§ 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:

(a) As algicide, disinfectants, and sanitizer, including irrigation system cleaning systems

- (1) Alcohols
- (i) Ethanol
- (ii) Isopropanol

(2) Chlorine materials - *Except*, That, residual chlorine levels in the water shall not exceed the maximum residual disinfectant limit under the Safe Drinking Water Act.

- (i) Calcium hypochlorite
- (ii) Chlorine dioxide
- (iii) Sodium hypochlorite
- (3) Hydrogen peroxide

(4) Soap-based algicide/demisters

(b) As herbicides, weed barriers, as applicable.

(1) Herbicides, soap-based - for use in farmstead maintenance (roadways, ditches, right of ways, building perimeters) and ornamental crops

(2) Mulches

(i) Newspaper or other recycled paper, without glossy or colored inks.

(ii) Plastic mulch and covers (petroleum-based other than polyvinyl chloride (PVC))

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

(d) As animal repellents - Soaps, ammonium - for use as a large animal 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) Boric acid - structural pest control, no direct contact with organic food or crops

(3) Elemental sulfur

(4) Lime sulfur - including calcium polysulfide

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

- (6) Soaps, insecticidal
- (7) Sticky traps/barriers
- (f) As insect attractants Pheromones
- (g) As rodenticides

(1) Sulfur dioxide - underground rodent control only (smoke bombs)

- (2) Vitamin D3
- (h) As slug or snail bait None
- (i) As plant disease control

(1) 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.

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

(3) Hydrated lime - must be used in a manner that minimizes copper accumulation in the soil.

(4) Hydrogen peroxide

(5) Lime sulfur

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

(7) Potassium bicarbonate

(8) Elemental sulfur

(9) Streptomycin, for fire blight control in apples and pears only

(10) Tetracycline (oxytetracycline calcium complex), for fire blight control only

(j) As plant or soil amendments.

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

(2) Elemental sulfur

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

(4) Lignin sulfonate - chelating agent, dust suppressant, floatation agent

(5) Magnesium sulfate - allowed with a documented soil deficiency

(6) Micronutrients - not to be used as a defoliant, herbicide, or desiccant. Those made from nitrates or chlorides are not allowed. Soil deficiency must be documented by testing.

(i) Soluble boron products

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

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

(8) Vitamins, B1, C, and E

(k) As plant growth regulators - Ethylene - for regulation of pineapple flowering

(I) As floating agents in postharvest handling

(1) Lignin sulfonate

(2) Sodium silicate - for tree fruit and fiber processing

(m) As synthetic inert ingredients as classified by the Environmental Protection Agency (EPA), for use with nonsynthetic substances or synthetic substances listed in this section and used as an active pesticide ingredient in accordance with any limitations on the use of such substances.

(1) EPA List 4 - Inerts of Minimal Concern (n)-(z) [Reserved]

§ 205.602 Nonsynthetic substances prohibited for use in organic crop production.

The following nonsynthetic substances may not be used in organic crop production:

(a) Ash from manure burning

(b) Arsenic

(c) Lead salts

(d) Sodium fluoaluminate (mined)

(e) Strychnine

(f) Tobacco dust (nicotine sulfate)

(g) Potassium chloride - unless derived from a mined source and applied in a manner that minimizes chloride accumulation in the soil.

(h) Sodium nitrate - unless use is restricted to no more than 20% of the crop's total nitrogen requirement.

(i)-(z) [Reserved]

§ 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) 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

(4) Chlorohexidine - 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

(5) Electrolytes - without antibiotics

(6) Glucose

(7) Glycerin - Allowed as a livestock teat dip, must be produced through the hydrolysis of fats or oils

- (8) Iodine
- (9) Hydrogen peroxide
- (10) Magnesium sulfate

(11) Oxytocin - use in postparturition therapeutic applications

(12) Parasiticides - Ivermectin - prohibited in slaughter stock, allowed in emergency treatment for dairy and breeder stock when organic system plan-approved preventive management does not prevent infestation. Milk or milk products from a treated animal cannot be labeled as provided for in subpart D of this part for 90 days following treatment. In breeder stock, treatment cannot occur during the last third of gestation if the progeny will be sold as organic and must not be used during the lactation period of breeding stock.

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

(14) Biologics - Vaccines

(b) As topical treatment, external parasiticide or local anesthetic as applicable.

(1) Iodine

(2) 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

(3) Lime, hydrated - (bordeaux mixes), not permitted to cauterize physical alterations or deodorize animal wastes.

(4) Mineral oil - for topical use and as a lubricant

(5) 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

(6) Copper sulfate

(c) As feed supplements - Milk replacers - without antibiotics, as emergency use only, no nonmilk products or products from BST treated animals

(d) As feed additives

(1) Trace minerals, used for enrichment or fortification when FDA approved, including:

(i) Copper sulfate

(ii) Magnesium sulfate

(2) 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 a synthetic substances listed in this section and used as an active pesticide ingredient in accordance with any limitations on the use of such substances.

EPA List 4 - Inerts of Minimal Concern.

(f)-(z) [Reserved]

§ 205.604 Nonsynthetic substances prohibited for use in organic livestock production.

The following nonsynthetic substances may not be used in organic livestock production:

(a) Strychnine

(b)-(z) [Reserved]

§ 205.605 Nonagricultural (nonorganic) substances allowed as ingredients in or on processed products labeled as "organic" or "made with organic (specified ingredients or food group(s))."

The following nonagricultural substances may be used as ingredients in or on processed products labeled as "organic" or "made with organic (specified ingredients or food group(s))" only in accordance with any restrictions specified in this section.

(a) Nonsynthetics allowed:

- (1) Acids
- (i) Alginic

(ii) Citric - produced by microbial fermentation of carbohydrate substances

- (iii) Lactic
- (2) Bentonite
- (3) Calcium carbonate
- (4) Calcium chloride
- (5) Colors, nonsynthetic sources only
- (6) Dairy cultures

(7) Diatomaceous earth - food filtering aid only

(8) Enzymes - must be derived from edible, nontoxic plants, nonpathogenic fungi, or nonpathogenic bacteria

(9) Flavors, nonsynthetic sources only and must not be produced using synthetic solvents and carrier systems or any artificial preservative.

(10) Kaolin

(11) Magnesium sulfate, nonsynthetic sources

- (12) Nitrogen oil-free grades
- (13) Oxygen oil-free grades

(14) Perlite - for use only as a filter aid in food processing

- (15) Potassium chloride
- (16) Potassium iodide
- (17) Sodium bicarbonate
- (18) Sodium carbonate
- (19) Waxes nonsynthetic
- (i) Carnauba wax
- (ii) Wood resin

(20) Yeast - nonsynthetic, growth on petrochemical substrate and sulfite waste liquor is prohibited

- (i) Autolysate
- (ii) Bakers
- (iii) Brewers
- (iv) Nutritional

(v) Smoked - nonsynthetic smoke flavoring process must be documented.

- (b) Synthetics allowed:
 - (1) Alginates

(2) Ammonium bicarbonate - for use only as a leavening agent

(3) Ammonium carbonate - for use only as a leavening agent

- (4) Ascorbic acid
- (5) Calcium citrate
- (6) Calcium hydroxide

(7) Calcium phosphates (monobasic, dibasic, and tribasic)

(8) Carbon dioxide

(9) Chlorine materials - disinfecting and sanitizing food contact surfaces, *Except*, That, residual chlorine levels in the water shall not exceed the maximum residual disinfectant limit under the Safe Drinking Water Act.

- (i) Calcium hypochlorite
- (ii) Chlorine dioxide
- (iii) Sodium hypochlorite

(10) Ethylene - allowed for postharvest ripening of tropical fruit

(11) Ferrous sulfate - for iron enrichment or fortification of foods when required by regulation or recommended (independent organization)

(12) Glycerides (mono and di) - for use only in drum drying of food

(13) Glycerin - produced by hydrolysis of fats and oils

(14) Hydrogen peroxide

(15) Lecithin - bleached

(16) Magnesium carbonate - for use only in agricultural products labeled "made with organic (specified ingredients or food group(s))," prohibited in agricultural products labeled "organic"

(17) Magnesium chloride - derived from sea water

(18) Magnesium stearate - for use only in agricultural products labeled "made with organic (specified ingredients or food group(s))," prohibited in agricultural products labeled "organic"

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

- (20) Ozone
- (21) Pectin (low-methoxy)

(22) Phosphoric acid - cleaning of food-contact surfaces and equipment only

- (23) Potassium acid tartrate
- (24) Potassium tartrate made from tartaric acid
- (25) Potassium carbonate
- (26) Potassium citrate

(27) Potassium hydroxide - prohibited for use in lye peeling of fruits and vegetables

only

(28) Potassium iodide - for use only in agricultural products labeled "made with organic (specified ingredients or food group(s))," prohibited in agricultural products labeled "organic"

(29) Potassium phosphate - for use only in agricultural products labeled "made with organic (specific ingredients or food group(s))," prohibited in agricultural products labeled "organic"

(30) Silicon dioxide

(31) Sodium citrate

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

(33) Sodium phosphates - for use only in dairy foods

(34) Sulfur dioxide - for use only in wine labeled "made with organic grapes," *Provided*, That, total sulfite concentration does not exceed 100 ppm.

(35) Tocopherols - derived from vegetable oil when rosemary extracts are not a suitable alternative

(36) Xanthan gum

(c)-(z) [Reserved]

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

The following nonorganically produced agricultural products 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.

Any nonorganically produced agricultural product may be used in accordance with the restrictions specified in this section and when the product is not commercially available in organic form.

(a) Cornstarch (native)

(b) Gums - water extracted only (arabic, guar, locust bean, carob bean)

(c) Kelp - for use only as a thickener and dietary supplement

(d) Lecithin - unbleached

(e) Pectin (high-methoxy)