



Organic Standards for Livestock Production

Highlights of the USDA's National Organic Program Regulations

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This collection of excerpts from the U. S. Department of Agriculture's National Organic Program provides the reader with key standards relevant to organic livestock producers. This publication should be used with excerpts for all certified organic operations, and organic crop production and handling of organic agricultural products, as applicable.

Highlights of the USDA's National Organic Program Regulations include key standards for:

- 1) All certified organic operations
- 2) Crop production
- 3) Livestock production
- 4) Handling (including processing)

Please use this publication in combination with the ATTRA publication *Organic Standards for All Organic Operations*, and others, if relevant to your organic operations.

Introduction

This publication provides easy reference to the standards relevant to organic livestock production. This set of excerpts from the USDA's National Organic Program Final Rule contains the general requirements for organic livestock management, including origin of livestock, feed, health care, living conditions, lists of allowed and prohibited substances and definition of terms most applicable to livestock production. While this publication includes the key standards that directly address organic livestock crop production, it is not a complete collection of all the standards with which organic livestock producers must comply. It must be used in conjunction with standards for all organic operations, organic crop production (including pasture or range) and handling of organic agricultural products, as applicable.

This set of excerpts is not a substitute for reading the entire set of standards. The regulatory texts of the National Organic Program standards are available on USDA's National Organic Program Web site, www.ams.usda.gov/nop/. To view the production and handling standards, click on "Regulations" under General Information. Under Regulatory Text, click on "Electronic

Code of Federal Regulations." This set of excerpts should also not be used as a substitute for verifying points of compliance for organic production and handling activities with an accredited organic certifier. For a list of certifiers, click on Certifiers under "I Want Information On" in the NOP Web site index (above).

Using this guide:

This is a collection of verbatim excerpts from key parts of the National Organic Program's Final Rule. Organic regulations are found under the USDA's Agricultural Marketing Service 7 CFR Part 205. CFR stands for Code of Federal Regulations. Part 205, the National Organic Program is found under Title 7: Agriculture, one of 50 broad subject areas that are subject to federal regulation.

The Organic Foods Production Act was enacted under the 1990 Farm Bill. The Act, as it is referred to in the text, authorized creation of the USDA National Organic Program to set national standards for the production, handling and processing of organically grown agricultural products. The NOP oversees mandatory certification of organic production. Producers who meet NOP standards may label their products as "USDA Certified Organic." The subparts reference organization levels in each excerpt.



The following sections of Part 205 of the National Organic Program are excerpted below:

- § 205.236 Origin of livestock
- § 205.237 Livestock feed
- § 205.238 Livestock health care practice standard
- § 205.239 Livestock living conditions
- § 205.301 Product composition

The National List of Allowed and Prohibited Substances

- § 205.603 Synthetic substances allowed for use in organic livestock production
- § 205.604 Non-synthetic substances prohibited for use in organic livestock production
- § 205.2 Terms defined [selected terms for livestock production]

Note: e-CFR Data used in this publication is current as of July 23, 2008.

Amendment dates are noted at the end of certain sections, such as Defined terms, the National List and also in some aspects of livestock production. Changes may be the result of legal actions, petitions to add or remove materials or technical corrections. Most other sections of the Rule have not changed since their original version. To find the most current version available, please go the electronic code of federal regulations. See instructions in paragraph two of the Introduction.

Excerpts

§ 205.236 Origin of livestock

(a) Livestock products that are to be sold, labeled or represented as organic must be from livestock under continuous organic management from the last third of gestation or hatching, except that:

(1) Poultry

Poultry or edible poultry products must be from poultry that has been under continuous organic

management beginning no later than the second day of life;

(2) Dairy animals

Milk or milk products must be from animals that have been under continuous organic management beginning no later than one year prior to the production of the milk or milk products that are to be sold, labeled or represented as organic, except

(i) That crops and forage from land, included in the organic system plan of a dairy farm, that is in the third year of organic management may be consumed by the dairy animals of the farm during the 12-month period immediately prior to the sale of organic milk and milk products; and

(ii) That, when an entire, distinct herd is converted to organic production, the producer may, provided no milk produced under this subparagraph enters the stream of commerce labeled as organic after June 9, 2007: (a) For the first nine months of the year, provide a minimum of 80 percent feed that is either organic or raised from land included in the organic system plan and managed in compliance with organic crop requirements; and (b) Provide feed in compliance with §205.237 for the final three months.

(iii) Once an entire, distinct herd has been converted to organic production, all dairy animals shall be under organic management from the last third of gestation.

(3) Breeder stock

Livestock used as breeder stock may be brought from a

non-organic operation onto an organic operation at any time, provided that if such livestock are gestating and the offspring are to be raised as organic livestock, the breeder stock must be brought onto the facility no later than the last third of gestation.

(b) The following are prohibited:

- (1) Livestock or edible livestock products that are removed from an organic operation and subsequently managed on a non-organic operation may be not sold, labeled or represented as organically produced.
 - (2) Breeder or dairy stock that has not been under continuous organic management since the last third of gestation may not be sold, labeled or represented as organic slaughter stock.
- (c) The producer of an organic livestock operation must maintain records sufficient to preserve the identity of all organically managed animals and edible and non-edible animal products produced on the operation.

[65 FR 80637, Dec. 21, 2000, as amended at 71 FR 32807, June 7, 2006]

§ 205.237 Livestock feed

- (a) The producer of an organic livestock operation must provide livestock with a total feed ration composed of agricultural products, including pasture and forage, that are organically produced and, if applicable, organically handled, except that non-synthetic substances and synthetic substances allowed under §205.603 may be used as feed additives and supplements.
- (b) The producer of an organic operation must not:
 - (1) Use animal drugs, including hormones, to promote growth;

- (2) Provide feed supplements or additives in amounts above those needed for adequate nutrition and health maintenance for the species at its specific stage of life;
- (3) Feed plastic pellets for roughage;
- (4) Feed formulas containing urea or manure;
- (5) Feed mammalian or poultry slaughter by-products to mammals or poultry; or
- (6) Use feed, feed additives and feed supplements in violation of the Federal Food, Drug and Cosmetic Act.

§ 205.238 Livestock health care practice standard

- (a) The producer must establish and maintain preventive livestock health care practices, including:
 - (1) Selection of species and types of livestock with regard to suitability for site-specific conditions and resistance to prevalent diseases and parasites;
 - (2) Provision of a feed ration sufficient to meet nutritional requirements, including vitamins, minerals, protein and/or amino acids, fatty acids, energy sources and fiber (ruminants);
 - (3) Establishment of appropriate housing, pasture conditions and sanitation practices to minimize the occurrence and spread of diseases and parasites;
 - (4) Provision of conditions which allow for exercise, freedom of movement and reduction of stress appropriate to the species;
 - (5) Performance of physical alterations as needed to promote the animal's welfare and in a manner that minimizes pain and stress; and

- (6) Administration of vaccines and other veterinary biologics.
- (b) When preventive practices and veterinary biologics are inadequate to prevent sickness, a producer may administer synthetic medications, provided that such medications are allowed under §205.603. Parasiticides allowed under §205.603 may be used on:
- (1) Breeder stock, when used prior to the last third of gestation but not during lactation for progeny that are to be sold, labeled or represented as organically produced; and
 - (2) Dairy stock, when used a minimum of 90 days prior to the production of milk or milk products that are to be sold, labeled or represented as organic.
- (c) The producer of an organic livestock operation must not:
- (1) Sell, label or represent as organic any animal or edible product derived from any animal treated with antibiotics, any substance that contains a synthetic substance not allowed under §205.603, or any substance that contains a non-synthetic substance prohibited in §205.604.
 - (2) Administer any animal drug, other than vaccinations, in the absence of illness;
 - (3) Administer hormones for growth promotion;
 - (4) Administer synthetic parasiticides on a routine basis;
 - (5) Administer synthetic parasiticides to slaughter stock;
 - (6) Administer animal drugs in violation of the Federal Food, Drug and Cosmetic Act; or
- (7) Withhold medical treatment from a sick animal in an effort to preserve its organic status. All appropriate medications must be used to restore an animal to health when methods acceptable to organic production fail. Livestock treated with a prohibited substance must be clearly identified and shall not be sold, labeled or represented as organically produced.

§ 205.239 Livestock living conditions

- (a) The producer of an organic livestock operation must establish and maintain livestock living conditions which accommodate the health and natural behavior of animals, including:
- (1) Access to the outdoors, shade, shelter, exercise areas, fresh air and direct sunlight suitable to the species, its stage of production, the climate and the environment;
 - (2) Access to pasture for ruminants;
 - (3) Appropriate clean, dry bedding. If the bedding is typically consumed by the animal species, it must comply with the feed requirements of §205.237;
 - (4) Shelter designed to allow for:
 - (i) Natural maintenance, comfort behaviors and opportunity to exercise;
 - (ii) Temperature level, ventilation and air circulation suitable to the species; and
 - (iii) Reduction of potential for livestock injury;
- (b) The producer of an organic livestock operation may provide temporary confinement for an animal because of:
- (1) Inclement weather;
 - (2) The animal's stage of production;

- (3) Conditions under which the health, safety or well-being of the animal could be jeopardized; or
 - (4) Risk to soil or water quality.
- (c) The producer of an organic livestock operation must manage manure in a manner that does not contribute to contamination of crops, soil or water by plant nutrients, heavy metals or pathogenic organisms and optimizes recycling of nutrients.

§ 205.301 Product composition

(a) Livestock feed

(1) A raw or processed livestock feed product sold, labeled or represented as “100-percent organic” must contain (by weight or fluid volume, excluding water and salt) not less than 100 percent organically produced raw or processed agricultural product.

(2) A raw or processed livestock feed product sold, labeled or represented as “organic” must be produced in conformance with §205.237.

(b) All products labeled as “100-percent organic” or “organic” and all ingredients identified as “organic” in the ingredient statement of any product must not:

- (1) Be produced using excluded methods, pursuant to §201.105(e) of this chapter;
- (2) Be produced using sewage sludge, pursuant to §201.105(f) of this chapter;
- (3) Be processed using ionizing radiation, pursuant to §201.105(g) of this chapter;
- (4) Be processed using processing aids not approved on the National List of Allowed and Prohibited Substances in subpart G of this part, except that products labeled

as “100-percent organic,” if processed, must be processed using organically produced processing aids;

(5) Contain sulfites, nitrates or nitrites added during the production or handling process, except that wine containing added sulfites may be labeled “made with organic grapes”;

(6) Be produced using non-organic ingredients when organic ingredients are available; or

(7) Include organic and non-organic forms of the same ingredient.

The National List of Allowed and Prohibited Substances

§ 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 eight 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.
- (10) Furosemide (CAS #-54-31-9)—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) Glycerine—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) Paraciticides. 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 for breeding stock.

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

(20) Phosphoric acid—allowed as an equipment cleaner, provided 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 eight days after administering to livestock intended for slaughter and a milk discard period of at least four 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 eight days after administering to livestock intended for slaughter and a milk discard period of at least four days after administering to dairy animals.

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

(1) Copper sulfate.

(2) Iodine.

(3) Lidocaine—as a local anesthetic. Use requires a withdrawal period of 90 days after administering to livestock intended for slaughter and seven days after administering to dairy animals.

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

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

(6) Procaine—as a local anesthetic, use requires a withdrawal period of 90 days after administering to livestock intended for slaughter and seven days after administering to dairy animals.

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

(c) As feed supplements—None.

- (d) As feed additives.
- (1) DL-Methionine, DL-Methionine—hydroxy analog, and DL-Methionine—hydroxy analog calcium (CAS #–59–51–8; 63–68–3; 348–67–4)—for use only in organic poultry production until October 1, 2008.
 - (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, for use with non-synthetic 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 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.

(g)–(z) [Reserved]

[72 FR 70484, Dec. 12, 2007]

§ 205.604 Non-synthetic substances prohibited for use in organic livestock production

The following non-synthetic substances may not be used in organic livestock production:

- (a) Strychnine.
- (b)–(z) [Reserved]

§ 205.2 Terms defined [selected terms for livestock production]

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

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

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

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

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

Biologics. All viruses, serums, toxins and analogous products of natural or synthetic origin, such as diagnostics, antitoxins, vaccines, live microorganisms, killed microorganisms and the antigenic or immunizing components of microorganisms intended for use in the diagnosis, treatment or prevention of diseases of animals.

Breeder stock. Female livestock whose offspring may be incorporated into an organic operation at the time of their birth.

Compost. The product of a managed process through which microorganisms break down plant and animal materials into more available forms suitable for application to the soil. Compost must be produced through a process that combines plant and animal materials with an initial C:N ratio of between 25:1 and 40:1. Producers using

an in-vessel or static aerated pile system must maintain the composting materials at a temperature between 131 degrees Fahrenheit and 170 degrees Fahrenheit for three days. Producers using a windrow system must maintain the composting materials at a temperature between 131 degrees and 170 degrees for 15 days, during which time the materials must be turned a minimum of five times.

Crop. A plant or part of a plant intended to be marketed as an agricultural product or fed to livestock.

Disease vectors. Plants or animals that harbor or transmit disease organisms or pathogens which may attack crops or livestock.

Excipients. Any ingredients that are intentionally added to livestock medications but do not exert therapeutic or diagnostic effects at the intended dosage, although they may act to improve product delivery by enhancing absorption or controlling release of the drug substance or other methods. Examples of such ingredients include fillers, extenders, diluents, wetting agents, solvents, emulsifiers, preservatives, flavors, absorption enhancers, sustained-release matrices and coloring agents.

Excluded methods. A variety of methods used to genetically modify organisms or influence their growth and development by means that are not possible under natural conditions or processes and are not considered compatible with organic production. Such methods include cell fusion, microencapsulation and macroencapsulation and recombinant DNA technology including gene deletion, gene doubling, introducing a foreign gene and changing the positions of genes when achieved by recombinant DNA technology. Such methods do not include the use of traditional breeding, conjugation, fermentation, hybridization, in vitro fertilization or tissue culture.

Feed. Edible materials that are consumed by livestock for their nutritional value. Feed may be concentrates (grains) or roughages (hay, silage or fodder). The

term “feed” encompasses all agricultural commodities, including pasture ingested by livestock for nutritional purposes.

Feed additive. A substance added to feed in micro quantities to fulfill a specific nutritional need, such as essential nutrients in the form of amino acids, vitamins and minerals.

Feed supplement. A combination of feed nutrients added to livestock feed to improve the nutrient balance or performance of the total ration and intended to be:

- (1) Diluted with other feeds when fed to livestock;
- (2) Offered free choice with other parts of the ration if separately available; or
- (3) Further diluted and mixed to produce a complete feed.

Fertilizer. A single or blended substance containing one or more recognized plant nutrients that is used primarily for its plant nutrient content and which is designed for use or claimed to have value in promoting plant growth.

Field. An area of land identified as a discrete unit within a production operation.

Forage. Vegetative material in a fresh, dried or ensiled state (pasture, hay or silage), which is fed to livestock.

Handle. To sell, process or package agricultural products, except such term shall not include the sale, transportation or delivery of crops or livestock by the producer thereof to a handler.

Immediate family. The spouse, minor children or blood relatives who reside in the immediate household of a certifying agent or an employee, inspector, contractor or other personnel of the certifying agent. For the purpose of this part, the interest of a spouse, minor child or blood relative who is a resident of the immediate household of a certifying agent or an employee, inspector, contractor or other personnel of the certifying agent shall be considered

to be an interest of the certifying agent or an employee, inspector, contractor or other personnel of the certifying agent.

Inert ingredient. Any substance (or group of substances with similar chemical structures if designated by the EPA) other than an active ingredient which is intentionally included in any pesticide product (40 CFR 152.3(m)).

Livestock. Any cattle, sheep, goat, swine, poultry or equine animals used for food or in the production of food, fiber, feed or other agricultural-based consumer products; wild or domesticated game or other non-plant life, except such term shall not include aquatic animals or bees for the production of food, fiber, feed or other agricultural-based consumer products.

Manure. Feces, urine, other excrement and bedding produced by livestock that has not been composted.

National List. A list of allowed and prohibited substances as provided for in the Act.

Natural resources of the operation. The physical, hydrological and biological features of a production operation, including soil, water, wetlands, woodlands and wildlife.

Non-synthetic (natural). A substance that is derived from mineral, plant or animal matter and does not undergo a synthetic process as defined in section 6502(21) of the Act (7 U.S.C. 6502(21)). For the purposes of this part, non-synthetic is used as a synonym for natural as the term is used in the Act.

Organic matter. The remains, residues or waste products of any organism.

Organic production. A production system that is managed in accordance with the Act and regulations in this part to respond to site-specific conditions by integrating cultural, biological and mechanical practices that foster cycling of resources, promote ecological balance and conserve biodiversity.

Organic system plan. A plan of management of an organic production or handling operation that has been agreed to by the producer or handler and the certifying agent and that includes written plans concerning all aspects of agricultural production or handling described in the Act and the regulations in subpart C of this part.

Pasture. Land used for livestock grazing that is managed to provide feed value and maintain or improve soil, water and vegetative resources.

Pesticide. Any substance which alone, in chemical combination or in any formulation with one or more substances is defined as a pesticide in section 2(u) of the Federal Insecticide, Fungicide and Rodenticide Act (7 U.S.C. 136(u) et seq.).

Practice standard. The guidelines and requirements through which a production or handling operation implements a required component of its production or handling organic system plan. A practice standard includes a series of allowed and prohibited actions, materials and conditions to establish a minimum level performance for planning, conducting and maintaining a function, such as livestock health care or facility pest management, essential to an organic operation.

Processing. Cooking, baking, curing, heating, drying, mixing, grinding, churning, separating, extracting, slaughtering, cutting, fermenting, distilling, eviscerating, preserving, dehydrating, freezing, chilling or otherwise manufacturing and includes the packaging, canning, jarring or otherwise enclosing food in a container.

Producer. A person who engages in the business of growing or producing food, fiber, feed and other agricultural-based consumer products.

Records. Any information in written, visual or electronic form that documents the activities undertaken by a producer, handler or

certifying agent to comply with the Act and regulations in this part.

Routine use of pesticide. The regular, planned or periodic use of pesticides.

Sewage sludge. A solid, semisolid or liquid residue generated during the treatment of domestic sewage in a treatment works. Sewage sludge includes but is not limited to: domestic septage; scum or solids removed in primary, secondary or advanced wastewater treatment processes and a material derived from sewage sludge. Sewage sludge does not include ash generated during the firing of sewage sludge in a sewage sludge incinerator or grit and screenings generated during preliminary treatment of domestic sewage in a treatment works.

Slaughter stock. Any animal that is intended to be slaughtered for consumption by humans or other animals.

Soil and water quality. Observable indicators of the physical, chemical or biological condition of soil and water, including the presence of environmental contaminants.

Synthetic. A substance that is formulated or manufactured by a chemical process or by a process that chemically changes a substance extracted from naturally occurring plant, animal or mineral sources, except that such term shall not apply to substances created by naturally occurring biological processes.

[65 FR 80637, Dec. 21, 2000, as amended at 72 FR 70484, Dec. 12, 2007]

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