Title 7 —Agriculture
Subtitle B —Regulations of the Department of Agriculture
Chapter I —Agricultural Marketing Service (Standards, Inspections, Marketing Practices), Department of Agriculture
Subchapter M —Organic Foods Production Act Provisions
Part 205 —National Organic Program

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Subpart G Administrative

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 plant disease control.

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

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

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

(4) Hydrated lime.

(5) Hydrogen peroxide.

(6) Lime sulfur.

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

(8) Peracetic acid—for use to control fire blight bacteria. Also permitted in hydrogen peroxide formulations as allowed in § 205.601(i) at concentration of no more than 6% as indicated on the pesticide product label.

(9) Potassium bicarbonate.

(10) Elemental sulfur.

(11) Polyoxin D zinc salt.

(j) As plant or soil amendments.

(1) Aquatic plant extracts (other than hydrolyzed)—Extraction process is limited to the use of potassium hydroxide or sodium hydroxide; solvent amount used is limited to that amount necessary for extraction.

(2) Elemental sulfur.

(3) Humic acids—naturally occurring deposits, water and alkali extracts only.

(4) Lignin sulfonate—chelating agent, dust suppressant.

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

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

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

(i) Soluble boron products.

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

(8) Liquid fish products—can be pH adjusted with sulfuric, citric or phosphoric acid. The amount of acid used shall not exceed the minimum needed to lower the pH to 3.5.

(9) Vitamins, 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, as amended at 68 FR 61992, Oct. 31, 2003; 71 FR 53302 Sept. 11, 2006; 72 FR 69572, Dec. 10, 2007; 75 FR 38696, July 6, 2010; 75 FR 77524, Dec. 13, 2010; 77 FR 8092, Feb. 14, 2012; 77 FR 33298, June 6, 2012; 77 FR 45907, Aug. 2, 2012; 78 FR 31821, May 28, 2013; 79 FR 58663, Sept. 30, 2014; 80 FR 77234, Dec. 14, 2015; 82 FR 31243, July 6, 2017; 83 FR 66571, Dec. 27, 2018; 84 FR 56677, Oct. 23, 2019; 87 FR 10938, Feb. 28, 2022; 87 FR 16375, Mar. 23, 2022; 87 FR 68027, Nov. 14, 2022]

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

(37) 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]