017. A current version of the Regulations can be viewed on the National Organic Program website at www.ams.usda.gov/nop.

The NOP Regulations are process based, and include management, production and recordkeeping requirements. It is imperative that producers and handlers read and understand these requirements.

This three-part manual includes the NOP Regulations, as well as NOFA-NY Certified Organic, LLC’s Guidance Manual and Policy Manual. While Accredited Certification Agencies are prohibited from consulting, our agency’s Guidance Manual is intended to provide some clarification to various sections of the Regulations. The Policy Manual outlines the policies established for certification by our agency and includes an overview of the application process, our fee structure, and compliance procedures.
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SOURCE: 65 FR 80637, Dec. 21, 2000, unless otherwise noted.

**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.


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 unavoidability 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.


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.

Biodegradable biobased mulch film. A synthetic mulch film that meets the following criteria:

1. Meets the compostability specifications of one of the following standards: ASTM D6400, ASTM D6868, EN 13432, EN 14995, or ISO 17088 (all incorporated by reference; see §205.3);

2. Demonstrates at least 90% biodegradation absolute or relative to microcrystalline cellulose in less than two years, in soil, according to one of the following test methods: ISO 17556 or ASTM D5988 (both incorporated by reference; see §205.3); and

3. Must be biobased with content determined using ASTM D6866 (incorporated by reference; see §205.3).

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 multi-ingredient 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 napthenic 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.

§205.3 Incorporation by reference.

(a) Certain material is incorporated by reference into this part with the approval of the Director of the Federal Register under 5 U.S.C. 552(a) and 1 CFR part 51. To enforce any edition other than that specified in this section, we must publish notice of change in the FEDERAL REGISTER and the material must be available to the public. All approved material is available for inspection at the USDA Agricultural Marketing Service, National Organic Program, 1400 Independence Avenue SW., Washington, DC 20250; (202) 720-3252, and is available from the sources listed below. It is also available for inspection at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call (202) 741-6030 or go to http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html.

(b) ASTM International, 100 Barr Harbor Drive, PO Box C700, West Conshohocken, PA 19428; phone 1-877-909-2786; http://www.astm.org/.


  (4) ASTM D6868-11 (“ASTM D6868”), “Standard Specification for Labeling of End Items that Incorporate Plastics and Polymers as Coatings or Additives with Paper and Other Substrates Designed to be Aerobically Composted in Municipal or Industrial Facilities,” approved February 1, 2011, IBR approved for §205.2.

(c) European Committee for Standardization; Avenue Marnix, 17-B-1000 Brussels; phone 32 2 550 08 11; www.cen.eu.


(d) International Organization for Standardization, 1, ch. de la Voie-Creuse, CP 56, CH-1211 Geneva 20, Switzerland; phone 41 22 749 01 11; www.iso.org.


(2) ISO 17556:2012(E) (“ISO 17556”), “Plastics—Determination of the ultimate aerobic biodegradability of plastic materials in soil by measuring the oxygen demand in a respirometer or the amount of carbon dioxide evolved,” August 15, 2012, IBR approved for §205.2.

[79 FR 58662, Sept. 30, 2014]

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 the amount specified in §3.91(b)(1) 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.


§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 though 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.
(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.

(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 animals, as allowed under §205.603.

(3) Fiber bearing animals, as allowed under §205.603.

(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.

[65 FR 80637, Dec. 21, 2000, as amended at 83 FR 66571, Dec. 27, 2018]

§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]

§§205.243-205.269 [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 §205.105(e);
2. Be produced using ionizing radiation, pursuant to §205.105(f);
3. Be processed using sewage sludge, pursuant to §205.105(g);
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.

[65 FR 80637, Dec. 21, 2000, as amended at 80 FR 6429, Feb. 5, 2015]

§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

§§205.312-205.399 [Reserved]

Subpart E—Certification

USDA National Organic Program 7 CFR Part 205, as of October 23, 2019 [33]
§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 §205.103;

(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.

[65 FR 80637, Dec. 21, 2000, as amended at 80 FR 6429, Feb. 5, 2015]

§205.401 Application for certification.

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

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

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

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

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

§205.402 Review of application.

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

   (1) Review the application to ensure completeness pursuant to §205.401;
(2) Determine by a review of the application materials whether the applicant appears to comply or may be able to comply with the applicable requirements of subpart C of this part;

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

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

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

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

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

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

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

§205.403 On-site inspections.

(a) On-site inspections.

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

(2)

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

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

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

(b) Scheduling.

(1) The initial on-site inspection must be conducted within a reasonable time following a determination that the applicant appears to comply or may be able to comply with the requirements of subpart C of this part: Except, That, the initial inspection may be delayed for up to 6 months to comply with the requirement that the inspection be conducted when the land, facilities, and activities that demonstrate compliance or capacity to comply can be observed.
(2) All on-site inspections must be conducted when an authorized representative of the operation who is knowledgeable about the operation is present and at a time when land, facilities, and activities that demonstrate the operation's compliance with or capability to comply with the applicable provisions of subpart C of this part can be observed, except that this requirement does not apply to unannounced on-site inspections.

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

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

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

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

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

(e) Documents to the inspected operation.

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

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

§205.404 Granting certification.

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

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

(1) Name and address of the certified operation;

(2) Effective date of certification;

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

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

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

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

(1) A description of each noncompliance;

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

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

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

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

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

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

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

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

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

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

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

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

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

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

(2) Request mediation pursuant to §205.663 or, if applicable, pursuant to a State organic program; or

(3) File an appeal of the denial of certification pursuant to §205.681 or, if applicable, pursuant to a State organic program.

(e) An applicant for certification who has received a written notification of noncompliance or a written notice of denial of certification may apply for certification again at any time with any certifying agent, in accordance
with §§205.401 and 205.405(e). When such applicant submits a new application to a certifying agent other than the agent who issued the notification of noncompliance or notice of denial of certification, the applicant for certification must include a copy of the notification of noncompliance or notice of denial of certification and a description of the actions taken, with supporting documentation, to correct the noncompliances noted in the notification of noncompliance.

(f) A certifying agent who receives a new application for certification, which includes a notification of noncompliance or a notice of denial of certification, must treat the application as a new application and begin a new application process pursuant to §205.402.

(g) Notwithstanding paragraph (a) of this section, if a certifying agent has reason to believe that an applicant for certification has willfully made a false statement or otherwise purposefully misrepresented the applicant's operation or its compliance with the certification requirements pursuant to this part, the certifying agent may deny certification pursuant to paragraph (c)(1)(ii) of this section without first issuing a notification of noncompliance.

§205.406 Continuation of certification.

(a) To continue certification, a certified operation must annually pay the certification fees and submit the following information, as applicable, to the certifying agent:

(1) An updated organic production or handling system plan which includes:
   
   (i) A summary statement, supported by documentation, detailing any deviations from, changes to, modifications to, or other amendments made to the previous year's organic system plan during the previous year; and
   
   (ii) Any additions or deletions to the previous year's organic system plan, intended to be undertaken in the coming year, detailed pursuant to §205.200;

(2) Any additions to or deletions from the information required pursuant to §205.401(b);

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

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

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

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

(d) If the certifying agent determines that the certified operation is complying with the Act and the regulations in this part and that any of the information specified on the certificate of organic operation has changed, the certifying agent must issue an updated certificate of organic operation pursuant to §205.404(b).
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-NOP, 1400 Independence Ave. SW., Room 2648 So. Bldg., Ag Stop 0268, Washington, DC 20250-0268.

(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.

[65 FR 80637, Dec. 21, 2000, as amended at 80 FR 6429, Feb. 5, 2015]

§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.

Link to an amendment published at 84 FR 56677, Oct. 23, 2019.

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—For pre-harvest use, residual chlorine levels in the water in direct crop contact or as water from cleaning irrigation systems applied to soil must not exceed the maximum residual disinfectant limit under the Safe Drinking Water Act, except that chlorine products may be used in edible sprout production according to EPA label directions.

   (i) Calcium hypochlorite.

   (ii) Chlorine dioxide.

   (iii) Hypochlorous acid—generated from electrolyzed water.

   (iv) 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. Also permitted in hydrogen peroxide formulations as allowed in §205.601(a) at concentration of no more than 6% as indicated on the pesticide product label.

(7) Soap-based algicide/demossers.

(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)).

      (iii) Biodegradable biobased mulch film as defined in §205.2. Must be produced without organisms or feedstock derived from excluded methods.

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

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

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

   (1) Ammonium carbonate—for use as bait in insect traps only, no direct contact with crop or soil.
(2) 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. Vitamin D₃.

(h) As slug or snail bait.

(1) Ferric phosphate (CAS # 10045-86-0).

(2) Elemental sulfur.

(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. Also permitted in hydrogen peroxide formulations as allowed in §205.601(i) at concentration of no more than 6% as indicated on the pesticide product label.

(9) Potassium bicarbonate.

(10) Elemental sulfur.

(11) Polyoxin D zinc salt.

(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.

(5) Magnesium oxide (CAS # 1309-48-4)—for use only to control the viscosity of a clay suspension agent for humates.

(6) Magnesium sulfate—allowed with a documented soil deficiency.

(7) Micronutrients—not to be used as a defoliant, herbicide, or desiccant. Those made from nitrates or chlorides are not allowed. Micronutrient deficiency must be documented by soil or tissue testing or other documented and verifiable method as approved by the certifying agent.

(i) Soluble boron products.

(ii) Sulfates, carbonates, oxides, or silicates of zinc, copper, iron, manganese, molybdenum, selenium, and cobalt.

(8) 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.

(9) Vitamins, B₁, C, and E.

(10) Squid byproducts—from food waste processing only. 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.

(11) 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. 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) As production aids. Microcrystalline cheesewax (CAS #’s 64742-42-3, 8009-03-8, and 8002-74-2)—for use in log grown mushroom production. Must be made without either ethylene-propylene co-polymer or synthetic colors.

(p)-(z) [Reserved]

§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) Rotenone (CAS # 83-79-4).

(g) Sodium fluoaluminate (mined).

(h) 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.

(i) Strychnine.

(j) Tobacco dust (nicotine sulfate).


§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) Activated charcoal (CAS # 7440-44-0)—must be from vegetative sources.

(7) Calcium borogluconate (CAS # 5743-34-0)—for treatment of milk fever only.

(8) Calcium propionate (CAS # 4075-81-4)—for treatment of milk fever only.

(9) Chlorhexidine (CAS # 55-56-1)—for medical procedures conducted under the supervision of a licensed veterinarian. Allowed for use as a teat dip when alternative germicidal agents and/or physical barriers have lost their effectiveness.

(10) 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) Hypochlorous acid—generated from electrolyzed water.
   
   (iv) Sodium hypochlorite

(11) Electrolytes—without antibiotics.

(12) 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.

(13) Glucose.

(14) Glycerin—allowed as a livestock teat dip, must be produced through the hydrolysis of fats or oils.

(15) Hydrogen peroxide.
(16) Iodine.

(17) Kaolin pectin—for use as an adsorbent, antidiarrheal, and gut protectant.

(18) 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.

(19) Magnesium sulfate.

(20) Mineral oil—for treatment of intestinal compaction, prohibited for use as a dust suppressant.

(21) Nutritive supplements—injectable supplements of trace minerals per paragraph (d)(2) of this section, vitamins per paragraph (d)(3), and electrolytes per paragraph (a)(11), with excipients per paragraph (f), in accordance with FDA and restricted to use by or on the order of a licensed veterinarian.

(22) Oxytocin—use in postparturition therapeutic applications.

(23) Parasiticides—prohibited in slaughter stock, allowed in emergency treatment for dairy and breeder stock when organic system plan-approved preventive management does not prevent infestation. 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. Allowed for fiber bearing animals when used a minimum of 36 days prior to harvesting of fleece or wool that is to be sold, labeled, or represented as organic.

   (i) Fenbendazole (CAS #43210-67-9)—milk or milk products from a treated animal cannot be labeled as provided for in subpart D of this part for: 2 days following treatment of cattle; 36 days following treatment of goats, sheep, and other dairy species.

   (ii) Moxidectin (CAS #113507-06-5)—milk or milk products from a treated animal cannot be labeled as provided for in subpart D of this part for: 2 days following treatment of cattle; 36 days following treatment of goats, sheep, and other dairy species.

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

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

(26) 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.

(27) Propylene glycol (CAS #57-55-6)—only for treatment of ketosis in ruminants.

(28) Sodium chlorite, acidified—allowed for use on organic livestock as a teat dip treatment only.

(29) 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.

(30) 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; and,

(ii) 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) Elemental sulfur—for treatment of livestock and livestock housing.

(3) Formic acid (CAS # 64-18-6)—for use as a pesticide solely within honeybee hives.

(4) Iodine.

(5) Lidocaine—as a local anesthetic. Use requires a withdrawal period of 8 days after administering to livestock intended for slaughter and 6 days after administering to dairy animals.

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

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

(8) Procaine—as a local anesthetic. Use requires a withdrawal period of 8 days after administering to livestock intended for slaughter and 6 days after administering to dairy animals.

(9) Sodium chlorite, acidified—allowed for use on organic livestock as teat dip treatment only.

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

(11) Zinc sulfate—for use in hoof and foot treatments only.

(c) As feed supplements—None.

(d) As feed additives.

(1) DL-Methionine, DL-Methionine—hydroxy analog, and DL-Methionine—hydroxy analog calcium (CAS #’s 59-51-8, 583-91-5, 4857-44-7, and 922-50-9)—for use only in organic poultry production at the following pounds of synthetic 100 percent methionine per ton of feed in the diet, maximum rates as averaged per ton of feed over the life of the flock: Laying chickens—2 pounds; broiler chickens—2.5 pounds; turkeys and all other poultry—3 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 and biologics used to treat organic livestock when the excipient is: (1) Identified by the FDA as Generally Recognized As Safe; (2) Approved by the FDA as a food additive; (3) Included in the FDA review and approval of a New Animal Drug Application or New Drug Application; or (4) Approved by APHIS for use in veterinary biologics.

(g)-(z) [Reserved]

§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 (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).

Attapulgite—as a processing aid in the handling of plant and animal oils.

Bentonite.

Calcium carbonate.

Calcium chloride.

Calcium sulfate—mined.

Carrageenan.
Dairy cultures.

Diatomaceous earth—food filtering aid only.

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

Flavors—nonsynthetic flavors may be used when organic flavors are not commercially available. All flavors must be derived from organic or 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 chloride.

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 (Wood resin).

Yeast—When used as food or a fermentation agent in products labeled as “organic,” yeast must be organic if its end use is for human consumption; nonorganic yeast may be used when organic yeast is not commercially available. Growth on petrochemical substrate and sulfite waste liquor is prohibited. For smoked yeast, nonsynthetic smoke flavoring process must be documented.

(b) Synthetics allowed:

Acidified sodium chlorite—Secondary direct antimicrobial food treatment and indirect food contact surface sanitizing. Acidified with citric acid only.

Activated charcoal (CAS #s 7440-44-0; 64365-11-3)—only from vegetative sources; for use only as a filtering aid.
Alginates.

Alginic acid (CAS #9005-32-7)

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 (CAS #9004-34-6)—for use in regenerative casings, powdered cellulose as an anti-caking agent (non-chlorine bleached) and filtering aid. Microcrystalline cellulose is prohibited.

Chlorine materials—disinfecting and sanitizing food contact surfaces, equipment and facilities may be used up to maximum labeled rates. Chlorine materials in water used in direct crop or food contact are permitted at levels approved by the FDA or EPA for such purpose, provided the use is followed by a rinse with potable water at or below the maximum residual disinfectant limit for the chlorine material under the Safe Drinking Water Act. Chlorine in water used as an ingredient in organic food handling must not exceed the maximum residual disinfectant limit for the chlorine material under the Safe Drinking Water Act.

i. Calcium hypochlorite.

ii. Chlorine dioxide.

iii. Hypochlorous acid—generated from electrolyzed water.

iv. Sodium hypochlorite.

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.

Hydrogen peroxide.

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.

Ozone.
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 carbonate.

Potassium citrate.

Potassium hydroxide—prohibited for use in lye peeling of fruits and vegetables except when used for peeling peaches.

Potassium lactate—for use as an antimicrobial agent and pH regulator only.

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—Permitted as a defoamer. Allowed for other uses when organic rice hulls are not commercially available.

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 lactate—for use as an antimicrobial agent and pH regulator only.

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.

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

Xanthan gum.

(c)-(z) [Reserved]

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

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

(a) Carnauba wax

(b) Casings, from processed intestines.
(c) Celery powder.

(d) Colors derived from agricultural products—Must not be produced using synthetic solvents and carrier systems or any artificial preservative.

(1) Beet juice extract color—derived from Beta vulgaris L., except must not be produced from sugarbeets.

(2) Beta-carotene extract color—derived from carrots (Daucus carota L.) or algae (Dunaliella salina).

(3) Black currant juice color—derived from Ribes nigrum L.

(4) Black/purple carrot juice color—derived from Daucus carota L.

(5) Blueberry juice color—derived from blueberries (Vaccinium spp.).

(6) Carrot juice color—derived from Daucus carota L.

(7) Cherry juice color—derived from Prunus avium (L.) or Prunus cerasus L.

(8) Chokeberry, aronia juice color—derived from Aronia arbutifolia (L.) Pers. or Aronia melanocarpa (Michx.) Elliott.

(9) Elderberry juice color—derived from Sambucus nigra L.

(10) Grape juice color—derived from Vitis vinifera L.

(11) Grape skin extract color—derived from Vitis vinifera L.

(12) Paprika color—derived from dried powder or vegetable oil extract of Capsicum annuum L.

(13) Pumpkin juice color—derived from Cucurbita pepo L. or Cucurbita maxima Duchesne.

(14) Purple sweet potato juice color—derived from Ipomoea batatas L. or Solanum tuberosum L.

(15) Red cabbage extract color—derived from Brassica oleracea L.

(16) Red radish extract color—derived from Raphanus sativus L.

(17) Saffron extract color—derived from Crocus sativus L.

(18) Turmeric extract color—derived from Curcuma longa L.

(e) 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.

(f) Fructooligosaccharides (CAS # 308066-66-2).

(g) Gelatin (CAS # 9000-70-8).

(h) Glycerin (CAS # 56-81-5)—produced from agricultural source materials and processed using biological or mechanical/physical methods as described under §205.270(a).

(i) Gums—water extracted only (Arabic; Guar; Locust bean; and Carob bean).
(j) Inulin-oligofructose enriched (CAS # 9005-80-5).

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

(l) Konjac flour (CAS # 37220-17-0).

(m) Lecithin—de-oiled.

(n) Orange pulp, dried.

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

(p) Pectin (non-amidated forms only).

(q) Potassium acid tartrate.

(r) Seaweed, Pacific kombu.

(s) Starches.
   
   (1) Cornstarch (native).
   
   (2) Sweet potato starch—for bean thread production only.

(t) Tragacanth gum (CAS #9000-65-1).

(u) Turkish bay leaves.

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

(w) Whey protein concentrate.

§205.607 Amending the National List.

(a) Any person may petition the National Organic Standards 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-NOP, 1400 Independence Ave. SW., Room 2648 So. Bldg., Ag Stop 0268, Washington, DC 20250-0268.

§§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 USDA, AMS Livestock Program and mailed to: USDA, AMS Livestock, Poultry and Seed Program, QAD, P.O. Box 790304 St. Louis, MO 63179-0304 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.

[65 FR 80637, Dec. 21, 2000, as amended at 80 FR 6429, Feb. 5, 2015]

§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 written 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) 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.

§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 products to be sold or labeled as “100 percent organic,” “organic,” or “made with organic (specified ingredients or food group(s)).”

(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. Samples may include the collection and testing of soil; water; waste; seeds; plant tissue; and plant, animal, and processed products samples. 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) A certifying agent must conduct periodic residue testing of agricultural products to be sold, labeled, or represented as “100 percent organic,” “organic,” or “made with organic (specified ingredients or food group(s)).” Samples may include the collection and testing of soil; water; waste; seeds; plant tissue; and plant, animal, and processed products samples. Such tests must be conducted by the certifying agent at the certifying agent's own expense.

(d) A certifying agent must, on an annual basis, sample and test from a minimum of five percent of the operations it certifies, rounded to the nearest whole number. A certifying agent that certifies fewer than thirty operations on an annual basis must sample and test from at least one operation annually. Tests conducted under paragraphs (b) and (c) of this section will apply to the minimum percentage of operations.

(e) Sample collection pursuant to paragraphs (b) and (c) 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 for determining the presence of contaminants in agricultural products.

(f) Results of all analyses and tests performed under this section will be available for public access, unless the testing is part of an ongoing compliance investigation.

(g) 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. Test results that exceed federal regulatory
tolerances must also be reported to the appropriate State health agency or foreign equivalent.

[77 FR 67251, Nov. 9, 2012]

§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.
§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, 7 CFR part 1, subpart H, 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 Team, 1400 Independence Avenue SW., Room 2648-So., Stop 0268, Washington, DC 20250-0268.

(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.


§§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]
NOFA-NY Certified Organic, LLC

Guidance to

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NOFA-NY Certified Organic, LLC
Guidance Manual

1. Introduction

NOFA-NY Certified Organic, LLC is an accredited organic certification agency which verifies and monitors compliance with the USDA National Organic Program Regulations. Organic certification is an annual process. Each operation receives at least one scheduled on-site inspection annually. Inspections must occur when the land, facilities and activities that demonstrate compliance or capacity to comply can be observed (i.e. growing season for crops, production time for handling, etc.).

2. The Organic System Plan (OSP) (205.201)

The term "organic system plan" refers to the management plan of an organic farming or handling operation that has been agreed to by the producer or handler and the certifying agent. It includes written plans concerning all aspects of organic agricultural production or handling described in the regulations. All operations seeking certification must develop an Organic System Plan (OSP). The NOFA-NY Certified Organic, LLC application for certification, in conjunction with all other audit trail records, will be considered the OSP. The OSP must be updated annually and as changes occur. This includes additions of new products, new fields, etc. Failure to notify the certification office of changes to the OSP that could affect compliance to the regulations may result in a noncompliance. Examples include, but are not limited to, selling product as organic prior to being added to the organic certificate and application of a new material to fields/livestock that could contain prohibited materials.

3. Components of the OSP for Farms (205.201)

Intent: A statement of understanding and intent to follow the practices described in the regulations.

Method: A description of the organic management plan for farms, including crop information, seed and transplant sources, production history, soil development plans and crop rotations. Farm maps, identifying all fields, greenhouses and other production areas, plus storage, processing and handling facilities are an integral part of an organic system plan. Livestock operations also include an animal inventory, health management plan, pasture plan and feed ration information.

Audit Trail: A required system of record keeping that shows that the applicant is indeed carrying out the practices for organic production and processing. The records must be sufficient to track crops from seed to sale and livestock from dam to market.

Affirmation: A signed document stating that the information supplied is accurate, true and complete.

4. Ownership / Management (OSP) (205.201)

For each operation seeking initial or continuing certification, establish main contact(s) familiar with the operation who are responsible for the following:

- Contact and communications with the certification program,
- Maintaining compliance with the USDA NOP Regulations,
- Informing the certification office of management changes within the operation,
- Providing records and guaranteeing accuracy of information provided in the application and at inspection.

Main contacts are able to make any changes, add/remove contacts and discuss all aspects of certification. Other contacts designated in the application are able to discuss certification, make changes to the OSP and participate in inspection, but cannot add/remove contacts.
One of these persons must be present at the inspection and must have access to all information regarding record keeping and technical aspects of the operation.

Failure to notify the Certification Office of changes to the authorized persons may jeopardize continued certification. If the Certification Office determines such changes result in lack of accountability for the certification process, additional on-site inspections may be necessary. The costs of these on-site inspections will be billed to the applicant.

5. **Split Operations (OSP) (205.201)**

The term “split operation” refers to an operation that produces or handles both organic and non-organic agricultural products. It is the responsibility of the producer of a split operation to submit a management plan that prevents commingling.

A split operation includes:

- Any non-certified livestock other than animals for traction or pets. Any feed or products for non-certified livestock, traction animals or pets must be segregated. Records and documentation for the feed and products for the non-certified livestock, traction animals/pets must be maintained as part of your audit trail and are available for review by the inspector. (Breeder stock included in the Organic System Plan that is being managed organically does not designate a split operation.)
- Any non-certified crops grown (including home use) and any non-certified value-added products produced
- Non-certified products purchased for re-sale.

Split operations utilizing the same planting, cultivation, harvesting, or processing equipment must clean out and/or purge equipment prior to use on organic crops, fields or products. Transitional fields are considered non-organic and equipment used on them should be cleaned prior to organic use. Equipment cleaning and purging must be documented and maintained in your records for all production types as applicable. For specifics on equipment cleaning and purging, see section 16.

If producing the same crops or products as organic and non-organic, separate harvest, processing, storage and sales records are required. Information on how certified and non-certified items are segregated/labeled in storage and at point of sale is required. There must be no possible confusion or commingling, especially if the same items exist as both organic and non-organic. Diagram/photo/signage showing segregation and labels used on non-organic products should be submitted as applicable.

6. **Notification (OSP) (205.201)**

Organic farmers must make every effort to be aware of, and prevent all possible sources of contamination of fields, irrigation water and facilities.

To protect the organic integrity of your operation from the unintentional application of prohibited substances, we recommend that you notify neighbors, utilities, state & local highways, railway companies & health departments of the organic status of the your farm. Copies of such letters should be sent to the certification office, and retained as part of your audit trail.

7. **Audit Trails for Certified Operations (205.103)**

All operations applying for initial or continuing certification are required to develop and maintain an audit trail record keeping system. All audit trail records must be maintained for a minimum of 5 years beyond their creation.

An audit trail must be able to trace any given product from the point of sale back to its origin. For operations selling at farmers’ markets, records of inventory brought to the market and a record of daily/weekly sales totals should be maintained. Farms marketing through CSA projects must also maintain harvest and distribution records. Split operations must maintain complete audit trail records for both certified & non-
certified crops. The audit trail system will be reviewed at inspection. *Failure to maintain an audit trail system will jeopardize certification.*

Examples of common audit trail records are listed below. Many of the examples are provided as blank forms in the annual certification application; others should be maintained by the operator. Not all records in this list are relevant to all operations.

**Farm / facility diagrams**

**Input Records:**
- Invoices/receipts
- Applied Amendments/Spray Record
- Custom work transactions

**Seeds and transplant records:**
- Purchase records for seeds
- Seed search documentation
- Transplant production records
- Certificates for purchased transplants
- Information indicating whether seeds are organic/non-organic/treated /untreated
- Non-GMO statements
- Verification of seed coating/inoculants

**Field Records:**
- Field history forms
- Field affirmations
- Field maps
- Application/custom work records and receipts
- Soil, water, and/or crop tests

**Harvest & Sales Records:**
- Field identification for each given crop
- Date of harvest
- Amount of crop harvested per acre, per field
- Type of harvest (corn silage, dry shelled corn, baleage, haylage or dry hay, etc.)
- Non-certified crop harvest and yields
- Storage records
- Sales records if sold from field
- Weigh slips
- Equipment clean out/purge logs
- Transportation records
- Records of any post harvest handling or processing (drying, grinding, etc.)
- Inventory of product brought to public or farmer's markets
- CSA distribution records
- Sap collection, syrup production records

**Livestock / Poultry Records:**
- Breeding and birthing records
- Hatching records
- Animal purchase records
- Identification records
- Loss / cull records
- Feed records (including source and feed rations for each animal type)
- Health and medication records
- Pasture plan, outdoor access records, milk pick up & quality reports
- Egg collection records

**Sales Records:**
- Sales receipts
- Shipping records
- Lot numbers
- Transaction certificates
- Farmer's markets inventory taken & daily sales totals
- Records of what is sold as organic and as non-organic

8. **Land Requirements (205.202)**

All fields and farm parcels to be certified (including active crop land, pasture, fallow land, wild crop & sugar bush) must have clear boundaries and be identified with a name, number or letter. For each field to be certified, New Field documentation that includes crop, seed, applied amendment, spray & pest control information for the previous three years must be submitted. If the field has not been owned or managed by the applicant for the last three years, a New Field Affirmation form signed by the previous owner or manager must be submitted. New Field documentation is also needed for greenhouses not located on already certified...
land including containers and bench seedling production areas. We encourage you to add new fields with your update application whenever possible. If fields are added after the annual inspection has taken place, an additional inspection will be necessary. The additional inspection will be billed to the applicant.

Once complete paperwork is submitted for new fields, you will be notified if crops can be removed from the field and stored separately prior to inspection. If crops are removed from the field prior to inspection without the certification office being contacted or approval given to do so, the crops will not be eligible for certification. Operations continuing certification may not market crops from new fields as organic until the inspection and final approval have been granted. Crops from new fields must be segregated from certified crops until the certification process is completed.

Split operations must provide information regarding both certified and non-certified production, including the use of land and management practices, crops grown including those that are genetically engineered, harvest, storage, labeling and sales records.

9. Field Maps (205.202)

Maps are required and should be 8 ½” by 11” in size, printed or in permanent ink & include the following:
- Field ID (Same ID on your application form) and perimeters,
- Acreages,
- Orientation (N, S, E & W),
- Surrounding land use (conventional adjoining fields, organically managed land, neglected, residential areas, woods, roadways, power lines, railroad tracks, etc.)
- Natural features (hedgerows, prevailing wind, fallow areas, woodlands, wetlands, riparian zones, waterways, etc.)
- Buffer zones
- Designation of fencing locations, shade areas and water for livestock operations (205.240).

For farms with multiple fields that are spread out, an "overview map", indicating location of fields in relation to the home farm must also be provided. This does not have to be to scale and can be a simple road map.

10. Land and Buffer Zones (205.202)

Buffer zones that are sufficient to prevent potential contamination must be established between certified organic and conventional land. The size of the buffer zones must be determined by the applicant based on various environmental factors of their specific operation. Factors such as runoff, predominant wind direction, water features, surrounding land use, among others should be considered.

Buffers can include windbreaks and living barriers such as a dense hedgerow. A dense hedge row less than 50' may offer better protection from contamination than a 50' open buffer zone.

The following examples are based on research results and guidance provided as starting points for minimum buffer zones, to ensure that the organic crop is not contaminated. Additional information and testing may be required.

- A minimum 50 ft. buffer zone where a certified field adjoins conventionally managed lands, including both farmland and residential areas. Buffer zones should be under the management control of the certified farmer.
- A minimum 250 ft. buffer zone if an air blast sprayer is used on the adjoining non-certified land.
- A minimum of an 800 ft. buffer zone is recommended if adjoining non-certified land is aerially sprayed.
- For adjoining GMO crops: distance between an organic crop and the same species genetically engineered crop must be sufficient to ensure no cross-pollination/genetic contamination. If cross pollination can occur, testing may be required. If organic corn adjoins GMO corn, there must be a plan to prevent contamination or a minimum of two weeks between when organic and GMO corn tassels and documentation of planting dates, corn seed day-lengths, and tassel dates will be required.
If the buffer is planted to the same crop as is grown in the field, documentation of what is done with the non-certified buffer crop is required. If harvested, non-certified harvest records and equipment cleanout logs need to be maintained. Crops grown in the buffer zone area cannot be marketed as certified organic, or used for feed or bedding for certified livestock or dairy cattle.

11. Genetically Altered Materials, Plants & Crops (205.105)

The use of genetically engineered materials (GMO) (see definitions: excluded methods) is prohibited under the National Organic Regulations. This includes all genetically engineered food crops and other agricultural products including, but not limited to:

- transgenic seeds
- plants and seeds bred to produce BT toxins
- herbicide tolerant plants
- bacteria that prevent frost damage
- Bovine growth hormone (rBGH) or bovine somatotropin (rBST)
- vitamins derived from genetically engineered sources
- enzymes derived from genetically engineered sources
- seed & forage inoculants derived from genetically engineered sources
- food processing materials derived from genetically engineered sources
- cloned animals

12. Soil Fertility & Crop Nutrient Management (205.203)

Producers should strive to leave the soil exposed as little as possible. When not growing crops, green manures, cover crops, and mulches are common practices used to increase soil biological activity, prevent erosion, fix nitrogen, recycle nutrients, increase soil organic matter, increase water penetration, and improve soil structure.

Fields to be certified must be under the management of the applicant. Certification of rented land is permitted, providing the applicant has management control of the field. Certified farmers are expected to build and maintain fertility and organic matter. It is not an acceptable organic practice to exploit existing soil nutrients in a manner that, over time, depletes the fertility of the soil.

Certified farmers must develop a management plan which includes weed and pest control, maintenance or improvement of soil fertility and crop nutrients, crop rotations, timely harvest of crops and cover cropping if applicable. Purchased inputs should be used as a last resort, only after management practices have failed. The certification office looks closely at all inputs used and documentation verifying their compliance will be required.

Micronutrients

Micronutrients (boron, cobalt, copper, iron, manganese, molybdenum, selenium, zinc) require a documented deficiency.

If micronutrients are in use/to be used, producers should be showing documented deficiency either via soil/tissue testing or plan that clearly explains why it’s needed and how it is beneficial to crop/soil in the OSP. Soil tests should be submitted every 2-3 years to show continued need and no build-up in the soil. If product being applied is a blend with a small amount of micronutrients, as long as tests don’t show excessive amounts in soil, this would be acceptable.

Manure

Spreading manure on frozen ground or snow is discouraged as it can contribute to run-off contamination. Short term piling or composting of manure is encouraged as an alternative to spreading on frozen ground providing pile location is suitable. All storage and field applications should be within NYS DEC regulations to avoid environmental pollution.

It is recommended that no more than fifteen tons per acre of raw cow manure and no more than five tons per acre of chicken manure be spread on fields per year. Incorporating manure directly after spreading reduces
volatilization of nitrogen.

If any form of manure or product containing manure (raw, aged, rotted) is to be used on crops for human consumption you must follow Raw Manure guidelines in NOP Regulations Section 205.203(c)(1).

Compost
In order for a compost containing manure to be approved for unrestricted use on organic crops grown for human consumption, documentation must be submitted to verify that the compost has been produced as outlined in the NOP Regulations, 205.203(c)(2). If the compost contains manure it must be applied using the raw manure guidelines unless composted in compliance with the regulations.

Organic matter consisting of only vegetative materials is allowed for unrestricted use as long as not containing any prohibited materials.

Producers must contact the certification office prior to using any new substance or product, including those that are OMRI listed as OMRI frequently adds and drops items.

13. Seeds and Planting Stock Sourcing and Management (205.204)
Certified organic seeds must be used unless not commercially available. Conventional untreated, non-GMO seeds may be used for crop production if the desired organic seeds are not available due to quality, quantity or form after attempting to obtain from at least three viable sources. Documentation showing seeds are untreated and non-GMO are required. Efforts to locate organic seeds must be documented and available for the inspector to review, such as letters, phone logs of discussions with suppliers, or catalogs. Seed potatoes, onion/garlic sets (small bulbs, NOT bare root plants) and sweet potato slips fall under these organic seed requirements.

Commercial availability cannot be a factor in organic sprout production; use of organic seeds is required.

Transplants (annual seedlings) must be certified organic. Use of non-certified transplants, without variance approval from the USDA, is prohibited. You cannot determine your own emergency for use of non-certified transplants including from a non-certified, exempt operation.

Perennial non-organic planting stock may be used if not commercially available as organic. Planting stock must be managed organically for one complete year before it may be represented as organic. Be sure that conventional perennial planting stock is purchased bare root if available.

Microbial inoculants are permitted for use on seeds if non-GMO (not derived from genetically engineered materials) and if all carriers are allowed. Be sure to get inoculants approved prior to use.

GMO seeds are prohibited.

Seeds with clay based pelletizing, which do not contain synthetic materials, or excluded methods, may be used. The compliance status of any seed treatments or coatings must be approved prior to use. Use of conventional, untreated non-approved pelleted seed does not disqualify land, but any crops grown with these cannot be sold as organic and future use of this seed must be discontinued.

14. Crop Rotation (205.205)
Crop rotation is defined as the practice of alternating the annual crops grown on a specific field in a planned pattern or sequence in successive crop years so that crops of the same species or family are not grown repeatedly without interruption on the same field. Perennial cropping systems employ means such as alley cropping, intercropping, and hedgerows to introduce biological diversity in lieu of crop rotation. Ideally an organic crop rotation system would contain crops from different plant groups, that are seeded at different times and that have different nutrient demands. An organic field crop rotation plan ideally includes row crops, legumes / sod crops and small grains. Production of annual vegetable crops should also include crop rotations. Using different crops with varying nutrient requirements assist in breaking weed cycles and in building soil fertility. The same row crop should not be planted two years in a row unless the rotation is clearly broken by a planting that encourages nutrient replenishment such as: cover cropping, under seeding, green manure plow downs, etc. The producer should have pictures available for inspection of cover crop to
be plowed down. The same crop may be grown for two, possibly three consecutive years with a cover crop between plantings, but this should not be part of the permanent crop rotation plan.

15. Materials for Use in Organic Production-Crop Pest, Weed & Disease Management (205.206)

When management practices described in section 205.206 of the NOP Regulations are insufficient to prevent or control pests and diseases, approved biological/botanical substances or a substance listed on section 205.601 may be used. The use of all pest control materials, synthetic or non-synthetic, must be approved prior to use. Certified organic producers are required to report use of all materials.

Producers should contact the certification office prior to using any new substance or product including those that are OMRI listed, as OMRI frequently adds & drops materials.

Agricultural plastic should be recycled if available. Burning or on-farm burying of agricultural plastic is prohibited.

Use of treated wood is prohibited on the organic production site where it comes into contact with organic crops or livestock. If treated lumber is used, there must be a buffer between the treated wood and livestock or crops. There are untreated alternatives available such as untreated white cedar, locust or fiberglass.

Plastic and synthetic mulches may be used for weed control provided they are pulled up at the end of the growing/harvest season. Synthetic mulch may be used on perennial crops that are harvested over more than one season, as long as it is removed prior to breaking down/degrading.


Chlorine materials allowed on the National List (205.601-606) include calcium hypochlorite, chlorine dioxide, hypochlorous acid and sodium hypochlorite. Operators must verify compliance of the chlorine product they intend to use.

**Crop operations**
Residual chlorine levels in the water in direct crop contact (when used pre-harvest) or as water from cleaning irrigation systems applied to soil should not exceed the maximum residual disinfectant limit under the Safe Drinking Water Act (SDWA) – 4 ppm or less.

Chlorine products may be used up to maximum labeled rates for disinfecting and sanitizing equipment or tools. No intervening event is necessary before equipment is used in contact with organic crops.

**Livestock operations**
Residual chlorine levels in the water in direct food or animal contact (for example, drinking water) should not exceed the maximum residual disinfectant limit under the SDWA.

Chlorine products may be used up to maximum labeled rates for sanitizing equipment or tools (including dairy pipelines and tanks). Label instructions should be followed regarding requirements for rinsing or not rinsing prior to the equipment’s next use.

**Wash Water for Post-Harvest Crops/Food/Seeds**
Water used in direct post-harvest crop or food contact (including flume water to transport fruits or vegetables, wash water in produce lines, egg or carcass washing, and seed sanitizing) is permitted to contain chlorine materials at levels approved by the Food and Drug Administration or the Environmental Protection Agency for such purpose. Rinsing with potable water that does not exceed the maximum residual disinfectant limit for the chlorine material under the Safe Drinking Water Act (4 ppm or less) must immediately follow this permitted use. Certified operators should monitor the chlorine level of the final rinse water, the point at which the water last contacts the organic product. The level of chlorine in the final rinse water must be 4 ppm or less.

Water from other than municipal sources must be documented to be potable if used to wash human consumption crops, eggs, or used in processing. Municipal water sources are exempt from test requirement; all other water sources should be tested for e-coli and coliform bacteria. An annual potable water test is required.
Irrigation Water and Contamination Concerns

Whether used for irrigation, stock, or washing fruits and vegetables, water might contain prohibited substances, depending on a particular farm and its upstream neighbors, previous use, or ground and surface water flow. In recent years, the ground and surface waters of New York State have been recognized as containing pollutants, notably nitrates and some of the widely and long used herbicides such as Atrazine. Many of these materials are not tested for in the usual NYS Department of Health surveys, so often property owners aren’t aware of the problems.

We recommend that producers and handlers investigate sources of water for potential problems. These include upstream land use (agricultural and industrial), neighbors with well problems, NYS Health Department information, and Soil and Water Conservation District information. If there is any possibility of contamination we recommend that the water be tested for suspected pollutants. We realize that this is an additional expense to the farmer / handler, but also a responsible action to ensure the quality of products. The certification office can ask that water sources be tested.

Flooding

Flooding raises concerns regarding the status of an organic operation due to the possibility that prohibited substances will be present in flood waters on their farms. Contaminants in flood water are commonly diluted to extremely low levels in flood waters and generally will not affect organic certification. Operators should contact the certification office if there are nearby facilities that produce contaminants which may have been carried by flood water, such as sewage, industrial chemicals and pesticides, or if there is visible evidence of residue from an unknown source. Testing for contaminants and further evaluation may be necessary.

Crops or processed products that have been in contact with flood waters are considered “adulterated” by the US Food and Drug Administration, and must not be sold for human consumption. Crops grown for livestock feed could be contaminated, but should be evaluated on a case by case basis. Some crops may be salvaged depending on the season, stage of growth and level of flood waters. Silt deposited from the flood water may carry harmful organisms that would likely remain in crops harvested from flooded fields. Operators should be mindful of the potential for illness to livestock if crops from flooded fields are used for feed.

There are several state and federal agencies providing disaster assistance. Since the specific agency may vary depending on individual circumstances, the following contact information is a starting point for obtaining information.

FEMA 1(800)621-3362, www.fema.gov
NY Farm Bureau 1(800)342-4143, www.nyfb.org
USDA Farm Service Agency (NY State) 1(315)477-6300, www.fsa.usda.gov

17. Equipment Cleaning and Purging

Equipment used for harvesting both certified and non-certified (including transitional) crops must be thoroughly cleaned prior to the harvest of the certified crop. In the case of combines, choppers and square balers, it is recommended that the equipment be thoroughly cleaned; then 50’ - 75’ of the certified crop be harvested and purged (disposed of or used as non-organic). The clean out of equipment must be documented along with amount and disposal of purged crop.

Planting equipment should be free of residue of seed treatments.

Dual use of spray equipment is strongly discouraged. The producer must be able to clearly prove that residue of a prohibited material does not remain in the sprayer before it is used on certified crops. Prior to use in organic production, a conventional or dual-use sprayer must be cleaned using an approved cleanout method (such as an allowed neutralizer followed by a triple water rinse) ensuring no chemical residue remains. Any removable parts where residue could collect should be identified and cleaned or changed. Clean-out must be documented. Office to approve written standard operating procedure to be kept on file.

Harvest, storage and shipping of all certified products should be done with the least possibility of contamination. If contamination should occur with the producer's knowledge, he/she must notify the certification office immediately in writing and must not market that contaminated product as certified organic. See Section 205.270 thru 205.311 of the NOP Regulations and Sections 26-32 of this manual for producing and/or packaging value added products.

Cooling
Acceptable storage conditions include regular, cooled, or controlled atmosphere. Manual and mechanical control of temperature and humidity is permitted, as is ice, or cold water cooling depending on water source.

Storage
Storage areas for certified organic crops must be a dedicated area that is clearly labeled, especially if conventional crops are also stored at same location. Commingling of organic and non-organic product is prohibited. Individual storage containers must be clearly identified as organic. Off site storage will need to be inspected or a Storage Facility Affidavit completed.

Pest Control in Storage
See Section 205.271, Facility Pest Management

Packaging Materials
See Section 205.272, Commingling and Contact with Prohibited Substances

19. Wild Crop (205.207)

Wild crop harvesting is a separate certification category, or scope, within the NOP Regulations. Unlike the regulations for crop production, “management” of wild crop areas is very limited. Crop management practices that aid production, such as cultivation, irrigation, use of shade cloth, introduction of new plants or seeds that are not from the existing plants would disqualify the area for Wild Crop certification.

Only minimal agricultural practices, such as reseeding from, and pruning of existing plants (only to the extent of removing dead portions) are allowed. Crops harvested from managed fields or areas impacted by active management cannot be considered wild even if naturally occurring. (Examples: black walnuts from a tree in a residential lawn area or milkweed from a pasture could not be considered wild). Harvesting must be sustainable, and production practices must maintain or improve the natural resources of the area. Care must be taken to ensure any rare, threatened or endangered plant or animal species in the wild crop areas are not negatively impacted. Training must be provided to all who will be harvesting wild crops to protect the ecosystem and viability of the habitat.

20. Transition to Organic Production and Certification

(a) General Information

Farms wishing to pursue organic certification are advised to obtain a copy of the National Organic Program Regulations early in their transition process. To qualify for organic certification, fields must be free of prohibited substances (including synthetic herbicides, pesticides, fertilizers and treated seed) during the three years prior to harvest of the agricultural product. During the 3-year transition period, all requirements of the NOP Regulations must be followed. This includes use of appropriate seeds, crop rotation systems, and appropriate soil amendments, pest and weed control practices and materials. Biological or botanical substances or a substance included on the National List of synthetic substances allowed for use in organic crop production, Section 205.601 through 205.606, may be used by operations in transition to certification.

A producer who is transitioning land to organic production may apply for official transition status at any time during the three year transition period. Applying for transition monitoring is optional and will in no way affect the certification decision once land is eligible. The process of transition monitoring is similar to actual certification with complete annual paperwork and on-site inspections.

If a farm decides to apply and is approved for Transition Monitoring, the certification office can issue a letter
to insurance companies, FSA office, or other agencies as requested by the applicant, stating that the farm is officially transitioning their land to organic production through our organization. For each subsequent year, the Organic System Plan must be updated and inspection conducted for verification purposes in order to maintain continual transition status.

(b) Dairy Transition

The certification of organic milk production involves both land and livestock management.

The transition period for a dairy herd is one year. This one-year transition period allows farmers to become familiar with alternative health care practices, organize record keeping systems, and generally become familiar with organic production and certification requirements. All certification requirements must be followed during the 1-year transition period. All animals to transition must remain on farm during the one year transition period, under your management.

Transition is a one-time, whole herd conversion. All animals that you intend to convert to organic dairy production must be on the farm at the beginning of transition. This is a one-time opportunity for a conventional dairy operation to transition their entire herd to organic production. Once transition begins, no more conventional animals may be brought to the farm.

100% organic feed is required for the entire one-year transition period. However, feed harvested from fields in their third year of transition (T3) that are included in the Organic System Plan may be used as part of the 100% organic feed requirement during the transition year. All T3 crops must be fed up or removed from the farm before the end of transition.

Organic dairy farms are required to provide animals with managed pasture with edible forage throughout the grazing season. Use of antibiotics and hormones is prohibited. Animals with docked tails may enter the transition program, but from the start of transition on, tail docking is prohibited.

Please refer to the livestock and crop sections of the guidance manual for more specific information.

The dairy herd transition process is a multi-step process. In order to begin the Transition process, a sufficient amount of land that is certifiable or in its third year of transition (T3) must be available to provide adequate supplies of pasture and forage to meet the 100% organic feed requirement. Even with an organic premium, it is not always economically feasible for farms to purchase large amounts of organic forages and organic grains. To begin the Transition process, we use as a guide, a minimum of .75 acres of total certifiable land for each 1000# animal unit, or 90% of your fields.

All non-certifiable fields should be in transition at the start of the one-year dairy herd transition. If a farm has non-certifiable (transitional) fields, there must be a plan developed to segregate crops harvested from non-certified fields, and a plan showing where these crops will be stored and what they will be used for.

**Please note: The date your application is received in the office is the date your transition officially starts, provided you are in compliance with the Organic Regulations at that time.

To Prepare for Transition Dairy Farms Should:

- Familiarize themselves with NOP organic regulations and requirements. Implement organic management practices for fields, including crop rotation requirements and seed requirements.
- Develop appropriate housing and pasture for dairy animals, including young stock.
- Implement managed pasture during the grazing season and outdoor access in the winter for all animals over six months old.
- Discontinue the use of antibiotics, hormones, and dry cow treatments.
- Search out and implement the use of alternative health care practices.

Organic certification does not necessarily guarantee a market for your milk. Since transition to organic production is costly and time consuming, it is in the best interest of each farm to secure a market before starting the transition process.
22. Livestock Production Recordkeeping Requirements

See section 6

22. Origin of Livestock (205.236)

Poultry intended to produce organic meat or eggs must be managed organically from the second day of life. Purchase records and flock ID records must be kept for all birds. Poultry that is on the farm prior to applying for certification will not qualify to produce organic eggs or meat.

All other livestock intended for organic slaughter (meat) or fiber, must be managed organically from the last third of gestation. The date an application is received is generally considered the start of organic management as long as feed/pasture is all from certifiable land or purchased organic.

Conventional animals that have been transitioned to organic dairy production will not qualify for organic slaughter (meat) or fiber. Animals must be managed 100% organically for a full year, including organic feed and healthcare practices, before qualifying to produce organic milk. Once a farm is certified for organic dairy production, all animals must be managed organically from the last third of gestation.

Female livestock used for breeder stock must be brought to the organic farm/placed under organic management prior to the last third of gestation for young stock to qualify for organic meat or fiber. Milk from non-certified breeder stock can only be used to feed their young stock. If young stock are not receiving milk from their own mother, they must receive 100% certified organic milk. Breeder stock, bulls, boars or other male animals intended for breeding purposes do not have to be certified organic, but should be managed organically while on the farm.

If organic meat animals are intended for organic retail cuts, the slaughterhouse must be certified to process organic meat (including any specialty meats – sausages, smoked items, etc.), organic certificate stating this obtained, and must be USDA inspected.

Livestock Purchases/Sales through Auction Facilities - Auction facilities must be certified organic to sell certified organic livestock. Any animals taken to auction must be sold as non-organic unless the facility is certified organic. Likewise, any animals purchased at auction will be considered non-organic unless the facility is certified and their organic certificate is obtained.

When selling an organic animal through a certified organic auction facility, the following documentation should accompany the animal/be provided to the auction facility:

- Organic certificate listing type of livestock (dairy cows, dairy replacements, beef cows, slaughter, etc.)
- NOFA-NY Animal List, NOFA-NY Livestock Organic Status Affirmation form or equivalent affirmation from seller verifying dairy/slaughter status of individual animals being sold.

*If slaughter status is not verifiable, then dairy animals should be clearly marked by auction facility/producer as not eligible for organic slaughter.*

A certified producer may hold an auction on their farm for the sale of their own organic livestock. An on-farm auction may not be used to sell livestock from any other certified operation. If a producer wishes to hold an on-farm auction to sell livestock from multiple farms, the producer must certify their operation to handle livestock auctions. This producer will be responsible for all paperwork, fees and documentation associated with the auction facility.

23. Livestock Feed (205.237)

Agricultural products fed to organic livestock, including pasture, must be certified organic.

The following are prohibited:

- Use of Non-Organic milk replacer
- Drugs, including hormones, to promote growth
- Feed formulas containing urea, manure or plastic pellets
- Mammalian or poultry slaughter by-products

All ruminants over six months of age must receive a minimum of 30% dry matter intake from pasture during the grazing season, which must be at least 120 days per year. (Most areas of New York State can graze more than 120 days per year.)

24. Livestock Health Care Practice Standard (205.238)

Castration, dehorning and removal of extra teats are permitted but must be performed at a young age, using the most humane methods available. Producers should avoid painful, disruptive procedures. Tail docking is prohibited for calves, cows and pigs. Tail docking to less than 3” and mulesing is prohibited for sheep. Minimal beak tipping and wing clipping in poultry is allowed, but the need must be documented. Debeaking is prohibited.

Producers should implement preventative practices, often accomplished through nutrition and approved supplements. Organic farmers must be “proactive” rather than “reactive”.

Historically, somatic cell count reports and bacteria counts have been used as a measure of animal health. Over the long term, organic dairy farmers with good herd health plans, good sanitation and ventilation and pasture nutrition should meet somatic cell count level and bacteria count levels as established for payment of the milk quality premium. Most organic milk companies require that annual averages are kept below 400,000 SCC and 50,000 SPC. Organic dairy producers are encouraged to discuss somatic cell count and bacteria thresholds with their prospective milk company. The above counts are recommended for dairy cattle; dairy sheep and dairy goats may have a higher count. Good sanitation practices in the barn, in the milking parlor and in the milk house, will help limit problems.

Antibiotics, hormones and animal by-products are strictly prohibited. An exception is Oxytocin, which is only allowed for post calving emergencies. It is not allowed for milk let down. Some milk companies prohibit its use.

Mineral formulations and salt must not contain prohibited substances. Common prohibited substances include mineral oil which is often used as a dust suppressant, artificial colors, artificial flavors, and yellow prussiate of soda, used as a flowing agent in salt.

Agricultural carriers in mineral formulations must be certified organic.

Synthetic amino acids are prohibited except DL-Methionine which is allowed only for poultry at the following rates: No more than 2# per ton for laying, 2.5# per ton for broiler chickens, or 3# per ton for turkeys and all other poultry types averaged per ton of feed over the life of the flock.

Vaccines are allowed. Producers must use non-GMO vaccines if they are available.

Homeopathy and herbs are allowed as long as there are no prohibited substances in the product.

Parasiticides are prohibited for slaughter stock and allowed in emergency treatment for dairy and breeder stock when preventative management does not prevent infestation. In breeder stock, treatment cannot occur during the last third of gestation or while nursing. Fenbendazole and moxidectin are the only allowed emergency treatments on the National List. There is a 2 day milk withhold for lactating cattle and 36 day milk withhold for lactating goats, sheep and other dairy species. Allowed for fiber bearing animals when used a minimum of 36 days prior to harvesting of fleece or wool to be sold, labeled or represented as organic. Producers must contact the certification office to ensure proper preventative measures have been taken and confirm animal ID’s prior to use. (If being used during non-business hours, notify the office as soon as possible after administering.)

Hydrated lime is allowed as an external pest control on livestock and for white wash of facilities. It is not allowed for use in barns to sanitize stalls or for deodorizing animal waste, to cauterize physical alterations or for soil application.

Iodine based pre-milking dips, udder wash or wipes, and post-dips may be used if ingredients are in compliance with section 205.603 of the National List. Teat dips must not contain prohibited substances.

Chlorhexidine-based teat dips are allowed only after other allowed dips have been documented to be
ineffective. The documentation must be provided to the certification office before approval to use chlorhexidine based dips will be granted.

Equipment cleaning and sanitizing materials may be used provided the active ingredients are allowed on section 205.603 of the National List.

Treatment of a sick animal must not be withheld to preserve organic status. If an animal will die without treatment with a prohibited substance, they must be appropriately treated. If a dairy animal, she must be removed from the farm. Documentation of the date of treatment, what they were treated for, what they were treated with, and the date they left the herd, if applicable, is needed.

Always check with the certification office before using any new material to be sure they have been reviewed and are allowed. All materials must be included on your materials list, which is part of your Organic System Plan.

25. Livestock Living Conditions (205.239)

All producers must practice good husbandry techniques and provide their livestock with adequate housing and feeding facilities. Animals must not be overcrowded, and must have the opportunity to exhibit their natural behaviors. Ruminants must have access to managed pasture during the entire grazing season. All animals must have outdoor access all year as applicable unless a valid exemption per 205.239 (b) and (c).

Any temporary confinement must be described in your Organic System Plan.

Good sanitation practices and adequate ventilation can prevent many problems. Many producers have used fly parasites for control of flies around barn areas with good results. Synthetic pesticide use in livestock facilities is prohibited.

The use of treated lumber in the construction of animal feeders, bunk silos, or any area where feed comes into contact with the wood, is prohibited. The use of treated fence posts is prohibited. Alternatives such as white cedar, locust, fiberglass and plastic are allowed. Animals may not have direct contact with treated wood. If a farm has installed treated fence posts in the past three years, a buffer will need to be established to prevent contact with organic crops or livestock.

All farms using agricultural plastic bale wrap, silage bags, etc., must develop a disposal plan. Agricultural plastics should be recycled if available. Burning or on-farm burying of agricultural plastic is prohibited.

Agricultural products used as bedding (hay, straw, corn stalks, etc.), must be organic. Non-agricultural products used as bedding (sawdust, wood chips, etc.) must be verified as untreated.

Swine
Swine must be provided with meaningful outdoor access as applicable. Pigs may not be totally confined in buildings and should be group housed, unless times of farrowing or suckling. Outdoor access must allow pigs the opportunity to exhibit their natural behavior, including rooting, wallowing, access to fresh air and direct sunlight, weather permitting, at the earliest age possible.

Poultry
Poultry must be provided with meaningful outdoor access as applicable. Birds may not be totally confined in buildings. Outdoor access must allow birds the opportunity to exhibit their natural behavior, including pecking on the ground, have access to fresh air and direct sunlight, weather permitting, at the earliest age suitable for the type of bird.

The poultry house should provide at least 1.5 square feet of floor space for chickens, and/or 3 square feet of floor space per turkey, for use during time of inclement weather. The use of cages is prohibited inside poultry houses. Outdoor access should provide at least the same square footage per bird as inside space.

Ruminants
Young stock less than 6 months old must be provided with adequate space such as box stalls, tie stalls, loose housing or hutches. Due to potential feed contamination young stock must not be tied in the manger area. Farmers are encouraged to begin pasturing of young animals as soon as possible.
All animals over six months of age must be provided with pasture throughout the grazing season. Animals should not be confined days or nights except for milking or exceptions listed in Section 205.239 (b) and (c). Rotated pastures and paddocks should be used, whenever possible, for animal health and welfare reasons. Pastures should not be continuously grazed without rest. .75 acres of pasture per 1000 lb. animal unit is recommended.

All animals over six months of age must have outdoor access during the non-grazing season. Total confinement is prohibited. A drop in production or slower growth is not valid reasons to deny outdoor access. The only exceptions are listed in 205.239 (b) and (c).

Operations raising organic ruminant slaughter stock do not have to meet the minimum 30% dry matter intake from pasture during the finishing period (which must not exceed 120 days), but animals must have access to pasture during this period. Total confinement during the finishing period is prohibited.

26. Pasture Practice Standard (205.240)

Producers with ruminant livestock must have a pasture plan as part of their OSP that shows the following:

- Pasture Management. Pasture must be managed as a crop to maximize pasture quality and intake. The plan must include practices used to manage pastures for continued production during the grazing season. (Examples: harvesting excess forage in the spring, mowing/clipping, frost seeding, dragging paddocks, etc.)
- Ration that provides a minimum of 30% dry matter intake from pasture during the grazing season, which must be at least 120 days per year. We will provide the formula to calculate dry matter intake.
- Average date the grazing season starts and ends. (Average date animals are turned out in the spring and taken off pasture in the fall.)
- Fields designated to pasture, including ID# or name and acreage.
- Grazing system used (intensive rotational, rotational, occasional rotation).
- Fencing system used.
- Water system used. (Is fresh water available in each pasture/paddock? If no, how will animals have access to water?)
- Shade available to animals as needed. (Describe plan to provide shade as necessary.)
- Soil fertility and seeding system.
- Erosion control and protection of natural wetlands and riparian area.
- Pasture records must be auditable.

Changes to the Pasture Plan must be approved by the certifier prior to implementation.

27. Production Types without Specific NOP Regulations

At this time, NOP regulations do not specifically define greenhouse, mushroom, maple syrup or sprout production requirements. Until the USDA publishes regulations for such production methods, producers may produce and label their products as organic based on current regulations. To qualify for certification, the producer or handler must comply with all applicable NOP regulations for production, handling and labeling, including the requirements concerning the use of natural and synthetic substances (the National List). To label a product as “100 percent organic”, “organic” or “made with organic (specified ingredients)”, the producer or handler must be certified by an accredited certifying agent.

GREENHOUSE PRODUCTION

A greenhouse is defined as any permanent, enclosed plant environment, with or without heat sources, including cold frames, porches, basement, etc.

A container or bench system grows plants in pots, flats or bags and growth medium is renewed. This system requires land be free of prohibited substances for last three years. New field documentation must be submitted for any container system built and maintained on land outside of already certified fields.

An in-ground system grows plants in grade or raised beds. This system requires land be free of prohibited substances.
substances for last three years. New field documentation must be submitted for any in-ground production outside of already certified fields.

Potting mixes must not contain prohibited materials. Manure or mixes containing manure that has not been composted according the NOP regulations, must be used following raw manure guidelines. Depending on the crop, 90 or 120 days are required between the date the transplant is placed in the certified field and the date of harvest, not the date the seed is planted in the mix or while growing in containers in the greenhouse. Transplants grown in a mix containing uncomposted manure must be grown out on-farm and cannot be sold as organic transplants.

Plants and soil must not be in direct contact with treated wood. In the construction of new greenhouses, producers need to avoid use of treated lumber or other prohibited materials. If treated wood is pre-existing or cannot be avoided, wood must be covered or a buffer established to prevent organic crops from touching the wood including root system as applicable.

To prevent commingling and contamination, organic and non-organic crops can be grown in the same structure only if the following conditions are met:

- An impermeable wall should separate organic and non-organic production if prohibited sprays are applied to the non-organic crop.
- The ventilation system must ensure that prohibited materials do not drift, or are otherwise conveyed to the organic production area.
- Separate watering systems must be established if prohibited fertilizers and/or pesticides are injected within the watering system.
- No contamination must occur through cross-pollination with genetically modified crops.
- Adequate facilities must separate organic and non-organic crops and production materials in storage, production or holding areas. Organic and non-organic crops and production areas must be clearly and conspicuously labeled.

NOFA-NY, LLC does not certify hydroponic operations at this time.

MUSHROOM PRODUCTION

Mushroom production will be consistent with the crop and soil management standards.

In split operations (producing both certified and non-certified mushrooms), production areas must be environmentally isolated to prevent cross contamination. Ventilation/production systems shall ensure that prohibited materials do not drift from non-certified area to certified areas. Individual rooms or areas used for mushroom production cannot have been treated with any material listed as prohibited in the National Organic Standards “National List” (sections 205.601 and 205.602) prior to inoculation of the growing medium and through the entire growing period.

Treated lumber must not come into contact with organic production including logs, substrate or mushrooms. Spawn substrate must be sourced organic unless not commercially available. According to NOP policy, purchased ready-to-use mushroom spawn must be certified organic. This includes pre-inoculated mushroom logs or grow blocks.

Conventional untreated, non-GMO spawn may be used for mushroom production, only if the desired spawn is not available due to quality, quantity or form after attempting to obtain from at least three viable sources. Search for organic spawn should be documented and available for review at inspections. If non-organic spawn is used, documentation verifying the production practices and non-GMO statement are needed.

Agricultural products used as substrate such as straw, grain, hulls, etc. must be untreated, however, it is strongly encouraged to be sourced organically and non-GMO. Non-agricultural products such as dowels, sawdust, etc. must be from an untreated source and must not contain prohibited materials. If non-organic substrate is sourced, documentation verifying production practices and untreated status is required. Wax used to seal holes must be compliant with the National List.
Mushroom supplements/fertilizers must be documented as part of the Organic System Plan and reviewed for compliance to the National List prior to use. If not previously reviewed, source and ingredient information may be needed.

The use of manure must follow the manure guidelines (120 days from application of manure to mushroom harvest) and compost containing manure must follow the compost guidelines (205.203(c)). Additional information on feedstocks and compost practices will be needed to approve composts for unrestricted use. Trees logged for use as mushroom logs must be harvested in a manner consistent with sustainable woodlot management. The harvest area must be free from treatment with prohibited substances for the three years prior to harvest. Producers who purchase logs must obtain an affirmation statement from the seller stating that no prohibited substances have been applied to the log harvesting area for at least three years. The laying yard for inoculated mushroom logs must be certified as a field. Outside growing areas should be protected from drift and are subject to the same buffer requirements as all certified fields.

**SPROUT PRODUCTION**

Organic seeds must be used in organic sprout production, regardless of commercial availability. Any substances used throughout the process must be on the National List as allowed for use in organic production. Producers need to take care to use compliant seed conditioning and sanitizing materials. Use of chlorine materials is allowed using the Chlorine guidelines in Section 16 of this manual.

**HEMP PRODUCTION**

As USDA establishes further guidance on federally regulated hemp production, the below guidance is subject to change at any time.

**Certified Producer Documents of Proof:**

- **Application for Authorization** – listing your operation as an authorized location including GPS coordinates of all fields and facilities to be certified for hemp production/processing.
- **Hemp Authorization/License** as a grower/processor, as applicable, issued by the State approved for the agricultural pilot program, i.e. New York State.
- **Hemp Production Affirmation** – verifying you are aware of and following the requirements for hemp production in your state and per the 2018 Farm Bill.

Cuttings/clones of hemp planting stock used in organic crop production systems must be certified organic unless not commercially available. When not commercially available in the needed quantity, quality or form based on at least three attempts to search for organic version, non-organic stock will be allowed if accompanied with untreated and non-GMO documentation.

- Cuttings/clones must have been produced without rooting hormones and other substances not listed on the National List of Allowed and Prohibited substances NOP 7 CFR 205.601 and 205.602 (National List).
- Hemp transplants must be certified organic.

Feminized seed: Naturally induced pollination (without the use of chemicals) is allowed to produce organic crop. Chemically induced pollination using materials not approved per the National List i.e. Silver Nitrate and Sodium Thiosulfate cannot produce organic crops and would be considered parallel production. Seeds from the treated mother plants would not be considered organic, however may be considered untreated/non-GMO seed when organic seed is not commercially available in the needed quantity, quality or form based on at least three attempts to search for organic version. Offspring plants may produce organic crops/seeds. A plan to ensure no commingling of organic and nonorganic products would be needed as well as verification that prohibited inputs do not come into contact with offspring plants/organic crops.

When raw manure is incorporated into fields where hemp crops for human consumption are grown, those crops would need to be harvested no less than 90 days from date of incorporation.

**Common Hemp Processing Practices in Regards to Organic Certification:**

CBD oil production sometimes includes the use of solvents. For certified organic processed products, solvents
must be certified organic or on the National List. Agricultural ingredients must be certified organic.

- Ethanol must be certified organic when used in products to be marketed in the “Organic” labeling category.
- Nonsynthetic/non-GMO Ethanol may be used in “Made with Organic” hemp labeling category products.
- Carbon Dioxide is an allowed synthetic.

**Labeling & Marketing**

All labels to be used on organic products must be approved by the certification office and developed in accordance with NOP 205.303 - 205.310. CBD/hemp products making health claims that market the product as “intending to prevent, treat, diagnose or cure a disease” are strongly discouraged.

Hemp being marketed under a business name not directly linked to your organic certification may require additional documentation verifying the certified operation and final handler. Operations using a co-packer will need to submit an organic certificate of the co-packing operation. The co-packer organic certificate must list the type of processing you are seeking and the co-packing operation should have a license to process hemp per their state regulations. Entities that wish to private label your organic hemp products would need to complete a Private Label Use Agreement Form.

**MAPLE SYRUP PRODUCTION**

NOFA-NY Certified Organic LLC’s guidelines for organic maple production are in accordance with the National Organic Program (NOP) standards. Weed and pest control, fertilization, cleaners, sanitizers and facility and forest management must all be in compliance. Producers should also ensure that they are in compliance with existing Federal, state and local food handling, sanitation and licensing requirements.

Only sap collected from a certified sugarbush area (stand) may be used in production of certified organic maple syrup or other maple products. Producers must complete a field history for each stand to be certified and tapped which includes management activities and materials/products applied to trees or land for the past three years. If the stand is located on rented land, a written rental or tapping agreement from the land owner, indicating year round compliance to NOP standards, must be included with the application. Maps are required and must include location of all stands, sugarhouse and collection tanks, main tap lines, adjoining land use, acreage, major roads, physical features and compass.

**Forest Management**

Producers are expected to observe good forest management practices to protect the sugarbush ecosystem. Be sure to include a description of all practices in your Organic System Plan (OSP) which may include encouraging species diversity, stand regeneration, thinning of excess or diseased trees, erosion control of forest soil and roads, use of non-synthetic fertility and pest controls, etc. When management practices are insufficient, synthetic materials allowed on the National Organic Standards “National List” (sections 205.601 and 205.602) may be used with prior approval. Be sure to get any materials approved by the certification office prior to use.

**Tapping**

Tapping should be based on the health and vigor of the tree determined by examination of the canopy in both the winter and summer. Producers must refrain from over-tapping of trees or the tapping of diseased trees or trees in decline.

Tapping guidelines based on tree diameter at breast height (54 inches from the ground), are as follows:

<table>
<thead>
<tr>
<th>Health Spout (5/16”)</th>
<th>Standard Spout (7/16”)</th>
<th>Number of Spouts</th>
</tr>
</thead>
<tbody>
<tr>
<td>9” – 14” diameter</td>
<td>10” – 20” diameter</td>
<td>1</td>
</tr>
<tr>
<td>15” – 21” diameter</td>
<td>21” – 25” diameter</td>
<td>2</td>
</tr>
<tr>
<td>22” diameter and over</td>
<td>26” diameter and over</td>
<td>3</td>
</tr>
</tbody>
</table>

Tapping trees in any manner other than described above must have approval from the certification office. Taps must be removed from the trees within 60 days of the end of sap flow. Single use taps, including biodegradable taps, must be removed from the forest and disposed of properly.
Wire to hang the mainline must be kept from damaging the trees it is attached to. Use of nails or bolts must be kept to a minimum.

Vacuum pumps are permitted, with monitoring of the pressure levels at the tap.
The use of paraformaldehyde and other tap hole pellets in any tapped trees is prohibited.
Trees that are tapped must not be marked with prohibited substances including synthetic paint (latex, oil, etc.).

Inspection
Inspection of sugarbush stands and processing facilities will be conducted annually during the tapping and production season for maple syrup (typically February-April). If also certifying crops or livestock which will require annual inspection during the growing season, the cost of the additional inspection will be billed to the producer.

Equipment, Storage and Lead Testing
Stainless steel, food grade plastic containers, or lead free metal buckets should be used for storage and collection of sap and syrup. Equipment should be in good condition with no flaking of epoxy coatings on tanks, or extreme degradation of metal buckets. The use of containers that previously contained prohibited materials (such as oil or other petroleum products) is prohibited. If metal buckets are to be used, they should be in good condition without excessive rust and corrosion. Producers should consider phasing out the use of galvanized buckets, as buckets manufactured previous to 1994 can contain lead in their soldering. If intending to use galvanized buckets where the manufacture date is unknown, or before 1994, producers are required to submit a yearly test of their syrup indicating lead levels are below the threshold of 250 ppb. In addition, periodic lead testing is recommended for all producers.

If gas or diesel powered motors are operating in a closed environment with a sap collection tank or where boiling takes place, they must be vented to the outside.

Equipment may be cleaned with water flush or other cleaning materials provided that a thorough hot water rinse or other intervening event is performed to remove all residues of prohibited substances. Approved chlorine materials may be used up to the maximum labeled rate for disinfecting and sanitizing lines, pans, tanks and other sap or syrup contact surfaces. Rinsing is not required unless mandated by the label. A Reverse Osmosis (RO) machine may be used. If synthetic materials used for storage of RO machine/membrane are not on the National List, the machine must be cleaned and rinsed thoroughly before organic maple syrup production begins. A standard operating procedure for the use of this machine and rinsing protocol must be described in the OSP.

Processing
Non-synthetic defoaming agents, including certified organic dairy products and certified organic oils must be used. Synthetic defoaming agents are prohibited unless included on the National List. Caution: Dairy products and some oils such as soybean and peanut oil are known allergens. If a producer chooses to use these as defoamers, it is recommended you provide this information on your label.

Settling tanks, traditional cone or flat filters (paper, felt, Orlon or nylon, sand (note sand must be documented as clean with no additives)), and pumping through food grade diatomaceous earth are acceptable filtering methods. Syrup filtered with diatomaceous earth can be labeled “organic”; however it cannot be labeled 100% organic. Other synthetic filtering aids are prohibited unless included on the National List.

Re-packaging certified organic syrup with the intent to label as certified organic by NOFA-NY Certified Organic, LLC must be done by a certified organic operation.

A schematic diagram of the sugarhouse indicating processing, storage areas and dimensions must be submitted.

Labeling and Recordkeeping
All labels must follow the NOP requirements and be submitted for approval prior to use.
Retail products must have labels that contain a certification statement (Certified organic by NOFA-NY, LLC or similar phrase) directly below the distributor info and are traceable (via lot numbers, etc.).
Bulk products must have a lot number; identification of organic status and certifier is recommended.
Records must be kept in sufficient detail to show compliance to the NOP requirements. Audit trail records must be able to track finished product from sale back to sap collection/boiling. Records to be kept include sap collection, production logs, sales invoices, receipts for inputs (defoamers, diatomaceous earth, etc.), lot numbering system, etc.

28. Handling OSP (205.201)

It is important that the information contained in the OSP provides sufficient detail to enable certification reviewers who are not familiar with your operation to have a clear understanding of your procedures.

Method: A detailed description of organic management throughout all stages of production, from initial ordering of ingredients to shipment of finished product is necessary. For split operations, procedures to prevent commingling and contamination are required. Each operation is unique and must develop an individual system. Some operations use color coded equipment and / or paperwork, designated storage areas, specific production schedules for this purpose.

Audit Trail Documentation: Up-to-date, comprehensive recordkeeping is necessary to verify that procedures are consistently followed, and finished products can be traced back to ingredient origin.

Facility Diagram: A schematic of the facility identifying storage areas, processing areas with equipment layout, shipping areas, location of cleaning materials. Flow of product may be included on the facility diagram or in a separate Flow Chart. Organic Control Points (OCP) should be identified. If a split operation, identification of dual use and/or designated equipment and storage areas is helpful.

Affirmation: A signed document stating that the information supplied is accurate, true and complete.

29. Handler Recordkeeping (205.103)

Audit trail documentation includes: schematic facility drawing, equipment list, product flow chart with organic control points, detailed description of the production process, lot numbering system, product formulations, water test, organic certificates, documentation of no prohibited methods for nonorganic ingredients and processing aids, finished product labels, ingredient orders, receipts, receiving logs, bill of lading (incoming/outgoing), batch/production logs, inventory (raw, finished product) records, cleaning/sanitizing materials, equipment cleanout, residue testing, pest control materials, pest control applications, sales invoices, shipping records, clean truck affidavits (incoming/outgoing).

Certified operations may not accept organic products without verifying source and certification of products. This is especially critical when receiving products from uncertified handlers and/or imports.

Uncertified Handlers

NOFA-NY certified operations may only source from uncertified handlers who provide full supplier traceability back to the last certified operation for each shipment. The following may be needed for complete traceability:

- For each delivery, uncertified handlers must provide a complete, current organic certificate for the last certified operation.
- Documents must be obtained linking directly back to the last certified operation, proving purchase/delivery/transfer to the uncertified handler.
  - Purchase invoices, BOL, and other audit trail records must designate products as organic and include a description of the product and amount transferred.
  - The last certified operation must be listed on invoices and/or lot numbers applied by the last certified operation must match lot numbers on uncertified handler audit trail records.
  - The actual items delivered should be checked to verify that the lot #, certifier, etc. on the package, barrel, tote, etc., are the same as those listed on the paperwork.
- All certified (secondary) suppliers must be approved by NOFA-NY as part of the certified operation’s Organic System Plan (OSP). If an uncertified supplier has a new certified source, that must be added to the OSP.

If a certified operation is sourcing organic produce or loose product from a supplier/distributor who is not
30. Handling Allowed and Prohibited Substances (205.105)

Sections 205.601 through 205.606 of the NOP Regulations are also referred to as the National List. The National List should be the first reference when determining compliance of nonorganic ingredients and other materials to be used on organic production.

Documentation is required for nonorganic ingredients, processing aids, boiler chemicals, cleaning and sanitizing materials and pest control materials, in order to verify if they are allowed for use in organic production. Examples of documentation that can be used, either individually or in combination, include non-GMO statements, product labels, SDS, and technical data sheets that list all components contained in a particular product. A form is also available from the certification office to be used for nonorganic ingredients, to ensure that sufficient information is provided.

31. Facility Pest Management (205.270)

The National Organic Program (NOP) outlines a specific order of pest control methods in areas where organic products are processed, handled, or stored.

- First use preventative measures such as good sanitation, then mechanical measures, such as mechanical, sticky, or pheromone traps.
- If preventative and mechanical measures do not adequately control pests, you may use NOP allowed materials from the National List, including carbon dioxide, nitrogen, Vitamin D3 bait, boric acid, diatomaceous earth, or soap products.
- If preventative, mechanical and National List materials are not effective; you may use synthetic pesticides provided there is no contact with organic product and food contact surfaces.

All pest control plans and materials must be approved by the certification office before implementation. Pest control records should be onsite and available for inspection. There are no NOP restrictions on the use of synthetic materials outside your facility or in non-organic production areas.

32. Commingling and Contact with Prohibited Substance Prevention (205.272)

Procedures must demonstrate that nonorganic and/or other prohibited products will not come into contact with organic product during production, in storage, and via packaging. For split operations, clear segregation with detailed recordkeeping is necessary to avoid accidental use of incorrect product.

For cleaning and sanitizing materials containing prohibited ingredients, procedures must clearly show that no residue from such materials remains on any food contact surfaces which could come in contact with organic product.

For pest control materials containing prohibited ingredients, the pest control plan must describe specific procedures to be followed to protect the integrity of organic product before and after pest control applications. For fogging or application of other materials requiring a withhold time, we recommend that the time specified by the manufacturer be doubled. All applications of pest control materials must be documented.

33. Product Composition (205.301)

The labeling category of organic products is based on the percentage of organic ingredients. Products must meet specific ingredient requirements to be sold, labeled, or represented as either “100% organic”, “organic” or “made with organic [specified ingredients or food group(s)]”.

“100% organic” requires every ingredient to be in the “100% organic” labeling category and every processing aid to be in the “100% organic” or “organic” category.

“Organic” products must contain no less than 95% organic ingredients. All remaining ingredients and
processing aids must be compliant with the National List. Please note that organic ingredients must be used if commercially available. Nonorganic agricultural ingredients must be listed in Section 205.606 of the National List, and documentation is required to verify the ingredient is not commercially available in organic form.

“Made with organic” must contain at least 70% organic ingredients. The remaining ingredients and processing aids must not be produced using prohibited methods (Section 205.301(f) (1) (2)). Requirements for the remaining nonorganic ingredients are less restrictive:

- Processing aids which are not on the National List may be used.
- Sulfites, nitrates and nitrites may be used.
- Nonorganic ingredients may be used when organic forms of the ingredient are available.
- Organic and nonorganic forms of the same ingredient may be used.

Products with less than 70% organic ingredients may identify the organic ingredients as such, provided those ingredients were produced in accordance with Organic Production and Handling Requirements in Subpart C of the NOP Regulations. The nonorganic ingredients may be produced with no restrictions. Products in this category cannot be represented as certified organic.

Livestock Feed may be labeled as “100% organic or “organic”. “100% organic” must contain all 100% organic ingredients. “Organic” must contain only organic agricultural ingredients. Nonagricultural ingredients that are consistent with livestock feed requirements described in Section 205.237 may be added.

34. Calculating the Percentage of Organically Produced Ingredients (205.302)

The percentage of organic ingredients is determined by weight. Water and salt are not certifiable and are excluded when calculating the percentage of organic ingredients.

The weight of all ingredients in a formulation including water and salt must total 100%. Water and salt are then deducted from this total, leaving the net weight of the finished product. The weight of the organic ingredients divided by the net weight of the finished product determines the labeling category.

For ingredients in the “made with organic” category, either the exact percentage of organic ingredients must be obtained, or the ingredient must be assumed to be 70% organic. This must be included in the calculations, and could affect the category of the finished product.

The percentage of all organic ingredients must be rounded down, rather than up. For example a formulation indicating 94.9% organic ingredients would round down to 94%, and be eligible for the “made with organic” labeling category rather than “organic”.

35. Labeling (205.303 through 205.310)

Requirements for retail packages are not the same as those for non-retail containers and products in other than packaged form. It is important to pay close attention to the specific requirements described in the applicable sections of the regulations for the each labeling category and type of packaging to be used. Requirements vary, including how organic ingredients must be identified, type size, use of seals and logos, etc.

All packaging / labels must be submitted to the certification office for review and approval prior to printing. Corrections to labels found to be non-compliant can be extremely costly.

Use of the USDA seal is allowed only for products in the “100% organic” and “Organic” labeling categories. The USDA seal is not allowed on products in the “made with organic” category, or products containing less than 70% organic ingredients. The USDA seal must be displayed in the colors specified in the NOP Regulations. Samples can also be found on the National Organic Program website.

The NOFA-NY Certified Organic, LLC logo may be displayed for “100% organic”, “organic” and “made with organic” products. This logo must also be in specific colors. Samples are available from the certification office.

If both the USDA seal and the NOFA-NY Certified Organic, LLC logos are to be used, the NOFA-NY Certified Organic, LLC logo must not be more prominently displayed than the USDA seal.
A “certifier statement” is required on all retail packaging labeled as “100% organic”, “organic”, and “made with organic” categories, as well as “100% organic” and “organic” livestock feed. The statement must be located directly below the distributor information, with no other information in-between. This statement must read: “Certified Organic by NOFA-NY LLC” or similar phrase. If the producer wishes to use an agency sold sticker that includes this statement, it must be located directly below their distributor or farm information.

For nonretail containers and products sold bulk, lot numbers are required.

36. Imports/Exports

When Importing or exporting organic products, the Organic System Plan should:

- Disclose whether the operation exports/imports products.
- Describe records the operation maintains for products imported/exported.
- Identify ingredients imported, including the source of those ingredients.
- Include the operation’s procedures for verifying source, certification, and compliance of imported ingredients.
- Describe procedures for verifying that imports were not fumigated or irradiated when crossing borders.

NOFA-NY requires acceptable documentation tracing each shipment of imported product back to the last certified handler prior to approval for sale as organic. Records must assure compliance with USDA NOP regulations and demonstrate clear chain of custody of the product.

NOFA-NY requires chain of custody records satisfy a complete audit trail back to certified handler of the product. Along with the organic supplier certificate, required records could include purchase records, shipping documents, transaction certificates, receiving records, bills of lading, labels, organic certificate of the source farm(s), etc. as applicable.

- Records should list lot numbers, amount, name of last certified operation, etc. so product can be traced through the supply chain.
- In addition records confirming organic integrity was maintained with respect to transport, fumigation and/or irradiation should be maintained such as phytosanitary certificates.
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NOFA-NY Certified Organic LLC
Policy Manual

It is important that farmers, processors and consumers understand the process we use to certify farms and processing operations. Many policies described in this manual are a direct requirement of the National Organic Program Regulations; others are created within the structure requirements of the regulations. Applicable Sections of the Regulations are identified in parentheses throughout this manual.

1. Organizational Structure, Authority, General Accreditation Policies, Administration

1.1. Legal Status

NOFA-NY Certified Organic is a Limited Liability Company (LLC) engaged in third party verification activities for agricultural producers and handlers of organic products.

NOFA-NY Certified Organic LLC is a wholly owned subsidiary of the Northeast Organic Farming Association of New York, Inc. (NOFA-NY). NOFA-NY is a non-profit, tax-exempt educational organization. NOFA-NY Certified Organic, LLC provides third party certification services, and is operated in the same non-profit manner as NOFA-NY, Inc. under the 501c (3) requirements.

1.2. Organizational Chart
1.3. Accreditation Status

NOFA-NY Certified Organic LLC received accreditation from the USDA National Organic Program (NOP) as of April 29, 2002. To maintain our accreditation, we submit annual update information to the NOP, and undergo on-site audits by NOP representatives to verify our program’s continued compliance with accreditation requirements.

NOFA-NY Certified Organic LLC refrains 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.

1.4. Authority of the Management Committee

A Management Committee, appointed by the Board of the Northeast Organic Farming Association of NY, Inc., has all powers to control and manage NOFA-NY Certified Organic LLC, as stated in the Operating Agreement between the Northeast Organic Farming Association of NY, Inc. and NOFA-NY Certified Organic LLC. The Management Committee sets policies for NOFA-NY Certified Organic LLC based upon NOP Regulations and recommendations from certification staff, contract reviewers and inspectors.

1.5. General Accreditation Policies

1.5.1. Confidentiality Policy

Members of the Management Committee, staff, inspectors, contract reviewers, and any other personnel shall maintain strict confidentiality with respect to the clients certified by NOFA-NY Certified Organic LLC. No business-related information pertaining to clients, obtained during the certification process, can be disclosed to third parties (with the exception of the Secretary of the USDA or the applicable State officials or their authorized representatives) unless permitted in writing by the certified producer or handler. An annual declaration adhering to this policy will be required of all Management Committee members, staff, inspectors, and contract reviewers.

1.5.2. Conflict of Interest Policy (§205.501(a) (11) (i-vi))

Conflicts of Interest shall be prevented by:

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;

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;

Not permitting any employee, inspector, contractor, or other personnel to accept payment, gifts, or favors of any kind, other than prescribed fees, from any operation inspected;

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

Requiring Management Committee members and 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;

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

Reconsider a certified operation’s application for certification and, if necessary, perform a new onsite 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 on-site inspection costs, shall be borne by the certifying agent;

Referring a certified operation to a different accredited certifying agent for re-certification and reimburse the operation for the cost of the re-certification 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.

1.5.3. Non-discrimination Policy

Any person (farm or handler) marketing organic product may apply for organic certification. NOFA-NY Certified Organic LLC shall not 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, marital or family status.

1.5.4. Reciprocity with other certifying agents/agencies

Certification decisions made by other USDA accredited certification programs shall be accepted as required by the National Organic Program Regulations.

A producer may substitute a plan prepared to meet the requirements of another Federal, state, or local government regulatory program, or another organic certification program, for the organic system plan provided that the submitted plan meets all requirements of the NOP regulations.

1.5.5. Acceptance of Applications

NOFA-NY Certified Organic LLC will accept all production or handling applications that fall within its areas 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.

1.5.6. Submission of Information and Fees to USDA/NOP

The following information will be prepared and submitted to the NOP by the Certification Director or by staff delegated by the Certification Director.

NOFA-NY Certified Organic LLC will submit its annual update/report to the USDA/NOP on or before the anniversary of the date accreditation was granted.

NOFA-NY Certified Organic LLC will submit its application for accreditation renewal to the USDA/NOP at least six months prior to the fifth anniversary of the date accreditation was granted and every five years thereafter.

NOFA-NY Certified Organic LLC may request amendment to the scope of its accreditation at any time. The application for amendment will be sent to the USDA/NOP and will contain information applicable to the requested change in accreditation, a complete and accurate update of the information submitted per NOP 205.503-205.504, and the applicable fees.

NOFA-NY Certified Organic LLC will submit timely updates to our list of certified operations throughout the year to the Organic Integrity Database. Producer information provided will include at minimum the name, address, and telephone number of each operation granted certification during the preceding year.

All fees and charges for certification activities, as well as refund policies, will be filed with the USDA/NOP. Fees for accreditation will be paid and submitted to USDA/NOP.

1.5.7. Cessation of Certification Activities

If NOFA-NY Certified Organic LLC is dissolved or its accreditation to the USDA/NOP is suspended/revoked*, all certification activities in each applicable area of accreditation will cease. All records concerning the applicable certification activities will be transferred to the Secretary.
* A proposed suspension or proposed revocation of accreditation may be appealed to the Administrator. An appeal of a noncompliance decision will be filed within the time period provided in the letter of notification or within 30 days from receipt of the notification.

1.5.8. Other

NOFA-NY Certified Organic LLC will hold the Secretary harmless for any failure on the part of NOFA-NY Certified Organic LLC to carry out the provisions of the NOP regulations.

NOFA-NY Certified Organic LLC will furnish reasonable security, in an amount and according to such terms as the Administrator of the AMS may by regulation prescribe, for the purpose of protecting the rights of certified production and handling operations.

1.6. Program Administration

1.6.1. The Management Committee

The Management Committee has all powers to control and manage NOFA-NY Certified Organic, LLC as stated in the Operating Agreement between the Northeast Organic Farming Association of NY, Inc. and NOFA-NY Certified Organic LLC, with the exception of granting certification.

The Management Committee sets policies for NOFA-NY Certified Organic LLC, based upon the NOP Regulations and recommendations from staff, inspectors, and contract reviewers.

1.6.2. Certification Staff

A Certification Director and other program staff are responsible for conducting the day to day work of NOFA-NY Certified Organic, LLC.

Inspectors, who are either employees or independent contractors, conduct the on-site inspections of farms and handling operations and submit inspection reports to the certification office.

Contract Reviewers are selected by the Certification Director and may be utilized in addition to office staff. Contract Reviewers may be certified producers, members of the general public, and/or inspectors, provided the conflict of interest requirements are met.

Staff and Contract Reviewers are responsible for evaluating applications and inspection reports for compliance with the NOP Regulations and deciding which operations qualify for certification. Reviewers are knowledgeable in the organic production type of the application that they are evaluating.

2. Organic Certification

2.1. Organic Certification Regulations, Certification Agency Policy and Guidance

The USDA National Organic Program Regulations are the basis for certification of organic production. Operations seeking initial or continuing certification are required to obtain a copy of the NOP Regulations. The NOP Regulations are included in a three-part manual with the NOFA-NY Certified Organic LLC Guidance and Policy Manuals, which is included in all application packets. Exempt and excluded operations may purchase the manuals so that they may fully comply with the NOP Regulations. Individual copies of the NOP Regulation, NOFA-NY Certified Guidance and Policy Manuals will be available on our website [www.nofany.org](http://www.nofany.org).

Changes to the NOP Regulations and/or NOFA-NY Certified Organic LLC Policy and Guidance Manuals (including in response to NOP Guidance and Instruction documents) will be sent as they occur to operations as separate pages for insertion to the existing manuals and added to any remaining application packets for initial certification. The changes will also be included in the manuals for the next printing.
2.2. Organic Certification Categories

NOFA-NY Certified Organic LLC provides organic certification in the following categories recognized by the National Organic Program:

- Crops [includes greenhouse, maple, mushroom, sprout production]
- Livestock [includes dairy (cow, goat, sheep), poultry]
- Handling
- Wild Crops

2.3. International Trade Agreements

Evaluation of compliance with the terms of these agreements is included in the annual certification review process for each NOP certification category. We offer certified operations equivalence verification for export to and import from Canada, European Union, Japan, Korea, Switzerland and export only to Taiwan.

Notification of Compliance Requirements:

- **Notifications received from the USDA’s National Organic Program:** Will be reviewed by Certification Director and Senior Certification Specialists to ensure timely training, compliance, and updates to Policy Manual.

- **Notifications to producers:** NOFA-NY Certified Organic LLC will notify its producers of the compliance requirements for each applicable export/import arrangement by letter or electronic mail with 14 days of notification by the NOP. Producers sign an Equivalency Arrangement Agreement Form confirming they will abide to critical variances, exclusions, product origin, and labeling requirements for specific foreign markets applicable to their operation.

Compliance controls: NOFA-NY Certified Organic LLC will ensure compliance with export/import arrangements through recordkeeping and inspections including residue testing (refer to section 2.9).

**Authorized Party:** The Handling Certification Coordinator will act as the authorized person in the issuance of the export certification and attest to its authenticity by affixing his/her signature to certificate. The Certification Director will act as an authorized back-up to ensure uninterrupted issuance of export certificates. The designated person(s) are responsible for all aspects of the issuance of the export certificate, including ensuring security of blank export certificates.

2.3.1. Equivalency Agreement between U.S. and Taiwan

**Export Arrangement:** This arrangement establishes the standards of the two countries with the exception of some critical variances that must be addressed in the certification and export process.

Critical Variances for Product Entering Taiwan

- NOP organic certified products containing at least 95% organic content and have their final processing occur in the U.S. may be exported to Taiwan.
- Products shipped to Taiwan must be produced “using zero prohibited substances”. Livestock and meat products must be produced without the use of systemic pain killers or analgesics, including the use of Lidocaine and Procaine (though these materials may be used in topical applications).

2.3.1.1. Export Documentation

Product entering Taiwan - A TM-11 Export certificate is required to ship NOP certified products. The export certificate must be reviewed and signed by an approved USDA-authorized certifier.

TM-11 Export Certificates
Identification Number: NOFA-NY Certified Organic LLC will assign a unique identification number to each export certificate issued that will begin with an acronym designating NOFA-NY Certified Organic LLC as the accredited certifying agency and the country code TW for the specific export arrangement stated above. Official country codes will be based on ISO 3166.

Identification Number Controls: NOFA-NY Certified Organic LLC will manage the assignment of export certificate numbers based on a spreadsheet listing available numbers assigned in chronological order by Country. This control log will also state disposition of export certificate to include those issued, voided or destroyed. The control log along with number assignment will be maintained by the Certification Director with backup responsibility by the Handling Coordinator.

Taiwan (TW) Export Certificate Requirements:
Verification of Export Requirement: NOFA-NY Certified Organic LLC will issue TM-11 Certificate only for products where the organic raw material content of the organic agriculture processed product is 95% or greater.

Compliance Statement Declaration: The export certificate will contain the following statement in the remark box declaring the applicable prohibitions:
For Processed Products and Crops: Organic agricultural products and organic processed products accompanied by this certificate were produced and processed using zero prohibited substances. For Livestock and Meat products: Organic livestock products accompanied by this certificate, were managed and produced without the use of systemic pain killers or analgesics, including the use of Lidocaine or Procaine.

2.3.1.2. Labeling Requirements:
Taiwan - For packaged retail products, labels or stickers must state the name of the USDA-authorized certifier and may use the USDA organic seal.

2.3.2. Equivalency Agreement between U. S. and Japan
Arrangement: This arrangement establishes the standards of the two countries as equivalent, with the exception of some critical variances that must be addressed in the certification and/or import/export process.

Critical Variances for Product Entering Japan
- NOP organic certified plants (including fungi) and plant based processed products containing at least 95% organic content that are produced within the U.S., or have their final processing or packaging (including label) occur in the U.S. may be exported to Japan with no critical variances.

Critical Variances for Product Entering the United States
- Japanese Agricultural Standards (JAS) certified plants (including fungi) and plant based processed products that are produced or have had final processing or packing occur within Japan may be imported to the U.S. with no critical variances.

2.3.2.1. Documentation
Product entering Japan - A TM-11 export certificate is required to ship NOP certified plants and plant based processed products to Japan under the Arrangement. The export certificate must be reviewed and signed by an approved USDA-authorized certifier. Organic products certified to the USDA organic regulations, but outside the scope of JAS, may also be imported to Japan. Examples include meats, dairy products and alcoholic beverages. These products (with the exception of alcohol) do not require a TM-11 export certificate.

TM-11 Identification Number: NOFA-NY Certified Organic LLC will assign a unique identification number to each export certificate issued that will begin with an acronym designating NOFA-NY Certified Organic
LLC as the accredited certifying agency and the country code JP for the specific export arrangement stated above. Official country codes will be based on ISO 3166.

TM-11 Identification Number Controls: NOFA-NY Certified Organic LLC will manage the assignment of export certificate numbers based on a spreadsheet listing available numbers assigned in chronological order by Country. This control log will also state disposition of export certificate to include those issued, voided or destroyed. The control log along with number assignment will be maintained by the Certification Director with backup responsibility by the Handling Coordinator.

Japan (JP) Export Certificate Requirements
Organic Agricultural Products and Processed Products: An Export Certificate will only be issued for organic plants including fungi or organic plant-based processed products.

Product entering U.S. - A NOP import certificate, completed by a JAS-authorized certifier is required to ship certified plants and plant –based products to the U.S. Organic products regulated by the JAS law may also be imported to the U.S. if they are certified to the USDA organic regulations. Examples include meats, dairy product, and alcoholic beverages. These products do not require an NOP import certificate.

2.3.2.2. Labeling Requirements:
Japan - Plant or plant-based processed products: For packaged retail products, labels or stickers must state the name of the USDA authorized certifier and may use the USDA organic seal. Products shipped from the United States and sold as organic in Japan are required to display the JAS seal. The seal may be applied in Japan by a JAS-certified importer or applied by U.S. companies through a consignment contract with a JAS-certified importer. Japan does not recognize the labeling category of 100% organic product. These products may be labeled “organic”. Per export requirements, Japan does not have a “made with” labeling category. Only products with 95% or more organic content may be labeled as organic in Japan.
 Livestock and Alcohol products: These products cannot use the JAS Organic seal. Products may display the USDA organic seal if compliant with USDA organic labeling requirements. These products may be labeled with the work “organic” in English or Japanese.

United States - For packaged retailed products, labels or stickers must state the name of the JAS certifier and may use the USDA Organic seal and/or the Japanese Agricultural Standard (JAS) Organic seal.

2.3.3. Equivalency Agreement between U. S. and European Union (EU)
Arrangement: This arrangement establishes the standards of the two countries as equivalent, with the exception of some critical variances that must be addressed in the certification and/or import/export process.

Critical Variances for Product Entering the EU
• Produce crops without antibiotics.
• Meet additional specifications for wine.
• Products must be either produced or have had final processing or packaging occur within the U.S.

Critical Variances for Product Entering the United States
• Produce livestock without antibiotics.
• Aquatic animals are excluded products.
• Meet additional specification for wine.
• Product must be produced or have had final processing or packaging occur within the EU.

2.3.3.1. Documentation
Product entering the EU - Ship products with an EU import certificate submitted through the TRACES Network located at https://webgate.ec.europa.eu/tracesnt/login. NOFA-NY Certified Organic certifier number is US-ORG-036. NOFA-NY Certified Organic LLC will provide training documents for this electronic submittal upon request.

Product entering the U.S. - A NOP import certificate, completed by an EU-authorized certifier, is required to ship products to the U.S.

2.3.3.2. Labeling requirements

European Union - For packaged retail products, labels or stickers must state the name of the USDA-authorized certifier and may use the USDA Organic seal and/or the EU Organic logo.

United States - For packaged retail products, labels or stickers must state the name of the EU certifying agent and may use the USDA Organic Seal and/or the EU Organic logo.

2.3.4. Equivalency Agreement between U. S. and Switzerland

Arrangement: This arrangement establishes the standards of the two countries as equivalent, with the exception of some critical variances that must be addressed in the certification and/or import/export process.

Critical variances for Product Entering the Switzerland
- Meet additional specifications for wine.
- Products must be either produced or have had final processing or packaging occur within the U.S.

Critical variances for Product Entering the United States
- Produce livestock without antibiotics.
- Meet additional specification for wine.
- Product must be produced or have had final processing or packaging occur within Switzerland.

2.3.4.1. Documentation

Product entering Switzerland - Ship products with a Swiss import certificate, reviewed and signed by a USDA-authorized certifier

Product entering the U.S. - A NOP import certificate, completed by a Swiss-authorized certifier, is required to ship products to the U.S.

2.3.4.2. Labeling requirements

Switzerland - For packaged retail products, labels or stickers must state the name of the USDA-authorized certifier and may use the USDA Organic seal.

United States - For packaged retail products, labels or stickers must state the name of the Swiss certifying agent and may use the USDA Organic Seal.

2.3.5. Equivalency Agreement between U. S. and Canada

Arrangement: The arrangement establishes the standards of the two countries as equivalent, with the exception of some critical variances that must be addressed in the certification and/or import/export process.

Critical Variances for Product Entering Canada
- Products must be produced without the use of sodium nitrate (Chilean nitrate).
- Products must not be produced using hydroponic or aeroponic methods.
- Livestock products (other than from ruminants) must be from animal systems that meet the stocking rates as set forth in the Canadian Standard (CAN/CGSB 32.310-2006).
Critical Variances for Product Entering the United States
• Livestock products must be produced without antibiotics as attested by suppliers or supplier certifiers.
• Import ship with documentation that state, “Certified in compliance with the terms of the U.S.-Canada Organic Equivalency Arrangement”.

Exclusions to the U.S./Canada Equivalence Arrangement
• Products outside the scope of the Canadian Organic Regime, such as pet food, personal care products, and aquaculture products (nori, spirulina, chlorella, and kelp) may not be exported from the United States to Canada under this equivalence arrangement.
• NOP-certified products outside the scope of COR may be sold in Canada as NOP certified without additional verification. In these cases reference to COR is prohibited.

Product Origin
• Product from anywhere in the world certified to NOP standards may be shipped to Canada and use the Canadian Organic Logo as long as the critical variances and the arrangement terms are met.
• Product from anywhere in the world certified to the Canadian Organic standards may be shipped to the United States and use the USDA NOP logo as long as the critical variance and the arrangement terms are met.

2.3.5.1  Documentation
Attestation Statement must be included on accompanying documents or packaging for all shipments of organic products exported between Canada and the U.S.

2.3.5.2  Labeling requirements
Canadian labeling requirements
• For retail products, labels or stickers must state the name of the U.S. certifying agent and may use the USDA Organic seal and/or the Canada Organic Biologique logo.
• All product labels must be in English and French.
• Wholesale products only require lot numbers.

United States labeling requirements
• For retail products, labels or stickers must state the name of the Canadian certifying agent and may use the USDA Organic seal and/or the Canada Organic Biologique logo.

2.3.6  Equivalency Agreement between U. S. and Korea
Arrangement: This arrangement establishes the standards of the two countries as equivalent for processed products, as defined in the Korean Organic Food Code, with the exception of some critical variances that must be addressed in the certification and/or import/export process.

Critical Variances for Product Entering Korea
• Only processed products as defined in the Korean Food code (listed below) are covered under the agreement.
  “Processed food” refers to a food manufactured, processed and packaged by adding food or food additives to food raw materials (agricultural, forestry, livestock, or marine products), transforming food raw materials (such as grinding or cutting) till their original form cannot be recognized, or mixing such transformed ones or adding food or food additives to such mixture.
  However, where, without the use of food additives or other materials, the agricultural, forestry, livestock, or marine products are simply cut, peeled, salted, ripened, or heated (except the cases where heating is performed for sterilization or heating causes significant changes to those products) till their original forms
can be recognized or where sanitary risks from treatment processes are not expected and food raw materials are simply treated so as to allow organoleptic identification of food quality, such food products are excluded from the definition of the processed food.”

- NOP organic certified processed products containing at least 95% organic content and have their final processing (as defined in the Korean Food Code) occur in the U.S. may be exported to Korea.
- Products must not contain apples and pears produced with the use of antibiotics.
- The arrangement allows both countries to check imported organic products to verify that residues of prohibited substances and methods are not present in the final product. If such residues are detected in Korea, the organic label may need to be removed.

Critical Variances for Product Entering the United States
- Livestock products must be produced without the use of antibiotics.
- Products must contain at least 95% organic content and have their final processing or packaging occurs within Korea.

2.3.6.1. Documentation
Products entering Korea - ship with the NAQS Import Certificate of Organic Processed Foods reviewed and signed by a USDA-authorized certifier.

Product entering U.S. - A NOP import certificate, completed by a Korean-authorized certifier, is required to ship products to the U.S.

2.3.6.2. Labeling requirements
Korean labeling requirements - Products meet the organic labeling requirements as defined by Korea’s Ministry of Agriculture, Food and Rural Affairs (MAFRA).

Labels must include the following information:
- “Manufactured by” -“Packaged in: USA” -The “Certified Organic By” statement
- Telephone number of the seller or importer
- Certificate number (which is the producer number found on the NOFA-NY Organic Certificate)
- Labels may include the Korean Organic Food Label and/or USDA Organic Seal.
- The word “organic” may be in English or Korean

United States labeling requirement - for packaged retail process products, labels or stickers must state the name of the Korean certifier and may use the USDA seal and/or the Korean Organic label.

2.4. Certification Annual Process
Organic Certification is an annual process which requires:

- Submission of a complete application (Organic System Plan) and payment of fees
- Initial Review/evaluation of application
- On-site inspection of farm and/or handling operation within 3 –10 months of receipt of a complete application.
- Final Review/evaluation of application and inspection report
- Certification Decision

2.4.1. Obtain Current Application Packet
Application packets can be obtained through the Certification Office or online at www.nofany.org for both initial and continuing certification. Operations seeking initial certification must obtain the current certification application packet which includes the current version of the NOP Regulations.
Certified operations are required to update their Organic System Plan (OSP) annually. Application packets for continuing certification will be provided by the Certification Office annually.

Crops*/Livestock/Wild Crop/Handling: sent by January 1.

*Update applications for Maple operations sent mid-November.

2.4.2. Attend Workshop

A certification workshop for initial Crop, Livestock and Wild Crop operations is generally held during the NOFA-NY Annual Conference in January each year. Additional workshops may also be available depending in participant interest, and may include workshops for Handling operations. Attendees will receive a $25.00 voucher toward the initial certification fee, with a limit of one voucher per operation.

Producers applying for initial certification are encouraged to attend workshops when they are available. The workshops provide information regarding specific certification requirements, and an opportunity for applicants to ask questions about the application and overall process. They help producers understand the necessary information and reduce the spent completing the paperwork.

2.4.3. Submit Complete Organic System Plan with Payment (§205.401(c))

Application packets include the paperwork which will comprise the operation’s Organic System Plan. All paperwork must be thoroughly completed in black or blue ink, or typed. An incomplete application cannot be evaluated, and a memo will be sent to the operator with a due date for submission of the missing information. Payment must be submitted at the time of application. Applications and supporting documentation must be in English. If in another language and translation is required, translation fees will be billed to producer.

Note that a plan prepared to meet the requirements of another Federal, State or local government regulatory program may be substituted for the NOFA-NY, LLC Organic System Plan document(s) as long as it includes all necessary information and meets the requirements of the National Organic Standards.

Operators seeking initial certification with NOFA-NY Certified Organic LLC must include the name(s) of any organic certifying agent(s) to which application has previously been made, the year(s) of such application, and the outcome of the application(s) submission. A copy of any notification of noncompliance or denial of certification issued to the operation, and a description of the actions taken by the operator to correct the non-compliances identified in the notification of non-compliance, and evidence of such correction must be submitted.

Operations continuing certification must include any deviations from and/or changes made to the previous year’s OSP, along with information regarding correction of noncompliances previously identified as required for continued certification, supported by documentation.

Once certified, an operation’s certification continues in effect until surrendered by the operation, or until suspended or revoked by NOFA-NY, the USDA Administrator, or other governing official. However, In order to maintain certification, an operation must update their certification annually.

Based upon an Initial Review of the application, other information necessary to determine compliance with the NOP Regulations may be requested, with a due date for submission of the information.

Applications must be postmarked or emailed as specified in the following sections for each certification category. Specific due dates are established annually to ensure they fall on a business day.

If the annual update information or notification of surrender of certification is not received by the established due date for continuing certification, Noncompliance Procedures will be initiated by the certification office.

2.4.3.1. Crop, Livestock, Wild Crop Operations
**Initial Certification.** Maple Applications are recommended to be submitted electronically or postmarked by the first business day in February. This will allow sufficient time to complete our initial review, perform the inspection during tapping, and make a final certification decision in time for your maple market season.

All other Initial Certification applications are recommended for submittal by the first business day in May. This will allow sufficient time to complete the certification process before harvest and before the USDA Cost Share Reimbursement deadline. Any application received after July 1 may become ineligible for reimbursement of first year certification fees under the USDA Cost Share Program requiring organic certification by September 30.

The initial certification process typically takes three months to complete from receipt of complete application with payment to receipt of certification decision. This period of time must allow for an in season inspection.

New applicants who submitted current year certification applications during the 4th quarter (October 1 and December 31) and pay a full Certification fee will be credited for a reduction in fees applied to their next year of certification. NOFA-NY will notify producers when applicable.

**Continuing Certification.** Maple OSP Annual Updates are to be submitted electronically or postmarked by January 15 (if this day falls on a weekend then the next business day allowed).

All other OSP Annual Updates are to be submitted electronically or postmarked by the last business day in February. Applications for initial certification submitted in the latter portion of the previous year are also subject to this due date.

OSP Annual Updates submitted electronically or postmarked after the date specified will be assessed a late fee as outlined in Section 5.1.4 & 5.8 of this manual, and will be subject to Noncompliance Notification Procedures.

Operations that submit a complete OSP update with full payment are eligible for an Early Bird Discount.

The continuing certification process typically takes on average eight months from receipt of renewal application with payment to receipt of continued certification decision.

**Expedited Certification.** Applications are typically processed within 30 days from receipt of complete application with payment including expedited fee to receipt of certification decision.

**2.4.3.2. Handling Operations**

**Initial Certification.** Applications for initial certification may be submitted at any time throughout the year. Any application received after July 1 may become ineligible for reimbursement of first year certification fees under the USDA Cost Share Program requiring organic certification by September 30.

The initial certification process typically takes three months to complete from receipt of complete application with payment to receipt of certification decision.

New applicants who submitted current year certification applications during the 4th quarter (October 1 and December 31) and pay a full Certification fee will be credited for a reduction in fees applied to their next year of certification. NOFA-NY will notify producers when applicable.

**Continuing Certification.** OSP Annual Updates are to be submitted electronically or postmarked by the last business day in February. Applications for initial certification submitted in the latter portion of the previous year are also subject to this due date or as advised in renewal application.

The continuing certification process typically takes on average eight months from receipt of renewal application with payment to receipt of continued certification decision.
Expedited Certification. Applications are typically processed within 30 days from receipt of complete application with payment including expedited fee to receipt of certification decision.

2.4.3. Producers switching to NOFA-NY from another certifier
Producer to provide current certificate, last inspection report, and determination letter (DL). If response needed on DL, response should also be provided.

NOFA-NY will obtain from current certifier on official certifier paperwork or letterhead the following:

- Listing of field IDs and acreage certified
- Listing of animals certified
- Letter of good standing
- Any outstanding noncompliances

2.4.4. Application/OSP Initial Review
Once an application for initial or continuing certification is received by the Certification Office with payment of the applicable fees and is determined to be complete, an Initial Review is conducted to evaluate whether or not the operation appears to be in compliance with the NOP Regulations and International Equivalency requirements. If additional information is needed to make this determination, a letter is sent to the operation requesting information to be submitted by a specific due date. If the requested information is not received by the due date, a No Response fee will be assessed as outlined in Section 5.8 of this manual, and will be subject to Noncompliance Notification Procedures.

If the OSP appears to be compliant or that the operation has the capacity to comply, an Initial Review Letter is sent to the operation detailing any additional information that must be available at the time of inspection. The file is forwarded to the inspector.

If the OSP is not compliant, or does not appear to be able to comply, Noncompliance Notification Procedures will be initiated.

2.4.5. Authorized Representative Signature
A signature identifies the signer and signifies that the signer understood and intended to carry out whatever was stipulated in the document that was signed.

A signature authenticates a document by linking the signer with the signed document. A signature may also express the signer’s approval or authorization of the signed document and what it contains, and his or her intent that it has legal effect. The signature provides evidence that the signer indeed did something and actually saw and approved a particular document at the time of signing.

A signature is often used to protect against fraud, impersonation, or intrusion.

The act of signing warns or puts the signer on notice that he or she may be making a legally binding commitment. The signature will show that a meaningful act occurred when the person approved the document. A signature should force the person to deliberate over the document and become aware of its significance before making it final.

E-signatures will be allowed with the above intent. Each electronic and digital signature is unique to authorized representative and must not be used or shared by anyone else. Each electronic and digital signature explicitly authenticates the employee executing the signature, and displays both the first and last name of the signer, and the time and date the electronic or digital signature was applied. The electronic and digital signature is considered invalid if the electronic record has been altered or modified after being signed. In addition, all regulations are applicable to e-records including retention, accessibility, confidentially, and disposition requirements.
2.4.6. **On-site Inspection**

The inspector schedules the on-site inspection for initial certification, annual inspections for continuing certification, and any additional inspections that may be necessary. An authorized representative who is knowledgeable about the operation must be present for the inspection and the inspection must be conducted when all land, facilities and activities that demonstrate compliance can be observed, except that this requirement does not apply to unannounced on-site inspections. For new operations, the initial inspection visit must be performed within six months following receipt of a complete application that appears to comply or may be able to comply with the NOP requirements. For already certified operations, inspections for continuing certification must be performed within 12 months of receipt of a complete update application and fees.

Failure to complete an annual inspection is cause for the issuance of a notification of Noncompliance and/or Denial/Proposed Suspension. Producers and inspectors must ensure that there is ample time for the inspection. The duration of an inspection varies by operation and from inspection to inspection. The inspector needs to view all documents that form the producer’s audit trail, and the producer must have complete input, harvest, production and sales records for no less than five years prior available for inspection, including all receipts for inputs, contracted services, and equipment rental.

2.4.7. **Final Review and Certification Decision**

Once the completed Inspection Report has been submitted, a Final Review of the OSP and Inspection Report is conducted to evaluate compliance with NOP Regulations, and a certification decision is made. The Certification Determination Notice is sent to the operation, indicating whether certification is approved, pending, or denied, and will include the following, as applicable:

- Areas of Noncompliance
- Minor Issues (Conditions for Continuing Certification/Conditions for Certification)
- Additional information needed with next annual update application
- Notes/Reminders

2.4.8. **The Organic Certificate**

When organic certification is approved, an Organic Certificate is issued. An updated organic certificate will be issued annually, after the annual update for the certified operation has been received, inspected, evaluated and approved for continued certification. A certificate may also be updated when new scope or product(s) approved.

The Organic Certificate is issued only in English, and contains the following information, as required by §205.404(b)(1-4) of the NOP Regulations and NOP Instruction 2603:

- Certified operation’s legal name and address, including a physical address if the mailing or legal address is not the physical location of the operation.
- Name, address, internet address and phone number of NOFA-NY Certified Organic LLC.
- Effective date of organic certification (the date the operation was initially certified by NOFA-NY to the NOP regulations) Note: certifying after surrender, suspension, or revocations will result in a new effective date.
- Anniversary Date (the date when certified operation is required to submit their next annual update).
- Category of certification (crops, livestock, handling, wild crops).
- Certified organic products covered under the organic certification.
- Label classification for processed organic products – 100%, Organic, and Made with Organic (specified ingredients or food groups) and Livestock Feed (Organic or 100% Organic).
- The statement – “once certified, a production or handling operation’s organic certification continues in effect until surrendered, suspended or revoked”. 
If any of the information specified on the certificate of a certified operation changes, the certifying agent must determine that the changes comply with the Act and the Regulations in this part, and issue an updated certificate of organic operation pursuant to 205.404 (b).

The certificate does not expire and is valid until surrendered, suspended, or revoked.

Certificate must identify only one “person” (typically a farm or business as defined in 7 CFR § 205.2) this “person” must be certified organic. Each certified organic operation must have its own organic certificate. Certification and certificates issued to certified operations are not transferrable to new owners in cases of mergers, acquisitions, or other transfers of ownership.

One entity, legal name examples

- Sole Proprietorship
- Partnership – General or limited
- Limited Liability Company (LLC)
- Corporation

New York State requires business to be conducted using a true legal name. As a result, those entities seeking to use a name other than their true legal name must file for a DBA.

One entity multiple locations

A Single person or single legal entity-business may elect to include all certified locations/facilities that are a part of their operation under one certification. If products are the same for all locations, the organic certificate will list the additional location address at the bottom. If products vary among locations, an addendum will be issued listing locations and products specific to that location.

If electing to have a single certificate in a person’s name or a business name that covers multiple locations and a noncompliance with any location progresses to suspension, the entire certification (all locations) could be suspended. To avoid this situation separate business locations may elect to be handled as separate certifications. If an applicant elects to have multiple locations on a certificate, please contact NOFA-NY so we may provide assistance in providing additional location certification fees and inspection quotes in Section 5.2.3.

2.4.9. International Trade Documents

The certification office will issue affirmations/affidavits/export certificates as applicable to verify existing international equivalency agreements. Affirmations/affidavits/export certificates will be issued only when requested by a certified operation and production practices and labels have been determined to be compliant with the requirements of the destination country.

Refer to Section 2.3. for International Equivalency Arrangements and Section 5.8 for fees.

2.4.10. Term of Certification

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 or the USDA AMS Administrator (§205.404(c)).

If a certified operation does not intend to continue certification with NOFA-NY Certified Organic, LLC, they must submit written notification and voluntarily surrender their certificate to the certification office prior to annual due date. Applications not submitted or surrendered by annual due date will be assessed a Certification Extension Fee as outlined in Section 5.8 of this manual. Charges will continue to be incurred until an application or a written notice of surrender is received. This also applies to operations switching certifiers. Charges will be a prorated fee based on prior year certification fee.
2.4.11. Changes and Additions to Existing Certification (Extension of Certification)

If an operation intends to add another category of certification, add fields, products, facilities, etc., complete information regarding the new production must be submitted to the certification office and approval must be granted prior to implementation or release of new production. Office staff or a Contract Reviewer will evaluate the documentation to verify compliance and determine whether or not an additional on-site inspection is necessary. If the new product(s) or production is similar to those already certified, an additional on-site inspection may not be required.

If certification is approved, the Organic Certificate will be updated to include the additional production.

We recommend that all potential products and areas of production be included with the initial or continuing certification paperwork. Additional fees will be assessed for changes to certification that take place outside the annual review and evaluation process.

2.4.12. Material Reviews

All materials and substances intended for use on NOFA NY, LLC certified farms are reviewed for compliance with Section 205.105 and Sections 205.600-604 (National List of Allowed and Prohibited Substances) of the National Organic Regulations. Review may be performed by the Certification Director, Senior Certification Specialists, Materials & Inspection Coordinator, and Certification Coordinators. Refer to Section 5.8 of this manual for fees associated with Material Reviews.

Together, NOFA-NY, LLC and Vermont Organic Farmers, LLC (VOF) have established a shared Livestock Materials Review Program, acting in accordance with NOP Interim Instruction 3012 and the combined internal policies of both organizations. The purpose of this shared program aims to conserve resources and standardize material reviews for producers within our region. NOFA-NY, LLC and VOF will share a co-authored list of approved and prohibited materials. The list will include reviews conducted by both programs.

2.4.12.1. OMRI-listed, WSDA-listed, CDFA-listed and EPA Approved for Organic Use Materials

NOFA-NY, LLC has a subcontracting agreement with OMRI, and consult with them as necessary. OMRI-listed, WSDA-listed, CDFA-listed and EPA Approved for Organic Use materials are allowed without further review, provided they are used as listed or as annotated in specific categories.

2.5. Temporary Variances

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 NOP.

Upon notification from the NOP of the establishment of a temporary variance, NOFA-NY Certified Organic LLC will notify each certified operation to which the temporary variance applies, along with all inspectors, reviewers and office staff. This will be done via direct mail/email. Temporary variances will be documented as part of the final review summary and taken into account for all applicable certification decisions.

2.6. The National List: Sourcing Inputs and Ingredients

Certified operations and those requesting initial certification must use organic agricultural inputs and ingredients, or those identified in the National List as allowed. The National List is comprised of Sections 205.601 through 205.606 of the NOP Regulations, and specifies the non-agricultural/non-organic and synthetic substances that are allowed for use in each category of organic production.

2.7. Withdrawal of Application / Surrender of Certification

Operations that have submitted application for initial or continuing certification may withdraw their application at any time. A written request is required to request a refund.

An operation that withdraws an application or surrenders certification shall be liable for the costs of services provided up to the date of withdrawal of the application, including inspection. Operations will
not be eligible for a refund after the on-site inspection has been conducted. Refer to Section 5.4 for refund policy.

If the certification fee was not paid in full and the amount paid at the date of withdrawal is not sufficient to cover costs incurred at the time of surrender, the balance will be billed to the operation.

If a certified operation does not intend to continue certification, they must submit written notification and voluntarily surrender their certification certificate to the certification office.

An operation that voluntarily withdraws an application or surrenders certification prior to the issuance of a Notice of Noncompliance will not be issued a notice of noncompliance.

An operation for initial certification that voluntarily withdraws its application prior to the issuance of a notice of certification denial will not be issued a notice of certification denial.

Section 2.4.10 of this manual outlines fees associated with operations who do not submit an annual application by annual due date with the intent to surrender certification or switch certifiers.

2.8. Monitoring Continued Compliance

Continued compliance of operations is monitored through complaint investigation, conducting unannounced on-site inspections, and residue testing. Producer responses to requests for additional information, changes in OSP, correction of noncompliances, etc., are monitored and tracked by the certification office by assigning a due date for submission.

Noncompliance Procedures will be initiated, or continued as applicable.

2.9. Testing for Residues (§205.670)(a-d)

Residue testing to monitor compliance will be conducted on a minimum of 5% of certified operations annually, pursuant to NOP Regulations. Samples may be collected during any on-site inspection, and may either be randomly selected or risk based.

2.9.1. Accessibility

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 USDA AMS Administrator, the applicable State organic program's governing State official, or NOFA-NY Certified Organic LLC.

2.9.2. Reasons for Testing

The USDA AMS Administrator, applicable State organic program's governing State official, or the certifying agent may require pre-harvest or post-harvest 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 State organic program's governing State official at their own expense, or at the NOFA-NY Certified Organic LLC Program expense.

2.9.3. Collection

The pre-harvest or post-harvest sample collection must be performed by an inspector representing the USDA AMS Administrator, applicable State organic program's governing State official, or NOFA-NY Certified Organic LLC. There shall be no charge to the inspector for samples taken. Sample integrity must be maintained throughout the chain of custody, and residue testing must be performed in an accredited laboratory. The specific sampling techniques used are dependent upon the testing requirements. Inspectors will work with the testing laboratory to meet their sampling requirements.
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.

2.9.4. Results Analysis
Results of analyses and tests performed under this section will be:

- Sent to the inspected operation.

Provided to the USDA AMS Administrator as needed; Except, that, where a State organic program exists, test results and analyses shall be provided to the State organic program's governing State official as needed by the applicable certifying party that requested testing; and available for public access, unless the testing is part of an ongoing compliance investigation.

Promptly reported to the Food and Drug Administration or the Environmental Protection Agency if test results indicate a specific agricultural product contains pesticide residues or environmental contaminants that exceed their regulatory action level / tolerances.

Promptly reported to the appropriate State health agency or foreign equivalent if test results exceed federal regulatory tolerances.

2.9.5. Conducting of Tests
Testing may be conducted during specific sample collection visits, annual inspections, spot inspections or unannounced inspections.

2.9.6. Exclusion from Organic Sale (§205.671)
When residue testing detects prohibited substances at levels that are greater than five (5) percent of the Environmental Protection Agency's tolerance for the specific residue detected or unavailable 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.

2.10. Emergency Pest or Disease Treatment (§205.672)
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 NOP requirements, the certification status of the operation shall not be affected as a result of the application of the prohibited substance as long as:

- 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 is not sold, labeled, or represented as organically produced;
- 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:
  - 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
  - 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.

2.10.1. Notification and Recordkeeping
Upon occurrence of Federal or State emergency pest or disease treatment, applicable certified operations, inspectors, reviewers and office staff will be notified of the requirements of 205.672 by direct mail/email.
Reviewers will include information in the final review summary and determination letter to the operation. Subsequent office review will ensure labeling and sales claims are compliant with the regulations.

3. Transition Monitoring

Operations interested in Transition Monitoring of land for crop production, or of a dairy herd will follow the certification process outlined in Section 2.4; however the Organic Certificate described in Section 2.4.8 will not be issued until the production areas have been fully approved for certification. Upon Final Review and Decision of an application for Transition Monitoring, a transition end date will be established.

3.1. Transition Monitoring – Land

Operations interested in third party verification of transition of land for organic crop production will complete the application for initial certification for the crop category, but pay Transition Monitoring fees. If approved for Transition Monitoring, the certification office will issue a letter to insurance companies, FSA offices or other agencies as requested by the applicant, verifying the operation is transitioning to organic production.

Annual update of information and payment of Transition Monitoring fees will be required to continue Transition Monitoring for periods over one year. At the beginning of the final year of transition, the operation will be evaluated for full certification, and will pay the certification fee based on projected gross organic sales.

3.2. Transition Monitoring - Dairy Herd

NOP Regulations allow for a one-time conversion of an entire distinct dairy herd to organic production.

3.2.1. Land

Land must either be eligible for certification or entering its third year of transition (T3) at the beginning of a dairy herd transition. If the land appears to be eligible for certification, the operation will apply for initial crop certification with Transition Monitoring for Dairy. If the land is in its third year of transition, the operation will apply for Land and Dairy Transition Monitoring.

3.2.2. Animals

All animals to be transitioned must be on the farm at the start of transition. Animals must be under continuous organic management for a minimum of one year before they can be certified to produce organic milk.

3.2.2.1. Existing Herd

An operation with an existing conventional herd will complete the application paperwork for a livestock application, which includes the necessary paperwork for crop certification. All of the documentation will be evaluated and the entire operation inspected. Prior to the end of transition of the dairy herd, an additional inspection may be necessary if there were areas of concern identified during the initial inspection, or if any area of production could not be observed at the time of initial inspection.

3.2.2.2. Herd addition after submission of crop application

An operation that does not have an existing herd and wishes to add Transition Monitoring of a dairy herd at a later date may either submit livestock paperwork at the time of initial certification of their land, or at a later date when they expect to obtain the animals. An animal list that includes all animals to be transitioned must be submitted upon prior to the planned transition start date.

4. The Inspection Process

4.1. Inspector Role

The inspector’s role is to observe and verify that the organic practices in the operation’s OSP are being implemented as described. Inspectors are the “eyes”, and are the connecting link between the operation and the
Certification Program. The individual conducting the inspection will not make a certification decision regarding an operation that he/she has inspected during the preceding 12-month period.

The Inspector is responsible for inspection and document review related to all aspects of the operation:

- Visiting all fields, production areas and facilities included in the OSP
- Identifying practices, materials, or production processes that are not in compliance with the NOP Regulations.
- Communicating areas of non-compliance to the operator and the Certification Program.
- Completion of all inspection forms associated with the inspection, and returning the operation’s file with the completed inspection report to the Certification office within 14 days of the inspection visit.

4.2. Inspector Choice

NOFA-NY Certified Organic LLC reserves the right to make all inspection assignments and the right to use subcontractors for inspection as necessary. An operation may not influence the choice of inspector or contact inspectors directly to solicit inspection assignments. The operation has the right to be informed about the identity of the inspector before the inspection visit, and may raise objections based on conflicts of interest or other reasons by submitting the objections, in writing, to NOFA-NY Certified Organic LLC, who rules whether the reasons are accepted and whether or not to reassign the inspection.

4.3. Inspection Scheduling

The Inspector is responsible for scheduling and completing all inspection visits. Inspections will be grouped by geographical areas whenever possible to minimize inspection travel costs. Inspections for initial applications will be scheduled as early in the season as possible, but must be scheduled within six months following receipt of a complete application that appears to comply or may be able to comply with the NOP requirements. The lengths of on-site inspections vary depending on the size and complexity of the operation.

4.4. Inspection Cancellation

Cancellation of an inspection appointment is very costly to the Certification Program. Producers should keep in mind that the inspector is likely working with other operations in their region when planning the inspection schedule. Cancellation of one inspection affects the other inspection appointments as well.

Scheduled on-site inspections may be cancelled up to one week prior to the appointment without penalty. Inspections cancelled 6 days or less from scheduled date will result in producer being billed for a cancelled inspection. Additionally, a producer not present at time of inspection that results in a cancellation will be responsible for actual cost of cancelled inspection.

Handling operations are billed for all costs incurred by the inspector for the canceled appointment, as well as the costs of the re-scheduled inspection.

4.5. Annual On-Site Inspection

4.5.1. Documentation Provided to Inspector

The Certification Program office provides the OSP and Inspection Letter to the Inspector for all operations, as well as the previous year’s inspection report for continuing operations.

4.5.2. Inspection Overview: All Operations

All operations are subject to inspection and review of documentation related to all aspects of their operation for compliance with the NOP Regulations and International Equivalency requirements. All production areas and documentation related to organic production must be available for review at the time of inspection. The practices and documentation, as well as those specific to each certification category listed below highlight the
components of the inspection process. Since individual operations differ, the inspection may include review and observation other than that specifically listed.

- Initial discussion with the operator regarding the process to be used to complete the inspection.
- Explanation to the applicant that the inspector is only an observer, and does not make the final certification decision.
- Field tissues, ingredient, finished product, pest management samples may be collected for testing.
- Observation and review of production practices and audit trail documentation.
- Equipment being used by the operation.
- Input materials and pest control materials, for use and appropriate storage.
- Audit Trail (Documentation of all activities and transactions of the operation in sufficient detail to be readily understood and audited). Refer to Section 4.8 for more detail.
- In/Out Balancing.
- Summary of Inspection Visit & Exit Interview with operator to discuss accuracy of observations, areas of noncompliance and additional information needed.
- A copy of the Exit Interview form will be provided to the applicant.
- A receipt for any tissue or product samples pulled. Samples must be provided to the inspector at no charge.

4.5.3. Inspection: Crop Operations
(In addition to Section 4.5.2 above)
- Inspection of all fields for which the operator is requesting certification or continuing certification.
- Processing areas (if applicable).
- Crop/product storage areas.
- All audit trail records (field amendment records, pest and disease control applications, purchases, equipment cleanout, harvest, storage, labels, adequacy of lot numbering system, etc.).

4.5.4. Inspection: Livestock Operations
(In addition to Section 4.5.2 and all areas in Section 4.5.3 above)
- Livestock housing areas and conditions.
- Animal identification system.
- Health remedies, medications and cleaning materials on hand.
- Feed supplies on hand.
- Milk handling practices, including cleaning materials.
- Slaughter facility.
- Poultry house areas and conditions; including outdoor access and adjoining land.
- Livestock audit trail records (purchased feed logs, organic certificates for purchased feed, livestock medication, pasture records for ruminants, breeding, chicks or pullets shipping documents hatching, loss and cull, egg production, etc.).

4.5.5. Inspection: Handling Operations
(In addition to Section 4.5.2 above)
All production areas.

Equipment.

Cleaning and sanitation logs.

Review of certification verification for ingredients.

Review of processing aids used, certification verification or allowance.

Review of product storage areas including (in-process storage areas, packaging, finished product storage, shipping areas).

Review of pest control practices.

All audit trail records (ingredients – purchase, organic certificates, non-organic compliance (not produced with genetically modified organisms, irradiation, sewage sludge); storage, production, pest control logs, cleaning/sanitizing logs, inventory, adequacy of lot numbering system, sales/shipping).

4.5.6. Inspection: Wild Crop Operations

(In addition to Section 4.5.2 and all areas of 4.5.3 above)

Inspection of designated wild cropping areas for which the operator is requesting certification or continuing certification.

Verification of species harvested.

Management, harvest and monitoring practices - protection of natural resources, rare species.

Training of harvesters.

4.6. Additional Inspection

Additional inspection may be needed to observe all production areas and practices:

If all the necessary information and/or documentation is not available for the inspector to review, or if certification is granted with a condition for additional inspection.

If more than one location is certified.

If production types require inspection at different times of the year. Crop/Livestock operations that also certify Maple production, for example, will require an inspection of Maple production in winter, and a separate inspection of Crop/Livestock production during the growing season.

To verify actions taken to correct noncompliance(s).

If the applicant cancels the scheduled inspection visit within one week of a scheduled inspection.

To assess compliance of changes and/or additions to the Organic System Plan.

The applicant will be billed for the actual costs of additional inspection(s) including additional review fees. Refer to Section 5.2.3 for fees.

4.7. Unannounced Inspection

A minimum of 5% of certified operations will have unannounced inspections each year. Operation to be inspected can be risk based or randomly selected by the certification office. Unannounced inspections may be conducted on an entire operation or be limited in scope with pre-determined areas for review and observation.

The Inspector will complete an Inspection Report and Exit Interview form for the applicable certification category if inspection of the entire operation is conducted. For inspections of limited scope, the Inspector will complete the Unannounced Inspection Report and the Exit Interview form.

The operation is not charged fees for unannounced inspection unless otherwise notified. Reasons for NOFA-NY charging a producer may include, but are not limited to: inspection identified areas of noncompliance; verification of corrective actions; observations of specific production stages such as planting, weeding, harvesting, cleaning,
packaging, etc.; a history of previous noncompliances; complaint or other investigation; or other reasons deemed appropriate by NOFA-NY.

4.8. Inspection Audit Procedures

Audit trail review is essential to the inspection process to ensure organic integrity and prevent fraud such as substituting ingredients and selling conventional products as organic.

The NOP Program Handbook Guidance 2601 states the inspection includes, but is not limited to: Reconciliation of the volume of organic products produced or received with the amount of organic products shipped, handled and/or sold, also known as trace-back audits or in-out balances

- **Audit Trail/Trace-back** – Documentation that demonstrates that a single organic product or organic finished product with ingredients sold can be traced back to an organic supplier or field harvest/seed purchase.

- **In/Out or Mass Balance** – A process of totaling the production capacity during a period of time and the total sales during same period including changes to beginning and ending inventories.
  
  Formula examples:
  
  a) Beginning inventory + Purchases – Ending inventory = Quantity available for planting or production
  
  b) Beginning inventory + Quantity harvested – Quantity used for seed/loss – Ending inventory = Quantity available for sale
  
  c) Beginning inventory + Production or Purchases – Ending inventory = Quantity available for sale

Operations applying for initial certification as well as operations continuing certification must make their records available for the inspector to review. Inspectors are required to review the entire record keeping system.

If the records necessary to complete the review are not available, or the audit review identifies areas of noncompliance, Compliance Notification Procedures will be initiated. An additional inspection visit may be necessary to verify correction of a noncompliance of this type.

Since operations applying for initial certification have not yet had organic sales for review, the inspector must review the proposed system and determine if it is adequate.

4.8.1. Crop

4.8.1.1. Audit Trail/Trace-back

Inspectors are required to verify if the record keeping system provides the information necessary to determine where organic product was grown/originated.

4.8.1.2. In/Out or Mass Balance

Production yields, available certified acreage, sales; and seed, seedling or transplant balances are compared to verify whether the certified acreage could yield the amount of organic product sold, based on regional averages maintained by government extension agents, input suppliers, crop advisors, buyers, crop insurance providers, other producers, and inspectors who have inspected similar crops in the region.

Discrepancies between the yield, available certified acreage and sales need to be clarified at the time of inspection. The operator should clarify whether crops from additional fields were included in the total harvest, whether certified crops were bought in and resold, etc.

4.8.2. Livestock Operation

4.8.2.1. Audit Trail/Trace-back

Audit trail review will be conducted on the crop portion of a livestock operation, as described in above Crop Operation. In addition, review of livestock records will be conducted, including purchase and sale of
animals and certified feed, herd health, animal tracking/identification, egg collection, milk pick-up and quality reports, pasture and outdoor access.

4.8.2. In/Out or Mass Balance
Herd size and production levels are compared to determine if production matches level of available feed, pasturing practices, etc.

4.8.3. Handling Operation

4.8.3.1. Audit Trail/Trace-back
A review of audit trail documentation is required to verify the flow of products and production, the record keeping system traces finished products back to the ingredient source(s), and that the formulation used is as described in the OSP. Inspectors do not perform a review of the audit trail based upon a lot number selected by the applicant. The Inspector will select a finished product lot number and will request all production records including formulation, processing, sales, outgoing bills of lading, warehouse, production reports, ingredient inventory, receiving logs, incoming bills of lading, ingredient purchase and organic verification documents including import records when applicable. Copies of audit trail documents will be included with the inspection report if any deficiencies are found.

Minor deficiencies in the audit trail system will be identified and included in the inspection report, as well as a description of changes the operator indicates they intend to make to correct those deficiencies.

4.8.3.2. In/Out or Mass Balance
Production records for a specified time period will be reviewed and compared to verify that sufficient quantities of ingredients have been purchased to produce the quantity of finished product produced and/or sold. Records may include weights and origin of incoming ingredients, production records, beginning and ending inventories, ingredients in storage, product in process, finished products in storage, sales/shipping records including imports when applicable.

Discrepancies in the In/Out Balancing Audit will be noted in the inspection report.

4.8.4. Wild Crop
Records related to species and amounts harvested will be reviewed to verify practices are as described in the OSP and are sustainable. Audit Trail/Trace-back & In/out or Mass Balance should be performed as applicable.

4.9. Collecting Analytical Samples during an Inspection
Samples of soil, crops, ingredients, and finished products may be collected for testing. Sample collection will follow standardized protocols. Samples must be properly collected, handled, stored, and transported. Sample Collection Logs and Chain of Custody forms are used to document collection, handling, storage, and transport activities. Analytical test results may be used in a court of law. Improper collection and handling of samples invalidates test results.

Inspectors collecting samples must be trained in proper sample collection techniques and procedures. The specific sampling techniques and procedures used are dependent upon the requirements for the type of testing to be conducted.

5. Fees and Financial Policies and Procedures
Funding for the operation of NOFA-NY Certified Organic LLC is obtained from fees paid by clients for certification services.

5.1. Certification Fees
Fees are established annually by the Management Committee. If payment is not received by the due date, Compliance Procedures will be initiated, late notices will be issued, and an additional billing fee assessed.
If a written request with supporting documentation for any deviation from the existing fee structure is submitted with an Annual Update application, it will be forwarded to the Management Committee for review. Decisions related to such requests will be made by the Management Committee within 90 days.

5.1.1. Certification Application Packet Fee
The Certification Application Packet includes: the USDA National Organic Program Regulations, NOFA-NY Certified Organic, LLC Guidance and Policy Manuals, the application paperwork with associated forms necessary for a complete Organic System Plan, and the Fee Determination Form. The NOP Regulations and Certification Manuals may also be purchased in hard copy form without application paperwork. Fees are:

- Certification Application Packet: $50.00
- NOP Regulations/LLC Guidance/Policy Manuals: $20.00

Electronic versions are available free of charge via email and on our website [www.nofany.org](http://www.nofany.org).

5.1.2. New Applicant Fees
An additional one-time new applicant fee of $75.00 is also required. An existing producer adding a location does not pay a new applicant fee.

5.1.3. Early Bird Discount - $50.00 or $25.00
To be eligible for an Early Bird discount, a complete annual update application with full payment of certification fees must be postmarked or emailed by the applicable early bird deadlines specified on the Fee Determination Form. Checks post-dated after deadline do not qualify for this discount.

5.1.4. Late Application Fees
For the Certification Program to run efficiently, applications for initial and continuing certification must be submitted by the due dates established for each certification category.

Initial Certification – Applications may be submitted throughout the year. No late application fee applies. Refer to Section 2.4.3 for submittal recommendation date to qualify for Cost Share Reimbursement.

Continuing Certification - Annual Update applications submitted after the due date established in the application packet will be charged a late fee of $150.00 plus $75.00 late payment fee. This fee does not qualify for Cost Share Reimbursement.

5.1.5. Split Payment Option
At least one-half of the certification fee must be submitted with the application for initial or continuing certification. The remaining balance must be paid by August 1st of each year. NOFA-NY Certified Organic Office Manager has the right to approve additional payment plan installment agreements. As outlined in Section 5.8 a Payment Plan Installment Fee of $10.00 per installment payment will be applied for any operation electing to pay certification fees in installments over and above split payment.

The Certification Program reserves the right to deny the Split Payment Option to operations with a poor payment history for two or more years. Applications received from operations with poor payment history will not be processed until the full fee is received and cleared. Poor payment history includes failure to pay any required fees by the applicable due date, and/or having checks returned unpaid. The option of split payment is not available after July 1st.

If any portion of the annual certification fee remains unpaid after August 1, a notice of noncompliance will be issued and an additional billing fee will be assessed. If the fee is not paid to correct the noncompliance, a Notice of Proposed Suspension or Denial of Certification will be issued.
5.1.6. **Certification Fees: Crop, Livestock, Wild Crop Operations**

Fees are set on a sliding scale, based upon the gross organic sales from certifiable fields, sugar bushes, livestock, wild harvest and handling facilities of the operation as noted below. The operator selects the category on the Certification Fee Determination form that is an accurate representation of their gross organic sales. Certification Fees are capped at $10,000 excluding additional fees.

Fees for initial certification are based upon the first year’s projected gross organic sales. Fees for continuing certification are based upon the previous year’s actual gross organic sales.

Sales documentation must satisfy the NOFA-NY Certified Organic, LLC and inspector and all such information will be kept confidential. Operations that cannot provide adequate documentation to support their claimed gross sales figure will be assessed an annual fee based on a gross sales figure determined by NOFA-NY.

### Annual Certification Fee Chart

<table>
<thead>
<tr>
<th>Gross Organic Sales</th>
<th>Certification Fee</th>
<th>Adding Handling (On/Off Farm processing)*</th>
</tr>
</thead>
<tbody>
<tr>
<td>From $0</td>
<td>To $15,000</td>
<td>Crop $625</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Crop &amp; Livestock $650</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Adding Handling (On/Off Farm processing)*</td>
</tr>
<tr>
<td>$15,001</td>
<td>$25,000</td>
<td>$675</td>
</tr>
<tr>
<td></td>
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</tr>
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<td>$4,200</td>
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<tr>
<td></td>
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<td>+$0</td>
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</tbody>
</table>
*Handling scope inspection fees may be billed to the applicant if higher costs incurred due to complexity.

Additional fees will be assessed for changes or additions to certification as outlined in Section 5.8.

5.1.6.1. **Transitioning Monitoring Fees – Land**

Transition Monitoring Fee $100.00 per year in transition.

Inspection Deposit $300.00 per year in transition.

If the actual cost of inspection exceeds the deposit, the operation will be billed the difference. If the actual inspection cost is less than the deposit, the difference will be refunded to the operation.

5.1.6.2. **Transition Monitoring Fees – Dairy**

$100.00 flat fee in addition to applicable Certification or Transition Monitoring fee for land.

If the operation’s land appears to be eligible for certification, the operation will pay the certification fee plus the Transition Monitoring fee.

If the operation’s land is in its third year of transition, the operation will pay the fee for Transition Monitoring for Land plus the Dairy Transition Monitoring fee.

Actual cost of additional inspection if necessary prior to end of transition.

5.1.7. **Certification Fees: Handling Operations**

Handling Operations are required to submit a **Base Certification Fee, Inspection Fee Deposit, and Sales Assessment Fee** with their application for initial or continuing certification. Sales documentation must satisfy the NOFA-NY Certified Organic, LLC and inspector and all such information will be kept confidential. Operations that cannot provide adequate documentation to support their claimed gross sales figure will be assessed an annual fee based on a gross sales figure determined by NOFA-NY.

Fees for handling operations are calculated as follows:

- Certification base fee of $300.00.
- Minimum Inspection deposit of $350.00 or you may elect to pay a deposit for the average inspection cost of $600.00.
- If the actual cost of inspection exceeds the deposit, the operation will be billed the difference. If the actual inspection cost is less than the deposit, the difference will be refunded to the operation.
- Sales Assessment: (Minimum Assessment allowed is $200.00 and Maximum amount is $12,000.00).
- **Initial Certification** – Calculation of ½ of 1% (0.005) of estimated gross organic sales from certificate date to end of current calendar year. Average time from receipt of completed application to certificate issuance is approximately 3 months.
- **Continuing Certification (renewal)** – Calculation of ½ of 1% (0.005) of last calendar year (Jan-Dec) gross organic sales of products and/or services.

Livestock Auction Barns are exempt from paying a sales assessment fee.

Distribution Operations will not pay the Sales Assessment of ½ of 1% (.005) of prior year’s gross organic sales. Instead they will pay per the following chart based on the number of organic skus being certified.
Crop and Livestock Scope Fee add on: Base fee of $250.00 (crop) or $300.00 (crop + livestock) plus added inspection fees is applicable.

Grass Fed handling operations certified to the Organic Plus Trust Grass Fed Organic Livestock Program (OPT) will include their organic grass fed gross organic sales as part of the sales assessment. Distributors will include in the number of SKUs.

Additional fees will be assessed for changes or additions to certification as outlined in Section 5.8.

### 5.2. Inspection Fees

#### 5.2.1. Crop, Livestock and Wild Crop Operations
Annual certification fees listed in Section 5.1.6 include the cost of one inspection visit*. The operation will be billed for the actual cost of any additional or unannounced inspections as applicable, including inspection cancellations as outlined in Section 4.4 & 5.2.5 of this manual. Additional inspection is required for Crop, Dairy or Livestock operations adding maple production. Operations with additional location(s) may also incur an additional inspection cost. *Additional fees for handling/processing may be incurred based on complexity.

#### 5.2.2. Handling Operations
The actual cost of inspection is billed to the operation, based on complexity of the operation and length of the inspection, and includes inspector travel, lodging and office expenses incurred. Inspection deposit will be deducted from actual cost of inspection and balance or credit will be billed once inspection has occurred.

#### 5.2.3. Additional Inspection/Review Fees
An additional inspection fee will be charged for any applicant who requires additional work by the Certification Review Staff or Certification Inspector. Conditions that may require an additional fee are as follows: a repeat inspection to gather new information or to inspect another part of the operation; an additional audit trail review of a farm or processing application; out of state travel; additional location or field 30 or more minutes from main operation; or inspection of a farmer/processor whose facilities are in different locations.

The minimum fees are:
- Additional Inspection: $150.00-$190.00 range (pending inspector fees billed) plus $25.00/hr. travel plus mileage (at current federal rate).
- Additional Review by Certification Staff: $65.00/hr.

#### 5.2.4. Unannounced Inspection Fees
The applicant will be billed for all direct costs for unannounced inspections related to compliance actions or investigations of complaints that results in a noncompliance, including those needed to verify compliance when considering reinstatement of a certification that has been suspended.
5.2.5. Inspection Cancellation
On-site inspection cancelled six (6) days or less from scheduled date will result in producer being billed for actual cost of cancelled inspection. Additionally, a producer not present at time of inspection that results in a cancellation will be responsible for actual cost of cancelled inspection.

5.3. Grass Fed Certification Fee
NOFA-NY currently offers an optional additional certification that is open to all ruminant livestock operations and handlers of ruminant livestock products who are currently certified organic by NOFA-NY Certified Organic, LLC.
- NOFA-NY 100% Grass Fed Certification: $100.00 per year (plus additional inspection if not included with annual inspection). This is an internal program developed by NOFA-NY Certified Organic.
- Organic Plus Trust Grass Fed Organic Livestock Program (OPT): $275.00 per year, with possible $30.00 fee for extra Grass Fed transitions as determined by NOFA-NY. Grass Fed certification required by some milk companies. NOFA-NY Certified Organic is accredited to this program.

5.4. Refund Policy - Certification or Transition Monitoring
An operation that has been denied certification or transition, or has submitted a written request (prior to on-site inspection, to either withdraw their application for, or surrender certification) will receive a refund of 50% of certification fees prior to inspection. Once inspection has occurred no refund will be allowed.
See Section 2.7 of this manual for withdrawal procedures and requirements.

5.5. Unpaid Fees
NOFA-NY Certified Organic LLC will make every effort to work with operations to set up a payment plan for past due certification fees.

Non-payment of certification fees, inspection fees, or handler sales assessment fees will result in initiation of Compliance Notification Procedures defined in Section 7.2.

Independent collection agencies may be utilized to obtain the past due certification and inspection fees.

5.6. Complaint, Investigation & Adverse Action Fee
Applicants and certified operations are responsible for reimbursing NOFA-NY for all costs incurred by NOFA-NY as a result of adverse actions, investigations, and legal issues involving the applicant or certified operation. Adverse actions may include but are not limited to: actions described in Section 7.2, including sanctions, adverse actions, complaints, appeals, mediation, litigation, or enforcement actions.

The costs that the applicant or certified producer must reimburse include but are not limited to: the costs of conducting mediation, investigations, conducting additional inspections, conducting discovery, and responding to subpoenas or other discovery requests. Costs are billed at $65.00/hour. NOFA-NY does not bill for pesticide residue testing.

When a formal mediation is necessary to resolve a non-administrative proposed adverse action, the cost of mediation will be split between NOFA-NY and the operation. However, if NOFA-NY prevails in a mediation, dispute, proceeding, or other contested action against the applicant or certified operation, the applicant, certified operation is responsible for paying all costs incurred by NOFA-NY including NOFA-NY reasonable attorneys' fees, expenses and costs.

5.7. Fees for Public Access to Information
The National Organic Program requires that specific information be made available to the public regarding the operations we certify. A current listing of our certified operations is available on the National Organic Program Organic Integrity Database website https://apps.ams.usda.gov/integrity/. A fee will be charged for previous lists of certified operations and other public information requested, based on the office time necessary to retrieve and copy the information from our files.
5.8. Additional Fees

The annual certification fee includes the Initial Review and Final Review of the application for initial or continuing certification. Review of changes or additions to certification, and other services that require additional staff time outside the annual process are billed separately at the Administrative Fee rate below.

Changes and additions to certification requiring inspection that are received after the Initial Review has been completed, but allow sufficient time to be evaluated and included in the annual inspection, will not be assessed additional inspection fees.

*An asterisk before additional fee titles below indicates fees that are not part of the cost share reimbursement program.

Expedited Application: $1,000.00 additional fee for top priority application processing. Locations outside of New York State may also incur added inspection fees. Continuing applicants adding a new scope or production type to an existing certification may be eligible for discounted expedited service. Contact the office for details.

- Expedited Service is only available at the discretion of the certification office, based on staff and inspector availability and current workload within the certification office at the time of the request.
- Typical certification decision is received within 30 days of receipt of completed application. This service does not mean a certification decision will be favorable.
- A completed Expedited Service Request form signed by the operator must be submitted with payment of the base fee.

*Incomplete Application: $35.00 fee will be charged for incomplete application received. Special allowances will be made for first time applications.

*Late Payment Fee: $75.00 will be charged for payment fees postmarked or submitted electronically after due date.

*Payment Plan Installment Fee: $10.00 per installment payment covering additional administration cost for operations electing to pay certification fees in installment. Not applicable to split payment option.

*No Response Fee: $30.00 will be charged for failure to respond to request by deadline (E.g. failure to respond to determination letters by due date).

*Reinstatement Request Fee: $200.00 Administrative fee will be assessed to process requests for reinstatement of a suspended operation, plus any other additional fees applicable based on the timing and nature of the suspension (E.g., annual certification fees, additional inspection fees). Producer will also be responsible for any past due balance from prior certification periods.

Certification Extension Fee: Monthly fee prorated from prior year certification fees for applications not submitted or surrendered within 30 days of application due date. Charges will continue to be incurred until an application or a written notice of surrender is received. Surrender of certification must occur no later than September 1.

Handling Scope Fee: $50.00 per year for Crop and/or Livestock operations who are seeking or have a handling scope certification. Additional fees for handling/processing may be incurred based on complexity.

Administrative fee: $65.00/hour (15 minute minimum = $12.50) for any service not otherwise specified.

Changes & Additions:

- Additional Inspection Fee: $150.00-$190.00 range plus $25.00/hour travel & Mileage
- Additional Review Fee (outside of annual review cycle): $65.00/hour – review of new fields, animals, new recipes, process, labels, certificate, final review rushed within two weeks of receiving file from inspector, etc.

- Additional Review Fee (materials): $50.00/hour (15 minute minimum = $12.50)

*Copies: $0.15 per page plus postage charge will be incurred for copies of application forms and/or inspection paperwork.
*Returned Check:* $25.00 plus bank fee for each time a check is returned as unpaid, for any reason. A returned check will disqualify operation from receiving any discounts such as early bird.

**NOP Import Certificates/Certificates of Inspection** *(for export through international equivalencies):* $50.00 each plus shipping charges, provide carrier/account info for billing as applicable.

*NOFA-NY Certified Organic, LLC Certification Director reserves the right to waive any fee due to an extenuating circumstance.*

6. **Rights, Responsibilities and Obligations**

6.1. **Certified Operations**

6.1.1. **Complying with Certification Requirements**
Organic certification is a voluntary third party verification process. By requesting initial or continuing certification, operators are agreeing to comply with all requirements of the NOP Regulations. Operators must sign the Applicant Affirmation statement of agreement contained in the certification application.

6.1.2. **Make Available all Necessary Components for Evaluation**
Access to all documentation and production areas, personnel for evaluation is required.

6.1.3. **Make Appropriate Certification Claims**
Certification claims must accurately reflect the approved category and production for which organic certification has been granted.

6.1.4. **Protect the Certifier from Disrepute**
Certification must be used in a manner that does not harm NOFA-NY Certified Organic, LLC and does not make unauthorized or misleading certification claims.

6.1.5. **Discontinue use of Certification Claims**
Use of certification claims must be immediately discontinued upon surrender, suspension or revocation of certification and any certification documents required by NOFA-NY Certified Organic LLC must be returned.

6.1.6. **Limit the Certification Claim**
Certified organic products must only be represented as certified in compliance with the NOP Regulations.

6.1.7. **Protect the Use of the Certification Claim**
Operations must make every effort to ensure that the certificate and/or inspection report is not used in a misleading manner, such as representing non-certified products or services as certified.

6.1.8. **Use the Certification Claim Correctly in Advertising and Marketing, including labels and seals**
To avoid mislabeling or cross labeling of products, and/or to avoid consumer confusion, certified operations must:

- Use the terms “100% Organic”, "organic" or “Made with organic [specified ingredients or food group(s)]” only on products produced in accordance with the USDA NOP Regulations.
- Display the USDA Seal only on products produced in accordance with requirements for the “100% Organic” or “Organic” category. The USDA seal must not be displayed on products in the “Made with Organic [specified ingredients or food group(s)]”
Display the statement: Certified Organic by: NOFA-NY Certified Organic LLC or similar phrase on labels that identify “100% Organic”, “Organic” or “Made with organic [specified ingredients or food group(s)]”
Submit all printed material (labels, brochures, advertising materials, etc.,) to the certification office for approval prior to use.
When marketing both certified organic and non-certified products for sale:
Maintain distinct separation between the certified and non-certified products.
Display signage in sufficient size and prominence to distinguish Certified crops from noncertified.
Clearly label individual bins, shelves, display areas, pick-your-own fields, etc.

6.1.9. Use the NOFA-NY Certified Organic, LLC Logo appropriately
The NOFA-NY Certified Organic, LLC logo/seal is optional; when used it should be displayed in black & white or color as provided. Prior approval from the certification office is required.

6.2. NOFA-NY Certified Organic LLC

6.2.1. Public Access to Information
The following information is available to the general public:
A list of operations certified by our agency during the current and 3 preceding years, including the name, type of operation (certification category), products produced and effective date of certification is available to the public for purchase in printed form. The current list is also free of charge on the National Organic Program Organic Integrity Database website.
A copy of a client's Certification Certificate issued during the current and 3 preceding years
The results of laboratory analyses for residues of pesticides and other prohibited substances conducted during the current and 3 preceding calendar years
Other business information, as permitted in writing by the producer or handler
Any other information must be requested directly from the operation. Upon their request, all client records are available to authorized representatives of the USDA Secretary or the State Organic program for review and copying during normal business hours.

6.2.2. Confidential Business Information
NOFA-NY Certified Organic LLC will maintain strict confidentiality with respect to its clients and not disclose to third parties, except as noted above, any business related information concerning the client obtained while conducting the certification process.

6.2.3. Change in Certification Status
To protect use of the NOFA-NY Certified Organic, LLC name and logo, a change in the certification status of an operation will be posted on the NOFA-NY website.

6.2.4. Notification of Changes

6.2.4.1. NOP Regulations
Certified operations will be sent a copy of changes in Regulations or guidance related to operators when published by the National Organic Program.

6.2.4.2. NOFA-NY Certified Organic, LLC Policy
NOFA-NY policy changes that are effective on January 1, applicable to a new certification year will be included with annual update applications or sent around the first of the year. Mid-year changes will be sent to all certified operations upon approval.

6.3. Certified Operations & NOFA-NY Certified Organic LLC

6.3.1. Code of Conduct

NOFA-NY Certified Organic, LLC seeks to continually maintain a work environment which ensures trust and respect for all producers, inspectors, NOFA staff and guests. In order to maintain our longstanding reputation in the community, we have established this Code of Conduct Policy to specify our expectations. All of these are important to our organization and to our producers’ success and must be adhered to, respected and honored by all.

The following is a list of behaviors that will not be tolerated:
- physically harming others
- verbally abusing others
- using profanity
- using intimidation tactics and/or making threats
- making malicious or harmful statements about others
- publicly disclosing another’s private information
- sexual or unwelcome harassment
- possession of dangerous or unauthorized material such as explosives or firearms

All NOFA producers, inspectors & staff members are responsible for adhering to the above code of conduct by showing mutual respect at all times.

7. Compliance: Noncompliance, Suspension, Revocation & Denial of Certification

As a certification agency accredited by the USDA National Organic Program, we must ensure that the operations we certify comply with NOP Regulations, and we take action accordingly if they do not comply. Noncompliance procedures outlined in the NOP Regulations will be followed.

7.1. Types of Sanctions

As the type and severity of noncompliance issues can range from violations of administrative requirements to fraud in organic production and marketing, the appropriate sanctions also vary. Administrative requirements include submission of annual update paperwork, payment of fees, and submission of any information requested by the certification office.

Denial of Certification is applicable only to operations requesting initial certification of an operation or part of an operation. Suspension or revocation is applicable only to continuing certified operations.

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 USDA AMS Administrator.

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.

7.2. Noncompliance Procedures

Operations that make false statements or knowingly sell or label a product as organic, except in accordance with the regulations, may be subject to legal action and/or civil penalties levied by the USDA.
7.2.1. **Notification of Noncompliance (§205.662)**
When an inspection, review, or investigation of an operation requesting initial or continuing certification reveals any noncompliance with the NOP Regulations a written notification of noncompliance shall be sent to the applicant/certified operation. Such notification shall provide:

- A description of each noncompliance
- The facts upon which the notification of noncompliance is based; and
- The date by which the applicant/certified operation must rebut or correct each noncompliance and submit supporting documentation of each such correction when correction is possible.

7.2.1.1. **Response from Operation**
Upon receipt of notification of noncompliance, the operation may:

- Correct non-compliances and submit a description of the corrective actions taken with supporting documentation to the certification office.
- Correct non-compliances 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
- Submit written information to rebut the noncompliance described in the notification of noncompliance.

Failure to response by due date stated will result in a no response fee. Refer to Section 5.8.

7.2.2. **Resolution of Non-Compliance (§205.662(b))**
Upon receipt of an operation's response to a Notification of Noncompliance, NOFA-NY Certified Organic LLC will:

- Evaluate the operation's corrective actions and supporting documentation submitted, evaluate the written rebuttal, conduct an on-site inspection if necessary, and
- When the corrective action or rebuttal is sufficient for the applicant to qualify for certification, issue the applicant a Notice of Resolved Noncompliance and approval of certification.

7.2.3. **Proposed Suspension or Revocation of Certification (§205.662(c))**
When rebuttal is unsuccessful or correction of the noncompliance is not sufficient for the applicant to qualify for certification, or corrective actions have not been submitted within the prescribed time period, the Certification Office shall issue a written Notification of Proposed Suspension or Revocation. The proposed suspension or revocation of certification shall apply to either 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:

- The reasons for the proposed suspension or revocation;
- The facts upon which the Notice (of Proposed Suspension or Proposed Revocation) is based and the relevant sections of the regulation, 7CFR Part 205 that are in violation
- The proposed effective date of such suspension or revocation;
- The impact of a suspension or revocation on future eligibility for certification;
- The proposed length of the suspension
The right to request mediation pursuant to Section §205.663 or to file an appeal according to Section §205.681.

7.2.4. Willful Violations (§205.662(d))
If the certification office has reason to believe that a certified operation has willfully violated the NOP Regulations, the certified operation will be sent a Notification of Proposed Suspension or Revocation of certification for the entire operation or a portion of the operation, as applicable to the noncompliance.

7.2.5. Suspension or Revocation of Certification (§205.662(e))
If the certified operation fails to correct the noncompliance, resolve the issue through rebuttal or mediation, or file an appeal of the proposed suspension or revocation of certification, NOFA-NY Certified Organic LLC shall send the certified operation a written Notification of Suspension or Revocation of certification for all or a part of the operation.

NOFA-NY Certified Organic LLC shall 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 of the NOP Regulations for the disputed non-compliance, while final resolution of either process is pending. However, a Notification of Suspension or Revocation of certification may be issued for a separate noncompliance.

Certification is not reinstated automatically once an operation has been suspended for the timeframe specified in the Notice of Suspension. Reinstatement must be requested by the operation.

7.2.6. Reinstatement of Suspended Operation
Once an operation’s certification has been suspended, only the NOP has the authority to approve its reinstatement. Certifiers may not approve or deny certification of a suspended operation without the NOP’s written approval. Suspended operations must complete a new application for certification with a certifier before requesting reinstatement in order to demonstrate compliance with the regulations.

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 for reinstatement of its certification. A written request must be submitted with 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. To be eligible for reinstatement, a suspended operation must have no outstanding noncompliances. The NOP will evaluate all documentation submitted and issue notification of approval or denial of the request.

7.2.6.1. Suspended Operation Request
The following steps are required for reinstatement consideration. The suspended operation must:

Correct all areas of noncompliance and submit complete evidence of the corrective actions to the certifying agency for review and evaluation.

Ensure their OSP is complete, in compliance and implemented as described.

Contact a certifier and submit a new application for certification. If the new certifier is different from the certifier that issued the suspension, the operator must inform the new certifier of its suspended status and the reasons for the suspension.

Pay all required certification fees.

Undergo successful inspection of their operation which verifies compliance with all areas of the NOP Regulations.
Submit a written request for reinstatement to the Secretary of Agriculture, care of the NOP requested certification reinstatement. Send the letter through the certifying agent, or directly to the NOP at: USDA, AMS, National Organic Program 1400 Independence Avenue, SW Room 2648, Stop 0268 Washington, DC 20250 or via email to AlfInBox@ams.usda.gov.

Retain copies of all documentation for future audit by the certifying agent and NOP.

7.2.6.2. Certifying Agent Evaluation and Recommendation

Upon receipt of corrective actions, complete OSP, and payment of required certification fees, NOFA-NY Certified Organic LLC will:

Evaluate the OSP and corrective actions whether or not the operation is compliant.

Notify the operation of any noncompliances according to 7 C.F.R. § 205.662(a). (Any noncompliances discovered after suspension as well as any remaining noncompliances that led to the operation's suspension must be addressed.)

Schedule a full onsite inspection to verify the operation's compliance with the regulations, provided that the NOP is deemed to comply. Onsite inspections should occur within the three month period prior to the NOP receiving the reinstatement request. Deviations from this procedure are to be justified and approved by the NOP.

The inspection must include verification of whether (1) products were sold, labeled, or represented as organic during the suspension period, and (2) there is a system in place that will prevent comingling of noncompliant product produced or inventoried during the suspension period.

If the certifier finds evidence of a noncompliance during the application review or inspection process, then it should issue a Notice of Noncompliance to the operation. In order to be reinstated, the operation applying for reinstatement must demonstrate resolution of all noncompliances, including those that led to the suspension and any additional noncompliances identified during the reinstatement review and inspection.

7.2.6.3. NOP Evaluation of Reinstatement Request

Once the NOP receives a reinstatement request, it should complete the following steps within approximately 30 days, although reinstatement requests with evidence of noncompliance may take longer:

Review the request for reinstatement along with the supporting documentation and contact the certifier if questions remain regarding the request. If the operation was suspended for a specific period of time, then the NOP may deny the request for reinstatement without further review until the suspension period has ended. If the certifier recommends reinstatement before completion of the suspension period, the certifier should explain to the NOP the rationale for doing so.

Approve the request if:

- All required documents have been submitted;
- The documentation clearly demonstrates the operation has corrected previously cited noncompliances, is in compliance with the regulations and is capable of remaining in compliance; and
- The review of the documentation does not find that the operation has an ongoing history of noncompliance indicating an inability or unwillingness to remain in compliance.

If the request is approved, the NOP will remove the operation from the public list of suspended operations. The NOP will issue a letter to the operation, with a copy to the certifier, stating that the NOP reinstates the organic certification of the operation, and all documents related to the reinstatement must be retained for future audit by the NOP.
If the request is denied, the NOP will issue a letter to the operation, with a copy to the certifier, stating the reasons for denying reinstatement.

7.2.7. Denial of Certification (§205.405)

When the corrective action or rebuttal submitted in response to Notification of Noncompliance is not sufficient for the applicant to qualify for certification, or a response has not been submitted by the due date specified in the Notification of Noncompliance, a written Notice of Denial of certification will be sent to the operation.

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.

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

- Reapply for certification either to NOFA-NY Certified Organic LLC or according to Section 7.2.1.1.
- Request mediation according to Section 8.
- File an appeal of the denial of certification According to Section 9, which parallels the NOP Regulations.

An operation applying for initial certification that 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. 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 Notification of Denial of certification and a description of the actions taken, with supporting documentation, to correct the non-compliances noted in the notification of noncompliance.

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.

Notwithstanding 7.2.4 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 without first issuing a notification of noncompliance.

7.2.8. Notification to Applicants/Certified Operations

Each notification of noncompliance, rejection of mediation, noncompliance resolution, proposed denial, suspension or revocation, and denial, suspension or revocation issued will be sent to the recipient’s place of business by USPS delivery confirmation or to recipient’s e-mail by Rpost so delivery can be tracked.

7.2.9. Notification of USDA AMS Administrator

NOFA-NY Certified Organic LLC will submit to the Administrator or the representative to whom authority has been delegated to act in the stead of the Administrator, a copy of any notice of denial of certification issued according to Section 6, notification of noncompliance, notification of noncompliance correction, notification of proposed suspension or revocation, and notification of suspension or revocation simultaneously with its issuance (as required by National Organic Program Standards §205.501(a)(15).

8. Mediation (§205.663)

All operations applying for initial or continuing certification who disagree with a certification decision may request mediation pursuant to the NOP Regulations.

The purpose of Mediation is to reach a Settlement Agreement with the operation that satisfies the interest of NOFA-NY Certified Organic LLC and the operation, and also conforming to OFPA and the NOP regulations. The process is confidential, quick/effective and voluntary with focus on preserving the relationship.
If mediation is accepted by NOFA-NY Certified Organic LLC, the mediation shall be conducted by a qualified mediator mutually agreed upon by the parties to the mediation. Mediation is not a legal proceeding or a determination of fault. It does not waive the other rights such as formal appeal.

8.1. Submitting a Request
Any dispute with respect to denial of certification or proposed suspension or revocation of certification may be mediated, at the request of the applicant for certification or certified operation, with acceptance by the certifying agent. Mediation shall be requested in writing to NOFA-NY Certified Organic LLC. Submission of documentation in response to adverse action may be accepted as a request for mediation if intent is clear. All requests for mediation will be evaluated by the certification office to determine if there is new information relevant to the original decision that could justify reconsideration.

8.2. Rejection of Request
If the certifying agent rejects the request for mediation, the certifying agent shall provide written notification to the applicant for certification or certified operation. 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.

8.3. Acceptance of Request
If the certifying agent accepts mediation, informal mediation or formal mediation with a qualified mediator mutually agreed upon by the parties, shall be conducted. 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.

Types of Mediation

Informal: NOFA-NY Certified Organic LLC Certification Staff may settle disputes informally with operations. No cost to operations for this type of mediation. Mediation can be as simple as offering a settlement agreement to the operator. The operator may accept or reject the settlement agreement, propose a counteroffer, or request a more formal mediation process. If an informal mediation process fails, NOFA-NY LLC has the right to reject a request for formal mediation.

- Typically addresses administrative issues and low level organic integrity issues
  Examples: Not submitting updated OSP by deadline, late payment of fees, and request for additional information from certifier not addressed by operation.

Formal: NOFA-NY Certified Organic LLC and operation will agree upon an outside Mediator including fees, time, location, and format (in-person or video). When a formal mediation is necessary to resolve a non-administrative proposed adverse action, the cost of mediation will be split between NOFA-NY and the operation. However, if NOFA-NY prevails in a mediation, dispute, proceeding, or other contested action against the applicant or certified operation, the applicant, certified operation is responsible for paying all costs incurred by NOFA-NY including NOFA-NY reasonable attorneys’ fees, expenses and costs.

- Typically addresses major organic integrity issues and repeat noncompliances for the same issue.

8.4. Agreement Period
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.

8.5. Compliance and Review
Any agreement reached during or as a result of the mediation process shall be in compliance with OFPA and NOP regulations. The Secretary may review any mediated agreement for conformity to OFPA and NOP regulations and may reject any agreement or provision not in conformance with OFPA or NOP regulations.
8.6. Settlement Agreement
The terms of any agreement must be mutually agreed upon, comply with the USDA organic regulations and include a timeframe by which any corrective actions will be completed. The Secretary may review any mediated agreement for conformity to the NOP and may reject any agreement or provision not in conformance with the OFPA or NOP regulations. NOFA-NY LLC may submit Settlement Agreement to NOP with request for review. The NOP will review Settlement Agreements during NOFA-NY LLC audit.

9. Appeal (§205.681 Appeals)

9.1. Submitting Appeal
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.

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.

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.

9.2. 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 non-appellable unless the decision is appealed in a timely manner.

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 or by some other medium that can be tracked.

9.3. Where and What to File
An applicant/certified operator may appeal a denial, proposed suspension or proposed revocation of certification by NOFA-NY Certified Organic LLC to the USDA Administrator, as specified in §205.681.

Appeals to the Administrator must be filed in writing and addressed to USDA-AMS-Administrator c/o NOP Appeals Team 1400 Independence Avenue SW Room 2642-South, STOP 0268 Washington, DC 20250-0268. An appeal may also be file to the NOP Appeals Team at NOPAppeals@ams.usda.gov.

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

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.

9.4. Public Notification of Change of Certification Status
Changes in the certification status of certified operations will be posted on the NOFA NY website only after any and all appeals have been concluded.
10. Complaint Policy and Procedures
Addressing complaints is an important component of operating a third party certification organization. Complaints or allegations against a NOFA-NY Certified Organic LLC certified operation for violations of the USDA National Organic Program that have been witnessed or evidence that producer is engaged in the application of a prohibited material, misleading or fraudulent labeling, commingling of conventional or organic products, or other violations of the standards, will be investigated in a timely manner.

Every NOFA-NY Certified Organic LLC producer has the right to a complete and fair investigation and review of complaint, as well as the right to appeal of a proposed suspension or revocation, or denial of certification.

While NOFA-NY Certified Organic LLC will make every effort (when requested) to keep complainant name confidential, NOFA-NY Certified Organic LLC cannot ensure that complainant identity would remain confidential in the event that NOFA-NY Certified Organic, LLC records were subpoenaed by a court of law or requested by subsequent county, state or federal investigators. Complainant is encouraged to fill out our Complaint Form to ensure accurate and complete documentation is received.

Complaints or criticisms regarding NOFA-NY Certified Organic, LLC or the certification program as a whole can be made to the USDA National Organic Program.

10.1. Complaints Procedures followed by NOFA-NY Certified Organic LLC
NOFA-NY Certified Organic LLC will investigate complaints of noncompliance with the NOP Regulations concerning production and handling operations certified as organic by us. Complaints related to the operations certified by our agency will be tracked through a computerized database, and copies of written complaints will be placed in the operation’s file.

Records related to complaints regarding the operation of the NOFA-NY Certified Organic LLC Certification Program will be maintained in a Complaint File. We will acknowledge receipt of the complaint and document the action taken and its effectiveness.

We must notify the USDA Administrator if any complaints identify a noncompliance of the NOP Regulations.

10.2. Complaints Procedures for Certified Operations
We recommend that certified operations address and maintain a record of all complaints they receive about their products' compliance with the NOP Standards, including:

- Responses to all complaints they receive about their products' compliance with the NOP Regulations.
- Documentation of actions taken to correct the cause of all complaints they receive about their products' compliance with the NOP Regulations.