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SUBCHAPTER M—ORGANIC FOODS PRODUCTION ACT PROVISIONS

PART 205—NATIONAL ORGANIC PROGRAM

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Subpart A—Definitions

§ 205.1 Meaning of words.

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

§ 205.2 Terms defined.

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

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

Action level. The limit at or above which the Food and Drug Administration will take legal action against a product to remove it from the market. Action levels are based on 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 Departure of Agriculture, or the representative to whom authority has been delegated to act in the stead of the Administrator.

Adverse action. A noncompliance decision that adversely affects certification, accreditation, or a person subject to the Act, including a proposed suspension or revocation; a denial of certification, accreditation, or reinstatement; a cease and desist notice; or a civil penalty.

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

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

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

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

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

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

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

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

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

Beak trimming. The removal of not more than one-quarter to one-third of the upper beak or the removal of one-quarter to one-third of both the upper and lower beaks of a bird in order to control injurious pecking and cannibalism.

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.

Caponization. Castration of chickens, turkeys, pheasants, and other avian species.

Cattle wattling. The surgical separation of two layers of the skin from the connective tissue along a 2-to-4-inch path on the dewlap, neck, or shoulders used for ownership identification.

Certification activity. Any business conducted by a certifying agent, or by a person acting on behalf of a certifying agent, including but not limited to: certification management; administration; application review; inspection planning; inspections; sampling; inspection report review; material review; label review; records retention; compliance review; investigating complaints and taking adverse actions; certification decisions; and issuing transaction certificates.

Certification office. Any site or facility where certification activities are conducted, except for certification activities that occur at certified operations or applicants for certification, such as inspections and sampling.

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.

Certification review. The act of reviewing and evaluating a certified operation or applicant for certification and determining compliance or ability to comply with the USDA organic regulations. This does not include performing an inspection.

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

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

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

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

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

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

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

Compost. The product of a managed process through which microorganisms break down plant and animal materials into more available forms suitable for application to the soil or as a component of mushroom substrate.

Conformity assessment system. All activities, including oversight, accreditation, compliance review, and enforcement, undertaken by a government to ensure that the applicable technical requirements for the production and handling of organic agricultural products are fully and consistently applied.

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, mushrooms, 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.

De-beaking. The removal of more than one-third of the upper beak or removal of more than one-third of both the upper and lower beaks of a bird.

De-snooding. The removal of the turkey snood (a fleshy protuberance on the forehead of male turkeys).

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.

Dubbing. The removal of poultry combs and wattles.

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, including but not limited to trading, facilitating sale or trade on behalf of a seller or oneself, importing to the United States, exporting for sale in the United States, combining, aggregating, culling, conditioning, treating, packing, containerizing, repackaging, labeling, storing, receiving, or loading.

Handler. Any person that handles agricultural products, except final retailers of agricultural products that do not process agricultural products.

Handling operation. Any operation that handles agricultural products, except final retailers of agricultural products that do not process agricultural 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.

Indoors or indoor space. The space inside of an enclosed building or housing structure available to livestock. Indoor space for avian species includes, but is not limited to:

(1) *Mobile housing*. A mobile structure for avian species with solid or perforated flooring that is moved regularly and allows birds to continuously access areas outside the structure during daytime hours.

(2) *Aviary housing*. A fixed structure for avian species that has multiple tiers or levels.

(3) *Slatted/mesh floor housing*. A fixed structure for avian species that has both: a slatted floor where perches,

feed, and water are provided over a pit or belt for manure collection; and litter covering the remaining solid floor.

(4) *Floor litter housing.* A fixed structure for avian species that has absorbent litter covering the entire floor.

Induced molting. Molting that is artificially initiated.

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.

Internal control system. An internal quality management system that establishes and governs the review, monitoring, training, and inspection of the producer group operation, and the procurement and distribution of shared production and handling inputs and resources, to maintain compliance with the USDA organic regulations.

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.

Mulesing. The removal of skin from the buttocks of sheep, approximately 2 to 4 inches wide and running away from the anus to the hock to prevent fly strike.

Mushroom. The fleshy, spore-bearing fruiting body of a fungus.

Mushroom mycelium. A mass of branching, thread-like hyphae (fungal structures).

Mushroom spawn. Mushroom spawn media colonized by mushroom mycelium that can be used to inoculate mushroom substrate.

Mushroom spawn media. The base material, such as grain, wood materials, or minerals, used to make mushroom spawn.

Mushroom substrate. The base material, such as grain, wood materials, composted materials, and/or other agricultural materials, on which mushroom production occurs.

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.

Non-ambulatory. As defined in 9 CFR 309.2(b).

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 exporter. The final certified exporter of the organic agricultural product, who facilitates the trade of, consigns, or arranges for the transport/shipping of the organic agricultural product from a foreign country to the United States.

Organic fraud. Deceptive representation, sale, or labeling of nonorganic agricultural products or ingredients as ''100 percent organic,'' ''organic,'' or ''made with organic (specified ingredients or food group(s)).''

Organic importer. The operation responsible for accepting imported organic agricultural products within the United States and ensuring NOP Import Certificate data are entered into the U.S. Customs and Border Protection import system of record.

Organic Integrity Database. The National Organic Program's electronic, web-based reporting tool for the submission of data, completion of certificates of organic operation, and other information, or the tool's successors.

Organic management. Management of a production or handling operation in compliance with all applicable provisions under 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.

Outdoors or outdoor space. Any area outside an enclosed building or enclosed housing structure. Enclosed housing structures with open sides (e.g., open-sided freestall barns) are not to be considered outdoors or outdoor space. Outdoor space for avian species includes, but is not limited to:

(1) Pasture pens (avian). Floorless pens, with full or partial roofing, that are moved regularly, provide direct access to soil and vegetation, and allow birds to express natural behaviors.

(2) Shade structures that are not enclosed.

Paper-based crop planting aid. A material that is comprised of at least 60% cellulose-based fiber by weight, including, but not limited to, pots, seed tape, and collars that are placed in or on the soil and later incorporated into the soil, excluding biodegradable mulch film. Up to 40% of the ingredients can be nonsynthetic, other permitted synthetic ingredients in §205.601(j), or synthetic strengthening fibers, adhesives, or resins. Contains no less than 80% biobased content as verified by a qualified third-party assessment (e.g., laboratory test using ASTM D6866 or composition review by qualified personnel).

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.

Perch. A rod- or branch-type structure above the floor or ground that accommodates roosting and allows birds to utilize vertical space.

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*).

Pet. Any domestic animal not used for the production and sale of food, fiber, or other agricultural-based consumer products.

Pet food. Any commercial feed prepared and distributed for pet consumption.

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.

Producer group member. An individual engaged in the activity of producing or harvesting agricultural products as a member of a producer group operation.

Producer group operation. A producer, organized as a person, consisting of producer group members and production units in geographic proximity governed by an internal control system under one organic system plan and certification.

Producer group production unit. A defined subgroup of producer group members in geographic proximity within a single producer group operation that use shared practices and resources to produce similar agricultural 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.

Pullets. Female chickens or other avian species being raised for egg production that have not yet started to lay eggs.

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.

Religious (or ritual) slaughter. Slaughtering in accordance with the ritual requirements of any religious faith that prescribes a method of slaughter whereby the animal suffers loss of consciousness by anemia of the brain caused by the simultaneous and instantaneous severance of the carotid arteries with a sharp instrument and handling in connection with such slaughtering.

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 establishment. Restaurants, delicatessens, bakeries, grocery stores, or any retail business with a restaurant, delicatessen, bakery, salad bar, bulk food self-service station, or other eat-in, carry-out, mail-order, or delivery service of raw or processed agricultural products.

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.

Stocking density. The liveweight or number of animals on a given area or unit of land.

Supply chain traceability audit. The process of identifying and tracking the movement, sale, custody, handling, and organic status of an agricultural product along a supply chain to verify the agricultural product's compliance with this part.

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.

Technical requirements. A system of relevant laws, regulations, regulatory practices, standards, policies, and procedures that address the certification, production, and handling of organic agricultural products.

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.

Third-year transitional crop. Crops and forage from land included in the organic system plan of a producer's operation that is not certified organic but is in the third year of organic management and is eligible for organic certification in one year or less.

Toe clipping. The removal of the nail and distal joint of the back two toes of a bird.

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

Transitioned animal. A dairy animal converted to organic milk production in accordance with §205.236(a)(2) that has not been under continuous organic management from the last third of gestation; offspring born to a transitioned animal that, during its last third of gestation, consumes third-year transitional crops; and offspring born during the one-time transition exception that themselves consume third-year transitional crops.

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

Unannounced inspection. The act of examining and evaluating all or a portion of the production or handling activities of a certified operation without advance notice to determine compliance with the Act and the regulations in this part.

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.

Vegetation. Living plant matter that is anchored in the soil by roots and provides ground cover.

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

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

[65 FR 80637, Dec. 21, 2000, as amended at 72 FR 70484, Dec. 12, 2007; 75 FR 7192, Feb. 17, 2010; 79 FR 58662, Sept. 30, 2014; 80 FR 6429, Feb. 5, 2015; 87 FR 19772, Apr. 5, 2022; 87 FR 68027, Nov. 14, 2022; 88 FR 3620, Jan. 19, 2023; 88 FR 75444, Nov. 2, 2023; 88 FR 86259, Dec. 13, 2023; 88 FR 89539, Dec. 28, 2023; 89 FR 104392, Dec. 23, 2024]

§ 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/.*

(1) ASTM D5988–12 (''ASTM D5988''), ''Standard Test Method for Determining Aerobic Biodegradation of Plastic Materials in Soil,'' approved May 1, 2012, IBR approved for § 205.2.

(2) ASTM D6400–12 (''ASTM D6400''), ''Standard Specification for Labeling of Plastics Designed to be Aerobically Composted in Municipal or Industrial Facilities,'' approved May 15, 2012, IBR approved for § 205.2.

(3) ASTM D6866–12 (''ASTM D6866''), ''Standard Test Methods for Determining the Biobased Content of Solid, Liquid, and Gaseous Samples Using Radiocarbon Analysis,'' approved April 1, 2012, IBR approved for § 205.2.

(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.*

(1) EN 13432:2000:E (''EN 13432''), September, 2000, ''Requirements for packaging recoverable through composting and biodegradation—Test scheme and evaluation criteria for the final acceptance of packaging,'' IBR approved for § 205.2.

(2) EN 14995:2006:E (''EN 14995''), December, 2006, ''Plastics—Evaluation of compostability—Test scheme and specifications,'' IBR approved for § 205.2.

(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.*

(1) ISO 17088:2012(E), (''ISO 17088''), ''Specifications for compostable plastics,'' June 1, 2012, IBR approved for § 205.2.

(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 the exempt operations described in § 205.101, each operation or portion of an operation that produces

or handles agricultural products 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 person or responsibly connected person 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.

[65 FR 80637, Dec. 21, 2000, as amended at 70 FR 29579, May 24, 2005; 80 FR 6429, Feb. 5, 2015; 88 FR 3621, Jan. 19, 2023]

§205.101 Exemptions from certification.

The following operations in paragraphs (a) through (h) of this section are 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, the applicable labeling requirements of subpart D of this part, and any requirements described in paragraphs (a) through (i) of this section.

(a) 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.

(b) A retail establishment that does not process organically produced agricultural products.

(c) A retail establishment that processes, at the point of final sale, agricultural products certified under this part as ''100 percent organic,'' ''organic,'' or ''made with organic (specified ingredients or food group(s)).''

(d) A handling operation that only handles agricultural products that contain less than 70 percent organic ingredients (as described in §205.301(d)) or that only identifies organic ingredients on the information panel.

(e) An operation that only receives, stores, and/or prepares for shipment, but does not otherwise handle, organic agricultural products that:

(1) Are enclosed in sealed, tamper-evident packages or containers prior to being received or acquired by the operation; and

(2) Remain in the same sealed, tamper-evident packages or containers and are not otherwise handled while in the control of the operation.

(f) An operation that only buys, sells, receives, stores, and/or prepares for shipment, but does not otherwise handle, organic agricultural products already labeled for retail sale that:

(1) Are enclosed in sealed, tamper-evident packages or containers that are labeled for retail sale prior to being received or acquired by the operation; and

(2) Remain in the same sealed, tamper-evident packages or containers that are labeled for retail sale and are not otherwise handled while in the control of the operation.

(g) A Customs broker (per 19 CFR 111.1) that only conducts customs business but does not otherwise handle organic agricultural products.

(h) An operation that only arranges for the shipping, storing, transport, or movement of organic agricultural products but does not otherwise handle organic products.

(i) Recordkeeping by exempt operations.

(1) Exempt operations described in paragraphs (a) and (c) through (f) of this section must make available to

representatives of the Secretary, upon request, records that:

(i) Demonstrate that agricultural products identified as organic were organically produced and handled; and

(ii) Verify quantities of organic agricultural products received and shipped or sold

(2) All records described in this section 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.

[88 FR 3621, Jan. 19, 2023]

§ 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; records must span the time of purchase or acquisition, through production, to sale or transport and be traceable back to the last certified operation;

(3) Include audit trail documentation for agricultural products handled or produced by the certified operation and identify agricultural products on these records as ''100% organic,'' ''organic,'' or ''made with organic (specified ingredients or food group(s)),'' or similar terms, as applicable;

(4) Be maintained for not less than 5 years beyond their creation; and

(5) 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.

[65 FR 80637, Dec. 21, 2000, as amended at 88 FR 3621, Jan. 19, 2023]

§ 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 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. This must include a description of the monitoring practices and procedures to verify suppliers in the supply chain and organic status of agricultural products received, and to prevent organic fraud, as appropriate to the certified operation's activities, scope, and complexity;

(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.

(c) In addition to paragraph (a) of this section, a producer group operation's organic system plan must describe its internal control system. The description of the internal control system must:

(1) Define the organizational structure, roles, and responsibilities of all personnel;

(2) Identify producer group production units and locations;

(3) Describe measures to protect against potential conflicts of interest and protect internal control system personnel from retribution;

(4) Define geographic proximity criteria for producer group members and producer group production units;

(5) Describe procedures for accepting new members into the producer group operation, including initial inspection and compliance determination;

(6) Describe characteristics of high-risk producer group members and producer group production units;

(7) Describe how shared resources, including production practices and inputs, are procured and provided to all producer group members and personnel;

(8) Describe how training, education, and technical assistance is provided to producer group members and internal control system personnel;

(9) Describe the system of records used to demonstrate compliance with this part, including traceability and mass-balance audits; and

(10) Describe how internal monitoring, surveillance, inspection, sanctions, and auditing are used to assess the compliance of all producer group members.

[65 FR 80637, Dec. 21, 2000, as amended at 88 FR 3622, Jan. 19, 2023]

§ 205.202 Land requirements.

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

(a) Have been managed in accordance with the provisions of §§ 205.203 through 205.206;

(b) Have had no prohibited substances, as listed in § 205.105, applied to it for a period of 3 years immediately preceding harvest of the crop; and

(c) Have distinct, defined boundaries and buffer zones such as runoff diversions to prevent the unintended application of a prohibited substance to the crop or contact with a prohibited substance applied to adjoining land that is not under organic management.

§ 205.203 Soil fertility and crop nutrient management practice standard.

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

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

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

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

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

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

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

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

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

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

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

(3) Uncomposted plant materials.

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

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

(2) A mined substance of low solubility;

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

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

(5) A plant or animal material that has been chemically altered by a manufacturing process: *Provided*, That, the material is included on the National List of synthetic substances allowed

for use in organic crop production established in § 205.601.

(e) The producer must not use:

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

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

§ 205.204 Seeds and planting stock practice standard.

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

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

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

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

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

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

(b) [Reserved]

§ 205.205 Crop rotation practice standard.

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

(a) Maintain or improve soil organic matter content;

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

(c) Manage deficient or excess plant nutrients; and

(d) Provide erosion control.

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

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

(1) Crop rotation and soil and crop nutrient management practices, as provided for in §§ 205.203 and 205.205;

(2) Sanitation measures to remove disease vectors, weed seeds, and habitat for pest organisms; and

(3) Cultural practices that enhance crop health, including selection of plant species and varieties with regard to suitability to site-specific conditions and resistance to prevalent pests, weeds, and diseases.

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

(1) Augmentation or introduction of predators or parasites of the pest species;

(2) Development of habitat for natural enemies of pests;

(3) Nonsynthetic controls such as lures, traps, and repellents.

(c) Weed problems may be controlled through:

(1) Mulching with fully biodegradable materials;

(2) Mowing;

(3) Livestock grazing;

(4) Hand weeding and mechanical cultivation;

(5) Flame, heat, or electrical means; or

(6) Plastic or other synthetic mulches: *Provided*, That, they are removed from the field at the end of the growing or harvest season.

(d) Disease problems may be controlled through:

(1) Management practices which suppress the spread of disease organisms; or

(2) Application of nonsynthetic biological, botanical, or mineral inputs.

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

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

§ 205.207 Wild-crop harvesting practice standard.

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

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

§§ 205.208–205.209 [Reserved]

§ 205.210 Mushroom production practice standard.

(a) The producer must manage mushroom production in accordance with the provisions of §§ 205.200, 205.201, 205.202 as applicable, 205.203(e), and 205.206(a)(2) and (3) and (b) through (f). The producer may manage crop nutrients for mushroom production in accordance with the provisions of § 205.203(d).

(b) The producer must manage mushroom substrate and mushroom spawn media, including spent mushroom substrate and mushroom spawn media, in a manner that does not contribute to contamination of crops, mushroom spawn, mushroom substrate, soil, or water by pathogenic organisms, heavy metals, or residues of prohibited substances.

(c) Mushroom substrate may be composed of the following materials in accordance with the conditions specified in this paragraph:

(1) *Composted plant and animal materials.* Compost used in mushroom substrate must be described in the organic system plan. It must be produced through a process that maintains a temperature of at least 131 °F for at least three days;

(2) *Uncomposted plant materials.* Uncomposted plant materials must be organically produced: *Except*, that, nonorganically produced uncomposted plant materials may be used when a functionally equivalent organically produced material is not commercially available. Prohibited substances must not be applied to nonorganically produced uncomposted plant materials after harvest. Operations that use nonorganically produced uncomposted plant materials in mushroom substrate (except for wood materials allowed under paragraph (c)(3) of this section) must describe in the organic system plan:

(i) The procedures used to search for organic materials and the records kept to document searches;

(ii) The criteria used to evaluate if functionally equivalent organic materials are commercially available; and

(iii) The recordkeeping system used to document purchases of nonorganic materials, including a summary of the type(s) and total amount of each nonorganic material used in mushroom substrate.

(3) Wood chips, sawdust, logs, or other materials derived from wood that have not been treated with a prohibited substance after harvest;

(4) Nonsynthetic substances, except those on the National List of nonsynthetic substances prohibited for use in organic crop production (§ 205.602); and

(5) Synthetic substances on the National List of synthetic substances allowed for use in organic crop production (§ 205.601).

(d) Mushroom spawn must be organic: *Except*, that, nonorganic mushroom spawn may be used to produce an organic crop when an equivalent organic mushroom spawn is not commercially available.

(1) Organic mushroom spawn requirements.

(i) Agricultural materials used as mushroom spawn media must be organic: *Except*, that, nonorganic wood materials in compliance with paragraph (c)(3) of this section are allowed.

(ii) Mushroom spawn media may contain materials allowed in mushroom substrate at paragraphs (c)(1), (4), and (5) of this section.

(iii) Organic mushroom spawn must be under continuous organic management after the mycelium is applied to the mushroom spawn media.

(2) Organic mushroom operations that produce their own mushroom spawn for their own organic mushroom production must use organic agricultural materials for mushroom spawn media, unless a functionally equivalent organic agricultural material is not commercially available: Except that, wood materials in compliance with paragraph (c)(3) of this section are allowed.

[89 FR 104392, Dec. 23, 2024]

§§ 205.211–205.235 [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*. Subject to the requirements of this paragraph, an operation that is not certified for organic livestock and that has never transitioned dairy animals may transition nonorganic animals to organic production only once. After the one-time transition is complete, the operation may not transition additional animals or source transitioned animals from other operations; the operation must source only animals that have been under continuous organic management from the last third of gestation.

Eligible operations converting to organic production by transitioning organic animals under this paragraph must meet the following requirements and conditions:

(i) Dairy animals must be under continuous organic management for a minimum of 12 months immediately prior to production of milk or milk products that are to be sold, labeled, or represented as organic. Only certified operations may represent or sell products as organic.

(ii) The operation must describe the transition as part of its organic system plan. The description must include the actual or expected start date of the minimum 12-month transition, individual identification of animals intended to complete transition, and any additional information or records deemed necessary by the certifying agent to determine compliance with the regulations. Transitioning animals are not considered organic until the operation is certified.

(iii) During the 12-month transition period, dairy animals and their offspring may consume third-year transitional crops from land included in the organic system plan of the operation transitioning the animals;

(iv) Offspring born during or after the 12-month transition period are transitioned animals if they consume third-year transitional crops during the transition or if the mother consumes third-year transitional crops during the offspring's last third of gestation;

(v) Consistent with the breeder stock provisions in paragraph (a)(3) of this section, offspring born from transitioning dairy animals are not considered to be transitioned animals if they are under continuous organic

management and if only certified organic crops and forages are fed from their last third of gestation (rather, they are considered to have been managed organically from the last third of gestation);

(vi) All dairy animals must end the transition at the same time;

(vii) Dairy animals that complete the transition and that are part of a certified operation are transitioned animals and must not be used for organic livestock products other than organic milk and milk products.

(3) *Breeder stock.* Livestock used as breeder stock may be brought from a nonorganic operation onto an organic operation at any time, *Provided,* That the following conditions are met:

(i) Such breeder stock must be brought onto the operation no later than the last third of gestation if their offspring are to be raised as organic livestock; and

(ii) Such breeder stock must be managed organically throughout the last third of gestation and the lactation period during which time they may nurse their own offspring.

(b) The following are prohibited:

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

(2) Breeder stock, dairy animals, or transitioned animals that have 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, including whether they are transitioned animals, and edible and nonedible animal products produced on the operation.

(d) A request for a variance to allow sourcing of transitioned animals between certified operations must adhere to the following:

(1) A variance from the requirement to source dairy animals that have been under continuous organic management from the last third of gestation, as stated in paragraph (a)(2) of this section, may be granted by the Administrator to certified operations that are small businesses, as determined in 13 CFR part 121, for any of the following reasons:

(i) The certified operation selling the transitioned animals is part of a bankruptcy proceeding or a forced sale; or

(ii) The certified operation has become insolvent, must liquidate its animals, and as a result has initiated a formal process to cease its operations; or

(iii) The certified operation wishes to conduct an intergenerational transfer of transitioned animals to an immediate family member.

(2) A certifying agent must request a variance on behalf of a certified operation, in writing, to the Administrator within ten days of receiving the request of variance from the operation. The variance request shall include documentation to demonstrate one or more of the circumstances listed in paragraph (d)(1) of this section.

(3) The Administrator will provide written notification to the certifying agent and to the operation(s) involved as to whether the variance is granted or rejected.

[87 FR 19772, Apr. 5, 2022]

§ 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 under this part, except as provided in § 205.236(a)(2)(iii) and (a)(3), 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; 87 FR 19773, Apr. 5, 2022]

§ 205.238 Livestock care and production practices standard.

(a) *Preventive health care practices.* The producer must establish and maintain preventive 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 of the animal, including vitamins, minerals, proteins 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) Physical alterations may be performed for identification purposes or the safety of the animal. Physical alterations must be performed: at a young age for the species, in a manner that minimizes stress and pain, and by

a person that is capable of performing the physical alteration in a manner that minimizes stress and pain.

(i) The following practices may not be routinely used and must be used only with documentation that alternative methods to prevent harm failed: needle teeth clipping (no more than top one-third of the tooth) in pigs and tail docking in pigs.

(ii) The following practices are prohibited: de-beaking, de-snooding, caponization, dubbing, toe clipping of chickens, toe clipping of turkeys unless with infra-red at hatchery, beak trimming after 10 days of age, tail docking of cattle, wattling of cattle, face branding of cattle, tail docking of sheep shorter than the distal end of the caudal fold, and mulesing of sheep.

(6) Administration of vaccines and other veterinary biologics.

(7) All surgical procedures necessary to treat an illness or injury shall be undertaken in a manner that employs best management practices to promote the animal's wellbeing and to minimize pain, stress, and suffering, with the use of allowed anesthetics, analgesics, and sedatives, as appropriate.

(8) Monitoring of lameness; timely and appropriate treatment of lameness for the species; and mitigation of the causes of lameness.

(b) *Preventive medicines and parasiticides.* Producers may administer medications that are allowed under § 205.603 of this part to alleviate pain or suffering, and when preventive practices and veterinary biologics are inadequate to prevent sickness. Parasiticides allowed under § 205.603 of this part 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 of this part.

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

(c) *Prohibited practices.* An organic livestock operation must not:

(1) Sell, label, or represent as organic any animal or product derived from any animal treated with antibiotics, any substance that contains a synthetic substance not allowed under § 205.603 of this part, or any substance that contains a non-synthetic substance prohibited in § 205.604 of this part. Milk from animals undergoing treatment with synthetic substances that are allowed under § 205.603 of this part but have associated withdrawal periods cannot be sold, labeled, or represented as organic during the withdrawal period but may be fed to calves on the same operation. Milk from animals undergoing treatment with prohibited substances cannot be sold, labeled, or represented as organic or fed to organic livestock.

(2) Administer synthetic medications unless:

(i) In the presence of illness or to alleviate pain and suffering, and

(ii) That such medications are allowed under § 205.603 of this part.

(3) Administer hormones for growth promotion, production, or reproduction, except as provided in § 205.603 of this part.

(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 neither the animal nor its products shall be sold, labeled, or represented as organically produced.

(8) Withhold individual treatment designed to minimize pain and suffering for injured, diseased, or sick animals, which may include forms of euthanasia as recommended by the American Veterinary Medical Association.

(9) Neglect to identify and record treatment of sick and injured animals in animal health records.

(10) Practice induced molting.

(d) *Parasite control plans.* (1) Organic livestock operations must have comprehensive plans to minimize internal parasite problems in livestock, including preventive measures such as pasture management, fecal monitoring,

and emergency measures in the event of a parasite outbreak.

(2) [Reserved]

(e) *Euthanasia.* (1) Organic livestock operations must have written plans for prompt, humane euthanasia for sick or injured livestock suffering from irreversible disease or injury.

(2) The following methods of euthanasia are not permitted: suffocation; manual blow to the head by blunt instrument or manual blunt force trauma; and the use of equipment that crushes the neck, including killing pliers or Burdizzo clamps.

(3) Following a euthanasia procedure, livestock must be carefully examined to ensure that they are dead.

[88 FR 75445, Nov. 2, 2023; 88 FR 86259, Dec. 13, 2023; 88 FR 89539, Dec. 28, 2023]

§ 205.239 Mammalian and non-avian livestock living conditions.

(a) The producer of an organic livestock operation must establish and maintain year-round livestock living conditions, which accommodate the wellbeing 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 paragraphs (b) and (c) of this section. 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 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 of this part, 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)(iii) of this part, and, if applicable, organically handled by operations certified under this part.

(4) Shelter designed to allow for:

(i) Over a 24-hour period, sufficient space and freedom to lie down, turn around, stand up, fully stretch their limbs, and express normal patterns of behavior;

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

(iii) Reduction of potential for livestock injury; and

(iv) Indoor housing must have areas for bedding and resting that are sufficiently large, solidly built, and comfortable so that animals are kept clean and dry, as appropriate for the species, and free of lesions.

(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.

(6) Housing, pens, runs, equipment, and utensils shall be properly cleaned and disinfected as needed to prevent cross-infection and build-up of disease-carrying organisms.

(7) Dairy young stock may be housed in individual pens until completion of the weaning process, provided that they have enough room to turn around, lie down, stretch out when lying down, get up, rest, and groom themselves; individual animal pens shall be designed and located so that each animal can see, smell, and hear other animals.

(8) Swine must be housed in a group, except:

(i) Sows may be housed individually at farrowing and during the suckling period; gestation and farrowing crates are prohibited;

(ii) Boars; and

(iii) Swine with multiple documented instances of aggression or for recovery from an illness.

(9) Piglets shall not be kept on flat decks or in piglet cages.

(10) For swine, rooting materials must be provided, except during the farrowing and suckling period.

(11) In confined housing with stalls for mammalian livestock, enough stalls must be present to provide for the natural behaviors of the animals. A cage must not be called a stall. For group-housed swine, the number of individual feeding stalls may be less than the number of animals, as long as all animals are fed routinely over a 24-hour period. For group-housed cattle, bedded packs, compost packs, tie-stalls, free-stalls, and stanchion barns are all acceptable housing as part of an overall organic system plan.

(12) Outdoor space must be provided year-round. When the outdoor space includes soil, vegetative cover must be maintained as appropriate for the season, climate, geography, species of livestock, and stage of production.

(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, however, lactation is not a stage of life that would exempt ruminants from any of the mandates set forth in this part;

(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, animals shall not be confined any longer than necessary for natural breeding or to perform artificial insemination. Animals may not be confined to observe estrus, and animals may not be confined after breeding to confirm pregnancy; and

(8) 4–H, National FFA Organization, 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. Notwithstanding the requirements in paragraph (b)(6) of this section, facilities where 4–H, National FFA Organization, and other youth events are held are not required to be certified organic for the participating animals to be sold as organic, provided all other organic management practices are followed.

(c) The producer of an organic livestock operation may, in addition to the times permitted under paragraph (b) of this section, 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: Except, That, any 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 dry matter intake (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. 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 without crowding and without competition for food. The finishing period shall not exceed one-fifth (⅕) 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.

[88 FR 75446, Nov. 6, 2023; 88 FR 86259, Dec. 13, 2023; 88 FR 89539, Dec. 28, 2023]

§ 205.240 Pasture practice standard.

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

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

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

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

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

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

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

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

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

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

(7) Soil fertility and seeding systems.

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

[75 FR 7194, Feb. 17, 2010]

§ 205.241 Avian living conditions.

(a) *Avian year-round living conditions.* The producer of an organic poultry operation must establish and maintain year-round poultry living conditions that accommodate the health and natural behavior of poultry, including: year-round access to the outdoors; shade; shelter; exercise areas; fresh air; direct sunlight; clean water for drinking; materials for dust bathing; and

adequate outdoor space to escape aggressive behaviors suitable to the species, its stage of life, the climate, and environment. Poultry may be temporarily denied access to the outdoors in accordance with paragraph (d) of this section. Continuous total confinement of poultry indoors is prohibited.

(b) *Indoor space requirements.* (1) Poultry housing must be sufficiently spacious to allow all birds to move freely, stretch both wings simultaneously, stand normally, and engage in natural behaviors.

(2) Producers must monitor ammonia levels at least weekly by taking measurements at the height of the birds' heads and implement practices to maintain ammonia levels below 20 ppm. When ammonia levels exceed 20 ppm, producers must implement additional practices and additional monitoring to reduce ammonia levels below 20 ppm. Ammonia levels must not exceed 25 ppm.

(3) For layers and all other fully feathered birds, artificial light may be used to prolong the day length, to provide up to 16 hours of continuous light per 24-hour period (*i.e.,* minimum of 8 hours of continuous darkness per 24-hour period). Artificial light intensity should be lowered gradually to encourage hens to move to perches or settle for the night. Artificial light spectrum may not be manipulated to increase feed intake and growth rate.

(4) Exit areas—poultry houses must have at least 1 linear foot of exit area for every 360 birds, measured across the base of the exit, but no less than one linear foot of exit area for flocks with fewer than 360 birds. Exit areas must be appropriately distributed and sized to ensure that all birds have ready access to the outdoors;

(i) If exit areas are not provided at a ratio of at least 1 linear foot per 360 birds, a certifier may approve practices that provide less than 1 linear foot per 360 birds only if an operation describes its practices (in the organic system plan) and demonstrates that ready access to the outdoors is provided for all birds;

(ii) Producers subject to requirements in 21 CFR part 118—Production, Storage, and Transportation of Shell Eggs, must take steps to prevent stray poultry, wild birds, cats, and other animals from entering poultry houses.

(5) Perches—for layers (Gallus gallus), six inches of perch space must be provided per bird. Perch space may include the alighting rail in front of the nest boxes. All layers must be able to perch at the same time except for aviary housing, in which 55 percent of layers must be able to perch at the same time. Floors in slatted/mesh floor housing cannot be counted as perch space.

(6) All birds must have access to areas in the house that allow for scratching and dust bathing, except, that mobile housing may meet this requirement when paired with outdoor space that provides birds with areas for scratching and dust bathing. Litter must be provided and maintained in a dry condition in the house.

(7) Non-mobile houses with slatted/mesh floors must have 15 percent minimum of solid floor area available with sufficient litter available for dust baths so that birds may freely dust bathe without crowding.

(8) For layers (*Gallus gallus*), indoor stocking density must meet one or both of the following rates, expressed in different terms.

(i) Mobile housing: not to exceed 4.5 pounds per square foot; or, alternatively, a rate of at least 1.5 square feet per bird will comply with the requirement.

(ii) Aviary housing: not to exceed 4.5 pounds per square foot; or, alternatively, a rate of at least 1.5 square feet per bird will comply with the requirement.

(iii) Slatted/mesh floor housing: not to exceed 3.75 pounds per square foot; or, alternatively, a rate of at least 1.8 square feet per bird will comply with the requirement.

(iv) Floor litter housing: not to exceed 3.0 pounds per square foot; or, alternatively, a rate of at least 2.2 square feet per bird will comply with the requirement.

(v) Other housing: not to exceed 2.25 pounds per square foot; or, alternatively, a rate of at least 3.0 square feet per bird will comply with the requirement.

(9) For pullets (*Gallus gallus*), indoor stocking density must not exceed 3.0

pounds of bird per square foot; or, alternatively, a rate of at least 1.7 square feet per bird will comply with the requirement.

(10) For broilers (*Gallus gallus*), indoor stocking density must not exceed 5.0 pounds of bird per square foot; or, alternatively, a rate of at least 2.0 square feet per bird will comply with the requirement.

(11) Indoor space includes flat areas available to birds, excluding nest boxes.

(12) Indoor space may include enclosed porches and lean-to type structures (e.g., screened in, roofed) as long as the birds always have access to the space, including during temporary confinement events. If birds do not have continuous access to the porch during temporary confinement events, this space must not be considered indoors.

(c) *Outdoor space requirements.* (1) Access to outdoor space and door spacing must be designed to promote and encourage outside access for all birds on a daily basis. Producers must provide access to the outdoors at an early age to encourage (*i.e.*, train) birds to go outdoors. Birds may be temporarily denied access to the outdoors in accordance with paragraph (d) of this section.

(2) At least 75 percent of outdoor space must be soil. Outdoor space with soil must include vegetative cover appropriate for the season, climate, geography, species of livestock, and stage of production. Vegetative cover must be maintained in a manner that does not provide harborage for rodents and other pests.

(3) Shade may be provided by structures, trees, or other objects in the outdoor area.

(4) For layers (*Gallus gallus*), outdoor space must be provided at a rate of no less than one square foot for every 2.25 pounds of bird in the flock; or, alternatively, a rate of at least 3.0 square feet per bird will comply with the requirement.

(5) For pullets (*Gallus gallus*), outdoor space must be provided at a rate of no less than one square foot for every 3.0 pounds of bird in the flock; or, alternatively, a rate of at least 1.7 square feet per bird will comply with the requirement.

(6) For broilers (*Gallus gallus*), outdoor space must be provided at a rate of no less than one square foot for every 5.0 pounds of bird in the flock; or, alternatively, a rate of at least 2.0 square feet per bird will comply with the requirement.

(7) Outdoor space may include structures that are not enclosed (e.g., with roof but no walls) and allow birds to freely access other outdoor space.

(d) *Temporary confinement.* The producer of an organic poultry operation may temporarily confine birds. Confinement must be recorded. Operations may temporarily confine birds when one of the following circumstances exists:

(1) Inclement weather, including when air temperatures are under 32 degrees F or above 90 degrees F.

(2) The animal's stage of life, including:

(i) The first 4 weeks of life for broilers (*Gallus gallus*);

(ii) The first 16 weeks of life for pullets (*Gallus gallus*); and

(iii) Until fully feathered for bird species other than *Gallus gallus*.

(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 various life stages nor egg laying is an illness or injury).

(6) Sorting or shipping birds and poultry sales, provided that the birds are maintained under continuous organic management, throughout the extent of their allowed confinement.

(7) For nest box training, provided that birds shall not be confined any longer than required to establish the proper behavior. Confinement for nest box training must not exceed five weeks over the life of the bird.

(8) For 4–H, National FFA Organization, 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 birds have arrived home at the conclusion of the event. During temporary confinement, birds must be under continuous organic management, including organic feed, for the duration of

confinement. Notwithstanding the requirements in paragraph (d)(6) of this section, facilities where 4–H, National FFA Organization, and other youth events are held are not required to be certified organic for the participating birds to be sold as organic, provided all other organic management practices are followed.

(e) *Manure management.* The producer of an organic poultry 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. The producer must also optimize recycling of nutrients and must manage outdoor access areas in a manner that does not put soil or water quality at risk.

[88 FR 75446, Nov. 6, 2023; 88 FR 86259, Dec. 13, 2023; 88 FR 89539, Dec. 28, 2023]

§ 205.242 Transport and slaughter.

(a) *Transportation.* (1) Certified organic livestock must be clearly identified as organic, and this identity must be traceable for the duration of transport.

(2) All livestock must be fit for transport to buyers, auction or slaughter facilities.

(i) Calves must have a dry navel cord and be able to stand and walk without human assistance.

(ii) Seriously crippled and non-ambulatory animals must not be transported for sale or slaughter. Such animals may be medically treated or euthanized.

(3) Adequate and season-appropriate ventilation is required for all livestock trailers, shipping containers, and any other mode of transportation used to protect animals against cold and heat stresses.

(4) During any transport and prior to slaughter, bedding must be provided on trailer floors and in holding pens, as needed, to keep livestock clean, dry, and comfortable. Use of bedding must be appropriate to the species and type of transport. Bedding is not required in poultry crates. When roughages are used for bedding, they must be certified organic.

(5) For transport that exceeds eight hours, measured from the time all animals are loaded onto a vehicle until the vehicle arrives at its final destination, the operation must describe how organic management and animal welfare will be maintained.

(i) The producer or handler of an organic livestock operation, who is responsible for overseeing the transport of organic livestock, must provide records to certifying agents during inspections or upon request that demonstrate that transport times for organic livestock are not detrimental to the welfare of the animals and meet the requirements of paragraph (a)(5) of this section.

(ii) [Reserved]

(6) Organic producers and handlers, who are responsible for overseeing the transport of organic livestock, must have emergency plans in place that adequately address possible animal welfare problems that might occur during transport.

(b) *Mammalian slaughter.* (1) Producers and handlers who slaughter organic livestock must be in compliance, as determined by FSIS, with the Federal Meat Inspection Act (21 U.S.C. 603(b) and 21 U.S.C. 610(b)), the regulations at 9 CFR part 313 regarding humane handling and slaughter of livestock, and the regulations of 9 CFR part 309 regarding ante-mortem inspection.

(2) Producers and handlers who slaughter organic exotic animals must be in compliance with the Agricultural Marketing Act of 1946 (7 U.S.C. 1621, *et seq.*), the regulations at 9 CFR parts 313 and 352 regarding the humane handling and slaughter of exotic animals, and the regulations of 9 CFR part 309 regarding ante-mortem inspection.

(3) Producers and handlers who slaughter organic livestock or exotic animals must provide all noncompliance records related to humane handling and slaughter issued by the controlling national, federal, or state authority and all records of subsequent corrective actions to certifying agents during inspections or upon request.

(c) *Avian slaughter.* (1) Producers and handlers who slaughter organic poultry must be in compliance, as determined by FSIS, with the Poultry Products Inspection Act requirements (21 U.S.C. 453(g)(5)); the regulations at paragraph (v) of the definition of ''*Adulterated*'' in

9 CFR 381.1(b), and 9 CFR 381.90, and 381.65(b)); and applicable FSIS Directives.

(2) Producers and handlers who slaughter organic poultry must provide all noncompliance records related to the use of good commercial practices in connection with slaughter issued by the controlling national, federal, or state authority and all records of subsequent corrective actions to the certifying agent at inspection or upon request.

(3) Producers and handlers who slaughter organic poultry, but are exempt from or not covered by the requirements of the Poultry Products Inspection Act, must ensure that:

(i) No lame birds may be shackled, hung, or carried by their legs;

(ii) All birds shackled on a chain or automated system must be stunned prior to exsanguination, with the exception of religious slaughter; and

(iii) All birds must be irreversibly insensible prior to being placed in the scalding tank.

[88 FR 75446, Nov. 6, 2023; 88 FR 86259, Dec. 13, 2023; 88 FR 89539, Dec. 28, 2023]

§§ 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.

(d) In addition to the substances described in paragraph (b) of this section, substances allowed under § 205.603(d)(2) and (3) may be used in or on pet food intended to be sold, labeled, or represented as ''organic'' or ''made with organic (specified ingredients or food group(s)),'' pursuant to § 205.301(b) and (c). Pet food must be labeled pursuant to subpart D of this part.

[65 FR 80637, Dec. 21, 2000, as amended at 89 FR 104393, Dec. 23, 2024]

§ 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 Imports to the United States.

Each shipment of organic agricultural products imported into the United States must be certified pursuant to subpart E of this part, labeled pursuant to subpart D of this part, be declared as organic to U.S. Customs and Border Protection, and be associated with valid NOP Import Certificate data.

(a) Persons exporting organic agricultural products to the United States must request an NOP Import Certificate from a certifying agent prior to their export. Only certifying agents accredited by the USDA or foreign certifying agents authorized under an organic trade arrangement or agreement may issue an NOP Import Certificate.

(b) The certifying agent must review an NOP Import Certificate request and determine whether the export complies with the USDA organic regulations. The certifying agent must have and implement a documented organic control system for intaking and approving or rejecting the validity of an NOP Import Certificate request. The certifying agent shall issue the NOP Import Certificate through the Organic Integrity Database only if the export complies with the USDA organic regulations.

(c) Each compliant organic import must be declared as organic to U.S. Customs and Border Protection by entering NOP Import Certificate data into the U.S. Customs and Border Protection's Automated Commercial Environment system. Organic imports must be clearly identified and marked as organic on all import documents including but not limited to invoices, packing lists, bills of lading, and U.S. Customs and Border Protection entry data. Only NOP Import Certificate data generated by the Organic Integrity Database are valid.

(d) Upon receiving a shipment with organic agricultural products, the organic importer must ensure the import

is accompanied by accurate NOP Import Certificate data and must verify that the shipment has had no contact with prohibited substances pursuant to §205.272 or exposure to ionizing radiation pursuant to §205.105, since export. The organic importer must have a documented organic control system to conduct this verification.

[88 FR 3622, Jan. 19, 2023]

§§ 205.274–205.289 [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, labeled pursuant to this subpart D, and must comply with the requirements in §205.273.

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

[65 FR 80637, Dec. 21, 2000, as amended at 88 FR 3622, Jan. 19, 2023]

§ 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 processed using ionizing radiation, pursuant to § 205.105(f);

(3) Be produced 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; 88 FR 3621, Jan. 19, 2023]

§ 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 of the combined organic ingredients at formulation by the total weight of all ingredients of the product at formulation. Water and salt added as ingredients at formulation are excluded from the calculation.

(2) Dividing the total fluid volume of the combined organic ingredients at formulation by the total fluid volume of all ingredients of the product at formulation if the product and ingredients are liquid. Water and salt added as ingredients at formulation are excluded from the calculation. If the liquid product is identified on the principal display panel or information panel as being reconstituted from concentrates, the calculation should be made based on single-strength concentrations of all ingredients.

(3) For products containing organically produced ingredients in both solid and liquid form, dividing the combined net weight of the solid organic ingredients and the net weight of the liquid organic ingredients at formulation by the total weight of all ingredients of the product at formulation. Water and salt added as ingredients at formulation are excluded from the calculation.

(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.

[65 FR 80637, Dec. 21, 2000, as amended at 88 FR 3622, Jan. 19, 2023]

§ 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.

(a) Nonretail containers used to ship or store certified organic agricultural products must display:

(1) Identification of the product as organic; and

(2) The production lot number, shipping identification, or other unique information that links the container to audit trail documentation.

(b) Audit trail documentation for nonretail containers must identify the last certified operation that handled the agricultural product.

(c) Paragraph (a)(1) of this section does not apply to nonretail containers used to ship or store agricultural products packaged for retail sale with organic identification visible on the retail label.

(d) 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 operations under § 205.101.

[88 FR 3622, Jan. 19, 2023]

§ 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 or processed by an exempt operation.

(a) An agricultural product organically produced or processed by an exempt operation must not:

(1) Display the USDA seal or any certifying agent's seal or other identifying mark which represents the exempt 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 processed by an exempt operation may be identified as an organic product or organic ingredient in a multi-ingredient product produced by the exempt 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.

[65 FR 80637, Dec. 21, 2000, as amended at 88 FR 3623, Jan. 19, 2023]

§ 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

§ 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 § 205.201;

(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.

(g) In addition to paragraphs (a) through (f) of this section, a producer group operation must:

(1) Be organized as a person;

(2) Use centralized processing, distribution, and marketing facilities and systems;

(3) Be organized into producer group production units;

(4) Maintain an internal control system to implement the practices described in §205.201(c) and ensure compliance with this part;

(5) Ensure that all agricultural products sold, labeled, or represented as organic are produced only by producer group members using land and facilities within the certified operation;

(6) Ensure that producer group members do not sell, label, or represent their agricultural products as organic outside of the producer group operation unless they are individually certified;

(7) Report to the certifying agent, at least annually, the name and location of all producer group members and producer group production units, the agricultural products produced, estimated yields, and size of production areas;

(8) Conduct internal inspections of each producer group member, at least annually, by internal inspectors with the member present, which must include mass-balance audits and reconciliation of each producer group member's and each producer group production unit's yield and group sales;

(9) Implement recordkeeping requirements to ensure traceability from production at each producer group member and production unit through handling to sale and transport;

(10) Implement procedures to ensure all production and handling by the producer group operation is compliant with the USDA organic regulations and the Act; and

(11) Address any other terms or conditions determined by the Administrator to be necessary to enforce compliance with the USDA organic regulations and the Act.

[65 FR 80637, Dec. 21, 2000, as amended at 80 FR 6429, Feb. 5, 2015; 88 FR 3623, Jan. 19, 2023]

§ 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 §205.201;

(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.

[65 FR 80637, Dec. 21, 2000, as amended at 88 FR 3623, Jan. 19, 2023]

§ 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) Inspections of a producer group operation must:

(i) Assess the internal control system's compliance, or ability to comply, with the requirements of § 205.400(g)(8). This must include review of the internal inspections conducted by the internal control system.

(ii) Conduct witness audits of internal control system inspectors performing inspections of the producer group operation.

(iii) Individually inspect at least 1.4 times the square root or 2% of the total number of producer group members, whichever is higher. All producer group members determined to be high risk by the certifying agent must be inspected. At least one producer group member in each producer group production unit must be inspected.

(iv) Inspect each handling facility.

(3)(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) *Unannounced inspections.* (1) A certifying agent must, on an annual basis, conduct unannounced inspections of a minimum of five percent of the operations it certifies, rounded up to the nearest whole number.

(2) Certifying agents must be able to conduct unannounced inspections of any operation they certify and must not accept applications or continue certification with operations located in areas where they are unable to conduct unannounced inspections.

(c) *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.

(d) *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 205.201, 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.

(4) Mass-balances, in that quantities of organic product and ingredients produced or purchased account for organic product and ingredients used, stored, sold, or transported (that is, inputs account for outputs); and

(5) That organic products and ingredients are traceable by the operation from the time of purchase or acquisition through production to sale or transport; and that the certifying agent can verify compliance back to the last certified operation.

(e) *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.

(f) *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.

[65 FR 80637, Dec. 21, 2000, as amended at 88 FR 3623, Jan. 19, 2023]

§ 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. The certificate of organic operation must be generated from the Organic Integrity Database and may be provided to certified operations electronically.

(c) In addition to the certificate of organic operation provided for in paragraph (b) of this section, a certifying agent may issue its own addenda to the certificate of organic operation. If issued, any addenda must include:

(1) Name, address, and contact information for the certified operation;

(2) The certified operation's unique ID number/code that corresponds to the certified operation's ID number/code in the Organic Integrity Database;

(3) A link to the Organic Integrity Database or a link to the certified operation's profile in the Organic Integrity Database, along with a statement, ''You may verify the certification of

this operation at the Organic Integrity Database,'' or a similar statement;

(4) Name, address, and contact information of the certifying agent; and

(5) ''Addendum issue date.''

(d) 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.

[65 FR 80637, Dec. 21, 2000, as amended of 88 FR 3623, Jan. 19, 2023]

§ 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.

(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.

[65 FR 80637, Dec. 21, 2000, as amended at 88 FR 3624, Jan. 19, 2023]

§ 205.406 Continuation of certification.

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

(1) A summary statement, supported by documentation, detailing any deviations from, changes to, modifications to, or other amendments made to the organic system plan submitted during the previous year;

(2) Any additions or deletions to the previous year's organic system plan, intended to be undertaken in the coming year, detailed pursuant to § 205.201;

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

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

(b) The certifying agent must arrange and conduct an on-site inspection, pursuant to § 205.403, of the certified operation at least once per calendar year.

(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).

[65 FR 80637, Dec. 21, 2000, as amended at 88 FR 3624, Jan. 19, 2023]

§§ 205.407–205.499 [Reserved]

Subpart F—Accreditation of Certifying Agents

§ 205.500 Areas and duration of accreditation.

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

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

[65 FR 80637, Dec. 21, 2000, as amended at 88 FR 3624, Jan. 19, 2023]

§ 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) Continuously use a sufficient number of qualified and adequately trained personnel, including inspectors and certification review personnel, to

comply with and implement the USDA organic standards.

(i) Certifying agents must demonstrate that all inspectors, including staff, volunteers, and contractors, have the relevant knowledge, skills, and experience required to inspect operations of the scope and complexity assigned and to evaluate compliance with the applicable regulations of this part.

(A) Certifying agents must demonstrate that inspectors continuously maintain adequate knowledge and skills about the current USDA organic standards, production and handling practices, certification and inspection, import and/or export requirements, traceability audits, mass-balance audits, written and oral communication skills, sample collection, investigation techniques, and preparation of technically accurate inspection documents.

(B) All inspectors must demonstrate successful completion of training that is relevant to inspection. Inspectors with less than one year of inspection experience must complete at least 50 hours of training within their first year and prior to performing inspections independently. Inspectors with one or more years of inspection experience must annually complete at least 10 hours of training if inspecting one area of operation (as defined at § 205.2) and an additional 5 hours of training for each additional area of operation inspected.

(C) Certifying agents must demonstrate that inspectors have a minimum of 2,000 hours of experience relevant to the scope and complexity of operations they will inspect before assigning initial inspection responsibilities.

(ii) Certifying agents must demonstrate that all certification review personnel, including staff, volunteers, or contractors, have the knowledge, skills, and experience required to perform certification review of operations of the scope and complexity assigned and to evaluate compliance with the applicable regulations of this part.

(A) Certifying agents must demonstrate that all certification review personnel continuously maintain adequate knowledge and skills in the current USDA organic standards, certification and compliance processes, traceability audits, mass-balance audits, and practices applicable to the type, volume, and range of review activities assigned.

(B) All certification review personnel must demonstrate successful completion of training that is relevant to certification review. Certification review personnel with less than one year of certification review experience must complete at least 50 hours of training within their first year performing certification review. Certification review personnel with one or more years of certification review experience must annually complete at least 10 hours of training if conducting certification review related to one area of operation and an additional 5 hours of training for each additional area of operation.

(iii) Certifying agents must maintain current training requirements, training procedures, and training records for all inspectors and certification review personnel.

(5) Demonstrate that all persons with inspection or certification review responsibilities have sufficient expertise in organic production or handling techniques to successfully perform the duties assigned. Sufficient expertise must include knowledge of certification to USDA organic standards and evidence of education, training, or professional experience in the fields of agriculture, science, or organic production and handling that relates to assigned duties.

(6) Conduct an annual performance evaluation of all persons who conduct inspections, certification review, or implement measures to correct any deficiencies in certification services.

(i) Witness inspections—certifying agents must ensure that each inspector is evaluated while performing an inspection at least once every three years, or more frequently if warranted. Inspectors with less than three years of inspection experience must undergo a witness inspection annually. Witness inspections must be performed by certifying agent personnel who are qualified to evaluate inspectors.

(ii) Certifying agents must maintain documented policies, procedures, and records for annual performance evaluations and witness inspections.

(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 (except for 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:

(i) For information that must be made available to any member of the public, as provided for in § 205.504(b)(5);

(ii) For enforcement purposes, certifying agents must exchange any compliance-related information that is credibly needed to certify, decertify, or investigate an operation, including for the purpose of verifying supply chain traceability and audit trail documentation; and

(iii) If a certified operation's proprietary business information is compliance-related and thus credibly needed to certify, decertify, or investigate that operation, certifying agents may exchange that information for the purposes of enforcing the Act, but the information in question still retains its proprietary character even after it is exchanged and all of the certifying agents that are involved in the exchange still have a duty to preserve the confidentiality of that information after the exchange.

(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 on-site 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. Certifying agents must provide information to other certifying agents to ensure organic integrity or to enforce organic regulations, including to verify supply chain integrity, authenticate the organic status of certified products, and conduct investigations;

(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) Maintain current and accurate data in the Organic Integrity Database for each operation which it certifies;

(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) Conduct risk-based supply chain traceability audits as described in the criteria and procedures for supply chain audits, per § 205.504(b)(7), and share audit findings with other certifying agents as needed to determine compliance, per paragraph (a)(13) of this section.

(22) Notify AMS not later than 90 calendar days after certification activities begin in a new certification office. The notification must include the countries where the certification activities are being provided, the nature of the certification activities, and the qualifications of the personnel providing the certification activities.

(23) 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.

[65 FR 80637, Dec. 21, 2000, as amended at 88 FR 3624, Jan. 19, 2023]

§ 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 through 205.663; 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 sharing information with other certifying agents and 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.

(7) A copy of the criteria to identify high-risk operations and agricultural products for supply chain traceability audits; and procedures to conduct risk-based supply chain traceability audits, as required in § 205.501(a)(21); and procedures to report credible evidence of organic fraud to the Administrator.

(8) A copy of reasonable decision criteria for acceptance of mediation, and a process for identifying personnel conducting mediation and setting up mediation.

(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.

[65 FR 80637, Dec. 21, 2000, as amended at 88 FR 3625, Jan. 19, 2023]

§ 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.

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

§ 205.511 Accepting foreign conformity assessment systems.

(a) Foreign product may be certified under the USDA organic regulations by a USDA-accredited certifying agent and imported for sale in the United States. Foreign product that is produced and handled under another country's organic certification program may be sold, labeled, or represented in the United States as organically produced if the U.S. Government determines that such country's organic certification program provides technical requirements and a conformity assessment system governing the production and handling of such products that are at least equivalent to the requirements of the Act and the regulations in this part.

(b) Countries desiring to establish eligibility of product certified under that country's organic certification program to be sold, labeled, or represented in the United States as organically produced may request equivalence determinations from AMS. A foreign government must maintain compliance and enforcement mechanisms to ensure that its organic certification program is fully meeting the terms and conditions of any equivalence determination provided by the U.S. Government pursuant to this section. To request an equivalence determination, the requesting country must submit documentation that fully describes its technical requirements and conformity assessment system. If the U.S. Government determines it can proceed, AMS will assess the country's organic certification program to evaluate if it is equivalent.

(c) USDA, working with other Federal agencies, will describe the scope of an equivalence determination.

(d) AMS will conduct regular reviews and reassessments of countries deemed equivalent to verify that the foreign government's technical requirements and conformity assessment system continue to be at least equivalent to the requirements of the Act and the regulations of this part, and will determine if the equivalence determination should be continued, amended, or terminated. AMS will determine the timing and scope of reviews and re-assessments based on, but not limited to, factors such as: the terms of the equivalence determination, changes to the foreign country's technical requirements or conformity assessment system, the results of previous reviews and re-assessments, instances of suspected or verified noncompliance issues, the volume of trade, and other factors contributing to the risk level of the equivalence determination.

(e) The U.S. Government may terminate an equivalence determination if the terms or conditions established under the equivalence determination are not met; if AMS determines that the country's technical requirements and/or conformity assessment program are no longer equivalent; if AMS determines that the foreign government's organic control system is inadequate to ensure that the country's organic certification program is fully meeting the terms and conditions under the equivalence determination; or for other good cause.

[88 FR 3625, Jan. 19, 2023]

§§ 205.512–205.599 [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.

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), (l), and (o) 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) Potassium hypochlorite—for use in water for irrigation purposes.

(v) 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 D_3.

(h) As slug or snail bait.

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

(2) Elemental sulfur.

(i) As crop 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 crop 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, 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.

(1) Ethylene gas—for regulation of pineapple flowering.

(2) Fatty alcohols (C6, C8, C10, and/or C12)—for sucker control in organic tobacco production.

(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) Production aids.

(1) Microcrystalline cheesewax (CAS #'s 64742–42–3, 8009–03–08, and 8002–74–2)—for use in log grown mushroom production. Must be made without either ethylene-propylene co-polymer or synthetic colors.

(2) Paper-based crop planting aids as defined in § 205.2. Virgin or recycled paper without glossy paper or colored inks.

(p)–(z) [Reserved]

[65 FR 80637, Dec. 21, 2000]

EDITORIAL NOTE: For FEDERAL REGISTER citations affecting § 205.601, see the List of CFR Sections Affected, which appears in the Finding Aids section of the printed volume and at *www.govinfo.gov*.

§ 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).

[68 FR 61992, Oct. 31, 2003, as amended at 83 FR 66572, Dec. 27, 2018]

§ 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) Oxalic acid dihydrate—for use as a pesticide solely for apiculture.

(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]

[72 FR 70484, Dec. 12, 2007, as amended at 73 FR 54059, Sept. 18, 2008; 75 FR 51924, Aug. 24, 2010; 77 FR 28745, May 15, 2012; 77 FR 45907, Aug. 2, 2012; 77 FR 57989, Sept. 19, 2012; 80 FR 6429, Feb. 5, 2015; 82 FR 31243, July 6, 2017; 83 FR 66572, Dec. 27, 2018; 84 FR 18136, Apr. 30, 2019; 86 FR 33484, June 25, 2021; 87 FR 10938, Feb. 28, 2022]

§ 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.*

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

(2) Agar-agar.

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

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

(5) Bentonite.

(6) Calcium carbonate.

(7) Calcium chloride.

(8) Calcium sulfate—mined.

(9) Carrageenan.

(10) Diatomaceous earth—food filtering aid only.

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

(12) 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.

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

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

(15) Kaolin.

(16) L-Malic acid (CAS # 97–67–6).

(17) Magnesium chloride.

(18) Magnesium sulfate, nonsynthetic sources only.

(19) Microorganisms—any food grade bacteria, fungi, and other microorganism.

(20) Nitrogen—oil-free grades.

(21) Oxygen—oil-free grades.

(22) Perlite—for use only as a filter aid in food processing.

(23) Potassium chloride.

(24) Potassium iodide.

(25) Pullulan—for use only in tablets and capsules for dietary supplements labeled ''made with organic (specified ingredients or food group(s)).

(26) Sodium bicarbonate.

(27) Sodium carbonate.

(28) Tartaric acid—made from grape wine.

(29) Waxes—nonsynthetic (Wood rosin).

(30) 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.*

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

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

(3) Alginates.

(4) Ammonium bicarbonate—for use only as a leavening agent.

(5) Ammonium carbonate—for use only as a leavening agent.

(6) Ascorbic acid.

(7) Calcium citrate.

(8) Calcium hydroxide.

(9) Calcium phosphates (monobasic, dibasic, and tribasic).

(10) Carbon dioxide.

(11) 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.

(12) 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.

(13) Collagen gel—as casing, may be used only when organic collagen gel is not commercially available.

(14) Ethylene—allowed for postharvest ripening of tropical fruit and degreening of citrus.

(15) Ferrous sulfate—for iron enrichment or fortification of foods when required by regulation or recommended (independent organization).

(16) Glycerides (mono and di)—for use only in drum drying of food.

(17) Hydrogen peroxide.

(18) Low-acyl gellan gum.

(19) Magnesium stearate—for use only in agricultural products labeled ''made with organic (specified ingredients or food group(s)),'' prohibited in agricultural products labeled ''organic''.

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

(21) Ozone.

(22) 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.

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

(24) Potassium carbonate.

(25) Potassium citrate.

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

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

(28) Potassium phosphate—for use only in agricultural products labeled ''made with organic (specific ingredients or food group(s)),'' prohibited in agricultural products labeled ''organic''.

(29) Silicon dioxide—Permitted as a defoamer. Allowed for other uses when organic rice hulls are not commercially available.

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

(31) Sodium citrate.

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

(33) Sodium lactate—for use as an antimicrobial agent and pH regulator only.

(34) Sodium phosphates—for use only in dairy foods.

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

(36) Taurine—for use only in pet food.

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

(38) Xanthan gum.

(c)–(z) [Reserved]

[68 FR 61993, Oct. 31, 2003]

EDITORIAL NOTE: For FEDERAL REGISTER citations affecting § 205.605, see the List of CFR Sections Affected, which appears in the Finding Aids section of the printed volume and at *www.govinfo.gov*.

§ 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/purple carrot juice color—derived from *Daucus carota* L.

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

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

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

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

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

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

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

(e) Cornstarch (native).

(f) Fish oil (Fatty acid CAS #'s: 10417–94–4, and 25167–62–8)—stabilized with organic ingredients or only with ingredients on the National List, §§ 205.605 and 205.606.

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

(h) Gelatin (CAS # 9000–70–8).

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

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

(k) Inulin—oligofructose enriched (CAS # 9005–80–5).

(l) Lecithin—de-oiled.

(m) Orange pulp, dried.

(n) Orange shellac—unbleached (CAS # 9000–59–3).

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

(p) Potassium acid tartrate.

(q) Seaweed, Pacific kombu.

(r) Tamarind seed gum.

(s) Tragacanth gum (CAS # 9000–65–1).

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

(u)—(w) [Reserved]

[72 FR 35140, June 27, 2007, as amended at 75 FR 77524, Dec. 13, 2010; 77 FR 8092, Feb. 14, 2012; 77 FR 33299, June 6, 2012; 77 FR 44429, July 30, 2012; 78 FR 31821, May 28, 2013; 79 FR 58663, Sept. 30, 2014; 80 FR 77234, Dec. 12, 2015; 82 FR 31244, July 6, 2017; 83 FR 66571, Dec. 27, 2018; 84 18136, Apr. 30, 2019; 85 FR 70435, Nov. 5, 2020; 87 FR 10938, Feb. 28, 2022; 88 FR 33816, May 25, 2023]

§ 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.

[65 FR 80637, Dec. 21, 2000, as amended at 68 FR 61993, Oct. 31, 2003; 80 FR 6429, Feb. 5, 2015]

§§ 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 enforcement action against any person who sells, labels, or provides other market information concerning an agricultural product if such label or information implies that such product is produced or handled using organic methods, if the product was produced or handled in violation of the Organic Foods Production Act or the regulations in this part.

(d) 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.

(e) 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.

[65 FR 80637, Dec. 21, 2000, as amended at 88 FR 3625, Jan. 19, 2023]

§ 205.661 Investigation.

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

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

§ 205.662 Noncompliance procedure for certified operations.

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

(1) A description of each noncompliance;

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

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

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

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

(1) The reasons for the proposed suspension or revocation;

(2) The proposed effective date of such suspension or revocation;

(3) The impact of a suspension or revocation on future eligibility for certification; and

(4) The right to request mediation pursuant to § 205.663 or to file an appeal pursuant to § 205.681.

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

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

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

(3) Within 3 business days of issuing a notification of suspension or revocation, or the effective date of an operation's surrender, the certifying agent must update the operation's status in the Organic Integrity Database.

(f) *Eligibility.* (1) A certified operation or a person responsibly connected with an operation whose certification has been suspended may at any time, unless otherwise stated in the notification of suspension, submit a request to the Secretary for reinstatement of its certification, or submit a request for eligibility to be certified. 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 7 CFR 3.91(b)(1)(xxxvi) per violation.

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

[65 FR 80637, Dec. 21, 2000, as amended at 75 FR 17560, Apr. 7, 2010; 79 FR 6430, Feb. 5, 2015; 88 FR 3626, Jan. 19, 2023]

§ 205.663 Mediation.

(a) A certifying agent must submit with its administrative policies and procedures: decision criteria for acceptance of mediation, and a process for identifying personnel conducting mediation and setting up mediation sessions per § 205.504(b)(8).

(b) A certified operation or applicant for certification may request mediation to resolve a denial of certification or proposed suspension or proposed revocation of certification issued by a certifying agent or State organic program.

(1) A certified operation or applicant for certification must submit any request for mediation in writing to the applicable certifying agent or State organic program within 30 calendar days of receipt of the notice of proposed suspension or proposed revocation of certification or denial of certification.

(2) A certifying agent or State organic program may accept or reject a request for mediation based on the decision criteria required in paragraph (a) of this section. Certifying agents must document these criteria and how the certifying agent applied the criteria to the request.

(3) If a certifying agent rejects a mediation request, it must provide this rejection, and the justification for the rejection, in writing to the applicant for certification or certified operation. The rejection must include the right to request an appeal, pursuant to § 205.681, within 30 calendar days of the date of receipt of the written notification of rejection of the request for mediation.

(4) When an operation appeals a rejection of mediation, the adverse action which is contested must not be finalized during the appeal proceeding.

(c) Both parties must agree on the person conducting the mediation.

(d) If a State organic program is in effect, the parties must follow the mediation procedures established in the State organic program and approved by the Secretary.

(e) The parties to the mediation have a maximum of 30 calendar days from the start of mediation to reach an agreement. Successful mediation results in a settlement agreement agreed to in writing by both the certifying agent and the certified operation. If mediation is unsuccessful, the applicant for certification or certified operation has 30 calendar days from receipt of a written notice of termination of mediation to appeal the denial of certification or proposed suspension or revocation pursuant to § 205.681.

(f) Any settlement agreement reached through mediation must comply with the Act and the regulations in this part. The Program Manager may review any mediated settlement 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.

(g) The Program Manager may propose mediation and enter into a settlement agreement at any time to resolve any adverse action notice.

[88 FR 3626, Jan. 19, 2023]

§ 205.664 [Reserved]

§ 205.665 Noncompliance procedure for certifying agents.

(a) *Notification.* (1) A written notification of noncompliance will be sent to the certifying agent when:

(i) 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; or

(ii) The Program Manager determines that the certification activities of the certifying agent, or any person performing certification activities on behalf of the certifying agent, are not compliant with the Act or the regulations in this part; or

(iii) The Program Manager determines that the certification activities at a certification office, and/in specific countries, are not compliant with the Act or the regulations in this part.

(2) Such notification must provide:

(i) A description of each noncompliance;

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

(iii) 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.

[65 FR 80637, Dec. 21, 2000, as amended at 88 FR 3626, Jan. 19, 2023]

§§ 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 an adverse action of the National Organic Program's Program Manager may appeal such decision to the Administrator.

(b) Persons subject to the Act who believe they are adversely affected by an adverse action 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 they are adversely affected by an adverse action 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) Persons subject to the Act who believe they are adversely affected by an adverse action of a certifying agent or a State organic program may request mediation as provided in § 205.663.

(e) All appeals must comply with the procedural requirements in § 205.681(c) and (d).

(f) 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.

(g) All appeals must be reviewed, heard, and decided by persons not involved with the adverse action being appealed.

[88 FR 3626, Jan. 19, 2023]

§ 205.681 Appeals.

(a) *Adverse actions by certifying agents.* 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 proposed 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 unless the parties resolve the issues through settlement, or the appellant waives or does not timely request a hearing. Such proceeding must 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) *Adverse actions by the NOP Program Manager.* A person affected by an adverse action, as defined by § 205.2, issued by the NOP Program Manager, may appeal to the Administrator.

(1) If the Administrator sustains an appeal, an applicant will be issued accreditation, a certifying agent will continue its accreditation, or an operation will continue its certification, a civil penalty will be withdrawn, and a cease and desist notice will be withdrawn, as applicable to the operation.

(2) If the Administrator denies an appeal, a formal administrative proceeding will be initiated to deny, suspend, or revoke the accreditation or certification and/or levy civil penalties unless the parties resolve the issues through settlement, the appellant waives a hearing, or the appellant does not timely request a hearing. Such proceeding must 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 must be filed in writing 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. An adverse action will become final and nonappealable unless an appeal is timely filed.

(d) *Where and what to file.* (1) Appeals to the Administrator and Requests for Hearing must be filed in writing and addressed to: 1400 Independence Ave. SW, Room 2642, Stop 0268, Washington, DC 20250, or electronic transmission, *NOPAppeals@usda.gov*.

(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 action and a statement of the appellant's reasons for believing that the action was not proper or made

in accordance with applicable program regulations.

[65 FR 80637, Dec. 21, 2000, as amended at 71 FR 53303, Sept. 11, 2006; 80 FR 6430, Feb. 4, 2015; 88 FR 3627, Jan. 19, 2023]

§§ 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 Severability.

If any provision of any subpart is declared invalid or the applicability thereof to any person or circumstance is held invalid, the validity of the remainder of any subpart or the applicability thereof to other persons or circumstances shall not be affected thereby.

[88 FR 75446, Nov. 6, 2023; 88 FR 86259, Dec. 13, 2023; 88 FR 89539, Dec. 28, 2023]

§§ 205.692–205.699 [Reserved]

PARTS 206–209 [RESERVED]