

Sunset 2020 Meeting 2 - Review
Livestock Substances §205.603
October 2018

Introduction

As part of the [Sunset Process](#), the National Organic Program (NOP) announces substances on the National List of Allowed and Prohibited Substances (National List) that are coming up for sunset review by the National Organic Standard Board (NOSB). The following list announces substances that are on the National List for use in organic livestock production that must be reviewed by the NOSB and renewed by the USDA before their sunset dates in 2022. This list provides the substance's current status on the National List, use description, references to past technical reports, past NOSB actions, and regulatory history, as applicable.

Request for Comments

Written public comments will be accepted through October 4, 2018 via www.regulations.gov. Comments received after that date may not be reviewed by the NOSB before the meeting.

Note: The materials included in this list are undergoing early sunset review as part of November 18, 2016 [NOSB recommendation](#) on efficient workload re-organization.

Reference: 7 CFR 205.603 Synthetic substances allowed for use in organic livestock production

[Alcohols: Ethanol, Isopropanol](#)

[Aspirin](#)

[Biologics, Vaccines](#)

[Electrolytes](#)

[Glycerin](#)

[Phosphoric acid](#)

[Lime, hydrated](#)

[Mineral oil](#)

[Sucrose octanoate esters](#)

Alcohols (i) Ethanol

Reference: **205.603(a)** As disinfectants, sanitizer, and medical treatments as applicable.

(1) Alcohols. (i) Ethanol-disinfectant and sanitizer only, prohibited as a feed additive.

Technical Report: [1995 TAP](#); [2014 TR Ethanol](#); [2014 TR Isopropanol](#)

Petition(s): N/A

Past NOSB Actions: [10/1995 NOSB minutes and vote](#); [11/2005 NOSB sunset recommendation](#); [10/2010 sunset recommendation](#); [10/2015 sunset recommendation](#)

Recent Regulatory Background: Sunset renewal notice published 06/06/12 ([77 FR 33290](#)); Sunset renewal notice published 03/21/17 ([82 FR 14420](#))

Sunset Date: 3/15/2022

Subcommittee Review

Use

The United States Environmental Protection Agency (US EPA) regulates all non-food applications of ethanol, including its use as a pesticide and plant growth regulator. According to the Reregistration Eligibility Decision for Aliphatic Alcohols, ethanol and isopropanol were registered in the US as early as 1948 as active ingredients in indoor disinfectants (US EPA, 1995). Approximately 48 ethanol products were registered for use as hard surface treatment disinfectants, sanitizers and mildewcides as of 2012 (US EPA, 2012a). Ethanol is also the active ingredient in certain plant growth regulator products.

Manufacture

Both fermentation and chemical synthesis procedures are used in the commercial production of ethanol for the preparation of disinfectant solutions, spirits, and industrial fuel sources. A variety of methods are available for the fermentative production of ethanol from carbon sources such as starch, sugar and cellulose using natural and genetically engineered strains of yeast or bacteria. Ethanol can also be produced synthetically through the direct or indirect hydration of ethylene and as a by-product of certain industrial operations.

International Equivalency

Several international organizations provide guidance on the application of synthetic ethanol in organic crop and livestock production as well as the processing of organic foods. Among these are international regulatory agencies (EU, Canada and Japan) and independent organic guidelines and standards organizations (Codex and IFOAM).

European Economic Community Council (EU) – Alcohols, presumably including ethanol, may be used for cleaning and disinfecting livestock building installations and utensils.

Canada – Canadian organic production standards permit the use of ethanol for a number of agricultural applications.

Japan – Ethanol may be used in the processing, cleaning, storage, packaging and other post-harvest processes when physical or methods using naturally derived substances are insufficient.

Codex Alimentarius – Ethanol is allowed when mechanical, physical and biological methods are inadequate for pest control.

IFOAM – Synthetic ethanol is an approved additive and processing/post-harvest handling aid when organic and natural sources are not available.

Environmental/Health Issues

Aside from accidental spills, the risk of environmental contamination from released ethanol is minimal. The release of strong acids and bases used in the production of ethanol due to improper handling/disposal could lead to serious environmental impairments and ecotoxicity in both terrestrial and aquatic environments. However, no incidents involving the release of these chemical feedstocks from ethanol production facilities have been reported. Further, lesser amounts of ethanol are constantly released to the environment from animal wastes, plants, insects, forest fires, and microbes without causing environmental impairment (HSDB, 2012). It is therefore unlikely that large-scale spills and associated environmental contamination will occur under the allowed use of ethanol as a sanitizer and disinfectant in organic livestock production.

Questions

1. Is ethanol still a commonly used substance in livestock?
2. Would you be able to meet the need for non-synthetic/non-GMO and/or organic ethanol if the demand for it were created by eliminating the listing for synthetic ethanol?

Public Comments

Public comments support ethanol remaining on the National List for antiseptic purposes because it is integral for preventing infection and the spread of pathogens while cleaning wounds. However, one commenter suggested the NOSB investigate the availability of non-synthetic ethanol from non-GMO fermentation organisms and feedstock, as well as the availability of organic ethanol.

Subcommittee vote

Motion to remove ethanol based on the following criteria in the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600(b) if applicable: N/A

Motion by: Jessie Buie

Seconded by Harriet Behar

Yes: 0 No: 6 Abstain: 0 Absent: 0 Recuse: 0

Alcohols (ii) Isopropanol

Reference: **205.603(a)** As disinfectants, sanitizer, and medical treatments as applicable. (1) Alcohols. (ii) Isopropanol-disinfectant only.

Technical Report: [1995 TAP](#); [2014 TR Ethanol](#); [2014 TR Isopropanol](#)

Petition(s): N/A

Past NOSB Actions: [10/1995 NOSB minutes and vote](#); [11/2005 NOSB sunset recommendation](#); [10/2010 sunset recommendation](#); [10/2015 sunset recommendation](#)

Recent Regulatory Background: Sunset renewal notice published 06/06/12 ([77 FR 33290](#)); Sunset renewal notice published 03/21/17 ([82 FR 14420](#))

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Use

Isopropanol is used for a variety of industrial and consumer purposes, ranging from chemical and solvent applications to medical and consumer usage. Agricultural uses of isopropanol include the disinfection of production tools and surfaces and topical antisepsis during medical treatments. Livestock producers may use alcohol (i.e., isopropanol and/or ethanol) solutions for sanitizing and disinfecting surfaces (e.g., production implements, troughs, and floor drains) and during medical treatments as a topical disinfectant (Jacob, 2013; Dvorak, 2008).

Manufacture

Chemical synthetic procedures are used in the commercial production of isopropanol that is used in the preparation of consumer-use disinfectants, industrial solvents, and specialty chemicals. Specifically, indirect and direct methods for the hydration of petroleum-derived propylene are the two primary commercial processes to produce isopropanol. In addition, smaller amounts of industrial isopropanol are generated through the hydration of acetone over transition-metal catalysts (Papa, 2011; Merck, 2006). A variety of methods are also available for the fermentative production of isopropanol from carbon sources, such as starch, sugar, and cellulose, using genetically engineered yeast and bacteria (Papa, 2011).

International Equivalency

A small number of international organizations provide guidance on the application of synthetic isopropanol in organic crop and livestock production as well as the processing of organic foods. Among these are the Canadian General Standards Board and the International Federation of Organic Agriculture Movements (IFOAM).

Canada – Canadian organic production standards permit the use of isopropanol for a number of agricultural applications.

IFOAM – Isopropanol is an approved synthetic equipment cleaner and equipment disinfectant. Isopropanol is also an allowed synthetic substance for pest and disease control and disinfection in livestock housing.

Environmental/Health Issues

Although isopropanol is a volatile organic compound and potentially contributes to the formation of ozone and photochemical smog, large-scale releases of isopropanol under the prescribed use pattern in organic crop production are unlikely. Isopropanol may enter the environment because of its manufacture in addition to its solvent and chemical intermediate uses. According to US EPA, isopropanol is slightly toxic to practically non-toxic based on acute oral and inhalation toxicity tests as well as primary eye and dermal irritation studies (EPA, 410 1995).

Questions

1. Is isopropanol still essential?
2. Would you be able to meet the need for non-synthetic/non-GMO and/or organic ethanol if the demand for it were created by eliminating the listing for synthetic isopropanol?

Public comments support isopropanol remaining on the National list for disinfectant use in livestock.

Subcommittee vote

Motion to remove isopropanol based on the following criteria in the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600(b) if applicable: N/A

Motion by: Jessie Buie

Seconded by: Harriet Behar

Yes: 0 No: 6 Abstain: 0 Absent: 0 Recuse: 0

Aspirin

Reference: **205.603(a)** As disinfectants, sanitizer, and medical treatments as applicable. (2) Aspirin-approved for health care use to reduce inflammation.

Technical Report: [1995 TAP](#); [2017 TR](#)

Petition(s): N/A

Past NOSB Actions: [04/1995 meeting minutes and vote](#); [11/2005 NOSB sunset recommendation](#); [10/2010 NOSB recommendation](#); [10/2015 sunset recommendation](#)

Recent Regulatory Background: Sunset renewal notice published 06/06/12 ([77 FR 33290](#)); Sunset renewal notice published 03/21/17 ([82 FR 14420](#))

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Manufacturing Process

The most prevalent method of synthesizing aspirin is via an esterification. Salicylic acid is treated with acetic anhydride, an acid derivative, causing a quantitative chemical reaction that turns salicylic acid's hydroxyl group into an ester group ($R-OH \rightarrow R-OCOCH_3$; Figure 2). This process yields aspirin and acetic acid, which are considered byproducts of this reaction. Small amounts of sulfuric acid (and occasionally phosphoric acid) are almost always used as a catalyst.

The chemical feedstocks for synthesizing aspirin are also manufactured through a chemical process. Salicylic acid is produced commercially via the Kolbe-Schmitt process. Here, phenol and sodium hydroxide react to make sodium phenoxide. The phenoxide comes into contact with CO_2 to form sodium salicylate. The salicylate is acidified to give salicylic acid. The acid is usually crystallized from aqueous solution to give a technical grade 99.5% salicylic acid product. For a pharmaceutical grade product, salicylic acid is further purified by sublimation.

The commercial process for acetic anhydride was developed by Wacker Chemie in 1922 and uses a chemical reaction between acetic acid and ethenone at a low temperature and pressure.

Specific Uses of the Substance

Aspirin (i.e., acetylsalicylic acid) is a nonsteroidal anti-inflammatory drug (NSAID) used for temporary relief of minor aches and pains due to headache, muscular aches, minor arthritis pain, toothache, backache, the common cold, and premenstrual and menstrual cramps. It is also used for temporarily reducing fever, the prevention of cardiovascular events, and the treatment of rheumatologic disorders.

Approved Legal Uses of the Substance

Aspirin is considered a pain reliever and fever reducer in the over-the counter, tentative final monograph for Internal Analgesic, Antipyretic, and Antirheumatic Drug Products for Over-the-Counter Human Use by the U.S. Food and Drug Administration (FDA) (53 Federal Register 46204, Nov. 16, 1988 and 21 CFR 343). Aspirin is included under 21 CFR 343.12 and 343.13 for the prevention of cardiovascular events and the treatment of rheumatologic disorders.

Aspirin is also listed at 7 CFR 205.603 as a synthetic substance allowed for the use in organic livestock production and is approved for health care use to reduce inflammation.

Its half life is short in cattle and it is not as beneficial in reducing pain as Flunixin. However, aspirin is usually given orally, which makes it easier and more usable for farmers in an emergency. Additionally, Flunixin must be administered under written orders of a licensed veterinarian and it has a restriction annotation for a withdrawal time.

A second pain medication approved for pain relief in organic livestock is Butorphanol (7 CFR 205.603(a)(5) and 21 CFR 522.246). Butorphanol is a synthetic opioid partial agonist analgesic; however, it also must be administered under a veterinarian's written orders, and it too is restricted by annotation to a withdrawal time.

Action of the Substance

Aspirin inhibits the biosynthesis of certain hormone-like substances called prostaglandins, which accounts for most of its clinical effect. Depending on where in the body these prostaglandins are produced, they may trigger pain, inflammation, fever, or blood clotting. Following absorption, aspirin is hydrolyzed to salicylic acid, which is the active metabolite for its major clinical effects. Aspirin also inhibits platelet aggregation by irreversibly inhibiting prostaglandin cyclooxygenase.

Public Comments:

During the Spring 2018 NOSB meeting the Livestock Subcommittee received several comments in favor of relisting aspirin and no comments against relisting aspirin. Some of the comments in favor of relisting included:

- This product is important to the humane treatment of organic animals and is commonly used to reduce inflammation.
- It is the only real-time responsive form for inflammation and fever management available. There are other products that are available but do not offer the same type of timely response to ensure animal health and wellbeing. This is also a proven remedy and is critical in organic livestock production.

This material satisfies the OFPA evaluation criteria and the Livestock Subcommittee supports the relisting of aspirin.

Subcommittee vote

Motion to remove aspirin from §205.603(a) based on the following criteria in the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600(b) if applicable: N/A

Motion by: Ashley Swaffar

Seconded by: Harriet Behar

Yes: 0 No: 6 Abstain: 0 Absent: 0 Recuse: 0

Biologics—Vaccines

Reference: **205.603(a)** As disinfectants, sanitizer, and medical treatments as applicable. (4) Biologics—Vaccines.

Technical Report: [2011 TR \(Vaccines from Excluded Methods\)](#); [2014 TR \(Aquaculture\)](#)

Petition(s): [2012 Petition \(Aquaculture\)](#)

Past NOSB Actions: [11/2005 NOSB sunset recommendation](#); [11/2009 NOSB recommendation on Vaccines at §205.105](#); [10/2010 NOSB sunset recommendation](#); [10/2014 recommendation on Vaccines from Excluded Methods](#); [10/2015 sunset recommendation](#)

Recent Regulatory Background: Sunset renewal notice published 06/06/12 ([77 FR 33290](#)) Sunset renewal notice published 03/21/17 ([82 FR 14420](#))

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In addition to the allowance of this category of synthetic materials on the National List (NL), there are other areas that address ‘biologics—vaccines’ in the USDA organic regulations.

§205.200 Terms defined:

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.

§205.105 Allowed and prohibited substances, methods, and ingredients in organic production and handling.

To be sold or labeled as “100 percent organic,” “organic,” or “made with organic (specified ingredients or food group(s)),” the product must be produced and handled without the use of:

(e) Excluded methods, except for vaccines: *Provided*, That, the vaccines are approved in accordance with §205.600(a)

The Organic Food Production Act (OFPA) specifically allows vaccines to be used in the absence of illness, while prohibiting all other medications from this use.

Vaccines are produced through a variety of methods that use natural pathogens grown in a culture (yeast, bacteria or cell), separation and purification of the vaccine, and addition of other materials that may enhance the efficacy of the vaccine. These methods will result in a live, modified live, or killed vaccine.

Vaccination against bacterial or viral infections is a cost effective and efficient method of lessening animal suffering and disease. A vaccine contains, or produces in the vaccinated individual, an antigen that stimulates an immune response and enables protection from the disease and/or future infection.

Public comment

There was universal agreement among producers, certifiers and organic advocacy groups that vaccines are an important health maintenance tool on the organic livestock farm, with agreement to relist with no other annotation.

At the same time, there were numerous comments stating the implementation of §205.105 (e) is inconsistent between certification agencies, with some certifiers asking producers to determine if the vaccine they wish to use is genetically modified, and others not asking this of their producers. Some ask for the information, but allow all vaccines to be used, others prohibit the use of GMO vaccines. There

was agreement, especially among certifiers and organic advocacy groups that the current wording in the regulation is leading to inconsistencies in certification and confusion among producers and certifiers on this material.

Discussion

The Livestock Subcommittee is aware of the inconsistencies as described in public comment around the use of GMO vaccines. The Subcommittee also recognizes the great importance vaccines play in the prevention of livestock disease, and that the presence of Biologics-Vaccines on the National List is not the area in the regulation that is causing the confusion and inconsistency in the use of GMO vaccines. The Subcommittee has reviewed this material and judged it to meet the OFPA criteria for placement on the NL.

When an organic livestock producer loses one or more of their animals, there is more than just that animal's production capability lost, even though that is significant. Many times, there have been many years, even decades of breeding and genetic selection resulting in that specific animal. When that animal is lost to the farm, all of those years of breeding and their unique genetics are also lost. The use of vaccines as a preventative can protect this long-term investment in genetic improvement, and vaccines remain an important tool in the organic livestock producer's toolbox to protect the investments that producers have in individual animals as well as their herds or flocks.

Subcommittee vote

Motion to remove biologics, vaccines from §205.603(a)(4) based on the following criteria in the Organic Foods Production Act (OFPA) and/or 7 CFR 205.603(b) if applicable: N/A

Motion by: Harriet Behar

Seconded by: Jesse Buie

Yes: 0 No: 4 Abstain: 0 Absent: 2 Recuse: 0

Electrolytes

Reference: [205.603\(a\)](#) As disinfectants, sanitizer, and medical treatments as applicable.

(8) Electrolytes—without antibiotics.

Technical Report: [1995 TAP](#); [2015 TR](#)

Petition(s): N/A

Past NOSB Actions: [10/1995 NOSB minutes and vote](#); [11/2005 sunset recommendation](#); [10/2010 sunset recommendation](#); [10/2015 sunset recommendation](#)

Recent Regulatory Background: Sunset renewal notice published 06/06/12 ([77 FR 33290](#)); Sunset renewal notice published 03/21/17 ([82 FR 14420](#))

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Electrolytes are considered animal drugs by the FDA, and in USDA organic production they may only be used when preventative practices are inadequate to prevent illness, and may not be given in absence of illness. Electrolytes are used to restore ionic balance, treating a variety of metabolic conditions such as hypocalcemia, scours, milk fever, dehydration, mastitis, ketosis, acidosis and more. Electrolyte balance is essential to maintain normal physiology and health of livestock. When there is an imbalance of cations such as sodium, potassium, calcium or magnesium, either too low or high, the health and life of

the animal is at risk. Stages of life, environmental stresses, stages of production such as birthing an animal, are all conditions that can throw the electrolyte balance off and would necessitate the use of this material to restore health and well-being to the animal.

Electrolytes are produced through industrial processes, fermentation, or may be mined. The major component of electrolyte formulations are salts and would have a variety of carriers or other ingredients (i.e., excipients) that enhance their properties, such as dextrose, citric acid, glucose, glycine, and more. The 2015 Technical Report (TR) has a detailed description of the various manufacturing processes.

Public Comment

In response to the questions of essentiality of this material in organic livestock production, and if there were any natural alternatives that could replace it, there was universal agreement among all commenters to retain this material on the National List, with no changes to the annotation. Organic certification agencies noted they certify many organic producers who use this material to maintain healthy livestock, both mammals and poultry. Environmental and consumer groups also supported this material as well as companies that market organic livestock products.

Discussion

This subcommittee believes this material satisfies the OFPA evaluation criteria. This material is used regularly and found to be essential by a large number of organic livestock producers. There were no negative public comments noted for this material.

Subcommittee Vote

Motion to remove electrolytes from §205.603(a)(8) based on the following criteria in the Organic Foods Production Act (OFPA) and/or 7 CFR 205.603(b) if applicable: N/A

Motion by: Harriet Behar

Seconded by: Dan Seitz

Yes: 0 No: 4 Abstain: 0 Absent: 2 Recuse: 0

Glycerin

Reference: **205.603(a)** As disinfectants, sanitizer, and medical treatments as applicable. (11) Glycerin— Allowed as a livestock teat dip, must be produced through the hydrolysis of fats or oils.

Technical Report: [2010 TAP \(Livestock\)](#)

Petition(s): N/A

Past NOSB Actions: [1999 NOSB recommendation](#); [11/2005 sunset recommendation](#); [10/2010 sunset recommendation](#); [10/2015 sunset recommendation](#)

Recent Regulatory Background: Sunset renewal notice published 06/06/12 ([77 FR 33290](#)); Sunset renewal notice published 03/21/17 ([82 FR 14420](#))

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Glycerin falls under OFPA section 6517(c)(1)(B)(i) that describes livestock medicines. Glycerin is a by-product of the soap manufacturing process. The oldest method of manufacture is by hydrolysis of natural fats & oils (either animal or vegetable): heat, steam, and pressure “split” the glycerin from the oil. The glycerin is concentrated in multistage evaporators and refined. Purification is achieved through

either an ion exchange process or a distillation system, but it can also be produced synthetically from propylene. If only heat, steam or pressure is used to split the ester bonds to liberate free glycerol from fat (i.e. triglycerides), then this is a hydrolysis reaction catalyzed by physical forces and is compatible with organic criteria. However, if glycerol is formed by the chemical reaction of sodium hydroxide, then glycerol is produced by a chemically catalyzed hydrolysis reaction and may be considered synthetic.

Glycerin has over 1,000 uses; however, its use in organic is limited to an ingredient in teat dips (§205.603(a)(11)). As an ingredient in teat dips it prevents teat irritation and improves skin conditioning. Glycerin does have some germicidal activity (Fox et al., 1990).

Glycerin is widely used as a carrier for other medications because it does not have detrimental chemical interactions with other substances, staying inert without changing the properties of whatever substance in which it is used. Furthermore, it acts as an emollient, reducing moisture evaporation of the skin. Glycerin mist can act as an inhalation irritant. It is easily digested with the same metabolism as carbohydrates.

Natural alternatives include castor oil and vegetable oils. There are some management tools for controlling mastitis, which include wiping debris from the teats, massaging the teat to loosen debris and stimulate milk letdown, wiping off the teat dip using individual cloths or paper towels, and applying the milking unit without air admission. None of the management tools seem to be effective alone.

The Livestock Subcommittee asked the following questions for the Spring 2018 meeting: (1) If there are non-food agricultural sources of glycerin available, should synthetic glycerin be removed from §205.603(a); and (2) How are certifiers tracking that the glycerin used as a teat dip is being produced through the hydrolysis of fats or oils?

The public comments were supportive of continued listing of glycerin as a livestock tip dip, and there were no responses to the questions.

Subcommittee vote

Motion to remove glycerin from §205.603(a) based on the following criteria in the Organic Foods Production Act (OFPA) and/or 7 CFR 205.603(b) if applicable: N/A

Motion by: Sue Baird

Seconded by: Harriet Behar

Yes: 0 No: 5 Abstain: 0 Absent: 1 Recuse: 0

Phosphoric acid

Reference: 205.603(a) As disinfectants, sanitizer, and medical treatments as applicable. (19) Phosphoric acid—allowed as an equipment cleaner, *Provided*, That, no direct contact with organically managed livestock or land occurs.

Technical Report: [2003 TAP \(Handling\)](#)

Petition(s): N/A

Past NOSB Actions: [10/1999 NOSB minutes and vote](#); [11/2005 sunset recommendation](#); [10/2010 sunset recommendation](#); [10/2015 sunset recommendation](#)

Recent Regulatory Background: Sunset renewal notice published 06/06/12 ([77 FR 33290](#)); Sunset renewal notice published 03/21/17 ([82 FR 14420](#))

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Phosphoric acid, (H₃PO₄), has many uses. As a cleaner, it is generally used to remove rust and mineral deposits found on metal equipment such as boilers and steam producing equipment. In dairy operations, it is used to remove calcium and phosphate salt deposits from processing equipment.

Phosphoric acid is a hazardous substance. The exact dangers of it depend on the concentration strength of the solution, with higher concentrations presenting greater hazards. Phosphoric acid, at 85 wt. %, is considered a corrosive chemical solution that can cause, through skin exposure and inhalation, severe skin burns, permanent eye damage, sore throat, shortness of breath, and even death—among other things.

Additional information requested by Subcommittee

1. Is the substance essential for organic livestock production?
2. Since the material was last reviewed, have additional commercially available alternatives emerged?

Public Comment

Written comments were submitted prior to the spring 2018 NOSB meeting by three organizations and one organic dairy farmer. All commenters support relisting the substance, as phosphoric acid is considered essential for the purposes for which it is allowed. One organization stated that because phosphoric acid is highly corrosive, it would be worthwhile to see whether EPA's Safer Choice program offered any potential alternatives. Another organization recommended that an annotation be added that clarifies when a rinse or purge is, or is not, required.

The subcommittee recommends continued listing of the substance because it satisfies OFPA criteria.

Subcommittee vote

Motion to remove phosphoric acid from §205.603(a) based on the following criteria in the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600(b) if applicable: N/A

Motion by: Daniel Seitz

Seconded by: Harriet Behar

Yes: 0 No: 6 Abstain: 0 Absent: 0 Recuse: 0

Lime, hydrated

Reference: 205.603(b) As topical treatment, external parasiticide or local anesthetic as applicable. (5) Lime, hydrated—as an external pest control, not permitted to cauterize physical alterations or deodorize animal wastes.

Technical Report: [1995 TAP](#); [2015 TR](#)

Petition(s): N/A

Past NOSB Actions: [10/1995 NOSB minutes and vote](#); [04/2006 sunset recommendation](#); [10/2010 sunset recommendation](#); [10/2015 sunset recommendation](#)

Recent Regulatory Background: Sunset renewal notice published 06/06/12 ([77 FR 33290](#)); Sunset renewal notice published 03/21/17 ([82 FR 14420](#))

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Specific Uses of the Substance

Under the USDA organic regulations for livestock production, hydrated lime is only permitted for use as an external parasiticide (7 CFR 205.603(b)(5)). Regarding livestock applications, the final rule states that hydrated lime may not be used to cauterize physical alterations (medical treatment) or deodorize animal wastes. Composition of hydrated or “slaked” lime consists primarily of calcium hydroxide [Ca(OH)₂] and magnesium hydroxide [Mg(OH)₂] at 50 - 95% and 0 - 50% of the substance, respectively. High purity forms of the substance contain greater than 90% calcium hydroxide.

Approved Legal Uses of the Substance

The USDA organic regulations currently permits the use of hydrated lime (calcium carbonate) for plant disease control in crop production (7 CFR §205.601(i)(4)) and external pest control in livestock production (7 CFR §205.603(b)(5)).

Discussion

The Livestock Subcommittee discussed the use of hydrated lime in both livestock and crop production, specifically, the relationship between crop use and livestock use and whether approval for use in one category affected the other. The following questions were posed to stakeholders:

1. Is the substance essential for organic livestock production and is it regularly used?
2. Since the material was last reviewed, have additional commercially available natural alternatives emerged?

Public comment

The majority of public comment supported relisting. Many commenters suggested that hydrated lime was essential for organic production in that it prevents the spread of pests among herds. A few commenters said that there are no alternatives to hydrated lime. The Subcommittee requests public comment on revising the annotation for hydrated lime.

Additional information requested from stakeholders

Is hydrated lime a useful tool for deodorizing animal waste?

Subcommittee vote

Motion to remove hydrated lime based on the following criteria in the Organic Foods Production Act (OFPA) and/or 7 CFR 205.603(b) if applicable: N/A

Motion by: A-dae Romero-Briones

Seconded by: Jessie Buie

Yes: 0 No: 6 Abstain: 0 Absent: 0 Recuse: 0

Mineral oil

Reference: **205.603(b)** As topical treatment, external parasiticide or local anesthetic as applicable.
(6) Mineral oil—for topical use and as a lubricant.

Technical Report: [2002 TAP](#); [2015 TR](#)

Petition(s): [2002 Petition](#)

Past NOSB Actions: [10/1995 NOSB minutes and vote](#); [11/2005 sunset recommendation](#); [10/2010 sunset recommendation](#); [10/2015 sunset recommendation](#)

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Approved Legal Uses of the substance

The USDA organic regulations currently permit the use of mineral oil in organic livestock production for direct topical application and as a lubricant under 7 CFR 205.603(b)(6). Regarding the use pattern, mineral oil acts as an external parasiticide when applied topically to animals infested with mites, lice and other parasites. Conventional operators orally administer mineral oil to lubricate the intestinal tract and dislodge intestinal obstructions in cattle and other ruminants. This medical practice is not currently approved in organic production, although a proposed rule by the National Organic Program (83 FR 2498, March 19, 2018) would allow for this use, if finalized

Discussion

In Subcommittee discussion, there was some concern about the manufacturing process and there was also brief discussion about the frequency of use in the organic community. A few members reiterated the importance of mineral oil to organic livestock farmers. The Subcommittee seeks input on the following questions:

1. Is mineral oil an essential material?
2. Are organic farmers using mineral oil as a lubricant?

Public comment

The majority of commenters considered mineral oil essential for organic agriculture and suggested re-listing. Most commenters indicated that they use mineral oil as a spray, and use it minimally (as little as one cup per animal) to control flies and mites. One commenter suggested de-listing mineral oil citing alternative substances to control pests

Subcommittee vote

Motion to remove mineral oil based on the following criteria in the Organic Foods Production Act (OFPA) and/or 7 CFR 205.603(b) if applicable: N/A

Motion by: A-dae Romero-Briones

Seconded by: Sue Baird

Yes: 0 No: 6 Abstain: 0 Absent: 0 Recuse: 0

Sucrose octanoate esters

Reference: **205.603(b)** As topical treatment, external parasiticide or local anesthetic as applicable.
(8) Sucrose octanoate esters (CAS #s-42922-74-7; 58064-47-4)—in accordance with approved labeling.

Technical Report: [2005 TR](#)

Petition(s): [2004 petition](#); [05/2004 petition amendment](#); [09/2004 petition amendment](#)

Past NOSB Actions: [08/2005 NOSB recommendation](#); [10/2010 sunset recommendation](#); [10/2015 sunset recommendation](#)

Recent Regulatory Background: Sunset renewal notice published 06/06/12 ([77 FR 33290](#)); Sunset renewal notice published 03/21/17 ([82 FR 14420](#))

Sunset Date: 3/15/2022

Subcommittee Review

Sucrose octanoate esters (SOEs) belong to the organic chemical family sucrose fatty acid esters (SFAEs). SOEs are manufactured from sucrose (table sugar) and an octanoic acid ester commonly found in plants and animals. SOEs, marketed as biopesticides, are intended to mimic the pest control properties of *Nicotiana glauca* Domin (wild tobacco) and other *Nicotiana* species, including wild tomato and wild potato species and the petunia plant. The petitioned substance is a soap derived from coconut oil fatty acids or palm kernel oil fatty acids. EPA has registered SOEs as a biopesticide for foliar spray on greenhouse, nursery, and field crops; for sciarid fly control in mushroom-growing media; and for varroa mite control on honeybees.

The listing at §205.603(b) specifically addresses the petitioned use for livestock (i.e., honey bees) as a control of varroa mites.

Effect on the Environment

SOEs are an effective adult miticide and also control other pests. SOEs are not harmful to fish, hazardous to bees, or phytotoxic. When applied according to EPA-approved label directions, no direct exposure of birds or aquatic organisms to SOE is expected.

SOEs biodegrade within approximately five days at approximately 68-80.6°F/20-27°C, in both aerobic and anaerobic conditions, so there is minimal potential for exposure to insects, fish, and other nontarget wildlife. A limited number of experiments have shown SOEs do not affect a range of predators and parasitoids that are killed by insecticidal soaps. Impacts on soil fauna have not been established.

Effect on Human Health:

SOEs have low toxicity to humans and are produced in a closed system. The 2005 technical report (TR) states that no sub-chronic, chronic, immune, or endocrine issues have been identified. An ocular risk exists but is unlikely if the product is used according to label.

Status:

The previous TR and/or NOSB recommendations do not provide sufficient information to evaluate SOEs relative to OFPA criteria for livestock production, specifically for varroa mite control on bees.

Public Comments

There were no substantive comments from beekeepers during the Spring 2018 public comment period on the continued listing of SOEs at §205.603(b); nevertheless there were comments from other livestock producers who stated that they were aware that SOEs are an important tool for beekeepers in controlling varroa mites in honey bees.

A public health advocacy organization commented that in view of the restrictive use of SOEs, and the difficulty that beekeepers are experiencing in maintaining the health of honey bee colonies, they supported keeping SOEs on the National List.

Additional information requested by Subcommittee

1. The TR does not address the toxicity of SOEs to non-targeted organisms, including predators, parasitoids, soil fauna, and aquatic organisms when exposed by spraying SOEs. Should there be further information requested about the toxicity of SOE to non-target organisms?
2. Is this product still being used, or are there other synthetic products that are more effective? If used, do we need to keep it available to be rotated with other products?

Subcommittee vote

Motion to remove sucrose octanoate esters (SOEs) from §205.603(b) based on the following criteria in the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600(b) if applicable: N/A

Motion by: Sue Baird

Seconded by: Jessie Buie

Yes: 2 No: 4 Abstain: 0 Absent: 0 Recuse: 0