



DEPARTMENT OF AGRICULTURE

Agricultural Marketing Service

7 CFR Part 205

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National Organic Program: USDA Organic Regulations

AGENCY: Agricultural Marketing Service, USDA.

ACTION: Notification of 2017 sunset review.

SUMMARY: This document addresses the 2017 sunset review submitted to the Secretary of Agriculture (Secretary) through the Agricultural Marketing Service's (AMS) National Organic Program (NOP) by the National Organic Standards Board (NOSB) following the NOSB's April 2015 and October 2015 meetings. The 2017 sunset review pertains to the NOSB's sunset review of 198 substances on the U.S. Department of Agriculture's (USDA) National List of Allowed and Prohibited Substances (National List). Consistent with the NOSB's sunset review, this publication provides notice on the renewal of 187 substances on the National List, and completes the 2017 National List sunset review for these renewed substances.

DATES: This document is effective March 15, 2017.

FOR FURTHER INFORMATION CONTACT: Requests for a copy of this document should be sent to Robert Pooler, Standards Division, National Organic Program, USDA-AMS-NOP, 1400 Independence Ave., SW., Room 2642-S., Ag Stop 0268, Washington, DC 20250-0268. Telephone: (202) 720-3252.

SUPPLEMENTARY INFORMATION: The National Organic Program (NOP) is authorized by the Organic Foods Protection Act (OFPA) of 1990, as amended (7 U.S.C. 6501 - 6522). The USDA Agricultural Marketing Service (AMS) administers the NOP. Final regulations

implementing the NOP, also referred to as the USDA organic regulations (7 CFR 205.1 – 205.690), were published December 21, 2000 (65 FR 80548), and became effective on October 21, 2002. Through these regulations, the AMS oversees national standards for the production, handling, and labeling of organically produced agricultural products. Since becoming effective, the USDA organic regulations have been frequently amended, mostly for changes to the National List in 7 CFR 205.601 – 205.606.

The National List identifies the synthetic substances that may be used and the nonsynthetic (natural) substances that may not be used in organic production. The National List also identifies synthetic, nonsynthetic nonagricultural, and nonorganic agricultural substances that may be used in organic handling. The OFPA and the USDA organic regulations, as indicated in § 205.105, specifically prohibit the use of any synthetic substance in organic production and handling unless the synthetic substance is on the National List. Section 205.105 also requires that any nonorganic agricultural substance and any nonsynthetic nonagricultural substance used in organic handling appear on the National List.

As stipulated by OFPA, recommendations to amend the National List are developed by the NOSB, operating in accordance with the Federal Advisory Committee Act (5 U.S.C. App. 2 et seq.), to assist in the evaluation of substances to be used or not used in organic production and handling, and to advise the Secretary on the USDA organic regulations. OFPA also requires a review of all substances included on the National List within 5 years of their addition to or renewal on the list. During this sunset review, the NOSB considers any new information pertaining to a substance's impact on human health and the environment, its necessity, and its compatibility with organic production and handling. If a listed substance is not reviewed by

NOSB and renewed by USDA within the five year period, its allowance or prohibition on the National List is no longer in effect.

AMS published a revision of the sunset review process in the Federal Register on September 16, 2013 (78 FR 56811). This revised process provides public notice on the renewal of National List substances. This renewal occurs after the NOSB review.

At its April 2015 and October 2015 public meetings, the NOSB considered 198 National List substances which have a 2017 Sunset date. AMS has reviewed and accepted the NOSB 2017 sunset review and recommendations. Table 1 lists the 187 synthetic and nonsynthetic substances on the National List that are renewed. These substances continue to be included on the National List with a new sunset date of March 15, 2022. The NOSB also recommended removing eleven substances considered during the 2017 sunset review process from the National List; these recommendations will be addressed in a separate rulemaking.

Table 1: Substances Renewed in 2017 Sunset Review

National List Section	Substance Listing
§ 205.601	Synthetic substances allowed for use in organic crop production.
(a)	As algicide, disinfectants, and sanitizer, including irrigation 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)	Sodium hypochlorite.
(4)	Hydrogen peroxide.
(7)	Soap-based algicide / demossers.
(b)	As herbicides, weed barriers, as applicable.
(1)	Herbicides, soap-based—for use in farmstead maintenance (roadways, ditches,

	right of ways, building perimeters) and ornamental crops.
(2)	Mulches.
(i)	Newspaper or other recycled paper, without glossy or colored inks.
(ii)	Plastic mulch or covers (petroleum-based other than polyvinyl chloride (PVC)).
(c)	As compost feedstocks—Newspapers or other recycled paper, without glossy or colored inks.
(d)	As animal repellents—Soaps, ammonium—for use as a large animal repellent only, no contact with soil or edible portion of crop.
(e)	As insecticides (including acaricides or mite control).
(1)	Ammonium carbonate—for use as bait in insect traps only, no direct contact with crop or soil.
(3)	Boric acid—structural pest control, no direct contact with organic food or crops.
(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 .
(i)	As plant disease control.
(2)	Coppers, fixed—copper hydroxide, copper oxide, copper oxychloride, includes products exempted from EPA tolerance, <i>Provided</i> , 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.
(9)	Potassium bicarbonate.
(10)	Elemental sulfur.
(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 sulfate—allowed with a documented soil deficiency.
(6)	Micronutrients—not to be used as a defoliant, herbicide, or desiccant. Those made from nitrates or chlorides are not allowed. Soil deficiency must be documented by testing.

(i)	Soluble boron products.
(ii)	Sulfates, carbonates, oxides, or silicates of zinc, copper, iron, manganese, molybdenum, selenium, and cobalt.
(7)	Liquid fish products—can be pH adjusted with sulfuric, citric or phosphoric acid. The amount of acid used shall not exceed the minimum needed to lower the pH to 3.5.
(8)	Vitamins B1, C, and E.
(k)	As plant growth regulators. Ethylene gas—for regulation of pineapple flowering.
(l)	As floating agents in post-harvest handling.
(2)	Sodium silicate—for tree fruit and fiber processing.
(m)	As synthetic inert ingredients as classified by the Environmental Protection Agency (EPA), for use with nonsynthetic substances or synthetic substances listed in this section and used as an active pesticide ingredient in accordance with any limitations on the use of such substances.
(1)	EPA List 4—Inerts of Minimal Concern.
(o)	As production aids. 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.
§ 205.602 Nonsynthetic substances prohibited for use in organic crop production.	
(a)	Ash from manure burning.
(b)	Arsenic.
(d)	Lead salts.
(e)	Potassium chloride—unless derived from a mined source and applied in a manner that minimizes chloride accumulation in the soil.
(f)	Sodium fluoaluminate (mined).
(h)	Strychnine.
(i)	Tobacco dust (nicotine sulfate).
§ 205.603 Synthetic substances allowed for use in organic livestock production.	
In accordance with restrictions specified in this section the following synthetic substances may be used in organic livestock production:	
(a)	As disinfectants, sanitizer, and medical treatments as applicable.
(1)	Alcohols.
(i)	Ethanol-disinfectant and sanitizer only, prohibited as a feed additive.
(ii)	Isopropanol-disinfectant only.
(2)	Aspirin-approved for health care use to reduce inflammation.
(3)	Atropine (CAS #-51-55-8)—federal law restricts this drug to use by or on the lawful written or oral order of a licensed veterinarian, in full compliance with the AMDUCA and 21 CFR part 530 of the Food and Drug Administration regulations. Also, for use under 7 CFR part 205, the NOP requires: (i) Use by or on the lawful written order of a licensed veterinarian; and (ii) A meat withdrawal period of at least 56 days after administering to livestock intended for slaughter; and a milk discard period of at least 12 days after administering to dairy animals.
(4)	Biologics—Vaccines.
(5)	Butorphanol (CAS #-42408-82-2)—federal law restricts this drug to use by or on the lawful written or oral order of a licensed veterinarian, in full compliance with

	the AMDUCA and 21 CFR part 530 of the Food and Drug Administration regulations. Also, for use under 7 CFR part 205, the NOP requires: (i) Use by or on the lawful written order of a licensed veterinarian; and (ii) A meat withdrawal period of at least 42 days after administering to livestock intended for slaughter; and a milk discard period of at least 8 days after administering to dairy animals.
(6)	Chlorhexidine—Allowed for surgical procedures conducted by a veterinarian. Allowed for use as a teat dip when alternative germicidal agents and/or physical barriers have lost their effectiveness.
(7)	Chlorine materials—disinfecting and sanitizing facilities and equipment. Residual chlorine levels in the water shall not exceed the maximum residual disinfectant limit under the Safe Drinking Water Act.
(i)	Calcium hypochlorite.
(ii)	Chlorine dioxide.
(iii)	Sodium hypochlorite.
(8)	Electrolytes—without antibiotics.
(9)	Flunixin (CAS #-38677-85-9)—in accordance with approved labeling; except that for use under 7 CFR part 205, the NOP requires a withdrawal period of at least two-times that required by the FDA.
(11)	Glucose.
(12)	Glycerin—Allowed as a livestock teat dip, must be produced through the hydrolysis of fats or oils.
(13)	Hydrogen peroxide.
(14)	Iodine.
(15)	Magnesium hydroxide (CAS #-1309-42-8)—federal law restricts this drug to use by or on the lawful written or oral order of a licensed veterinarian, in full compliance with the AMDUCA and 21 CFR part 530 of the Food and Drug Administration regulations. Also, for use under 7 CFR part 205, the NOP requires use by or on the lawful written order of a licensed veterinarian.
(16)	Magnesium sulfate.
(17)	Oxytocin—use in postparturition therapeutic applications.
(18)	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. Milk or milk products from a treated animal cannot be labeled as provided for in subpart D of this part for 90 days following treatment. In breeder stock, treatment cannot occur during the last third of gestation if the progeny will be sold as organic and must not be used during the lactation period for breeding stock.
(i)	Fenbendazole (CAS #43210-67-9)—only for use by or on the lawful written order of a licensed veterinarian.
(ii)	Ivermectin (CAS #70288-86-7).
(iii)	Moxidectin (CAS #113507-06-5)—for control of internal parasites only.
(19)	Peroxyacetic / Peracetic acid (CAS #-79-21-0)—for sanitizing facility and processing equipment.
(20)	Phosphoric acid—allowed as an equipment cleaner, <i>Provided</i> , That, no direct contact with organically managed livestock or land occurs.
(21)	Poloxalene (CAS #-9003-11-6)—for use under 7 CFR part 205, the NOP requires

	that poloxalene only be used for the emergency treatment of bloat.
(22)	Tolazoline (CAS #-59-98-3)—federal law restricts this drug to use by or on the lawful written or oral order of a licensed veterinarian, in full compliance with the AMDUCA and 21 CFR part 530 of the Food and Drug Administration regulations. Also, for use under 7 CFR part 205, the NOP requires: (i) Use by or on the lawful written order of a licensed veterinarian; (ii) Use only to reverse the effects of sedation and analgesia caused by Xylazine; and (iii) A meat withdrawal period of at least 8 days after administering to livestock intended for slaughter; and a milk discard period of at least 4 days after administering to dairy animals.
(23)	Xylazine (CAS #-7361-61-7)—federal law restricts this drug to use by or on the lawful written or oral order of a licensed veterinarian, in full compliance with the AMDUCA and 21 CFR part 530 of the Food and Drug Administration regulations. Also, for use under 7 CFR part 205, the NOP requires: (i) Use by or on the lawful written order of a licensed veterinarian; (ii) The existence of an emergency; and (iii) A meat withdrawal period of at least 8 days after administering to livestock intended for slaughter; and a milk discard period of at least 4 days after administering to dairy animals.
(b)	As topical treatment, external parasiticide or local anesthetic as applicable.
(1)	Copper sulfate.
(2)	Formic acid (CAS # 64-18-6)—for use as a pesticide solely within honeybee hives.
(3)	Iodine.
(4)	Lidocaine—as a local anesthetic. Use requires a withdrawal period of 90 days after administering to livestock intended for slaughter and 7 days after administering to dairy animals.
(5)	Lime, hydrated—as an external pest control, not permitted to cauterize physical alterations or deodorize animal wastes.
(6)	Mineral oil—for topical use and as a lubricant.
(7)	Procaine—as a local anesthetic, use requires a withdrawal period of 90 days after administering to livestock intended for slaughter and 7 days after administering to dairy animals.
(8)	Sucrose octanoate esters (CAS #s-42922-74-7; 58064-47-4)—in accordance with approved labeling.
(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 maximum levels of synthetic methionine per ton of feed: Laying and broiler chickens—2 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.
(f)	Excipients, only for use in the manufacture of drugs used to treat organic livestock

	when the excipient is: Identified by the FDA as Generally Recognized As Safe; Approved by the FDA as a food additive; or Included in the FDA review and approval of a New Animal Drug Application or New Drug Application.
§ 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.
§ 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)).”	
(a)	Nonsynthetics allowed:
	Acids (Alginic; Citric—produced by microbial fermentation of carbohydrate substances; and Lactic).
	Attapulgate—as a processing aid in the handling of plant and animal oils.
	Bentonite.
	Calcium carbonate.
	Calcium chloride.
	Dairy cultures.
	Diatomaceous earth—food filtering aid only.
	Enzymes—must be derived from edible, nontoxic plants, nonpathogenic fungi, or nonpathogenic bacteria.
	Flavors, nonsynthetic sources only and must not be produced using synthetic solvents and carrier systems or any artificial preservative.
	Kaolin.
	Magnesium sulfate, nonsynthetic sources only.
	Nitrogen—oil-free grades.
	Oxygen—oil-free grades.
	Perlite—for use only as a filter aid in food processing.
	Potassium chloride.
	Potassium iodide.
	Sodium bicarbonate.
	Sodium carbonate.
	Waxes—nonsynthetic (Carnauba wax; and Wood resin).
	Yeast—When used as food or a fermentation agent in products labeled as “organic,” yeast must be organic if its end use is for human consumption; nonorganic yeast may be used when organic yeast is not commercially available. Growth on petrochemical substrate and sulfite waste liquor is prohibited. For smoked yeast, nonsynthetic smoke flavoring process must be documented.
(b)	Synthetics allowed:
	Acidified sodium chlorite—Secondary direct antimicrobial food treatment and indirect food contact surface sanitizing. Acidified with citric acid only.
	Alginates.
	Ammonium bicarbonate—for use only as a leavening agent.
	Ammonium carbonate—for use only as a leavening agent.
	Ascorbic acid.
	Calcium citrate.

	Calcium hydroxide.
	Calcium phosphates (monobasic, dibasic, and tribasic).
	Carbon dioxide.
	Chlorine materials—disinfecting and sanitizing food contact surfaces, <i>Except, That,</i> residual chlorine levels in the water shall not exceed the maximum residual disinfectant limit under the Safe Drinking Water Act (Calcium hypochlorite; Chlorine dioxide; and Sodium hypochlorite).
	Ethylene—allowed for postharvest ripening of tropical fruit and degreening of citrus.
	Ferrous sulfate—for iron enrichment or fortification of foods when required by regulation or recommended (independent organization).
	Glycerides (mono and di)—for use only in drum drying of food.
	Glycerin—produced by hydrolysis of fats and oils.
	Hydrogen peroxide.
	Magnesium chloride—derived from sea water.
	Magnesium stearate—for use only in agricultural products labeled “made with organic (specified ingredients or food group(s)),” prohibited in agricultural products labeled “organic”.
	Nutrient vitamins and minerals, in accordance with 21 CFR 104.20, Nutritional Quality Guidelines For Foods.
	Ozone.
	Phosphoric acid—cleaning of food-contact surfaces and equipment only.
	Potassium acid tartrate.
	Potassium carbonate.
	Potassium citrate.
	Potassium phosphate—for use only in agricultural products labeled “made with organic (specific ingredients or food group(s)),” prohibited in agricultural products labeled “organic”.
	Sodium citrate.
	Sodium hydroxide—prohibited for use in lye peeling of fruits and vegetables.
	Sodium phosphates—for use only in dairy foods.
	Sulfur dioxide—for use only in wine labeled “made with organic grapes,” Provided, That, total sulfite concentration does not exceed 100 ppm.
	Tocopherols—derived from vegetable oil when rosemary extracts are not a suitable alternative.
	Xanthan gum.
§ 205.606 Nonorganically produced agricultural products allowed as ingredients in or on processed products labeled as “organic.”	
Only the following nonorganically produced agricultural products may be used as ingredients in or on processed products labeled as “organic,” only in accordance with any restrictions specified in this section, and only when the product is not commercially available in organic form.	
(a)	Casings, from processed intestines.
(b)	Celery powder.
(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 (pigment CAS #7659-95-2).
(3)	Black currant juice color (pigment CAS #'s: 528-58-5, 528-53-0, 643-84-5, 134-01-0, 1429-30-7, and 134-04-3).
(4)	Black/Purple carrot juice color (pigment CAS #'s: 528-58-5, 528-53-0, 643-84-5, 134-01-0, 1429-30-7, and 134-04-3).
(5)	Blueberry juice color (pigment CAS #'s: 528-58-5, 528-53-0, 643-84-5, 134-01-0, 1429-30-7, and 134-04-3).
(6)	Carrot juice color (pigment CAS #1393-63-1).
(7)	Cherry juice color (pigment CAS #'s: 528-58-5, 528-53-0, 643-84-5, 134-01-0, 1429-30-7, and 134-04-3).
(8)	Chokeberry—Aronia juice color (pigment CAS #'s: 528-58-5, 528-53-0, 643-84-5, 134-01-0, 1429-30-7, and 134-04-3).
(9)	Elderberry juice color (pigment CAS #'s: 528-58-5, 528-53-0, 643-84-5, 134-01-0, 1429-30-7, and 134-04-3).
(10)	Grape juice color (pigment CAS #'s: 528-58-5, 528-53-0, 643-84-5, 134-01-0, 1429-30-7, and 134-04-3).
(11)	Grape skin extract color (pigment CAS #'s: 528-58-5, 528-53-0, 643-84-5, 134-01-0, 1429-30-7, and 134-04-3).
(12)	Paprika color (CAS #68917-78-2)—dried, and oil extracted.
(13)	Pumpkin juice color (pigment CAS #127-40-2).
(14)	Purple potato juice (pigment CAS #'s: 528-58-5, 528-53-0, 643-84-5, 134-01-0, 1429-30-7, and 134-04-3).
(15)	Red cabbage extract color (pigment CAS #'s: 528-58-5, 528-53-0, 643-84-5, 134-01-0, 1429-30-7, and 134-04-3).
(16)	Red radish extract color (pigment CAS #'s: 528-58-5, 528-53-0, 643-84-5, 134-01-0, 1429-30-7, and 134-04-3).
(17)	Saffron extract color (pigment CAS #1393-63-1).
(18)	Turmeric extract color (CAS #458-37-7).
(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).
(i)	Gelatin (CAS # 9000-70-8).
(j)	Gums—water extracted only (Arabic; Guar; Locust bean; and Carob bean).
(l)	Kelp—for use only as a thickener and dietary supplement.
(m)	Konjac flour (CAS # 37220-17-0).
(n)	Lecithin—de-oiled.
(p)	Orange pulp, dried.
(q)	Orange shellac-unbleached (CAS # 9000-59-3).
(r)	Pectin (non-amidated forms only).
(t)	Seaweed, Pacific kombu.
(u)	Starches.
(1)	Cornstarch (native).
(2)	Sweet potato starch—for bean thread production only.
(x)	Wakame seaweed (<i>Undaria pinnatifida</i>).

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